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Datasheet for the decision of 19 December 2006

Case Number: T 0466/05 - 3.3.03

Application Number: 92300654.8

Publication Number: 0497524

IPC: A61K 39/09

Language of the proceedings: EN

Title of invention:
Polysaccharide antigens from streptococcus pneumoniae

Patentee:
Merck & Co., Inc.

Opponent:
SmithKline Beecham Biologicals SA

Headword:
-

Relevant legal provisions:
EPC Art. 83, 84, 100(a), 100(b), 100(c), 123(2), 123(3)
RPBA Art. 10a(1), 10b, 10b(1)

Keyword:
"Sufficiency of disclosure (no)"
"Late filed requests - admitted"
"Error of judgement - procedural violation (no)"

Decisions cited:
G 0009/91, T 0256/87, T 0092/92, T 0492/92, T 0225/93, T 0960/98, T 0943/00

Catchword:
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Case Number: T 0466/05 - 3.3.03

D E C I S I O N
of the Technical Board of Appeal 3.3.03
of 19 December 2006

Appellant: (Patent Proprietor)
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Decision under appeal: **Decision of the Opposition Division of the European Patent Office dated 15 April 2003 and posted 18 January 2005 revoking European patent No. 0497524 pursuant to Article 102(1) EPC.**

Composition of the Board:

Chairman: R. Young
Members: C. Idez
E. Dufrasne

Summary of Facts and Submissions

I. The grant of the European patent No. 0 497 524 in the name of Merck & Co. Inc. in respect of European patent application No. 92 300 654.8 filed on 27 January 1992 and claiming priority of the US patent application No. 646573 filed on 28 January 1991 and of the US patent application No. 807941 filed on 19 December 1991 was announced on 15 July 1998 (Bulletin 1998/29) on the basis of 6 claims.

Claims 1 to 5 read as follows:

"1. A capsular polysaccharide of Streptococcus pneumoniae having on average less than about 1200 repeat units per molecule and a polydispersity between about 1.0 and 1.4, a molecular weight between about 1 x 10^5 and 1 x 10^6, and a level of contamination by pneumococcal group-specific C-polysaccharide below 3.0% of the type-specific polysaccharide.

2. The polysaccharide of Claim 1 having an antigenicity index between 0.7 and 1.1, and an intrinsic viscosity between 0.6 and 3.0 dL/g, wherein said polysaccharide is derived from any of the subtypes of Streptococcus pneumoniae selected from: 1, 2, 3, 4, 5, 6B, 7F, 8, 9N, 9V, 10A, 11A, 12F, 14, 15B, 17F, 18C, 19F, 19A, 20, 22F, 23F, and 33F.

3. The polysaccharide of Claim 2 wherein said polysaccharide is derived from:

1) Streptococcus pneumoniae 6B, said polysaccharide having:

a) a number-average molecular weight, M_N, between 3×10^5 and 6×10^5;

b) a partition coefficient K_d (peak), of about 0.60 ± 0.05;

c) a weight-average molecular weight, M_W, between 3×10^5 and 7×10^5;

d) an intrinsic viscosity in 0.1 M sodium phosphate, pH 7.2, between 1.0 and 2.0; and

e) less than about 1000 repeating units per molecule on average;

2) Streptococcus pneumoniae 14, said polysaccharide having:

a) a M_N between 3×10^5 and 8×10^5;

b) a K_d (peak) of about 0.60 ± 0.05;

c) a M_W between 4×10^5 and 1×10^6; and

d) an intrinsic viscosity in 0.1 M sodium phosphate, pH 7.2, between 0.6 and 1.6;

3) Streptococcus pneumoniae 19F, said polysaccharide having:

a) a M_N between 2×10^5 and 6×10^5;

b) a K_d (peak) of about 0.65 ± 0.05;

c) a M_W between 2×10^5 and 6×10^5;

d) an intrinsic viscosity in 0.1 M sodium phosphate, pH 7.2, between 1.0 and 2.0; and

e) less than about 1000 repeating units per molecule, on average;

