

Current legal and factual background

1. Article 53 of the European Patent Convention (EPC) provides for exclusions from patentability. Article 53(b) of the EPC excludes from patentability plant or animal varieties or essentially biological processes for the production of plants or animals. On this ground, the Enlarged Board of Appeal (EBoA) of the European Patent Office (EPO) decided on 25 March 2015 the Tomatoes II and Broccoli II cases (G 2/12 and G 2/13, respectively), **allowing** patentability of plants and animals obtained by essentially biological processes.
2. On 24 November 2016, the European Commission released the Notice (2016/C411/03) which clarified the interpretation of certain articles of *Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological inventions* (“the Bio Directive”). The Commission concluded that the EU legislator’s intention when adopting the Bio Directive was to exclude from patentability products (plants and animals) derived from essentially biological processes.
3. Rule 28(2) of the Implementing Regulations to the Convention on the Grant of European Patents (amended in 2017) provides: “*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 rule sought to prevent the granting of patents on plants or animals as such if the plant or animal was obtained exclusively by an essentially biological process (i.e. conventional breeding of plants or animals based on natural phenomena, such as crossing or selection).
4. Article 164 (2) EPC provides that: “*In case of conflict between the provisions of EPC and those of the Implementing Regulations, the provisions of EPC shall prevail*”.
5. In Decision T 1063/18 of 5 December 2018, a Technical Board of Appeal of the European Patent Office concluded that in the light of Art. 164 (2) EPC, the case law of the EBoA in the form of decisions G 2/12 and G 2/13 had priority over Rule 28(2) of the Implementing Regulations. The Board concluded that the decisions G 2/12 and G 2/13 were based on the provisions of Article 53(b) EPC, which take precedence over the amended provisions of Rule 28(2) of the Implementing Regulations to the EPC,

again allowing patentability of plants and animals obtained through an essentially biological process.

6. Recognising the need to clarify the inconsistency arising in EPO case law, the President of the European Patent Office invoked Article 112 (1)(b) and referred two points of law to the EBoA concerning Case G 3/19, namely:

Question 1:

Having regard to Article 164(2) EPC, can the meaning and scope of Article 53 EPC be clarified in the Implementing Regulations to the EPC without this clarification being a priori limited by the interpretation of said Article given in an earlier decision of the Boards of Appeal or the Enlarged Board of Appeal

Question 2:

If the answer to question 1 is yes, is the exclusion from patentability of plants and animals exclusively obtained by means of an essentially biological process pursuant to Rule 28(2) EPC in conformity with Article 53(b) EPC which neither explicitly excludes nor explicitly allows said subject-matter?

7. By decision of the President of EPO, the European Patent Office **has stayed** all examination and opposition proceedings relating to patents and patent applications in which the decision depends on the patentability of a product obtained by an essentially biological process. As a consequence, the number of patent applications and oppositions is significantly increasing.

The position of the Polish Patent Office (“PPO”) on the patentability of inventions related to products that are obtained through essentially biological processes

The PPO’s practice

8. The PPO shares the interpretation of certain articles of the Bio Directive and the position presented by the Commission in its 2016 Notice (2106/C411/03). Incidentally, the wording of the above-mentioned documents is the same as the relevant provisions of the EPC and the Implementing Regulations to the EPC.
9. According to the PPO’s practice, inventions relating to products that are derived from essentially biological processes do not meet the condition of being susceptible

of industrial application as they are not reproducible. Therefore, products resulting from essentially biological processes have not been and are not patentable.

The PPO's position is supported by Polish patent system users as well as right holders, including: plant breeders (e.g. Polish Seed Trade Association, the association Forum of Organic Agriculture named M. Górny), users of the International Convention for the Protection of New Varieties of Plants (UPOV Convention), institutions dealing with the legal protection of plant varieties (i.e. The Research Center for Cultivar Testing), Polish governmental authorities, such as the Polish Ministry of Agriculture and Rural Development, and some other institutions competent in the subject matter.

The PPO's position is furthermore supported by the fact that there are no court rulings which could provide grounds on which exclusion from patentability of products obtained by essentially biological methods could be challenged or corrected.

