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Datasheet for the decision of 14 January 2016

Case Number: T 0099/13 - 3.3.07

Application Number: 01981824.4

Publication Number: 1324776

IPC: A61K47/02, A61K47/12, A61K47/18, A61K39/395

Language of the proceedings: EN

Title of invention:
REDUCED-VISCOSITY CONCENTRATED PROTEIN FORMULATIONS

Patent Proprietors:
Genentech, Inc.
Novartis AG

Opponents:
Arecor Limited
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AbbVie Bioresearch Center Inc.
Synthon B.V.

Relevant legal provisions:
EPC Art. 111(1), 123(2)
EPC R. 101(1)

Keyword:
Admissibility of appeal - appeal sufficiently substantiated (yes)
Amendments - added subject-matter (no)
Appeal decision - remittal to the department of first instance (yes)

Decisions cited:
T 1269/06, T 0667/08

Catchword:
see point 2.3

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Case Number: T 0099/13 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 14 January 2016

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Decision under appeal: **Decision of the Opposition Division of the European Patent Office posted on 26 October 2012 revoking European patent No. 1324776 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman J. Riolo
Members: D. Semino
D. T. Keeling

Summary of Facts and Submissions

I. Ten notices of opposition were filed against European Patent No. 1 324 776 in which revocation of the patent in its entirety was requested on the grounds of lack of novelty and of inventive step, of insufficiency of disclosure and of extension of the subject-matter beyond the content of the application as filed (Article 100(a), (b) and (c) EPC).

II. The decision of the opposition division to revoke the patent was announced at the oral proceedings on 2 October 2012. It was based on a set of claims filed as main request with letter of 7 November 2011 and on six auxiliary requests.

Claims 1, 18 and 19 of the main request read as follows:

"1. A stable liquid formulation comprising an immunoglobulin in an amount of at least 80 mg/ml and a salt and/or buffer in an amount of at least 100 mM, and having a kinematic viscosity of 50 mm^2 /s or less at 25°C, wherein the immunoglobulin is the antibody rhuMAb-E25, rhuMAb-E26, or rhuMAb-E27."

"18. A method of reducing the kinematic viscosity of a formulation containing an immunoglobulin in an amount of at least 80 mg/ml, comprising the addition of a salt and/or buffer in an amount of at least 100 mM, wherein the immunoglobulin is the antibody rhuMAb-E25, rhuMAb-E26, or rhuMAb-E27."

"19. The method of Claim 18 wherein said salt is selected from the group consisting of sodium chloride, sodium thiocyanate, ammonium thiocyanate, ammonium

sulfate, ammonium chloride, calcium chloride and arginine hydrochloride."

A condition on kinematic viscosity "at 25°C" was also present in claims 7 and 23 of the main request.

III. The decision of the opposition division, as far as relevant to the present decision, can be summarised as follows:

a) The main request did not meet the requirements of Article 123(2) EPC. In particular, the specification "at 25°C" in claims 1, 7 and 23 with reference to the condition on the kinematic viscosity could not be directly and unambiguously derived from the application as filed. While it was clear that a disclosure of viscosity without the temperature of the measurement was incomplete, the specific temperature indicated in the claims was not the only one disclosed in the examples and was not applicable to all embodiments. All examples with a measurement of viscosity at 25°C related to the same antibody, similar antibody concentrations and used the same viscometer for the measurement. The specific temperature could not be extracted in isolation from the examples, because it was not sufficiently independent from the other features thereof. Document D125 (Supplementary Data filed by the patent proprietor with letter of 7 November 2011), in particular, showed that the viscometer used for the measurement of viscosity strongly influenced the obtained results. Moreover, the specific temperature could not be taken as a standard temperature from common general knowledge. In addition, the features "a buffer" in claim 18 and

"arginine hydrochloride" in claim 19 had been disclosed in the application as filed only in combination with the condition on the kinematic viscosity. This was very clear from how the several embodiments of the invention and their features were presented in the application.

b) The auxiliary requests did not meet the requirements of Article 123(2) EPC for one or more of the reasons outlined for the main request or for further reasons.

