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Title of invention:
Immunoglobulin purification

Patent Proprietor:
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Headword:
Immunoglobulin purification/F. HOFFMANN-LA ROCHE

Relevant legal provisions:
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Keyword:
Main request, auxiliary requests 1 to 8: sufficiency of disclosure - (no);
Referral to the Enlarged Board of Appeal - (no)

Decisions cited:
G 0002/88, G 0001/03, T 0939/92, T 0601/05, T 1859/08

Catchword:

Europäisches Patentamt
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Beschwerdekammern

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Case Number: T 0945/18 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 14 December 2021

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Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 30 January 2018 revoking European patent No. 2379108 pursuant to Article 101(3)(b) EPC**

Composition of the Board:

Chair	B. Claes
Members:	R. Morawetz
	M. Blasi

Summary of Facts and Submissions

I. The appeal of the patent proprietor (appellant) lies from the decision of the opposition division revoking European patent No. 2 379 108 ("the patent"), entitled "*Immunoglobulin purification*".

II. Seven oppositions were filed against the patent. The opposition proceedings were based, *inter alia*, on the ground for opposition under Article 100(b) EPC. Opponents 1 to 7 are respondents I to VII in the appeal proceedings.

III. The decision under appeal dealt with sets of claims of a main request and auxiliary requests 1 to 11. The opposition division held, *inter alia*, with respect to auxiliary request 1, that claim 1 was directed to obtaining *any* immunoglobulin in monomeric form, but that many immunoglobulins could not be obtained in monomeric form within the narrow pH range recited in the claim. The same considerations were held to apply to claim 1 of auxiliary requests 2 and 3. Accordingly, the invention as defined in claim 1 of auxiliary requests 1 to 3 was not sufficiently disclosed (Article 83 EPC). With respect to the sets of claims of auxiliary requests 4 to 6, the opposition division held that amended claim 1 extended the protection conferred by the patent (Article 123(3) EPC). Claim 1 of auxiliary requests 7 to 11 was considered to be unclear (Article 84 EPC).

IV. With the statement setting out the grounds of appeal, the appellant submitted sets of claims of a main request and auxiliary requests 1 to 8. The sets of claims of the main request and auxiliary requests 1

and 2 and of auxiliary requests 6, 7, 8 are identical to the sets of claims of auxiliary requests 1, 2, 3 and 4, 5, 6 respectively, on which the decision under appeal was based. The sets of claims of auxiliary requests 3, 4 and 5 were newly filed on appeal.

Claim 1 of the main request reads:

"Use of a membrane anion exchange chromatography material for obtaining an immunoglobulin in monomeric form depleted of immunoglobulin aggregates and immunoglobulin fragments in a method which comprises the following step:
applying an aqueous, buffered solution comprising an immunoglobulin in monomeric and in aggregated form and immunoglobulin fragments to said anion exchange chromatography material, wherein the aqueous, buffered solution has a pH value of from pH 8.0 to pH 8.5, whereby the immunoglobulin depleted of immunoglobulin aggregates and immunoglobulin fragments is recovered from the flow-through of the anion exchange chromatography material and thereby an immunoglobulin in monomeric form is obtained."

Claim 1 of auxiliary request 1 differs from claim 1 of the main request in that an additional step is inserted after the "whereby-clause" at the end of the claim as follows: "*wherein said method comprises prior to the anion exchange chromatography step an additional protein A chromatography step.*"

Claim 1 of auxiliary request 2 is identical to claim 1 of auxiliary request 1 except that the pH range is limited to "*pH 8.5*".

Claim 1 of auxiliary requests 3, 4 and 5 is identical to claim 1 of the main request and auxiliary requests 1 and 2 respectively, but with the term "*immunoglobulin*" amended to read "*monoclonal immunoglobulin*".

Claim 1 of auxiliary requests 6, 7 and 8 is identical to claim 1 of the main request and auxiliary requests 1 and 2 respectively, except that the term "*immunoglobulin*" is replaced by the expression "*monoclonal antibody*".

V. Respondents I and V provided replies to the statement of grounds of appeal addressing substantive issues. They made submissions concerning, *inter alia*, claim construction and the requirements of Article 83 EPC.

VI. The board scheduled oral proceedings, as requested by the appellant and respondents I, V and VII. It issued a communication under Article 15(1) RPBA in which it indicated its preliminary opinion with respect to, *inter alia*, the construction of claim 1 of the main request and the requirements of Article 83 EPC.

