

Christoph Then (*No Patents on Seeds!*) - Short comment on the expert opinion:

***“Legal options for changing the patent protection of plants in Germany, Europe and international law - Expert opinion commissioned by the Bundestagsfraktion Bündnis 90 /Die Grünen”***

***No Patents on Seeds! welcomes the publication of the expert opinion***

The current debate on the future regulation of plants obtained from new genomic techniques (NGTs) has led the EU Parliament and the EU Council of Ministers to take an in-depth look at the question of whether, and to what extent, patents can be granted in the plant breeding sector. The EU Commission has announced that it will submit a statement on this issue.

The expert opinion considers various proposals to limit or exclude patents on plants, including current EU Parliament (P9TA (2024)0067) decisions and a proposal made by the Belgian Council Presidency (14.5.2024, 9904/24). It also addresses a proposal put forward by the Austrian government to ban patents on random mutagenesis (<https://www.parlament.gv.at/gegenstand/XXVII/ME/229?selectedStage=100>). This expert report is therefore an important contribution to the current debate.

The overall conclusion: *“The expert report shows that, despite the dense network of regulations at international, European and national level, there is certainly scope for restricting patent protection for plants. However, this scope lies less in the patentability of plants or in exclusions from patent protection, but rather in the scope of protection.”*

***No Patents on Seeds! only partially supports the expert opinion in regard to:***

- **The EU Parliament proposal:** *No Patents on Seeds!* shares the expert assessment that the desired ban on the patenting of NGT plants can only be achieved by amending the European Patent Convention (EPC). The EU Parliament decision would evidently have no effect at all on either European Patent Office (EPO) practice or the patenting of NGT plants. In addition, the EU Parliament decided in favour of banning patents on plants obtained from random mutagenesis. Contrary to the opinion expressed in the expert opinion, *No Patents on Seeds!* believes that this part of the EU Parliament decision could be effectively implemented by making the wording of EU Directive 98/44/EC more precise. This would also be effective in regard to the EPO grant procedure.
- **The Belgian Council Presidency proposal:** this proposal seeks to link the planned deregulation of genetically NGT plants in Category 1 (and the associated easier market access) with a waiver for patent applications. *No Patents on Seeds!* shares the view in the expert opinion that this proposal would violate the current unitary European legal framework for the approval of genetically engineered plants. *No Patents on Seeds!* also agrees with the assessment that the proposal (in accordance with current EPO practice) would, in many cases, be completely ineffective, as it could be circumvented by patent applications for plants in which the relevant mutations are triggered by random mutagenesis.

- **National patent law in Austria:** *No Patents on Seeds!* agrees with the opinion expressed in the report that this amendment is contentious. However, we differ in that we cannot see any actual contradiction between this national law and the EPC and EU Directive 98/44/EC. Contrary to the opinion expressed in the report, *No Patents on Seeds!* also believes that the national legislator has sufficient leeway to clarify the interpretation of patent law.

### **The reasons for dissenting opinion:**

- **Classification of random mutagenesis as an 'essentially biological process'**

From the perspective of patent law, the processes used in random mutagenesis cannot be equated to genetic engineering processes. Random mutagenesis has clear characteristics of conventional breeding (or essentially biological processes). It uses specific chemical substances or physical stimuli (sunlight, irradiation) to initially bring about an increase in genetic diversity, which is subsequently used for crossing and selection. However, the process cannot be used to specifically and directly insert certain traits into the genome. The desired gene variants can only afterwards be selected from the resulting greater genetic diversity (see also *No Patents on Seeds!*, 2024, Table 4, page 17).

According to the decisions of the Enlarged Board of Appeal of EPO on 'Broccoli 1' and 'Tomato 1' (G2/07 und G1/08), a plant breeding process can only be patented if it „*by itself introduces a trait into the genome or modifies a trait in the genome of the plant produced*“ (Point 3 of the decision).

Based on G2/07 and G1/08, the following criteria should be applied to establish whether this kind of process was applied: *“This is the case, for example, for 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 (cf T 356/93 supra). However, in such cases the claims should not, explicitly or implicitly, include the sexual crossing and selection process.”*

**Since random mutagenesis does not allow the insertion of a trait ex-ante, but only its selection ex-post, random mutagenesis implies further steps of crossing and selection in order to achieve the desired trait. Thus, random mutagenesis, although it uses technical aids, would be considered an 'essentially biological process' from the perspective of patent law.**

The current legal situation, allows new methods, e.g. irradiation to induce mutations, to be patented. However, it cannot be implied that the scope of such patents would this extend to the production of the plants (due to the specific provisions in Article 53 (b)).