IV. The patent proprietors (appellants) lodged an appeal against that decision. With the statement setting out the grounds of appeal the appellants filed 18 sets of claims as main request and as auxiliary requests 1 to 17.

The main request corresponded to the main request on which the decision was based.

V. With the reply to the statement of grounds respondents-opponents 5 submitted the following pieces of evidence:

D140: Rosencranz et al., "Clinical Laboratory Measurement of Serum, Plasma, and Blood Viscosity", Am. J. Clin. Patho., 2006, volume 125(suppl. 1), pages S78 to S86
D141: Sandhagen, "Analysis of Heamorheological Variables-Methodology and Reference Values", Upsala J. Med. Sci., 1989, volume 94, pages 81 to 87
D142: Hunnius, "Pharmazeutisches Wörterbuch", Walter de Gruyter, Berlin, New York, 1993, page 744

VI. In a communication sent in preparation of oral proceedings, the Board summarised the points to be dealt

with, and provided a preliminary view concerning the amendments in the main request and the possibility of remittal.

VII. Oral proceedings were held on 14 January 2016.

VIII. The arguments of the appellants, as far as relevant to the present decision, can be summarised as follows:

Main request - amendments

a) The addition of the condition on viscosity in claims 1, 7 and 23 to define the temperature as 25°C did not provide the skilled person with any new technical teaching, because a measurement of viscosity did not make sense without temperature and 25°C was the only temperature which could be seriously contemplated by the skilled person. The added temperature was directly derivable from the application as filed, because it was explicitly and repeatedly disclosed in the examples therein, and unambiguously derivable, because the skilled person would rule out any other interpretation. Moreover, it was not inextricably linked to the other features of the examples, in particular to the nature or concentration of the protein and to the specific viscometer (in this respect reference was made to the case law on intermediate generalisation). In this respect, it was relevant that the general teaching of reducing viscosity for high protein concentration formulations was independent of the specific protein and what was claimed was not a method of measurement for which the choice of the instrument could be of interest. Document D125 did not form part of the common general knowledge and was of no relevance.

Example 5, in which a lower temperature was used, was a comparative example and was characterised by a very low concentration of the antibody. In summary the conclusion of the opposition division was incorrect, as it disregarded the technical context relevant in the specific case contrary to the approach on added matter in the case law, which stressed the importance of assessing the content of the application as filed from the point of view of the skilled person.

b) The feature related to the addition of at least 100 mM salt and/or buffer in claim 18 and the option of arginine hydrochloride as a salt in claim 19 without the condition on the kinematic viscosity did not present the skilled person with any new technical teaching. In this respect the opposition division had applied a purely semantic analysis of the application as filed and had considered the disclosure at page 5 of the description in isolation from the disclosure of the method in the claims and in other parts of the description, which was not correct.

Remittal

c) Added matter was the only ground of opposition discussed at the oral proceedings before the opposition division and decided upon. On that basis, the case should be remitted.

IX. The arguments of the respondents, insofar as relevant to the present decision, can be summarised as follows:

Dismissal for lack of reasoning (respondent-opponent 3)

a) The appeal should be dismissed already for the reason that the ground for revocation relating to claim 19 had not been dealt with in the statement setting out the grounds of appeal.

Main request - amendments

b) The decision of the opposition division concerning the amendments was correct. With respect to the temperature of 25°C for the viscosity condition, it was not directly and unambiguously derivable from the application as filed. The general part of the description providing the general teaching of the invention did not mention any temperature and reconstitution at 25°C had nothing to do with the measurement of viscosity. The specification of a temperature was, however, a drastic limitation, which generated a new invention. Measurement at 25°C was present only in the examples. However, it was not the only temperature used therein and the considerations of the appellants on the lack of relevance of example 5 were only allegations, as there was no reason for the skilled person not to consider the viscosity measurement accomplished therein. Moreover, the examples were all designed for specific purposes without addressing the relevance of the conditions of the measurement and the specific temperature could not be extracted from the examples independently of the other features thereof (in particular the specific protein and the specific viscometer). The influence of the viscometer was apparent not only from documents D140 and D141, but also from the data of the appellants in D125. In addition, the specific