4) Streptococcus pneumoniae 23F, said polysaccharide having:

a) a M_N between 2×10^5 and 6×10^5;

b) a K_d (peak) of about 0.54 ± 0.05;
c) a M_W between 4 x 10^5 and 8 x 10^5;
d) an intrinsic viscosity in 0.1 M sodium phosphate, pH 7.2, between 1.5 and 3.0; and
e) less than about 1000 repeating units per molecule, on average,

5) Streptococcus pneumoniae 4, said polysaccharide having:
a) a M_N between 2 x 10^5 and 4 x 10^5;
b) a K_d (peak) of about 0.65 ± 0.05;
c) a M_W between 2 x 10^5 and 5 x 10^5;
d) an intrinsic viscosity in 0.1 M sodium phosphate, pH 7.2, between 1.0 and 3.0; and
e) less than about 600 repeating units per molecule, on average;

6) Streptococcus pneumoniae 9V, said polysaccharide having:
a) a M_N between 3 x 10^5 and 6 x 10^5;
b) a K_d (peak) of about 0.65 ± 0.05;
c) a M_W between 3 x 10^5 and 7 x 10^5;
d) an intrinsic viscosity in 0.1 M sodium phosphate, pH 7.2, between 1.0 and 2.0; and
e) less than about 800 repeating units per molecule, on average;

7) Streptococcus pneumoniae 18C, said polysaccharide having:
a) a M_N between 2 x 10^5 and 6 x 10^5;
b) a K_d (peak) of about 0.65 ± 0.05;
c) a M_W between 2 x 10^5 and 6 x 10^5;
d) an intrinsic viscosity in 0.1 M sodium phosphate, pH 7.2, between 1.5 and 3.0. and

e) less than about 700 repeating units per molecule, on average.

4. A composition, useful as a vaccine against between one and seven subtypes of Streptococcus pneumoniae, said composition comprising an inert carrier and one or more of the Pn-Ps compounds of Claim 3 in an unconjugated state, and optionally comprising additional antiviral, antibacterial, or immunomodulatory immunogens or compounds, wherein said additional antiviral, antibacterial, or immunomodulatory compounds are selected from among aluminum hydroxide, aluminum phosphate, or alum, or Freunds or the Ribi adjuvant, an interleukin or interferon, or from among one or more of the vaccines against hepatitis B, hepatitis A, non-A non-B hepatitis, AIDS, diptheria-pertussis-tetanus, measles, mumps, rubella, varicella and Haemophilus influenzae b.

5. A process for making a capsular polysaccharide of Streptococcus pneumoniae having less than about 1200 repeat units per molecule and a polydispersity no greater than 1.4, which comprises:
a)
i) Culturing Streptococcus pneumoniae, killing the pathogenic bacteria and isolating crude capsular polysaccharide, or
ii) solubilizing crude Streptococcus pneumoniae capsular polysaccharide available from the ATCC;
(b)
i-Optionally, adsorbing onto Whatman DE52 anionic impurities at a solution pH of about 5;
ii-Partially hydrolyzing the Pn-Ps in solution to an endpoint viscosity predetermined to diminish the Pn-Ps

binding to anti-pneumococcal type specific antibody by no more than 30% as compared with crude Pn-Ps by:
1. heating at 50 to 150°C for between 1 to 48 hours;
2. sonicating for intervals of 5 seconds to 5 minutes, depending on the power setting of the sonication probe, followed by periods of cooling and additional sonication; or
3. physically shearing the polysaccharide in a Gaulin-homogenizer at pressures between 13,8 and 103 MPa (2000 and 15000 PSI); and
(c) Fractionating the hydrolyzed Pn-Ps and selecting a fraction having a molecular weight in the range between $1x10^5$ and $1x10^6$ by:
i-differential alcohol solubility using isopropanol at concentrations predetermined to precipitate the desired Pn-Ps size range; or
ii-fractionation on a size-exclusion liquid chromatography column capable of including and fractionating polysaccharides in the size range between $1x10^4$ and $1x10^6$."

Claim 6 was dependent on Claim 5.

II. On 15 April 1999, a Notice of Opposition was filed against the patent by SmithKline Beecham Biologicals SA in which revocation of the patent in its entirety was requested on the grounds of lack of novelty and lack of inventive step (Article 100(a) EPC) and on the ground of insufficiency of disclosure (Article 100(b) EPC).