VII. In response thereto, respondents I, II, IV, V, VI and VII announced that they would not be attending the oral proceedings. The appellant, for its part, made further submissions with respect to claim construction and sufficiency of disclosure.

VIII. Oral proceedings were held by videoconference in the absence of respondents I, II, IV, V, VI and VII in accordance with Rule 115(2) EPC and Article 15(3) RPBA.

During the oral proceedings the appellant submitted the following questions for referral to the Enlarged Board of Appeal:

"1. If a claim to the use of a known compound for a particular purpose, which is based on a technical effect which is described in the patent, is to be interpreted as including that technical effect as a limiting functional technical feature relevant in the assessment of patentability under Article 54 EPC (G 2/88), can the same technical feature be disregarded as a limiting functional technical feature in the assessment of patentability under Article 83 EPC?

2. Does it make a difference in the assessment of patentability under Article 83 EPC whether said limiting functional technical feature is literally expressed in the claim or is inherent in the claim?"

At the end of the oral proceedings, the Chair announced the board's decision.

IX. The following documents are referred to in the present decision:

D7 Ion Exchange Chromatography & Chromatofocusing, (2004), Handbooks from Amersham Biosciences, Chapter 1 including coverpage, bibliographic pages and final page indicating the publication date, pages 1 to 28

D20 http://www.agrisera.com/en/info/molecular-weight-and-isoelectric-point-of-various-Immunoglobulins, page 1

D25 Fahrner R.L. *et al.*, Biotechnology & Genetic Reviews (2001), Vol. 18, pages 307 to 327

D30 Jiskoot W. *et al.*, Journal of Immunological Methods, (1989), Vol. 124, pages 143 to 156

X. The appellant's arguments are summarised below.

Main request - claim 1

Claim construction

The claim was for the use of a known compound for a new purpose within the meaning of decision G 2/88 (headnote III, Reasons, points 9 and 9.1). That decision provided a "self-correcting mechanism" for non-medical use claims. Thus, a claim directed to a use of a compound for a particular purpose, which was based on a technical effect described in the patent, should be interpreted as including that technical effect as a functional technical feature.

The technical effect described in the patent was that the immunoglobulin in monomeric form did not bind to the stationary phase whereas the immunoglobulin in aggregated form and/or the immunoglobulin fragments did bind to the stationary phase and were removed therewith from the solution (see lines 17 to 21 in paragraph [0024]). The skilled person would have understood that solutions with different pH values were used in the Examples of the patent in order to determine the pI value of the immunoglobulins (see Examples 1, 2, 3 and 4, Figures 1a, 1b, 2b and 3). The skilled person would have furthermore understood which pI the immunoglobulins needed to have to be separated from aggregates and fragments in order to be in the flow-

through in the claimed use, namely a suitable pI. Therefore, in addition to the two functional limitations explicitly recited in the claim, i.e. the claimed purpose and the technical result, an additional functional technical feature limiting the claim to particular immunoglobulins was implied based on the effect described in the patent. This functional technical feature excluded from the claim all immunoglobulins which could not be obtained in the desired form due to their pI value "*by way of legal construction*".

The claim construction must be the same in relation to all patentability requirements. The legal fiction provided by decision G 2/88 in terms of a limitation of a claim in the context of assessing novelty applied also in the context of assessing sufficiency of disclosure. It applied all the more in the present case, in which the technical effect was explicitly stated in the claim. The effect that was stated in the claim was "self-corrected" with the result that antibodies that could not be separated were not embraced by the claim.

Also for medical use claims the approach that the technical effect was a functional technical feature of a claim that excluded non-working embodiments despite the absence of a functional limitation in the claim was applied in the case law. In decision T 601/05 of 24 April 2008, the claim was "self-corrected" with the result that antibodies which were not useful (i.e. had no pharmaceutical effect) were not covered "*by way of legal construction*" (see Reasons, point 6.5). In decision T 1859/08, the achievement of the therapeutic effect was considered a technical feature of the claim although it was not stated in the claim

(see Reasons, point 13).

The same had to apply for the use claim under consideration where the effect was explicitly stated in the claim. Accordingly, the claim under consideration was "self-corrected" and embodiments not achieving the effect were not covered by it.