temperature was not disclosed in the context of a cut-off value of 50 mm^2/s or less for the kinematic viscosity (the viscosity values in the examples were well below this limit) and there was no standard temperature in the art for the viscosity measurement, as shown by several documents disclosing different temperatures and different instruments. On that basis, it could not be said that the skilled person would rule out any other interpretation, so that the case law regarding drafting defects or inconsistencies did not apply. In this context, it was relevant that compliance with the requirements of Article 123(2) EPC did not allow for the presence of the slightest doubt and that the requirements were there to prevent an applicant from improving its position.

c) With regard to method claim 18, the feature regarding the addition of salt and/or buffer in an amount of at least 100 mM was taken, as far as the option "salt or buffer" was concerned, from page 5 of the description, where, however, it was disclosed only in combination with a specific reduction of the kinematic viscosity and did not relate to the specific antibodies rhuMAb-E25, -E26 and -E27. Moreover, for the option "salt and buffer" the quantitative condition of an amount of at least 100 mM implied a condition on the sum of the two, which was not derivable from the cited passage. Document D142 showed that the molarity alone did not directly determine the ionic strength of the formulation, which was the crucial parameter. A further difference with respect to original claim 31 concerned the selection of "kinematic" viscosity. Finally "arginine hydrochloride" in claim 19 was also disclosed in

the original application in combination with a specific reduction of the kinematic viscosity.

Remittal (respondents-opponents 1, 3 and 9)

d) The case should not be remitted to avoid prolongation of the period of legal uncertainty. Moreover, the remaining grounds had been extensively elaborated in writing by all parties in spite of the fact that the statement of grounds dealt only with the amendments, so that a decision could be taken without offence to the right to be heard of the appellants.

X. The appellants requested that the decision under appeal be set aside and the case be remitted to the opposition division for further prosecution on the basis of the main request or of one of auxiliary requests 1 to 17, all filed with the grounds of appeal.

XI. Respondents-opponents 1, 3, 5, 6, 8 and 9 requested that the appeal be dismissed.

Respondents-opponents 1, 3 and 9 requested that, in the event that the ground of added subject-matter were found not to prejudice maintenance of the patent in amended form, the case not be remitted to the opposition division. Respondents-opponents 5, 6 and 8 requested that, in the event that the ground of added subject-matter were found not to prejudice maintenance of the patent in amended form, the case be remitted to the opposition division.

Respondents-opponents 3, 5 and 8 requested that the auxiliary requests not be admitted into the proceedings.

Respondents-opponents 2, 4, 7 and 10 did not file any requests in appeal.

Reasons for the Decision

Admissibility of the appeal

1. The argument of respondent-opponent 3 regarding dismissal of the appeal due to lack of reasoning throws doubts on the admissibility of the appeal. Even if none of the respondents addressed the issue of admissibility of the appeal, nor requested that the appeal be rejected as inadmissible (Rule 101(1) EPC), this issue must be checked ex officio in every phase of the proceedings (Case Law of the Boards of Appeal, 7th edition 2013, IV.E.2.7), in particular if doubts exist.

1.1 Respondent-opponent 3 alleged that one of the three reasons under Article 123(2) EPC for which the main request was found not to be in compliance with the EPC by the opposition division, namely the one relating to claim 19, was not dealt with at all in the statement of grounds.

1.2 In this respect the Board observes that paragraph 268 on page 61 of the statement of grounds specifically addresses the issue related to claim 19 by saying "For analogous reasons, method claim 19 of the Main Request does not present the skilled person with any new technical teaching, because arginine chloride is explicitly mentioned in connection with the method of the invention at page 5 of the application at line 17".