- **Patentability of non-genetically engineered plants**

From a historical perspective, Decision T356/93 did not result in more patents being granted for plants and animals under Article 53 (b). EPC legislation and interpretation have been amended since then, but only to allow patents on genetic engineering processes for the production of plants and animals. The starting point in this respect was EU Patent Directive 98/44/EC, which subsequently resulted in new rules for the interpretation of the EPC and the national patent laws. EU Patent Directive 98/44/EC and Decision G1/98 therefore only opened up the prohibitions in Article 53 (b) in relation to genetically engineered plants.

In this context, the question of exclusion from patentability of plants obtained from random mutagenesis must be considered in a more differentiated way than is the case in the expert opinion.

An exclusion of plants from random mutagenesis could conceivably be essential, but must at very least be regarded as possible, even if current EPO practice (or resp. a 'prevailing opinion') does not support this interpretation of the law.

It is important to note that random mutagenesis must be distinguished from genetic engineering not only for historical reasons. There are numerous other criteria that can be used to draw a technical or biological distinction between conventional breeding and genetic engineering techniques (see, for example, *No Patents on Seeds!*, 2024, page 16f).

Against this historical backdrop (the emergence of the EU Patent Directive) and the technical and biological differences between random mutagenesis and genetic engineering, it is evident that the exemption to the prohibitions in Article 53 (b) cannot be applied to plants derived from random mutagenesis.

Furthermore, it is not necessarily decisive whether random mutagenesis is regarded as an 'essentially biological process'. Rather, the decisive factor is whether random mutagenesis meets the requirements of Directive 98/44/EC, i.e. whether it can be regarded as a technical invention in accordance with the EU Patent Directive.

**Plants obtained from random mutagenesis must therefore be distinguished historically, biologically, technically and legally from genetically engineered plants. They cannot be regarded as equivalent from the perspective of patent law. Plants obtained from random mutagenesis are therefore subject to the general prohibition from patenting in Article 53 (b).**

The differences in outcome between the *No Patents on Seeds!* analysis and the expert opinion can be explained, amongst other things, by the fact that the expert opinion did not address the historical, biological, technical or legal differences.

However, these differences are of central importance. They show, contrary to the expert opinion, that a 'full exclusion' of patents on plants and animals is possible based on the wording of Article 53(b), and that this must be applied in the conventional breeding sector (including random mutagenesis), as EU Directive 98/44/EC only introduced certain exceptions to this full exclusion for genetically engineered plants.

The expert opinion does not question the current practice of granting patents on conventional plant breeding (random mutagenesis) and even appears to endorse this practice in its statements. *No Patents on Seeds!*, concludes that the expert opinion is therefore unduly reducing the scope for shaping future practice.

- **Proposal to solve urgent problems**

For the reasons outlined above, there is certainly sufficient scope for enforcing a ban on the patenting of plants obtained from random mutagenesis at both a national and EU level. The prohibition would simply fall within the scope of the interpretation of the EPC; it would not require any substantive change to the EPC. As can be seen from the present cases and problem analyses (*No Patents on Seeds!*, 2024), this ban is both urgent and necessary, as it could significantly improve the access that plant breeders have to biodiversity essential for breeding and marketing new varieties. It must also be seen as urgently necessary in the public interest.

Possible steps in correcting European Patent Office practice include an amendment to EU Patent Directive 98/44/EC and/or a corresponding Administrative Council of the EPO decision to amend the EPC rules of interpretation. See *No Patents on Seeds!*, 2024, (page 23) for an example of wording that could be used to amend the interpretation of the EPC.

**In this context, political decisions should not aim to regulate intellectual property rights for conventionally-bred plants in patent law (as could be inferred from the expert opinion). Access should be organised independently from patent law and firmly established within the framework of plant variety protection and full application of the breeders' privilege.**

In contrast, the current legal situation (and in agreement with the expert opinion) would not easily allow the exclusion from patentability of plants obtained from new genetic engineering. It would be difficult and not implementable at EU level. Calling for a diplomatic conference of the 39 contracting states of the EPC would be more promising. It takes longer periods of time to plan the conferences and outcomes are difficult to predict. This might possibly allow the proposals in the expert opinion regarding the restriction of the effects of patent protection to come to the fore.

**Further information:**

*No Patents on Seeds!* (2024) Seed patents: A huge challenge for the European Union - Analysis of the problem, case studies and potential solutions <https://www.no-patents-on-seeds.org/en/report-2024>

The expert opinion commissioned by the Greens:

[https://www.gruene-bundestag.de/fileadmin/dateien/downloads/Weitere\\_Dokumente/Rechtsgutachten\\_Biopatentrechtsreform\\_Gruene\\_Bundestag.pdf](https://www.gruene-bundestag.de/fileadmin/dateien/downloads/Weitere_Dokumente/Rechtsgutachten_Biopatentrechtsreform_Gruene_Bundestag.pdf)