The Case Law of the Boards of Appeal, 9th edition 2019, section I.C.8.1.3; decision T 1822/12 (Reasons, point 3.1 and the decisions cited in the sub-points) and decision T 1039/09 (Reasons, point 11) confirmed that the criteria set out in decision G 2/88 were applicable to the claim at issue.

Referral of questions to the Enlarged Board of Appeal

The appellant requested that, in the event of the board considering that the legal construction provided by decision G 2/88 was only relevant for assessing novelty and not for assessing sufficiency of disclosure, the first question (see section VIII) be referred to the Enlarged Board of Appeal.

The appellant requested that, in the event of the board distinguishing between functional technical features explicitly mentioned in the claim and functional technical features implied due to legal construction/ fiction, the second question be referred (see section VIII) to the Enlarged Board of Appeal.

Sufficiency of disclosure (Article 83 EPC)

The claimed invention was sufficiently disclosed in the patent because, upon proper construction, the technical effect being part of the claim acted as a "self-

correcting mechanism" and non-working embodiments were not covered by the claim. The skilled person, having regard to document D7, would understand the claimed invention and could carry it out for immunoglobulins with a suitable pI.

In view of the common general knowledge, the skilled person could ascertain without undue burden that all immunoglobulins with a pI below 8.0 to 8.5 would be unsuitable in the claimed use due to their negative charge at the claimed pH. These immunoglobulins were not within the claimed scope.

No serious doubts had been raised, substantiated by verifiable facts, thereby showing that the invention could not be put into practice over the whole ambit claimed for all immunoglobulins with a suitable pI.

Decision G 1/03 (see Reasons, point 2.5.2) supported the appellant's case because the skilled person was aware of a large number of conceivable immunoglobulins having a suitable pI that could be purified within the pH range recited in the claim.

The requirements of Article 83 EPC were met.

Auxiliary requests 1 to 8 - claim 1

Sufficiency of disclosure (Article 83 EPC)

The claimed invention was sufficiently disclosed because non-working embodiments were not covered by the claims as a consequence of the "use" feature.

XI. Respondent I's arguments are summarised below.

Main request - claim 1

Claim construction

The term "*an immunoglobulin*" was not limited, e.g. with respect to the immunoglobulin's pI, and immunoglobulins differed substantially in their pI values (see document D20, page 1, and document D30, page 153, right-hand column, second paragraph).

The claim recited the purpose as a limiting functional technical feature, expressed as a technical effect.

According to decision G 2/88 the purpose of a use claim was limiting. This did not mean, however, that any immunoglobulin that could not be purified in flow-through mode at pH 8.0 to pH 8.5 was excluded from the claimed use. The purpose of the claim read as follows: "*for obtaining an immunoglobulin in monomeric form depleted of immunoglobulin aggregates and immunoglobulin fragments*". The purpose, i.e. the technical effect, had to be achievable for any immunoglobulin.

Also for a second medical use claim, in order for the requirement of sufficiency of disclosure to be met, a functional technical feature recited in the claim had to be plausibly achievable over the entire ambit of the claim based on the teaching of the patent and the common general knowledge.

Sufficiency of disclosure (Article 83 EPC)

The claim required the membrane anion-exchange

chromatography material to be usable for obtaining any immunoglobulin in monomeric form within the pH range of pH 8.0 to pH 8.5 (see decision G 1/03, Reasons, point 2.5.2).

Due to the fundamental interaction between pI and pH and the relevance thereof in anion-exchange chromatography, the claimed invention, for a large portion of the scope, offended against generally accepted laws of physics and chemistry.

Non-working embodiments were part of the claimed subject-matter and the claim thus failed to meet the requirements of Article 83 EPC.

Auxiliary requests 1 to 8

Sufficiency of disclosure (Article 83 EPC)

Claim 1 of each of these requests failed to meet the requirements of Article 83 EPC for the same reasons as given for the invention in claim 1 of the main request.

XII. Respondent V's arguments are summarised below.

Main request - claim 1

Claim construction

The functional technical feature "*for obtaining an immunoglobulin in monomeric form ...*" constituted a limitation on the use of the membrane anion-exchange chromatography material. It identified a purpose which related to any immunoglobulin. If that purpose could not be achieved for some immunoglobulins, then these embodiments were not excluded from the claim, but the

invention defined in the claim lacked sufficiency of disclosure.

