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Case Number: T 0336/17 - 3.3.04

Application Number: 04804635.3

Publication Number: 1711513

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Language of the proceedings: EN

Title of invention:
Nanofiltration of factor VII solutions to remove virus

Patent Proprietor:
Novo Nordisk Health Care AG

Opponents:
Baxter International Inc.
Laboratoire Français du Fractionnement et des Biotechnologies

Headword:
Nanofiltration of factor VII solutions/NOVO NORDISK

Relevant legal provisions:
EPC Art. 123(2)

Keyword:
Amendments - added subject-matter (yes)

Decisions cited:
T 1241/03, T 1621/16

Catchword:

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Beschwerdekammern

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Case Number: T 0336/17 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 18 March 2021

Party as of right (Opponent 1)	Baxter International Inc. One Baxter Parkway Deerfield, IL 60015 (US)
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Representative:	J A Kemp LLP 14 South Square Gray's Inn London WC1R 5JJ (GB)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 22 December 2016 concerning maintenance of the European Patent No. 1711513 in amended form.**

Composition of the Board:

Chair	B. Claes
Members:	R. Morawetz
	L. Bühler

Summary of Facts and Submissions

I. The appeal by opponent 2 ("appellant") lies from the opposition division's interlocutory decision according to which European patent No. 1 711 513 ("the patent") as amended in the form of auxiliary request 1, and the invention to which it relates, were found to meet the requirements of the EPC. The patent proprietor is the respondent in these proceedings.

II. The patent, entitled "*Nanofiltration of factor VII solutions to remove virus*", was granted for European patent application No. 04 804 635.3, which was filed as an international application under the PCT with the number PCT/EP2004/053206 and was published as WO 2005/054275 ("application as filed" or "application").

Claims 1, 2, 3, 4, 5, 7, 42 and 43 as filed read:

"*1. A method for removing viruses from a liquid Factor VII composition, said composition comprising one or more Factor VII polypeptides, at least 5% of said one or more Factor VII polypeptides being in the activated form, said method comprising subjecting said solution to nanofiltration using a nanofilter having a pore size of at the most 80 nm.*

2. The method according to claim 1, wherein as [sic] *at least 7%, e.g. at least 10%, of the one or more Factor VII polypeptide are in the activated form.*

3. The method according to claim 1, wherein the activated form of the Factor VII polypeptide represents 5-70%, such as 7-40%, e.g. 10-30%, of the mass of the

one or more Factor VII polypeptides.

4. The method according to claim 1, wherein the activated form of the Factor VII polypeptide represents 50-100%, such as 70-100%, e.g. 80-100%, of the mass of the one or more Factor VII polypeptides.

5. The method according to claim 1, wherein the activated form of the Factor VII polypeptide represents 20-80%, such as 30-70%, e.g. 30-60%, of the mass of the one or more Factor VII polypeptides.

7. The method according to any of the preceding claims, wherein the concentration of the Factor VII polypeptide(s) in the liquid composition is in the range of 0.01-5 mg/mL [sic], *such as in the range of 0.05-2.0 mg/mL* [sic].

42. A method for high-level elimination of the presence of active viruses in a liquid Factor VII composition, the method comprising the steps of (i) inactivating viruses by the method defined in any of the claims 35-41, and (ii) removing viruses by the [sic] *any of the methods defined in any of the claims 1-35, in any order.*

43. The method according to claim 42, wherein the step of inactivating viruses precedes the step of removing viruses."

III. Two oppositions were filed against the patent in its entirety. The opposition proceedings were based, *inter alia*, on the ground for opposition under Article 100(c) EPC.

IV. The opposition division decided, *inter alia*, that the subject-matter of claim 1 as granted did not extend beyond the content of the application. The patent was maintained on the basis of auxiliary request 1. Claim 1 of this request is identical to claim 1 as granted.

V. In their statement of grounds of appeal, the appellant submitted arguments, *inter alia*, to the effect that the subject-matter of claim 1 as granted extended beyond the content of the application.