1.3 This paragraph, by citing a passage of the description and making reference to previous arguments developed for claim 18, gives clear reasons why according to the

appellants the decision was not correct with respect to claim 19. This paragraph was apparently not identified by respondent-opponent 3 in the analysis of the (long) statement of grounds. Indeed, respondent-opponent 3 disregarded the paragraph in the argumentation and gave no reason why it should not be sufficient.

1.4 On this basis, the objection of respondent-opponent 3 is unfounded.

1.5 The respondents raised no other issues with regard to admissibility of the appeal and the Board does not see any reason to discuss any other requirement in further detail, with the consequence that the appeal is admissible.

Main request - amendments

2. With regard to claim 1 of the main request, the disputed point is whether the specification of the temperature for the viscosity condition ("at 25°C") is directly and unambiguously derivable from the application as filed.

2.1 Firstly, the Board sees no reason to consider the condition in claim 1 as originally filed in which no temperature is present ("having a kinematic viscosity of 50 cs or less") as a defective one which needs to be corrected. While it is known that viscosity is strongly dependent on temperature, so that a condition without the specification of the temperature may be unclear, the absence of a temperature cannot be seen as a manifest mistake which must be corrected.

2.2 The case law relating to correction of errors does not therefore apply, so that it is not relevant to establish whether the skilled person would rule out any other

interpretation of original claim 1 than the one in which the specification "at 25°C" is added. The fact that that there is no standard temperature in the art for the viscosity measurement, as shown by the respondents with reference to several cited documents, is for the same reason not relevant.

2.3 Secondly, with regard to the present issue as well as to the following ones concerning further amendments, it is important to recall, in line with the case law (see e.g. T 667/08 of 20 April 2012, point 4.1.4; T 1269/06 of 20 September 2007, point 2), that the assessment of the requirements of Article 123(2) EPC should be done on the same basis as for all other patentability issues (e.g. novelty and inventive step), namely from the standpoint of the skilled person on a technical and reasonable basis avoiding artificial and semantic constructions.

2.4 The skilled person, reading claim 1 as originally filed from the standpoint of a technician working in the field, would read the broad condition expressed therein with regard to the viscosity measurement as a condition to be met at the temperature of use of the claimed formulation and would turn to the description to find further information in this respect.

2.5 In the description the skilled person would first find clear statements which confirm this technical reading. In the description of the prior art, when the problems of the prior art are analysed, it is said that "Highly viscous formulations are difficult to manufacture, draw into a syringe and inject subcutaneously" (page 2, lines 4 and 5), clearly indicating that high viscosity values are problematic in the conditions of manufacture and use. Immediately after this analysis, when the scope of the invention is identified, it is said that "The

present invention is directed to providing a high concentration protein formulation with reduced viscosity, which is easy to handle and is suitable for subcutaneous administration" (page 3, lines 4 to 6), which specifies that the reduced viscosity is to be achieved in the conditions of handling and use of the formulation.

2.6 When it comes to actual disclosure of temperature values for handling and using the formulation and to the measurement of viscosity, it is specified that the preferred temperature of reconstitution is 25°C (page 37, lines 5 and 6) and the viscosity measurement is accomplished at 25°C in examples 1 to 4, 6 and 7 and at 6°C in example 5 (pages 39 to 42).

2.7 While this information alone is sufficient to conclude that 25°C is the preferred temperature in the application as originally filed at which it is desired that the viscosity condition is met, it is further noted that the only example in which a different temperature is used (example 5 on page 41) is an example which does not fall under claim 1 as originally filed, as the concentration of the protein (rhuMAb E25) of 21 mg/ml is well below the lower value of the range indicated in original claim 1 ("at least about 80 mg/ml").

2.8 On that basis it is concluded that the amended viscosity condition with the specification of the temperature of measurement "at 25°C" is directly and unambiguously derivable from the application as filed.

