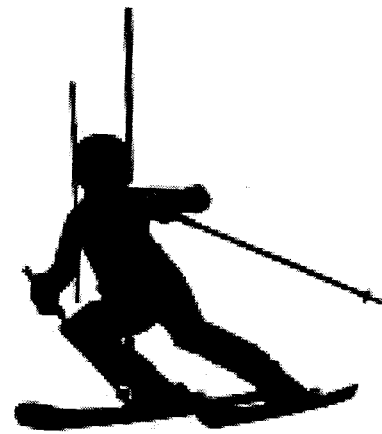


Useless slalom poles – The long story of patenting prohibition in the field of plant and animal breeding

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EPC 2000 Article 53

Exceptions to patentability

European patents shall not be granted in respect of:

(b) plant or animal varieties or essentially biological processes for the production of plants or animals; this provision shall not apply to microbiological processes or the products thereof;

Rule 26 General and definitions

(5) A process for the production of plants or animals is essentially biological if it consists entirely of natural phenomena such as crossing or selection.

Rule 27

Patentable biotechnological inventions

Biotechnological inventions shall also be patentable if they concern:

b) plants or animals if the technical feasibility of the invention is not confined to a particular plant or animal variety;

c) a microbiological or other technical process, or a product obtained by means of such a process other than a plant or animal variety.

EU 98/44 Article 4

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.

3. Paragraph 1(b) shall be without prejudice to the patentability of inventions which concern a microbiological or other technical process or a product obtained by means of such a process.

The starting point

We start from a common consensus that for social reasons the production of basic food should not be monopolised through patents and licensing fees. We start from a second common consensus that the conventional breeding of plants and animals in agriculture should not be influenced, steered or monopolised in any way by means of patents belonging to non-agricultural patentees (e.g. seed producing industries).

The problem of statutory patenting prohibition

Inventions are arranged for the application and examination procedure in a written patent application containing a often voluminous specification of the technical teaching and the so-called „patent claims“ which delimit the new content from the state of the art. Such „patent claims“ are the basis for examination of the patentability of the invention (novelty, inventive step, industrial application) and for the scope of protection after the grant of the patent.

However, such patent claims are currently used by the EPO also for assessing patentability of inventions under the statutory restrictions of Art. 53 EPC and Art. 4 of 98/44 indicated above. This is in obvious contradiction to the wording of these legislative texts which explicitly treat inventions, plant varieties, processes, but *not* patent claims.

This use of the „patent claims“ enables patent holders to avoid the statutory patenting prohibition *merely by clever and skilful drafting of such claims*, although the teaching of the invention as judged on its technical content would not be patentable under the statutory restrictions.

The fine art of avoiding patenting prohibition

- Avoiding species-specific claims for plants: If a transgenic plant variety is excluded from patenting, the skilful inventor will draft his claims *not species-specific* and will thereby cover a (great) number of plant species in which he is not even interested.

Example: EP 242 236 PGS Plant Genetic Systems; T 356/93 of 21. February 1995

21. Nichtbiologisch transformierte Pflanze mit einer stabil in das Genom ihrer Zellen integrierten fremden DNA-Nucleotidsequenz, die für ein Protein codiert, dessen nichtsortenspezifische enzymatische Wirkung einen Glutamin-Synthetase-Inhibitor neutralisieren oder inaktivieren kann, wobei die Expression des Proteins unter der Steuerung eines von den Polymerasen der Pflanzenzellen erkannten Promotors erfolgt.

This ruling was confirmed in **G 1/98** (Novartis II) and is now covered explicitly by Art. 4(2) of 98/44 and Rule 27 (b) EPC.

- **Breeding processes:** **G 1/08** of 9.12.2010 (Broccoli) distinguishes activities of genetic engineering and other, i.e. conventional activities of breeding. Genetical engineering steps result in the breeding process being technical and hence not falling under the prohibition of Art. 53 b). Therefore, the skilful inventor will add a trivial and redundant transgenic step to an otherwise conventional breeding process (e.g. SMART breeding). Thus, the process will be „technical“ and will not fall under the prohibition of art. 53 b).

- **Product vs. process:** If a conventional breeding process is barred from being patented by **G 1/08**, e.g. SMART Breeding (Selection with Markers and Advanced Reproductive Technologies), the skilful inventor will draft claims covering the product of the process, advantageously in the form of product-by-process claims. This is explicitly admitted by Art. 4(3) and Rule 27 c) and is currently discussed in the tomato case **G 1/08, T 1242/06**: From a process of breeding tomato plants the claims were transformed to product claims: A tomato fruit of the species *Lycopersicon esculentum* which is naturally dehydrated (as of 8.11.11).

- **Cutting-off:** If a breeding process as a whole is barred from being patented under Art. 53 b) since it contains conventional (i.e. biological) steps, the skilful inventor will cut off the critical steps and will draft a patent claim containing only non-critical technical steps (but so-called technical bottlenecks) which will nevertheless allow to monopolise the whole process.

In the context of SMART breeding this could e.g. be achieved by claiming only some genetic markers, their isolation and their use for selecting. In conventional animal breeding the claims can be e.g. limited to the technical steps of separating sperms by flowcytometry not mentioning the use in the breeding process.

G 2 / 06 – At last Thomson/ Wisconsin of 25.11.2008 criticised this obvious circumvention of the statute:

21. *Secondly the Appellant (= Wisconsin) contends that, in order to fall under the prohibition of Rule 28 c) (...) EPC, the use of human embryos must be claimed.*

22. *However, this Rule (...) does not mention claims, but refers to „invention“ in the context of its exploitation. What needs to be looked at is not just the explicit wording of the claims but the technical teaching of the application as a whole as to how the invention is to be performed. (...)*

To restrict the application of Rule 28 c) (...) EPC to what an applicant chooses explicitly to put in his claim would have the undesirable consequence of making avoidance of the patenting prohibition merely a matter of clever and skilful drafting of such claim.

This ruling was confirmed by the ECJ in C34/10 (embryonic stem cells / Brüstle) of 18.10.2011, No. 49 and 50.

- **Instrumental means or use vs. process:** If a process and the product of this process are barred from being patented under Art. 53 b), the skilful inventor will draft patent claims containing means or instruments to implement the process (again: technical bottlenecks) or containing a specific use of the product. Such claims can again be sufficient to monopolise the process or the product.

Example: Instead of claiming a process of animal breeding the flowcytometric apparatus separating the sperms, or the dye used to colour the sperms for flowcytometry are claimed.

Stop avoiding patenting prohibition: Whole content approach

- In the field of statutory restrictions of patenting of Art. 53 b) the *whole content* of the technical teaching of the invention, not only the skilfully drafted patent claims should be considered to decide whether the prohibition of Art. 53 b) applies.

To prevent the far too easy avoidance of patenting prohibition of Art. 53 b) / Art. 4 in the future it is recommended to add a new paragraph to both articles stating that the whole content of the technical teaching of an invention should be considered (*whole content approach*) including the inevitable technological context of the invention, and *not* only the skilfully drafted claims (*claims only approach*):

„For evaluating the patentability of an application under this article the whole content of the invention will be considered.“

„In the same way contents of the invention which are not explicitly disclosed will be considered for evaluating patentability, such as inevitable pre-treatment steps, unavoidable consequences and exclusive and unavoidable uses.“

The broadening to pre-treatments, consequences and unavoidable uses is recommended to prevent applicants from concealing and cutting off potentially critical steps (contents) of their inventions in order to circumvent patenting prohibition.