The following documents have been *inter alia* cited in the course of the opposition proceedings:

L1: B. Bednar et al. "Molecular size analysis of capsular polysaccharide preparations from *Streptococcus pneumoniae*", Carbohydrate Research, Vol. 243, 1993, pages 115-130;

L2: S. Harding et al. "Molecular weight determination of polysaccharides", Advances in Carbohydrate Analysis; Vol. 1, 1991, pages 63-144;

L5: Declaration of Dr Jean Smal dated 18 September 2002; and

L6: Declaration of Dr Jean Smal dated 12 February 2003.

III. By a decision announced orally on 15 April 2003 and issued in writing on 18 January 2005, the Opposition Division revoked the patent.

The decision of the Opposition Division was based on a main request as submitted with letter dated 12 February 2003 of the Patent Proprietor and on two auxiliary requests as submitted during the oral proceedings of 15 April 2003.

According to the decision, Claim 1 of the main request infringed Article 123(3) EPC, and did not meet the requirements of Article 84 EPC.

The first auxiliary request was refused because Claim 1 thereof did not meet the requirements of Article 123(2) EPC. Concerning the second auxiliary request it was held in the decision that it met the requirements of Articles 123(2), 123(3), 84 and 54 EPC, but that it did

not fulfil the requirements of Article 83 EPC, since the obtaining of the partition coefficient K_d range and the obtaining of the intrinsic viscosity range recited in Claim 1 were not enabled.

IV. A Notice of Appeal was filed on 17 March 2005 by the Appellant (Patent Proprietor) with simultaneous payment of the prescribed fee.

V. With the Statement of Grounds of Appeal filed on 27 May 2005, the Appellant submitted a new main request and nine auxiliary requests, as well as, *inter alia*, the following documents:

Curriculum Vitae of Dr G. Berth; and

L12: Declaration of Dr G. Berth, dated 26 May 2005.

It also submitted arguments concerning sufficiency of disclosure which may be summarized as follows:

(i) The fundamental issue in relation to insufficiency was that the Opponents had nowhere demonstrated that the skilled person could not reproduce the claimed invention. The burden of proof in this matter was on the Opponents.

(ii) The Opposition Division was incorrect to focus on the details of measuring parameters.

(iii) The Opposition Division had found that the skilled person could not measure the parameter K_d on the basis of the disclosure of the patent since there was no indication of what buffer system should be used.

(iv) The specification provided the skilled person with the general guidance on the measurement of K_d on page 4. Exemplary temperatures, standards, sample and injection volumes, Vo/Vi ratio and standard K_d values were also given.

(v) It would have been within the technical capabilities of the skilled person to select an appropriate chromatography column which would have enabled the measurement of K_d within the values indicated in the claims. Reference was made to the decisions T 492/92 of 18 January 1996 and T 960/98 of 9 April 2003 (both not published in OJ EPO).

(vi) There would also have been no difficulty for the skilled person to select an appropriate buffer system when measuring K_d.

(vii) As explained in the declaration of Dr. Berth (L12), a buffer system was needed when measuring the partition coefficient of polysaccharides dissolved in water in order to suppress polyelectrolyte effects. This was part of the common general knowledge of the skilled person.

(viii) Since the variation in the amounts of buffer giving good effects was fairly small, i.e. in the range of 0.05 and 0.2 M, there would be no undue burden on the skilled person to find an appropriate amount on a case-by-case basis.

(ix) Furthermore, if the amount of buffer was varied, within appropriate amounts, similar values of K_d would be obtained.

(x) An exemplary amount of buffer was provided in Example 30 at page 34 line 14 where 0.2 M sodium acetate was used.

(xi) The Opposition Division had found that a reproducible method for measuring the intrinsic viscosity was not disclosed, since there was no disclosure of the concentration values of polysaccharide which should be used to extrapolate this value.

(xii) The fact that methods were disclosed in the specification at the bottom of page 4 as to how intrinsic viscosity could be measured was evidence that it was within the common general knowledge of the skilled person to do so.

(xiii) The Patent Proprietor had proposed a method based on the size exclusion chromatography (SEC) method. The Opposition Division had considered that this method was insufficiently described due to the absence of information concerning the concentration of analyte loaded into the column.