2.9 None of the additional arguments of the respondents is able to change this conclusion.

2.9.1 The question of which may be the reasons why the measurement is done at 6°C in example 5 is indeed not relevant, as the example does not fall under original claim 1 and as all other examples together with the information in the general part of the description give a basis for the measurement at 25°C.

2.9.2 Further, there is no technical basis for considering the temperature of the viscosity measurement as inextricably linked to other features of the examples. Firstly, the temperature used in the examples is to be read, as analysed above, in conjunction with the general teaching of the application as originally filed. Secondly, there is no technical reason, nor any indication in the application as filed that the desired reduction in viscosity may be dependent on the protein used, so that according to which antibody is chosen, a different temperature of measurement may be required. Finally, with regard to the specific viscometer used in the examples, the fact that different instruments are suitable in different viscosity ranges and have different accuracy (as shown e.g. by D140, D141 and D125) may be relevant, if at all, to the question of clarity and sufficiency, but not to the issue of added matter.

2.9.3 The fact that the temperature of 25°C is not literally disclosed in the context of a cut-off value of 50 mm^2/s or less, as the viscosity values in the examples are well below this limit, is also of no relevance in view of the general disclosure of the viscosity condition in the claims and in the description and in view of the disclosure of 25°C as the preferred temperature of use and of measurement of viscosity.

2.9.4 Finally, it is true that by the addition of the temperature a much more limited class of formulations is defined, but this is perfectly acceptable, if, as shown above, a basis for the limitation can be found.

2.10 The conclusion reached for claim 1 of the main request is equally valid for the other claims (claims 7 and 23) in which the specification "at 25°C" is added to the viscosity condition.

3. With regard to the method claims of the main request, the point of dispute concerns the presence of the features "and/or buffer" in claim 18 and "arginine chloride" in claim 19 without a specific reduction of the kinematic viscosity.

3.1 The original application concerns protein formulations with reduced viscosity, as well as a method of reducing viscosity of concentrated protein formulations ("Field of the invention" on page 1, lines 6 to 9). These two related aspects correspond to original independent claims 1 and 31, which read as follows:

"1. A stable liquid formulation comprising a protein in an amount of at least about 80 mg/ml and a salt and/or buffer in an amount of at least about 50 mM, and having a kinematic viscosity of about 50 cs or less."

"31. A method of reducing the viscosity of a formulation containing high concentration of a protein comprising the addition of a salt in an amount of at least about 50 mM."

3.2 It is clear from this wording that, while original claim 1 includes a specific range of viscosity, this is not the case for original claim 31 which indicates the

viscosity reduction as the purpose of the method without specifying a viscosity range. This makes perfect technical sense, as while for the product claim a reference to viscosity can constitute a technical feature only with the specification of a value, for the method claim the purpose of the method ("reducing the viscosity") is a technical feature independently of the presence of a quantitative condition.

3.3 Possible salts to be used in the method of claim 31 are indicated in original claim 33, which is directly dependent on claim 31 (therefore also without a quantitative value of viscosity) and lists "sodium chloride, sodium thiocyanate, ammonium thiocyanate, ammonium sulfate, ammonium chloride and calcium chloride". A similar list of salts to be used in the method is present in the description (page 5, lines 16 to 19), where also "arginine hydrochloride" is listed together with the salts of claim 33.

3.4 While it is true that the cited list in the description is in a paragraph starting with an indication of a method for reducing viscosity in which the reduction of the kinematic viscosity "to 50 cs or less" (page 5, lines 6 to 9) is present, there is no technical reason why the salts listed in claim 33 could be used in a method as claimed in original claim 31 (without the limitation to a specific viscosity range), while for arginine hydrochloride a specific limitation would be needed.

3.5 The skilled person, reading the original claims and the cited paragraph of the description in combination, would understand that the salts identified in the two very similar lists are interchangeable and would derive from that a direct and unambiguous disclosure of arginine

chloride as an alternative to the salts of original claim 33 in the method of original claim 31. A different reading based on the literal wording of the paragraph on page 5 could be semantically correct, but would disregard the technical understanding of the skilled person. In other words, the feature "arginine chloride" cannot be seen as inextricably linked to the condition that the kinematic viscosity is to be reduced to 50 cs or less, so that the feature can be added to the method claim independently of the condition without adding undisclosed subject-matter.