Amendments to the Polish Patent Law

10. The Polish Parliament's work on the amendment to the Act on Industrial Property Law ("IPL") is reaching its final stage. In fact, it is our understanding that on 16 October 2019 the Parliament is going to vote on the bill. The new law will include a provision which **explicitly** excludes from patentability products that are obtained through essentially biological processes. It reads as follows: "*Patents shall not be granted on:*

(a) plant and animal varieties,

(b) essentially biological processes for the breeding of plants and animals, and

*(c) **products obtained by such processes**".*

To the best of our knowledge, no opinion questioning the validity of introducing the above-mentioned amendment to IPL has been to this date submitted before the Polish Parliament.

Assessment of the current situation related to G 3/19

11. The Bio Directive was founded on the belief that for maintaining and encouraging investment in biotechnology, effective and harmonised protection across all Member

States must be ensured. The provisions of the Bio Directive have been incorporated into both the EPC (precisely to the Implementing Regulations to the EPC) and to national patent law of the Member States.

The Commission reviewed the context and provisions of the Bio Directive and in its Notice (2016/C 411/03) concluded that the European Union legislators' intention when adopting the Biotech Directive was to exclude products emanating from essentially biological processes from patentability.

12. Pursuant to Article 26(1) of the Implementing Regulations to the EPC, the Bio Directive should be used as a supplementary means of interpretation.

13. On 29 June 2017, the Administrative Council of the EPO decided to amend the Implementing Regulations to the EPC and introduced exceptions to patentability under Rule 28(2). In line with said Rule: "*European patents shall not be granted in respect of plants or animals exclusively obtained by means of an essentially biological process*". This indicates the acceptance of the interpretation of certain articles of the Bio Directive as laid down in the EC Notice.

14. While accepting and respecting the EBoA's right to make independent decisions, it should be pointed out that having:

- a clear and understandable interpretation of certain articles of the Bio Directive (EC Notice),
- the provision which indicates the Bio Directive as a supplementary means of interpretation (Rule 26(1) of the Implementing Regulations to the EPC),
- presence of Rule 28(2) excluding from patentability products obtained through essentially biological processes in the binding legal framework,

the PPO believes that there are grounds to maintain Rule 28(2) as a supplementary means of interpretation of Article 53(b) of the EPC and to recognise such inventions as excluded from patentability.

15. It seems that in the past the EBoA had presented its stance on the relationship between Rules set out in the Implementing Regulations and Articles of the EPC, specifically, in Case G 1/98. Foreseeing the problems that may emerge in the future, the EBoA had already delivered its opinion, namely:

“Having regard to Art. 164(2) EPC 1973, the board then had to examine whether or not the new rules insofar as they related to Art. 53(a) EPC 1973 were in conformity with that Article.

Following G 1/98 (OJ 2000, 111), the board adopted the view that the rules related to the articles were to be only interpretative. They only gave a more detailed interpretation of the meaning of Art. 53 EPC 1973 as intended from its inception, and hence were applicable to cases already pending before their introduction” (Case Law of the Boards of Appeal of the European Patent Office, 6th edition, 2010, p. 41).

Hence the EBoA had already looked once into the meaning and relationship between the Rules of the Implementing Regulations to the EPC and Articles of the EPC, asserting that the Rules of the Implementing Regulations should be treated as interpretative in relation to the Articles of the EPC.

16. As provisions of the Bio Directive have been introduced into the Implementing Regulations, decisions to grant European patents for biotechnological inventions are de facto based on them.
17. One can hypothesise that challenging the abovementioned approach could potentially trigger questioning of other decisions that have a legal basis “only” in the wording of the provisions of the Implementing Regulations.
18. It is worth mentioning that the considerable majority of NPOs in Europe assess patentability of inventions based on the Bio Directive and the interpretation of its provisions, as it was laid down in the EC Notice.

Conclusions

19. Given the current legal situation that has arisen from the decision in G3/19 case, it seems justified to call for resolving the conflict in a manner that is lawful and that preserves legal certainty. Inconsistency in interpretation of provisions of law between the EPC and the Bio Directive compromises European case law harmonisation.
20. It is in the interest of all EU Member States to avoid legal disharmony and the probability of risk that European patents on products obtained through essentially biological methods will have to be revoked by respective national authority of the

Member States. Such a situation not only endangers stability of the internal market but also may hinder access to plant breeding material and use of innovative solutions in the field of bio technology.

21. The fact that all 28 EU Member States and the 10 Contracting States to the EPO voted in favour of the introduction of Rule 28(2) also serves to show the will of the latter to interpret the Rule in line with the EC Notice.
22. It is therefore necessary to frame an unequivocal, conclusive and, if feasible, speedy solution of the issue for the benefit of all users of the patent system in Europe, and the general public.