Opposition against European Patent EP 2373154 B1

Title: BARLEY AND MALT-DERIVED BEVERAGES WITH LOW DIMETHYL SULFIDE LEVEL
Application number: 09771493.5
Proprietor: Carlsberg Breweries A/S, Heineken Supply Chain B.V.
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Opponents:

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Arche Noah, represented by Christian Schrefel, Chairman

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Brot für die Welt, represented by Dr Klaus Seitz, Head of Policy Department

Campact, represented by Christoph Bautz, Executive Director

Evangelischer Dienst auf Lande, represented by Ricarda Rabe, kommissarische Vorsitzende

Gen-ethisches Netzwerk, represented by Birgit Peuker, board member

IG Nachbau, represented by Georg Janssen, Executive Director

Noah, represented by Erling Frederiksen, Spokesperson

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Opposition is filed against the patent as a whole. Revocation of the whole patent and if necessary a public hearing of the opposition is requested.

Reasons for opposition:

1. The patent violates Art. 53(b) EPC, and more specifically, the prohibition on patenting essentially biological processes for breeding.

2. Further, the patent is not inventive and therefore violates Art. 52 (1) in combination with Art. 56.

1. Violation of Article 53(b)

1.1 The content of the patent and its teaching

The patent claims barley plants derived from essentially biological processes for breeding that can be used for the production of beverages with reduced levels of both dimethyl sulfide (DMS) and/or its precursor S-methyl-L-methionine (SMM). The barley plants are described as carrying a mutation in the gene encoding methionine-S-methyltransferase (MMT) that causes a total loss of MMT function.

Claim 6 reads:

> *"A barley plant, or part thereof, wherein the barley plant carries a mutation in the gene encoding methionine-S-methyltransferase (MMT) that causes a total loss of MMT function"*

As the patent description shows, these plants were derived from random mutagenesis triggered by chemical substances.

On page 13 of the patent as granted, the steps of the invention are described as follows:

> *(i) Mutagenizing barley plants, and/or barley cells, and/or barley tissue, and/or barley kernels, and/or barley embryos, thereby obtaining generation M0 barley; and*
> *(ii) Propagating (e.g. breeding) said mutagenized barley plants, kernels, and/or embryos for ≥2 generations, thereby obtaining barley plants of generation Mx, wherein x is an integer ≥2; and*
> *(iii) Obtaining a sample of said Mx barley plants; and*
> *(iv) Determining the level of SMM in said sample; and*
> *(v) Selecting plants wherein the sample comprises less than 10 ppb SMM, preferably less than 5 ppb SMM, more preferably no detectable SMM; and*
> *(vi) Sequencing at least part of the MMT gene; and*
> *(vii) Selecting plants carrying a mutation in the MMT gene;*

1.2 The scope of the patent

Claim 6 as granted not only covers barley plants from the processes described in the patent, but also plants inheriting similar or same genetic conditions and phenotypical characteristics stemming from native traits or other methods applied in conventional breeding.

1.3 Legal analysis

Article 53(b) of the European Patent Convention (EPC) as well as Article 4 of EU Directive 98/44/EC exclude:

> *"essentially biological processes for the production of plants or animals."*

This provision was defined for the first time in Article 2 (2) of EU Directive 98/44/EC and was subsequently adopted as part of the Implementation Regulation of the EPC (Rule 26 (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."

The European Patent Office (EPO) forwarded several questions to the Enlarged Board of Appeal (EBA) after finding that the definition in the EU Directive was very difficult to apply in legal practice.

Decisions G2/07 and G1/08

In 2010, in its decisions G2 /07 and G1/08, the EBA formulated the following definition for "essentially biological processes":

"1. A non-microbiological process for the production of plants which contains or consists of the steps of sexually crossing the whole genomes of plants and of subsequently selecting plants is in principle excluded from patentability as being "essentially biological" within the meaning of Article 53(b) EPC."

Additional technical steps, such as usage of DNA sequences for the selection of the plants, are not sufficient to override the exclusion in Article 53(b):

"2. Such a process does not escape the exclusion of Article 53(b) EPC merely because it contains, as a further step or as part of any of the steps of crossing and selection, a step of a technical nature which serves to enable or assist the performance of the steps of sexually crossing the whole genomes of plants or of subsequently selecting plants."

On the other hand, what was patentable is defined as follows:

"3. If, however, such a process contains within the steps of sexually crossing and selecting an additional step of a technical nature, which step by itself introduces a trait into the genome or modifies a trait in the genome of the plant produced, so that the introduction or modification of that trait is not the result of the mixing of the genes of the plants chosen for sexual crossing, then the process is not excluded from patentability under Article 53(b) EPC."

As a result, the EPO continues to grant patents on methods of genetically engineering plants and animals because those processes are considered to be a *step of a technical nature, "which step by itself introduces a trait into the genome"*.

There remains some legal uncertainty concerning random mutagens: From the perspective of patent law random mutagenesis is not 'technical' because the changes in the genome are not introduced by specific technical means. Nevertheless, according to the definition implemented by the EBA, it could be considered to be a "*step in itself to introduce a trait into the genome without crossing and selection*". As a result, the decision of the EPA leaves some grey areas and there is, as yet, no legal certainty or clarity.