VI. Opponent 1 filed a notice of appeal but subsequently withdrew their appeal. Accordingly, opponent 1 is a party as of right to the appeal proceedings.

VII. In reply to the appellant's statement of grounds of appeal, the respondent maintained the set of claims of auxiliary request 1 underlying the decision under appeal as their main (sole) request and provided their counter-arguments.

Claim 1 of the main request reads as follows:

"1. A method for removing viruses from a liquid recombinant Factor VII composition, said composition comprising one or more Factor VII polypeptides, wherein the concentration of the Factor VII polypeptides is in the range of 0.01 to 5 mg/ml, and wherein the activated form of the Factor VII polypeptides represents 50-100% of the mass of the one or more Factor VII polypeptides in the composition;
said method comprising subjecting said solution to nanofiltration using a nanofilter having a pore size of at the most 80 nm."

VIII. Further written submissions were received from the appellant and the respondent.

IX. The board summoned the parties to oral proceedings as requested and issued a communication pursuant to Article 15(1) RPBA in which it informed the parties, *inter alia*, that it was of the preliminary opinion that the subject-matter of claim 1 of the sole request on file extended beyond the content of the application.

X. In response, the respondent filed further written submissions. Opponent 1 indicated that they would not attend the oral proceedings.

XI. With the consent of the appellant and the respondent, the oral proceedings were held by videoconference. During the oral proceedings, the appellant withdrew their request for reimbursement of the appeal fee. At the end of the oral proceedings, the Chair announced the board's decision.

XII. The appellant's arguments are summarised as follows.

Main (sole) request

Amendments (Article 123(2) EPC) - claim 1

The claimed subject-matter was a combination of various characteristics relating to Factor VII (FVII), namely (i) it was recombinant and it had (ii) a specific range of concentration and (iii) a specific degree of activation.

The different characteristics were disclosed in the application, but not in this specific combination.

Features (ii) and (iii)

Claims 3, 4 and 5 as filed disclosed low, high and average activation degrees of FVII, respectively, and thus had a different technical content.

Also, in the description of the application as filed, three alternative groups of embodiments relating to the same three different activation degrees as referred to in the claims were disclosed (see page 5, lines 19 to 24).

The selection of an activation degree disclosed in claim 4 as filed for the claimed subject-matter represented a first choice between the three alternative groups of embodiments relating to different degrees of activation disclosed in claims 3, 4 and 5 or on page 5 of the application as filed. Furthermore, claim 4 as filed specified three alternative ranges without giving any preference, and the choice of the "*50-100%*" range thus represented a further selection.

Claim 7 as filed disclosed two alternative concentration ranges, and the choice of "*0.01-5 mg/ml*" represented yet a further selection.

Claims 42 and 43 as filed concerned inactivation and removal of viruses in any order and did not provide any indication that all the claims could be combined.

The application disclosed that the concentration of the FVII polypeptide was given by the preceding process steps (see page 11, lines 37 to 39).

Unlike in the case underlying decision T 1621/16 (see Reasons, points 1.4 and 1.7.2), in the present case,

the application did not disclose convergent lists and no preference was indicated for any degree of activation or concentration range. It was not correct either that the broadest range had been taken for the degree of activation and the concentration of FVII, compare claim 1 as filed.

In decision T 1259/16 (see Reasons, point 39), the board had commented on the factual basis underlying case T 1241/03. Decisions T 1413/16 and T 375/15 concerned situations similar to the case in hand where lists of equivalent alternatives were disclosed without any indication of a preference for any of them.

Feature (i)

The application contained several embodiments, including, but not limited to, "*recombinant techniques*". A further choice therefore had to be made to arrive at the recombinant embodiment. The disclosure on page 3, lines 11 to 14 of the application was not generally applicable to all embodiments of the invention. Recombinant techniques were disclosed in a very specific context as an example of large-scale production processes of liquid FVII compositions comprising a "*significant ratio of activated FVII polypeptide*" (see page 3, lines 11 to 14).
A "*significant ratio*" was "*at least 5%, such as at least 7%, e.g. at least 10%*" (see page 5, lines 16 to 18).