(xiv) This was however part of the common general knowledge of the skilled person.

(xv) The precise measuring conditions for a well-known parameter did not affect the reproducibility of the invention. The mere fact that differing values might be

obtained would be an issue for Article 84 EPC not Article 83 EPC.

(xvi) According to Dr Berth's declaration methods of measuring intrinsic viscosity were well within the capabilities of the skilled reader. In particular, it was conventional, and convenient, to choose a highly dilute solution of a polysaccharide in order to obtain an acceptable approximate value of intrinsic viscosity.

VI. With its letter dated 7 October 2005, the Respondent (Opponent) submitted the following documents:

L9: Declaration of Dr Stephen Harding dated 7 October 2005, and

L10: Declaration of Dr Jean Smal dated 7 October 2005.

It also presented arguments concerning sufficiency of disclosure which may be summarized as follows:

(i) If a patentee had defined a product through the use of parameters, then in order for a skilled person to be able to follow the teaching of the specification he must be able to accurately measure the parameter as intended by the patentee in order to be able to make the precise product that was intended to be claimed.

(ii) Concerning the intrinsic viscosity parameter, a skilled person must know the concentration of the polysaccharide used for the determination of the intrinsic viscosity.

(iii) Intrinsic viscosity varied considerably with respect to concentration.

(iv) Unless the skilled person was sure that he was measuring the parameter in the precise way intended by the patentee, he could never be sure that he had made the product claimed.

(v) Consequently, the product claimed could not be described in a manner sufficiently clear and complete for it to be made by the skilled person.

(vi) Concerning K_d the recitation of buffer conditions was essential for the skilled person to use this parameter properly to know he had made the claimed product (cf. also document L10).

(vii) The Patent Proprietor had given no guidance as to which temperature viscosity measurements which were meant to define the claimed population of polysaccharides should be carried out at.

(viii) Viscosity was highly dependent on temperature (cf L9 and L10).

(ix) The skilled person would not be able to reproduce a particular polysaccharide population with certainty if it was defined only with reference to a viscosity value without reference to temperature.

VII. With its letter dated 2 November 2005, the Respondent submitted the following documents:

L10b: Declaration of Dr Jean Smal dated 25 October 2005, and

L11: X. Guo et al. "Determination of molecular weight of heparin by size exclusion chromatography with universal calibration"; Analytical Biochemistry Vol. 312 (2003), pages 33-39.

VIII. In a communication dated 9 October 2006, annexed to the Summons to Oral Proceedings scheduled to take place on 19 December 2006, the Board presented its provisional view on points concerning the allowability of the requests then on file under Article 123(2), 123(3) and 84 EPC, the determination of the partition coefficient Kd, the intrinsic viscosity and the target end-point viscosity, the use of the universal calibration method for determining the molecular weight and the polydispersity of capsular polysaccharides, and the compliance of the decision under appeal with the requirements of Article 113(1) EPC in view of the apparent admission of the opposition ground according to Article 100(c) EPC into the opposition proceedings.

IX. With its letter dated 17 November 2006, the Appellant submitted a new main request and four auxiliary requests, as well as the following documents:

L19: Second declaration of Dr Gisela Berth dated 17 November 2006; and

L20: Declaration of Dr Michael Gentzler dated 16 November 2006.

Claim 1 of the main request read as follows:

"1. A capsular polysaccharide of Streptococcus pneumoniae having on average less than about 1200 repeat units per molecule and a polydispersity between about 1.0 and 1.4, a molecular weight between about 1 x 10^5 and 1 x 10^6, a level of contamination by pneumococcal group-specific C-polysaccharide below 3.0% of the type-specific polysaccharide, an antigenicity index between 0.7 and 1.1, and an intrinsic viscosity between 0.6 and 3.0 dL/g, wherein said polysaccharide is derived from any of the subtypes of Streptococcus pneumoniae selected from: 1, 2, 3, 4, 5, 6B, 7F, 8, 9N, 9V, 10A, 11A, 12F, 14, 15B, 17F, 18C, 19F, 19A, 20, 22F, 23F, and 33F.

Claims 2 to 5 of the main request correspond to Claims 3 to 6 as granted.

