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**Datasheet for the decision
of 23 January 2009**

Case Number: T 0190/07 - 3.3.10

Application Number: 00903788.8

Publication Number: 1144015

IPC: A61L 2/02

Language of the proceedings: EN

Title of invention:

Treating protein-containing liquids

Patentee:

COMMON SERVICES AGENCY

Opponent:

CSL Behring GmbH

Headword:

-

Relevant legal provisions:

EPC Art. 83

Keyword:

"Sufficiency of disclosure (yes): disclosure sufficient even in the absence of examples falling under the claims - effect relevant to technical problem and not to sufficiency"

Decisions cited:

T 1129/97, T 0840/01, T 0645/05

Catchword:

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Case Number: T 0190/07 - 3.3.10

D E C I S I O N
of the Technical Board of Appeal 3.3.10
of 23 January 2009

Appellant: CSL Behring GmbH
(Opponent) Emil-von-Behring-Strasse 76
D-35041 Marburg (DE)

Representative: Lauppe, Hans Friedrich
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Respondent: COMMON SERVICES AGENCY
(Patent Proprietor) Trinity Park House
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Representative: Horner, Martin Grenville
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Decision under appeal: Decision of the Opposition Division of the
European Patent Office posted 8 December 2006
rejecting the opposition filed against European
patent No. 1144015 pursuant to Article 102(2)
EPC 1973.

Composition of the Board:

Chairman: R. Freimuth
Members: P. Gryczka
D. S. Rogers

Summary of Facts and Submissions

- I. A notice of opposition was filed in which revocation of European patent 1 144 015 in its entirety was requested on the sole ground of insufficiency of disclosure (Article 100(b) EPC).
- II. The Appellant (Opponent) lodged an appeal against the decision issued in writing on 8 December 2006, by which the Opposition Division rejected the opposition since it held that the European patent disclosed the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.
- III. At the oral proceedings, which took place in front of the Board on 23 January 2009, the Proprietor of the patent in suit (Respondent) filed an amended set of eleven claims as a main request, this main and sole request superseding the requests filed previously in writing.

Claim 1 of said main request reads as follows:

"1. Use of a depth filter for removal of abnormal infective prion proteins associated with transmissible spongiform encephalopies (TSEs) from an aqueous liquid containing a natural product, which comprises passing the liquid through the depth filter which is formed of a matrix comprising solid particles of porous material and having a pore size providing a retention less than 6 μm , the solid porous particles being a mixture of kieselguhr and perlite particles; and so removing any abnormal infective prion proteins which may be present

in the liquid; the liquid and filter being free of cationic charged material."

IV. According to the Appellant, the two filters used in the examples of the patent in suit, namely "Seitz KS80" and "Seitz K200P", were not free of cationic charged materials as required by the claimed invention. This was shown, *inter alia*, by the documents:

- (1) Declaration dated 25 February 2005 of M. Leibnitz and M. Baranowski from "Pall SeitzSchenk Filtersystems GmbH" regarding the filters "Seitz KS80 and K200P" with annexed pages 6, 7, 9 and 11 of the technical brochure SSF P104 from SeitzSchenk Filtersystems,
- (11) Declaration dated 26 March 2007 of M. Leibnitz and M. Baranowski from "Pall SeitzSchenk Filtersystems GmbH" regarding the filters "Seitz KS80 and K200P", and
- (12) EP-B-0 734 285.

Since none of the examples fall under the claimed use, the patent in suit did not disclose a concrete way of carrying out the invention. In addition, the claimed feature requiring that the pore size provided a retention of less than 6 μm was not decisive for the invention since the filter "Seitz K700" having a larger pore size resulting in a retention of 6 to 15 μm was also suitable for the removal of prions as shown by the documents:

- (9) Technical brochure "Seitz depth filters, the technological lead" from "Seitz-Filter-Werke", pages 1 to 17 (no date), and
- (10) Copy of a document named "Evaluation of TSE removal procedures in the manufacture of plasma products" by Benoît Flan, WHO Consultation on Tissue Infectivity Distribution in TSEs, 14 to 16 September 2005.