Page 3, line 37 to page 4, line 10 of the application did not provide a pointer to the specific combination involving "*recombinant*" FVII and an activation rate of "*50-100%*". Rather, it disclosed that virus filtration could be performed at any stage of the purification

process and that the activation degree was "*typically around 2%*" at the beginning of the purification process and "*90% or more*" before FVII was obtained as a drug substance (see page 4, lines 8 to 10).

The terms used in the application, i.e. "*typically*", "*generally*", "*preferably*" and "*normally*", had different meanings, and "*typically*" did not indicate a preference (see page 3, line 13, page 4, line 4, page 5, line 28, and page 12, line 13).

Examples 1 to 4 of the application did not relate to the claimed invention, as the degree of activation was below 50%. In Example 5, bulk drug substance was used, the degree of activation was 98% and the concentration was 1.46 mg/ml. Bulk drug substance could come from fermentation broth or from plasma (see page 3, last line to page 4, line 8). Example 5 did not provide a pointer to the claimed combination of features.

Since a pointer to the combination of "*recombinant*" FVII with a degree of activation of "*50-100%*" and a concentration of "*0.01 - 5 mg/ml*" was lacking in the application as filed, the claim related to added subject-matter.

XIII. The respondent's arguments are summarised as follows.

Main (sole) request

Amendments (Article 123(2) EPC) - claim 1

The claim was based on claim 1 as filed to which further features had been added.

Features (ii) and (iii)

The feature relating to the degree of activation of FVII (feature (iii)) had been further defined based on claim 4 as filed, and the concentration of FVII (feature (ii)) disclosed in claim 7 as filed had been incorporated into claim 1.

The claims as filed provided a clear pointer to the feature of the degree of activation claimed in combination with the concentration range as claimed because claim 7 was dependent on any of the preceding claims, including claim 4, and claims 2 to 5 referred to claim 1. Also, claims 42 and 43 pointed to the claimed combination of features.

In claim 4 as filed, the more preferred range had been selected. The other ranges were optional. Even though more claims were directed to the degree of activation, it did not take away from the fact that a clear disclosure of the degree of activation was now claimed in claim 4.

The sentence on page 11 of the application, on a normal reading, specified that the FVII concentration was "*typically*" in the range of "*0.01-5 mg/ml*" underlining the general nature of this teaching. Thus, there was no selection involved but merely the addition of a feature that the skilled person understood to apply to any of the embodiments of the invention.

From the application, the skilled person would understand that nanofiltration should be done in the context of activated FVII in the concentrations as claimed. Thus, page 3, lines 2 to 6 of the application disclosed that the liquid Factor VII composition

comprised a "*significant ratio*" of FVIIa; page 5, line 16 ff, explained the term "*significant ratio*"; and the skilled person understood that that comprised "*50-100%*". Page 3, lines 37 to 38 of the application confirmed that nanofiltration could be applied even after FVII had been "*partially or fully activated*", and "*50-100%*" activation was consistent with this disclosure. Page 11, lines 37 to 39, disclosed that the concentration was generally in the range of "*0.01-5 mg/ml*".

In decision T 1241/03 (see point 7 of the Reasons), the board had come to the conclusion that claims to formulations comprising compounds in specific concentrations did not need to have a literal basis in a single passage of the application as originally filed, as long as the exact concentrations and ranges as claimed were disclosed as such in the original application.

According to decision T 1621/16, a distinction should be made between amendments selected from a list where the options in the list are convergent, compared to a list of options of non-converging elements, for example, in a list of mutually exclusive alternatives.