Decisions G2/12 and G2/13

In further decisions (G2/12 and G2/13), the Enlarged Board of Appeal at the EPO decided that plants and animals derived from "essentially biological" breeding can be patented, even though the process is excluded under Article 53(b), EPC.

EU Commission interpretation

In November 2016, the EU Commission drew up an explanatory statement on the interpretation of Article 4 of EU Directive 98/44/EC (Commission Notice on certain articles of Directive 98/44/EC

of the European Parliament and of the Council on the legal protection of biotechnological inventions (2016/C 411/03), Official Journal of the European Union, 8.11.2016). In its conclusion it states that:

> *"the Commission takes the view that the EU legislator's intention when adopting Directive 98/44 /EC was to exclude from patentability products (plants/animals and plant/animal parts) that are obtained by means of essentially biological processes."*

This explanatory statement is in clear contradiction to the decisions of the Enlarged Board of Appeal at the EPO (G2/12 and G2/13). Since 1999, when the EPO adopted the provisions of EU Directive 98/44/EC, the EPO has to some extent been bound by the interpretation of the institutions of the EU in regard to its specific articles. Consequently, the EPO should now adapt its legal practice in accordance with the interpretation presented by EU institutions.

Further, the EU Commission – based on the history and the text of the EU Directive - also presented some guidance on what is regarded as patentable:

> *"The trigger point for ensuring the patentability of either a plant or an animal is the technical process, such as for instance the insertion of a gene into a genome. Essentially biological processes are not of a technical nature and therefore, according to the position taken by the legislator, they cannot be covered by a patent."*

This interpretation at least partially diverges from the one given by the EPA in G2/07 and G1/08.

In general, the definition provided by the EU Commission follows the distinction between genetic engineering and conventional breeding. It clearly defines the technicality of methods which are patentable: The meaning of the expression "insertion of a gene into a genome" as a method used in genetic engineering can be understood historically (in regard to Directive 98/44/EC), and also technically and legally, for example, EU Directive 2001/18 and its predecessor Directive 90/220/EEC are based on a similar definition for genetically modified organisms that need to be regulated.

Indeed, Directive 98/44/EC in Recitals 1, 2, 52 and 53 as well as in Article 16 uses the expression "genetic engineering". Further, in Recital 32 the expression "genetic modification" is used and Recital 9 and 10 deal with "biotechnology" in the sense of genetic engineering. This wording – and the history of the Directive – clearly shows that the EU intent is to allow patents on methods of genetic engineering, but not on methods applied in 'conventional' breeding.

Therefore, the guidance drawn up by the EU Commission provides more legal certainty and clarity than the one previously developed by the EBA (G1/07 and G2/08). It is derived from the context and the history of the EU Directive. Consequently, there now has to be an assumption that the EPO will adapt its legal practice accordingly. In consequence, the decision G2/07 and G1/08 of the Enlarged Board of Appeal has to be understood as follows: Only if material inserted from outside into the cell by itself introduces a trait into the genome or modifies a trait in the genome of the plant produced, so that the introduction or modification of that trait is targeted and not derived at random, then the process is not excluded from patentability under Article 53(b) EPC.

1.4 Conclusions on Article 53(b)

In short, the relevant steps of the invention are:

(1) random mutagenesis

(2) propagation by crossing for a period of more than two generations

(3) selection of the relevant plants by biochemical methods
(4) additional sequencing of relevant genes.

In the light of Article 53(b), the steps 1-3 of the invention have to be regarded as essentially biological, while step 4 has to be seen as an additional step, not changing the character of the invention as being "essentially biological".

Consequently, claims 6-9 as well as claim 16 have to be revoked.

2. Violation of Art 52 (1) in combination with Art 56

2.1 The content of the patent and its teaching

In regard to the inventiveness of the patent, the following observations can be made:

- As the patent description shows, the relevant biochemical processes of the occurrence and impact of dimethyl sulfide (DMS) and/or its precursor S-methyl-L-methionine (SMM) as well as the function of the methionine-S-methyltransferase (MMT) were all known previously.
- Further, the decisive method of chemical mutagenesis applied to the kernels using NaN_3, was developed by other breeders.
- Methods for screening the plants were adopted by the patent holder to render them more effective, however, no new methods for selecting the plants with the relevant characteristics were invented.
- The methods for additional sequencing of the gene were known previously, therefore, this additional step does not add anything to the inventiveness of the patent. Although the relevant DNA sequences are used to characterise the plants as claimed, they are added matter unnecessary for performing the teaching as described in the patent.
- The overall outcome of the process as described was not surprising, but intended: Barley with reduced activity in methionine-S-methyltransferase (MMT) can be used for the production of beverages with reduced levels of both dimethyl sulfide (DMS) and/or its precursor S-methyl-L-methionine (SMM).
- The fact that other breeders have tried before to produce similar plants by other technical means, does not render the patent inventive. According to the patent description, the method applied to introduce the genomic variant is not always successful, and mostly depends on a sufficient number of kernels and the application of effective screening. This cannot be regarded as inventive in itself (page 3 of the patent as granted):

  "Although far from always possible, finding a particular mutant after NaN 3 treatment is dependent on persistence and an effective screening method, and thus far from always successful."

2.2 Conclusions on Art 52 (1) in combination with Art 56.

In the light of Article 52 in combination with Art 56 EPC, the whole patent has to be revoked due to lack of inventiveness.

Annexes:
Signed formulas of the opponents