The first auxiliary request differed from the main request only in that the reference to the subtypes 1, 2, 3, 5, 7F, 8, 9N, 10A, 11A, 12F, 15B, 17F, 19A, 20, 22F and 33F of Streptococcus pneumoniae had been deleted from Claim 1.

Claim 1 of the second auxiliary request read as follows:

"A capsular polysaccharide of Streptococcus pneumoniae having on average less than about 1200 repeat units per molecule and a polydispersity between about 1.0 and 1.4, a molecular weight between about 1 x 10^5 and 1 x 10^6, and a level of contamination by pneumococcal group-specific C-polysaccharide below 3.0% of the type-

specific polysaccharide, obtainable by a process comprising:
a)
i) Culturing Streptococcus pneumoniae, killing the pathogenic bacteria and isolating crude capsular polysaccharide, or
ii) solubilizing crude Streptococcus pneumoniae capsular polysaccharide available from the ATCC;
b) Partially hydrolyzing, by enzymatic or chemical treatment or by heating, sonicating, or physically shearing the polysaccharide; and
c) fractionating the product of step (b)."

Claim 1 of the third auxiliary request differed from Claim 1 of the second auxiliary request in that it has been redrafted as a process claim for the manufacture of the capsular polysaccharide.

Claim 1 of the fourth auxiliary request corresponded to granted Claim 5.

The Appellant also argued essentially as follows:

(i) Admission of the ground of opposition according to Article 100(c) EPC:

(i.1) There had been no discussion of the admissibility of this ground at the Oral Proceedings of the Opposition Division.

(i.2) There had certainly been no presentation in writing of the introduction of this ground and the essential legal and factual reasons which would substantiate it.

(i.3) Consequently the Patent Proprietor was not fully informed of the case to be met at the Oral Proceedings, and it was hence unable to present comments on the admissibility of this ground, as required by Article 113(1) EPC.

(i.4) In view of this substantial procedural violation, this portion of the decision should be set aside and reimbursement of the appeal was warranted assuming the Proprietor would succeed on the other issues in this appeal.

(ii) Concerning sufficiency of disclosure:

(ii.1) As shown in document L20 intrinsic viscosity of the polysaccharides of the invention was practically the same when measured at temperatures between 20 and 25°C.

(ii.2) This issue had been raised in a Summons to Oral Proceedings deemed to be received exactly two months before the Oral Proceedings. Very limited time had been provided for the Appellant to produce data to prove a point in their favour which was never previously argued against them.

(ii.3) In the absence of alternative information in the specification, the skilled person would assume that intrinsic viscosity should be measured at room temperature (i.e. in a range of 20-25°C).

(ii.4) The temperature data provided by the Respondent in L9 and L10 related to end-point viscosities, not to intrinsic viscosities.

(ii.5) The skilled person would assume that intrinsic viscosity should be measured in water.

(ii.6) The Patent Proprietor had never stated that the skilled person would measure intrinsic viscosity in any medium other than water.

(ii.7) The actual reason why the Opposition Division held intrinsic viscosities to be insufficiently disclosed was because they believed them to be concentration dependent. This was, however, wrong.

(ii.8) The skilled person had a number of methods available for measuring intrinsic viscosity. One method involved taking a single measurement combined with the MALLS technique (cf. document L12).

(ii.9) An alternative method was to use a viscometer, such as an Ubbelohde viscometer (cf. L20).

(ii.10) Consequently, it was believed that the intrinsic viscosity was sufficiently disclosed in the patent.

(ii.11) K_d was a parameter which told the skilled person what type of chromatography column to use (cf. L19).

(ii.12) The Board had misunderstood the comments of the undersigned in his letter of 23 December 1999, at page 21, third paragraph.

(ii.13) As explained by L19 (paragraph 8) and L1 (page 150), the value of K_d was relatively insensitive to the amount of buffer used, provided that conventional quantities are utilised.

(ii.14) Further, there was no suggestion in the specification that any solvent other than water would be used when chromatographing pneumococcal polysaccharides.

(ii.15) The skilled person would again assume that measurements should be made at room temperature absent other instructions. In any event, no evidence of any appreciable change in K_d between 20 and 25°C had been submitted by the Opponent in these proceedings.