In accordance with the case law, also for functionally limited claims it needed to be assessed whether the skilled person was able to obtain substantially all embodiments falling within the ambit of the claims.

Sufficiency of disclosure (Article 83 EPC)

The appellant had not challenged the opposition division's decision that not all immunoglobulins could be obtained in monomeric form under the conditions required by the claim, specifically the narrow pH range.

Auxiliary requests 3 to 5

Admittance (Article 12(4) RPBA 2007)

The requests had been filed late.

Auxiliary requests 1 to 8 - claim 1

Sufficiency of disclosure (Article 83 EPC)

The limitations introduced did not overcome the deficiencies applying to the main request.

XIII. Respondent III's arguments are summarised below.

Referral of questions to the Enlarged Board of Appeal

The questions (see section VIII) were not relevant to the appellant's case.

XIV. Respondents II, IV and VI did not submit any arguments or requests during the appeal proceedings.

XV. The appellant requested that the decision under appeal be set aside and that the patent be maintained in amended form based on the set of claims of the main request or, in the event of this request not being granted, that the questions as filed during the oral proceedings be referred to the Enlarged Board of Appeal or, alternatively, that the patent be maintained in amended form based on the set of claims of one of auxiliary requests 1 to 8 (all claim requests having been filed with the statement of grounds of appeal).

Respondents I, III, V and VII requested that the appeal be dismissed. Respondent V furthermore requested that auxiliary requests 3 to 5 not be admitted into the appeal proceedings.

Reasons for the Decision

1. The appeal complies with Articles 106 to 108 and Rule 99 EPC and is admissible.

Background

2. It was common ground that the person skilled in the art knows the principles of ion exchange in general and anion exchange in particular (see, e.g., document D7, page 11, and document D25, page 322). There was a consensus that the person skilled in the art understands that, to obtain the immunoglobulin in monomeric form in the flow-through of the membrane anion-exchange chromatography material, the immunoglobulin must have a net neutral or net positive charge, whereas the immunoglobulin aggregates and

immunoglobulin fragments must have a net negative charge in order to be retained by the membrane anion-exchange chromatography material. The person skilled in the art furthermore knows that the charge state of a molecule is determined by its isoelectric point (pI) and that, at a pH that is greater than its pI, a molecule has a net negative charge, whereas, at a pH that is lower than its pI, the molecule has a net positive charge. The fact that immunoglobulins may differ in their pI values was likewise accepted to be generally known to the skilled person (see, e.g., Table of document D20, and document D30, page 153, right-hand column, first full paragraph).

Main request - claim 1

The claimed subject-matter - claim construction

3. The main issue of the case is the construction of the claim, the claim being identical to claim 1 of auxiliary request 1, underlying the decision under appeal. The opposition division held that the claim was directed to obtaining *any* immunoglobulin (having any pI value) in monomeric form.

4. The category of a claim and its technical features constitute its subject-matter (see decision G 2/88, OJ EPO 1990, 93, Reasons, point 2.6). The claim at issue is for the use of a known compound - "*a membrane anion exchange chromatography material*" - for a particular purpose - "*obtaining an immunoglobulin in monomeric form depleted of immunoglobulin aggregates and immunoglobulin fragments*". The claim furthermore comprises the physical step of applying an aqueous, buffered solution with a pH from 8.0 to 8.5 and comprising an immunoglobulin in monomeric and in

aggregated form and immunoglobulin fragments to said anion exchange chromatography material. Finally, the technical result of the claimed use is specified in the claim as a functional technical feature as follows: "*whereby the immunoglobulin depleted of immunoglobulin aggregates and immunoglobulin fragments is recovered from the flow-through of the anion exchange chromatography material and thereby an immunoglobulin in monomeric form is obtained*".

5. It is evident from the preceding point that none of the technical features recited in the claim nor the wording of the claim restrict the term "*immunoglobulin*" technically. The claim is thus understood to concern the use of the membrane anion-exchange chromatography material for obtaining any immunoglobulin in monomeric form depleted of immunoglobulin aggregates and immunoglobulin fragments by applying an aqueous, buffered solution with a pH from 8.0 to 8.5 comprising an immunoglobulin in monomeric and in aggregated form and immunoglobulin fragments to said anion-exchange chromatography material.