The values in claims 4 and 7 as filed represented converging alternatives; "*50-100%*" was the broadest range set out in claim 4 and "*0.01-5 mg/ml*" was the broadest range set out in claim 7. The broadest form of the features relating to the degree of activation and to the concentration of FVII had been combined. In line with decision T 1621/16, amending a claim by selecting elements from lists of converging elements did not add any subject-matter.

The decisions relied on by the appellant concerned situations where the claims did not provide a basis for the claimed subject-matter.

Feature (i)

A basis for specifying that FVII was recombinant was disclosed on page 3, lines 11 to 14 of the application. Here, it was indicated that the Factor VII polypeptides were "*typically*" obtained by processes involving recombinant techniques. This provided a very general disclosure and so the skilled person would have understood that this feature applied to any of the embodiments of the invention.

The skilled person derived from page 3, line 13 of the application, which disclosed "*more typically*" as meaning "*more preferred*", a preference for recombinant techniques. This was consistent with page 4, line 5 of the application, and Example 1, which disclosed a fermentation broth and thus recombinant production, whereas plasma was only mentioned once in the application, see page 4.

Example 5 provided a pointer to the claimed combination of features.

The amendments in the claim did not involve a singling out of a combination of features that was not directly and unambiguously derivable for the skilled person from the application as filed, and therefore the claim did not contravene Article 123(2) EPC.

XIV. Opponent 1, party as of right to the appeal proceedings, 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 revoked.

The respondent requested that the appeal be dismissed.

Reasons for the Decision

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

Main (sole) request

Amendments (Article 123(2) EPC) - claim 1

2. The application discloses a method for improving the viral safety of liquid Factor VII (FVII) compositions by applying nanofiltration for the removal of virus particles as one of the steps of the overall purification process for the FVII polypeptide (see page 1, lines 1 to 4, and page 4, lines 1 to 10). FVII, a plasma glycoprotein, exists in plasma mainly as a zymogen which is cleaved by Factor Xa into its activated form (FVIIa) (see page 1, lines 10 to 12).

3. Claimed is a method for removing viruses from a liquid FVII composition comprising one or more FVII polypeptides by subjecting the composition to nanofiltration using a nanofilter having a pore size of at the most 80 nm. The FVII polypeptides in the claim are characterised by three features:
(i) they are recombinant;
(ii) the concentration of the FVII polypeptides is in the range of 0.01 to 5 mg/ml; and
(iii) FVIIa represents 50-100% of the mass of the one

or more FVII polypeptides in the composition (see section VII.). The latter feature is also referred to in the following as "activation degree of FVII".

4. The claim is identical to claim 1 of the main request underlying the decision under appeal for which the opposition division held that a basis was disclosed in claims 1, 4 and 7 as filed in combination with page 3, lines 11 to 14 of the application and the disclosure in the examples of the same. On appeal, the appellant maintained that the subject-matter of the claim extended beyond the content of the application.

5. It is undisputed that the claim is based on claim 1 as filed, to which features (i), (ii) and (iii) have been added. It is further undisputed that features (i), (ii) and (iii) are disclosed in the application, but not in combination.

6. The board agrees with the established jurisprudence of the boards of appeal that a combined selection of features cannot be derived directly and unambiguously, using common general knowledge, and seen objectively and relative to the date of filing, from the whole of the application as filed, in the absence of any pointer to the particular combination (see Case Law of the Boards of Appeal of the European Patent Office, 9th edition 2019, sections II.E.1.6.1 and II.E.1.6.2).

7. At issue is thus whether the application as filed provides a pointer to the claimed combination of features. It has been established in the case law of the boards of appeal that the fact that features in question are mentioned in the application as being "*preferred*" may act as a pointer for a combined selection of features. Furthermore, examples are also

considered to provide preferred embodiments of an invention that can provide pointers towards a combination of features (*ibid.*).