Furthermore, the experimental data filed by the Appellant during the opposition proceedings with a letter dated 10 March 2005 (document (2)) and in the present appeal proceedings with a letter dated 13 April 2007 (document (13)) showed that the degree of removal of prion protein achieved in the examples of the opposed patent could only be achieved under specific operating conditions, namely by controlling the ratio of flow rate per filter area. Since, this ratio was not indicated in the claims, nor mentioned in the description of the patent specification, an essential feature of the claimed invention had not been disclosed. Thus, the invention was not disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

- V. According to the Respondent the feature requiring that the liquid and filter be free of cationic charged materials had to be interpreted as meaning that they should be free of cationic material which contributed to a reduction of biological activity of the biologically active proteins. This requirement was met by the two filters "Seitz KS80" and "Seitz K200P" used in the examples of the patent specification since they

contained cationic charged material without, however, contributing to a reduction of biological activity. In any case, even if these examples were considered as not illustrating the invention, the description of the patent specification gave sufficient information to carry out the invention without undue burden.

Furthermore, it was common general knowledge that any filtration process had to be optimized by adjusting the operating conditions, such as the ratio of flow rate per filter area. Thus, the experiments conducted by the Appellant and in which a high removal of prions was achieved showed in fact that the invention could be carried out by a skilled person and was thus sufficiently disclosed in the sense of Article 83 EPC.

- VI. The Appellant requested that the decision under appeal be set aside and that the patent be revoked.

- VII. The Respondent requested that the decision under appeal be set aside and that the patent be maintained on the basis of the main request submitted at the oral proceedings on 23 January 2009.

- VIII. At the end of the oral proceedings the decision of the Board was announced.

Reasons for the Decision

- 1. The appeal is admissible.

- 2. *Amendments*

Claim 1 of the main and sole request has been amended by incorporating in claim 1 as granted the feature specifying that the solid porous particles are a mixture of kieselguhr and perlite particles. This amendment is based on claim 4 of the application as filed and restricts the protection conferred by the patent as granted. Consequently, the amended claim 1 fulfils the requirements of Article 123(2) and (3) EPC.

Dependent claims 2 to 11 correspond respectively to claims 2, 3 and 6 to 13 of the patent as granted.

3. *Insufficiency of disclosure (Article 100(b) EPC)*

Since the patent was exclusively opposed under Article 100(b) EPC, the sole issue to be decided in this appeal is whether the patent in suit provides sufficient information which enables the skilled person to perform the invention as defined in the claims, taking into account common general knowledge.

- 3.1 The claimed invention relates to the use of a depth filter for removal of prion proteins and is defined by the nature of the filter, i.e. a depth filter free of cationic charged material and formed of a matrix comprising solid particles of porous material and having a pore size providing a retention less than 6 μm , the solid porous particles being a mixture of kieselguhr and perlite particles, and by the purpose of the use, i.e. to remove abnormal infective prion proteins from an aqueous liquid free of cationic charged material and containing a natural product.

The filter to be used to carry out the claimed invention is described with regard to its pore size, its composition and dimensions in claim 1 and in paragraphs [0016], [0021] and [0022] of the patent specification. With this information, the skilled person has no difficulty to determine which filters are suitable for the claimed use. The purpose of the use of the filter, i.e. the removal of prion proteins from an aqueous liquid containing a natural product, although being self explanatory from the wording of claim 1 on its own, is also described in more detail in paragraphs [0014] and [0020] of the patent specification. The patent specification thus gives sufficient information for the skilled person to determine for what purpose the filter is used. Furthermore, it has not been contested that the filters described in the patent specification would be suitable for the purpose indicated in claim 1, in other terms that such filters will remove to a certain extent prion proteins from aqueous liquids.

In these circumstances, the Board arrives at the conclusion that the patent specification gives the skilled person sufficient information to carry out the claimed invention without undue burden.

- 3.2 According to the Appellant the claimed feature requiring that the pore size of the filters provided a retention of less than 6 μm was not decisive for the invention since the filter "Seitz K700" having a larger pore size resulting in a retention of 6 to 15 μm was also suitable for the removal of prions as shown by the documents (9) and (10).

However, that filters with a higher retention than 6 µm could also be suitable for the removal of prions does not imply a *contrario* that the filters defined in claim 1 with a retention of less than 6 µm are not suitable for this purpose. Thus, this argument of the Appellant must be rejected.