6. Relying on decision G 2/88 (*supra*, Reasons, points 9 and 9.1), the appellant argued as follows: in addition to the two functional limitations explicitly recited in the claim, i.e. the claimed purpose and the technical result, a further functional technical feature limiting the claim to particular immunoglobulins was to be implied based on the effect described in the patent "*by way of legal construction*" as a consequence of the claim being drafted in the format "new use of a known compound for a particular purpose". This additional functional technical feature excluded from the claim all immunoglobulins which could not be obtained in the desired form in the recited pH range of pH 8.0 to

pH 8.5 due to their unsuitable pI value.

7. In decision G 2/88 (*supra*, Reasons, points 1, 2.3, 9, 9.1 and 10.3 and Order, point (iii)) the Enlarged Board of Appeal addressed, *inter alia*, the proper interpretation of Article 54 EPC in relation to use-claims where the only novel feature was the purpose of such use and this purpose was stated in the claim. In that context the Enlarged Board held that a claim to the use of a known compound A for a particular purpose B, which is based on a technical effect described in the patent, "*should be interpreted (in appropriate cases) as also including as a technical feature the function of achieving purpose B, (because this is the technical result)*" (G 2/88, *supra*, Reasons, point 9.1).

8. The board agrees with the appellant that claim construction needs to be the same regardless of whether novelty or sufficiency of disclosure is at stake. However, the board does not share the view of the appellant that the criteria developed in decision G 2/88 (*supra*, see point 7 above) can be relied upon to read into the claim at hand a further implicit functional technical feature limiting the claim to particular immunoglobulins having a "suitable pI". The board's reasoning in this respect is set out below.

9. As correctly pointed out by the respondents, according to decision G 2/88 (*supra*), the purpose of the use claim is limiting. In the claim at issue, the claimed purpose is the use of a membrane for "*obtaining an immunoglobulin in monomeric form depleted of immunoglobulin aggregates and immunoglobulin fragments*". Accordingly, this is the purpose that must

be achieved for any and all immunoglobulins.

10. Construing the claim in accordance with the criteria developed in decision G 2/88 (*supra*, see point 7 above) has, in the board's view, the effect that the function of achieving that claimed purpose is implied in the claim as a functional technical feature, i.e. that any immunoglobulin is obtained in monomeric form in the recited pH range of pH 8.0 to pH 8.5. Since the claim at issue already explicitly recites the function of achieving the claimed purpose as an explicit functional technical feature anyway (see point 4 above), the claim at issue is in fact not *further* limited when applying the criteria of decision G 2/88 (*supra*).

11. The appellant's case rests on the premise that decision G 2/88 *(supra)* requires that a functional technical feature, which reflects the technical effect actually described in the patent and which is less than the technical effect explicitly claimed, be implied in the claim as a "self-correcting" feature "*by way of legal construction*".

12. However, the legal fiction provided by G 2/88 (*supra*) is the inclusion - as a functional technical feature - of the function of achieving the claimed purpose (see point 7 above). On the other hand, no findings were made in decision G 2/88 (*supra*) with respect to the proper interpretation of use claims reciting a purpose that cannot be achieved over the whole ambit of the claim in view of the teaching of the patent and taking into account the common general knowledge of the skilled person.

13. In the board's view it is in particular not derivable from decision G 2/88 (*supra*) that an implicit

limitation is to be read into the claim providing a "self-correcting mechanism" excluding non-working embodiments from the claim under consideration, if the claimed features fail to deliver the technical effect aimed for and if consequently the claimed purpose cannot be achieved across the whole ambit of the claim.

14. Furthermore, the board recalls that it is established in the case law of the boards of appeal - and the board agrees - that even limiting features explicitly mentioned in the description but not in the claims are not to be read into the claims (see Case Law of the Boards of Appeal, 9th edition 2019, II.A.6.3.2 and II.A.6.3.4). In the case at hand, the limiting feature "suitable pI" is not even explicitly mentioned in the patent but would need to be inferred by the skilled person from the examples.

15. In a further line of argument the appellant submitted - while relying on interlocutory decision T 601/05 of 24 April 2008 (Reasons, point 6.5) and decision T 1859/08 (Reasons, point 13) - that also this case law on medical use claims considered that non-working embodiments were excluded by way of "legal fiction/ self-correction" from purpose-restricted claims.