Features (ii) and (iii)

8. The claims as filed (see section II.) disclose various activation degrees of FVII, e.g. low (see claim 3), medium (see claim 5) or high degrees of activation (see claim 4). No preference for a particular level of activation is derivable from the claims. Furthermore, claim 4 does not explicitly disclose any preference for "*50-100%*" as the degree of the activated form of FVII (feature (iii)) over the other activation degrees disclosed in that claim. Such a preference is not derivable from the disclosure of further exemplary degrees of activation falling within the range of "*50-100%*" in that claim either.

9. The board hence concurs with the appellant that a twofold selection is required to arrive at the amendment concerning a degree of activation of "*50-100%*" (feature (iii)). The first selection concerns the choice of a high degree of activation among the embodiments relating to the various alternative degrees of activation of FVII, i.e. from claims 2 to 5. The second selection occurs within the alternative ranges of a high degree of activation disclosed in claim 4.

10. Claim 7 as filed discloses two ranges for the concentration of FVII in the liquid composition, a broader range (0.01-5 mg/ml) and a narrower range (0.05-2.0 mg/ml), which is given as an example of the broader range. Again, no preference for the range of "*0.01-5 mg/ml*" (feature (ii)) is derivable from the

claim.

11. The board therefore also concurs with the appellant that a further selection - from among the concentration ranges disclosed in claim 7 - is required to arrive at the amendment concerning the concentration range of "*0.01-5 mg/ml*" in claim 1 (feature (ii)).

12. As no preference is discernible for any particular activation degree or concentration range of FVII (see claims 4 and 7 as filed), the respondent's allegation that preferred features have been selected to arrive at the claimed combination of features cannot be accepted.

13. Moreover, claim 7 as filed, being dependent on "*any preceding claim*", does not point to claim 4 in particular. In fact, claims 3, 4 and 5 as filed represent alternative technical content (see also point 8. above and point 20. below). Accordingly, the respondent's further allegation that the claims provided a clear pointer to the feature of the degree of activation claimed in combination with the concentration range as claimed is not found persuasive either.

14. Finally, the fact that claim 42 discloses that removing viruses can be carried out by "*any of the methods defined in any of the claims 1-35 in any order*" does not point to a method for removing viruses from an FVII composition characterised by features (ii) and (iii).

15. The subject-matter of claims 1, 2, 3, 4, 5 and 7 is also disclosed in the description:

"*A second aspect of the present invention relates to a method for removing viruses from a liquid Factor VII*

composition, said composition comprising one or more Factor VII polypeptides, at least 5% of said one or more Factor VII polypeptides being in the activated form, said method comprising subjecting said solution to nanofiltration using a nanofilter having a pore size of at the most 80 nm." (see page 2, lines 10 to 14)

"*According to one aspect of the invention, a feature is that a significant ratio, i.e. at least 5%, such as at least 7%, e.g. at least 10%, of the one or more Factor VII polypeptides are in the activated form (i.e. the bioactive, cleaved form of a Factor VII polypeptide (i.e. a Factor VIIa polypeptide)). In further embodiments, the Factor VIIa polypeptide represents 5-70%, such as 7-40%, e. g. 10-30%, of the mass of the one or more Factor VII polypeptides. In other embodiments, the Factor VIIa polypeptide represents 50-100%, such as 70-100%, e. g. 80-100%, of the mass of the one or more Factor VII polypeptides. In still other embodiments, the Factor VIIa polypeptide represents 20-80%, such as 30-70%, e. g. 30- 60%, of the mass of the one or more Factor VII polypeptides.*" (see page 5, lines 19 to 24)

"*Furthermore, the concentration of the Factor VII polypeptide in the liquid composition is typically also given by the preceding process steps, but will normally lie in the range of 0.01-5 mg/mL* [sic]*, such as in the range of 0.05-2.0 mg/mL* [sic]" (see page 11, lines 37 to 39).

16. From these passages it is also evident that the various degrees of activation of FVII are disclosed as alternative embodiments in the application, and no preference for "*50-100%*" of FVII being in the activated form (feature (iii)) can be discerned from page 5 of

the application either.