3.6 In view of that the presence of arginine chloride in the list in claim 19 of the main request does not result in subject-matter which extends beyond the content of the application as filed.

3.7 The same applies to the objected feature of claim 18 of the main request.

3.8 It is true that originally claim 31 indicates "the addition of a salt in an amount of at least about 50 mM" and that the feature "salt and/or buffer in an amount of at least 100 mM" appears either in the cited paragraph on page 5 or in several other instances with reference to the product (e.g. original claim 1 and page 3, line 17 to page 4, line 25), wherein in both cases it is formally disclosed in combination with a reduction of the kinematic viscosity "to 50 cs or less". However, there is no technical reason why "the addition of a salt in an amount of at least about 50 mM" should be independent of the specific viscosity condition while the feature "salt and/or buffer in an amount of at least 100 mM" should make sense only when the viscosity range is specified.

3.9 Here again salts and/or buffer are disclosed as interchangeable throughout the application (see e.g. page 3, line 17 to page 4, line 25; page 5, lines 12 to 20; page 16, lines 18 to 20; claims 1 to 9 and 46 to 53), so that the added feature cannot be seen as inextricably linked to the condition that the kinematic viscosity is to be reduced to 50 cs or less and it can be added to the method claim independently of it without adding undisclosed subject-matter. Moreover, the quantitative condition ("in an amount of at least 100 mM") is repeatedly referred to "salts and/or buffers" in the cited passages. The considerations of the respondents concerning the relationship between the molarity and the ionic strength with reference to D142 have in this respect no influence on the conclusion reached.

3.10 As to the specification that the viscosity is a kinematic viscosity in claim 18 of the main request with respect to original claim 31, even disregarding that it is the only type of viscosity specifically and repeatedly disclosed in the embodiments of the application, it is at most the limitation to one of two disclosed possibilities ("kinematic viscosity" and "absolute viscosity", see page 19, lines 22 to 29), which does not result in added matter.

3.11 For these reasons, claim 18 does not result in subject-matter which extends beyond the content of the application as filed.

Remittal

4. Although the EPC does not guarantee the parties an absolute right to have all the issues in the case considered by two instances, it is well recognised that

any party may be given the opportunity of two readings of the important elements of a case. The essential function of an appeal is to consider whether the decision issued by the first-instance department is correct. Hence, a case is normally referred back if essential questions regarding the patentability of the claimed subject-matter have not yet been examined and decided by the department of first instance.

4.1 In particular, remittal is considered by the boards in cases where a first-instance department issues a decision against a party solely upon some issues which are decisive for the case, and leaves other essential issues outstanding. If, following appeal proceedings, the appeal on the particular issues is allowed, the case is normally remitted to the first-instance department for consideration of the undecided issues (Article 111(1) EPC).

4.2 The observations made above apply in full to the present case. The opposition division decided that the claimed subject-matter did not meet the requirements of Article 123 EPC, but did not consider further issues, including sufficiency, novelty and inventive step. These issues, however, formed *inter alia* the basis for the request that the patent be revoked in its entirety and must therefore be considered as essential substantive issues in the present case.

4.3 The respondents who were not in favour of a remittal simply mentioned general circumstances, which normally apply (avoiding prolongation of the period of legal uncertainty, grounds discussed at lengh in writing during opposition) and did not invoke any specific reasons which could be considered by the Board strong

enough to justify a deviation from the principles mentioned above.

5. Thus, the Board has reached the conclusion that, in the circumstances of the present case, it is appropriate to remit the case to the opposition division for further prosecution on the basis of the claims of the main request.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the opposition division for further prosecution.

The Registrar: The Chairman:

S. Fabiani J. Riolo

Decision electronically authenticated