16. The board does not share the appellant's view. In point 6.5 of decision T 601/05 (*supra*) - the first decision considered by the appellant to provide evidence that a medical use claim was "self-corrected" to exclude non-working embodiments by way of legal construction - the board held that the pharmaceutical effect was a feature of the product claim at issue. It thus considered that "*the question to be answered in the context of Article 56 EPC is not whether all the compositions covered by the claim are pharmaceutically*

useful since compositions not meeting this criterion are not encompassed by the claim due to its wording. Hence, the situation underlying decision T 939/92 is different and the decision is not applicable here."

17. In the relevant part of decision T 601/05 (*supra*), the board was concerned with the assessment of inventive step (Article 56 EPC) and more particularly with the issue of whether the objective technical problem was solved by the claimed subject-matter. The board distinguished between situations where the problem to be solved consisted in the achievement of an effect, which effect was stated in the claim, and situations where the problem to be solved consisted in achieving an effect, which effect was not stated in the claim, as in the case underlying decision T 939/92 (OJ EPO 1996, 309). It held that the question of whether or not all of the claimed compounds achieved the claimed effect arose only in the latter case. Since in the case dealt with by the board the effect was a feature of the claim, and compositions not pharmaceutically useful were thus not encompassed by that claim, decision T 939/92 was not applicable. Therefore, the question of whether the problem was solved by the claimed subject-matter did not arise.

18. However, this is not the same as holding that non-working embodiments are excluded from the claim by way of legal fiction or that the claim is "self-correcting", as asserted by the appellant. Indeed, in the subsequent decision, decision T 601/05 of 2 December 2009 (see Reasons, points 33 to 44), the same board held for the same claim - that was considered in the earlier interlocutory decision T 601/05 (*supra*) - that a whole class of compounds falling under the terms of the claim could not be

produced on the basis of the teaching in the patent. This did not have the consequence that these embodiments were excluded by way of legal fiction from the claim. Instead, the board held that the skilled person could not carry out the claimed invention over the breadth of claim 1 with the consequence that the requirements of Article 83 EPC were not fulfilled.

19. In the second decision relied on by the appellant, decision T 1859/08, the claim at issue was a second medical use claim for the "*Use of an anti-ErbB2 antibody in the preparation of a medicament for treatment to provide clinical benefit as measured by increased time to disease progression of malignant breast cancer characterised by overexpression of ErbB2 in a human patient* (...)". The board held that the claim "*includes, as a technical feature of the claim, the achievement of a clinical benefit in breast cancer patients as measured by an increased time to disease progression*" (see Reasons, point 13).

20. It is indeed established case law of the boards of appeal that, when a therapeutic application is claimed in the form of a second medical use claim, attaining the claimed therapeutic effect is a functional technical feature of the claim (see Case Law of the Boards of Appeal, 9th edition 2019, section II.C.7.2 and decision T 609/02 cited therein). Decision T 1859/08 is in line with that case law.

21. It is furthermore also established in the case law that, if the claimed therapeutic effect is not achieved over the whole ambit of the claim, then there is a lack of sufficiency of disclosure (see G 1/03, OJ EPO 2004, 413; Reasons, point 2.5.2 and decision T 609/02, Reasons, point 9). The board cannot deduce from these

principles any basis for a "self-correcting" effect by way of a legal fiction such that embodiments not achieving the claimed effect are not covered by the claim.

22. Finally, the board notes that the case at hand is not concerned with the applicability of the criteria developed in decision G 2/88 (*supra*, see point 7 above) to the claim at issue. What is in dispute is the consequence of the application of those criteria to the claim at issue (see points 11 to 13 above). The appellant's reliance on case law confirming that decision G 2/88 (*supra*) is applicable to use claims (section I.C.8.1.3 of the CLBA) therefore does not assist its case. Furthermore, none of the decisions recited in that section of the CLBA was relied on by the appellant in support of its argument as to a "*self-correction*" mechanism excluding non-working embodiments from the claim.