17. Nor can any preference be discerned for a concentration range of "*0.01-5 mg/ml*" (feature (ii)) over the concentration range of "*0.05-2.0 mg/ml*" on page 11 of the application (see point 15. above). Contrary to the submission by the respondent, the concentration of FVII is not disclosed in the application as being "*typically*" in the range of "*0.01-5 mg/ml*" but rather "*typically also given by the preceding process steps*". The respondent's allegation that a concentration range of "*0.01-5 mg/ml*" is disclosed in the application as being generally applicable to all embodiments of the invention such that no selection would be required finds thus no confirmation.

18. The respondent's line of argument that the skilled person would understand from the application as a whole that nanofiltration should be conducted in the context of FVII with the degree of activation and in the concentrations as recited in the claim is not found persuasive either, for the following reasons.

19. The disclosure of a "*significant ratio of activated Factor VII polypeptide*" on page 3, lines 11 to 12 of the application does not point to a degree of activation of "*50-100%*", because the application defines a "*significant ratio*" to mean "*at least 5%, such as at least 7%, e.g. at least 10%, of the one or more Factor VII polypeptides are in the activated form*" and not "*50-100%*" (see page 5, lines 16 to 18, and point 15. above).

20. Furthermore, the board concurs with the appellant that the disclosure that "*nanofiltration may be applied even after Factor VII polypeptide bulk has been partially or*

fully activated" (see page 3, lines 37 to 38) does not point to a degree of activation of "*50-100%*" either, because in the subsequent paragraphs the application discloses that the methods of the invention are applicable "*as one of the steps of the overall purification process for the Factor VII polypeptide*" (see page 4, lines 1 to 2) and that "[t]*he content of Factor VII polypeptide in the activated form is initially (i.e. from the harvest step) typically around 2%, and increases in the course of the purification process to 90% or more before the polypeptide is obtained as a drug substance*" (see page 4, lines 8 to 10). Thus, if nanofiltration is applied, for example after the harvest step, the application discloses that the degree of activation is 2%, i.e. substantially lower than 50%.

21. As regards the specific decisions referred to by the respondent, the board considers that the factual basis of decision T 1241/03 is not comparable to the factual basis of the case in hand. In the case underlying decision T 1241/03, the preferred value for each parameter was explicitly indicated in the application as filed. In the light of that disclosure, the board considered that the combination of compounds in specific concentrations found a basis in the application as filed (see Reasons, points 6 and 7). In the present case, no preference for any degree of activation or range of concentration is apparent from the application as filed.

22. The respondent cannot, in the board's view, rely on the finding in decision T 1621/16 with respect to amendments based on selection from converging lists. In fact, in decision T 1621/16, the board distinguished between amendments based on multiple selections from a

list of converging alternatives (i.e. a list of options ranked from the least to the most preferred, wherein each of the more preferred alternatives is fully encompassed by all of the less preferred and broader options in the list) and amendments based on selections from a list of non-converging alternatives (i.e. a list of mutually exclusive or partially overlapping alternatives).

23. In the present case, the different values disclosed for the degree of activation of FVII are partially overlapping alternatives, i.e. they represent non-converging lists (compare claims 1 to 5 as filed, see section II.). In this respect, the board held in decision T 1621/16 that each non-converging alternative represents a distinct feature and selecting specific elements from such lists leads to a singling out of an invention from among several distinct alternatives, which might provide an unwarranted advantage if there is no way to anticipate which of the different inventions will eventually be protected (see Reasons, point 1.7.2). Furthermore, an activation degree of "*at least 5%*" (see claim 1 as filed) is broader than "*50-100%*" (feature (iii)), and the respondent's further argument in that context, that the broadest form of the features relating to the degree of activation and to the concentration of FVII had been combined, therefore does not succeed either.