- 3.3 Furthermore, according to the Appellant experimental data (documents (2) and (13)) showed that a high degree of removal of prion protein could only be achieved under specific operating conditions, namely by controlling the ratio of flow rate per filter area. Since, this ratio was not indicated in the claims, nor mentioned in the description of the patent specification, an essential feature of the claimed invention has not been disclosed.

However, the degree of removal of prion proteins is an issue relating to the technical problem solved by the invention to be considered when assessing inventive step. Thus, it is not relevant for sufficiency of disclosure, as the claimed use only requires the removal of prions without defining to what extent prions should be removed (see decision T 645/05, point 4.2 of the Reasons and T 840/01, point 1.3 of the Reasons, both decisions not published in OJ EPO). Thus, this objection of the Appellant must also be rejected.

- 3.4 Finally, according to the Appellant the two filters used in the examples of the patent in suit, namely "Seitz KS80" and "Seitz K200P", were not free of cationic charged materials as required by the claimed invention. The patent specification thus gave no concrete example illustrating the invention with the

consequence that the requirements of sufficiency of disclosure were not met.

According to the declarations (1) and (11) of the manufacturer of the two "Seitz" filters, these filters contain cationic charged material coming from the binder, namely a polyamido-amine-epichlorhydrin resin, used for the preparation of the filters. That this type of binder generates cationic charged material is also confirmed by document (12), page 3, lines 12 and 13.

- 3.4.1 This finding was not contested by the Respondent who recognised that the filters "Seitz KS80" and "Seitz K200P" contained cationic charged material, but argued that this feature of the claimed invention had to be interpreted as meaning that the filters should be free of cationic material which contributes to a reduction of biological activity of the biologically active proteins. According to the Respondent, this requirement was met by the two filters "Seitz KS80" and "Seitz K200P" since they contained cationic charged material which did not contribute to a reduction of biological activity.

However, the wording of claim 1 is clear with regard to the feature requiring that the filter has to be free of cationic charged material since the claim unambiguously requires that such material is not present at all in the filter. Since the claim itself is clear in this respect, the interpretation of the claim made by the Respondent, giving to the feature "*the filter being free of cationic charged material*" a different meaning, namely that cationic charged material can be present to a certain extent in the filter, must be rejected (see

decision T 1129/97, point 2.1.2 of the reasons, OJ EPO 2001, 273). In addition the interpretation made by the Respondent is not supported by the facts, since the claimed feature requiring that the filter is free of cationic charged material is in line with the description of the invention in the patent specification on page 3, line 6, where the filter is also described as being free of cationic material. The indication that cationic material may contribute to a reduction of the biological activity on page 3, line 23 and 24 merely gives the reason why such material should be absent.

Therefore, the examples 1 and 4 in which respectively the filters "Seitz KS80" and "Seitz K200P" were used, do not illustrate the claimed invention.

3.4.2 However, since the invention is sufficiently disclosed in the patent specification (see point 3.2 *supra*), the fact that none of the examples illustrates the claimed invention has, in the present case, no negative impact on the sufficiency of disclosure since a worked example is not necessary for the skilled person to be able to carry out the invention.

3.4.3 The Appellant did not maintain his written objections that decision T 292/85, OJ EPO 1989, 275, required a concrete example for a disclosure of an invention to be sufficient and that the patent in suit did not comply with the requirements of Rule 42(1)(e) EPC since it contained no example in accordance with the claimed invention. The Board sees no reason to go into the details of these objections *ex officio*, given that these objections are *prima facie* unconvincing.

3.5 Consequently, the Appellant's challenge to the sufficiency of disclosure of the invention under Article 100(b) EPC is rejected.

4. Remittal

Since the claims were substantially amended during the appeal proceedings, it is appropriate to remit the case to the first instance for adaptation of the description exclusively to reflect the amendment to claim 1.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the department of first instance with the order to maintain the patent on the basis of claims 1 to 11 of the main request received during the oral proceedings of 23 January 2009 and a description to be adapted thereto.

The Registrar

The Chairman

C. Rodríguez Rodríguez

R. Freimuth