23. In view of the above considerations, the limitation invoked by the appellant cannot be read into claim 1. Indeed, the board agrees with the opposition division and the respondents that the claim is not limited to the use of a membrane anion-exchange chromatography material for obtaining immunoglobulins having a suitable pI in monomeric form. Instead, it is understood to be directed to the use of a membrane anion-exchange chromatography material for obtaining *any* immunoglobulin in monomeric form. The claim thus requires that the technical effect be obtained for all immunoglobulins and not only for immunoglobulins having a suitable pI by applying "*an aqueous, buffered solution comprising an immunoglobulin in monomeric and in aggregated form and immunoglobulin fragments to said anion exchange chromatography material, wherein the*

aqueous, buffered solution has a pH value of from pH 8.0 to pH 8.5".

Request for referral of questions to the Enlarged Board of Appeal (Article 112(1)(a) EPC)

24. Pursuant to Article 112(1)(a) EPC, the boards of appeal refer questions to the Enlarged Board either of their own motion or upon request from a party, in order to ensure uniform application of the law or if a point of law of fundamental importance arises, if they consider that a decision is required for the above purposes and if the answer to that question is relevant for deciding the case in question.

25. The appellant requested the referral of two questions filed during the oral proceedings (see section VIII above for the exact formulation) to the Enlarged Board of Appeal.

26. The board understands that the first question asks whether the legal fiction provided by decision G 2/88 (*supra*) is only relevant for novelty and not for sufficiency of disclosure. In view of point 8 above, this question is irrelevant.

27. Since the board does not distinguish between functional technical features explicitly mentioned in the claim and functional technical features that are implied (see point 10 above), the second question is likewise irrelevant.

28. The requirements for a referral are not therefore fulfilled. Accordingly, the board decided to reject the appellant's request.

Sufficiency of disclosure (Article 83 EPC)

29. Article 83 EPC requires that the application disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. It is established case law of the boards of appeal that the application must contain sufficient information to allow a person skilled in the art, using common general knowledge, to carry out the invention within the whole area that is claimed (see CLBA, section II.C.5.4). In other words, the skilled person has to be able to obtain substantially all embodiments falling within the ambit of the claim.

30. The appellant did not dispute the fact that not all immunoglobulins can be separated within the narrow pH range recited in the claim. It submitted, as its main line of argument, that the skilled person could carry out the claimed invention with immunoglobulins having a suitable pI whereas non-working embodiments were excluded from the claim by way of legal construction.

31. This line of argument cannot succeed in view of the claim construction adopted by the board (see point 23 above).

32. The appellant's further argument, namely that the description contained sufficient information regarding the relevant criteria for finding appropriate alternatives having a suitable pI, likewise fails.

33. It is required that appropriate alternatives be available over the claimed range (see decision G 1/03, *supra*, Reasons, point 2.5.2). In the case at hand, this means for the use of a membrane anion-exchange chromatography material for obtaining

any immunoglobulin in monomeric form, irrespective of the immunoglobulin's pI (see point 23 above).

34. The board concludes from the above considerations, in line with the decision under appeal, that the claimed subject-matter comprises non-working embodiments and that the patent with the set of claims of the main request thus fails to meet the requirements of Article 83 EPC.

Auxiliary requests 1 to 8

Consideration of auxiliary requests 3 to 5

35. The admittance of auxiliary requests 3 to 5 was contested by respondent V. However, in view of the board's conclusion on the issue of sufficiency of disclosure (see below), there is no need for the board to give reasons for considering all auxiliary claim requests in substance.

Sufficiency of disclosure (Article 83 EPC)

36. Claim 1 of auxiliary requests 1 to 8 pertains to the use of a membrane anion-exchange chromatography material for obtaining an immunoglobulin, a monoclonal immunoglobulin or a monoclonal antibody (depending on the claim request) in monomeric form depleted of aggregates and fragments.

37. None of the amendments made have any effect on the construction of claim 1 of auxiliary requests 1 to 8. The observations set out above for claim 1 of the main request (see points 29 to 34) thus apply, *mutatis mutandis*, to claim 1 of auxiliary requests 1 to 8. In fact, the appellant accepted the finding that the

requirements of Article 83 EPC are not met if the claim construction is the same as for the main request.

38. The board concludes that the claimed subject-matter comprises non-working embodiments and that the patent with the set of claims of each of auxiliary requests 1 to 8 thus fails to meet the requirements of Article 83 EPC.

Order

For these reasons it is decided that:

1. The request to refer questions of law to the Enlarged Board of Appeal is rejected.

2. The appeal is dismissed.

The Registrar: The Chair:

A. Chavinier Tomsic B. Claes

Decision electronically authenticated