24. The board has not heard any argument as to why the skilled person would combine in particular a degree of activation of "*50-100%*" (feature (iii)) with a concentration of "*0.01-5 mg/ml*" (feature (ii)) when being aware from reading the application as a whole that both, the degree of activation (see page 4, Table and lines 8 to 10, reproduced in point 20. above) and

the concentration of FVII (see page 11, lines 37 to 39, reproduced in point 15. above) are dependent on the stage in the purification process, and furthermore being aware from page 4, lines 8 to 10 of the application that a degree of activation of "*90% or more*", and thus *a fortiori* a degree of activation of 100% (feature (iii)) correspond to a late stage in the purification process before the FVII is obtained as a drug substance. Indeed, in Example 5, a degree of activation of 98% is associated with a concentration of 1.320 mg/ml. The board considers that, without any indication in the application as a whole that the degree of activation (feature (iii)) and the concentration range (feature (ii)) claimed correspond to the same step in the purification process, their combination has to be considered arbitrary.

Feature (i)

25. As for feature (i) of the claim, page 3, lines 11 to 14 of the application discloses that "[t]*he liquid Factor VII composition, e.g. those comprising a significant ratio of Factor VII polypeptides, can in principle be prepared from the dry Factor VII constituents, but are more typically obtained from large-scale production processes, e.g. processes involving recombinant techniques*". (emphasis added)

26. The board concurs with the appellant that "*recombinant techniques*" are disclosed in that passage as an example (see "*e.g.*") of large-scale production processes. A general applicability of "*recombinant*" to any of the embodiments of the invention is thus not derivable from that passage.

27. The respondent's submission that the person skilled in the art would understand from page 3, lines 11 to 14, that the FVII polypeptides were "typically, i.e. generally" obtained by processes involving recombinant techniques and so they would further understand that this feature applied to any of the embodiments of the invention is thus not found persuasive.

28. In the oral proceedings before the board, the respondent has further submitted that the expression "*more typically*" on page 3, line 13, actually meant that Factor VII was "more preferably" obtained by recombinant production.

29. Even if the board were to accept the respondent's interpretation of the expression "*more typically*", the board still concurs with the appellant that the passage in question (see point 25.) would indicate a preference for large-scale production processes in general but not for "*recombinant techniques*" in particular, as these are disclosed as an example only for large-scale production processes.

30. In the board's view, no preference for recombinant production of FVII can be derived from the remainder of the application either. Page 4, lines 4 to 6, relied on by the respondent, discloses that the content of FVII polypeptide in the activated form in "*a typical purification process starting from harvested material from the a* [sic] *fermentation broth (or from human (or mammalian) plasma) can be outlined as follows ...*".

31. It is evident that recombinantly produced FVII and plasma-derived FVII are disclosed as equivalent alternative starting points for a typical purification

process of FVII including nanofiltration as one step.

32. Example 5, which was alleged by the respondent as providing a pointer to the combination of "*recombinant*" FVII with features (ii) and (iii), relates to the filtration of "*FVII bulk drug substance*" (see page 22, line 5). Pursuant to the application, bulk drug substances can come from fermentation broth or from plasma (see page 3, last line to page 4, line 8), and it is thus not evident that Example 5 even relates to an embodiment involving recombinant FVII. For this reason alone, the respondent's argument does not succeed.

Conclusion

33. The board concludes from the above considerations that, absent of any pointer in the application as a whole to the claimed combination of features, the subject-matter of claim 1, which results from the combination of feature (iii), not originally disclosed as a preferred embodiment of the degree of activation of FVII in the context of the claimed method, with feature (ii), not originally disclosed as a preferred (or a generally applicable) embodiment of the concentration of FVII in the context of the claimed method, and feature (i), also not disclosed as being a preferred (or a generally applicable) embodiment for the production of FVII, provides the skilled person with new technical information which they cannot directly and unambiguously derive from the application as filed.

34. Thus, the claimed subject-matter extends beyond the content of the application and the claim contravenes Article 123(2) EPC.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

The Registrar: The Chair:

I. Aperribay B. Claes

Decision electronically authenticated