(ii.16) Choosing an appropriate flow rate for use in a particular column was part of the common general knowledge of the skilled person. No evidence had been submitted to the contrary.

(ii.17) Columns were designed for particular flow rates, and using columns within the manufacturer's specifications would enable appropriate values of K_d to be obtained.

(ii.18) The patent provided exemplary columns, which in any case were part of the common general knowledge, the skilled person would use a very conventional solvent (water), a conventional temperature (room temperature) and column-specific standard flow rates.

(ii.19) Concerning target end-point viscosities, it was noted that the Opposition Division had not found this term to be insufficiently disclosed.

(ii.20) The skilled person would conventionally measure target end-point viscosities in water.

(ii.21) Target end-point viscosities were given as ranges rather than precise values. Each range varied by more than 15%. It would not therefore, matter whether measurements were made at 20°C or 25°C since the end point viscosity range was wide enough to encompass this variation.

X. In its letter dated 17 November 2006, the Respondent essentially relied on its previous submissions. Concerning the introduction of the ground of opposition according to Article 100(c) EPC, it was argued that no concern had been expressed in that respect by the Patent Proprietor in its Statement of Grounds of Appeal. It hence did not seem that it had had reservation on the admission of that ground.

XI. With its letter dated 21 November 2006, the Appellant submitted the following document:

L20A:Second declaration of Dr. Michael Gentzler.

XII. In its letter dated 28 November 2006 the Respondent argued essentially as follows:

(i) The new requests and the new declarations had been filed at a very late stage. Their filing amounted to an abuse of proceedings. They should not be admitted.

(ii) Concerning sufficiency of disclosure:

(ii.1) The burden was now on the Appellant to prove that the decision of the Opposition Division was incorrect.

(ii.2) The measurement of K_d was sensitive to change of conditions, in particular buffer conditions, and the patent did not disclose the method for determining K_d in a manner which reliably retained the validity of this parameter for the solution to the technical problem.

(ii.3) Concerning intrinsic viscosity, the preferred method of measurement advocated by the application as filed was given at the bottom page 4 of the application as filed.

(ii.4) This was a method of measuring the reduced viscosity at a single unspecified concentration and equating this to be the intrinsic viscosity. This "preferred method" of assessing intrinsic viscosity was concentration dependent.

(ii.5) Reference was also made in that respect to document L12 (paragraph 14).

(ii.6) The patent did not disclose such concentration information in a manner which reliably retained the validity of the intrinsic viscosity parameter for the solution to the technical problem.

(ii.7) In respect of target end-point viscosity, evidence had been provided by the Respondent

(paragraphs 16 and 17 of L9) that this measurement was significantly temperature dependent.

(ii.8) The patent in suit did not disclose such temperature information in a manner which reliably retained the validity of the end-point viscosity parameter for the solution to the technical problem.

(iii) A substantial procedural violation did not take place at first instance. The Patentee's behaviour and submissions up until 17 November 2006 were consistent with a party who was fully aware of the situation to the extent that no hint of a procedural violation was alluded to in the section of the Appellant's statement of appeal concerning this point of appeal.

XIII. With its letter dated 30 November 2006, the Appellant submitted a new first page of the main request submitted with letter of 17 November 2006, in which Claim 1 thereof had been amended, in that the reference to the subtype 7F of Streptococcus pneumoniae had been deleted in that claim.

It also argued essentially as follows:

(i) Paragraph III of the Annex to the Summons to Oral Proceedings contemplated that amendments could be made.

(ii) Documents L20 and L20A had been submitted in response to points raised by the Board.

XIV. Oral proceedings were held before the Board on 19 December 2006.

(a) At the oral proceedings, following preliminary observations from the Board as to whether or not the ground of opposition under Article 100(c) EPC had been introduced by the Opposition Division at the oral proceedings of 15 April 2003, and hence as to whether the refusal of the first auxiliary request by the Opposition Division would amount to a procedural violation or merely to an error in law, the Appellant indicated that it withdrew its request for reimbursement of the appeal fee.

(b) After deliberation, the Board having informed the Parties that the ground of opposition under Article 100(c) EPC did not form part of the proceedings, the discussion focussed on the admission of the requests submitted by the Appellant with its letters dated 17 November and 30 November 2006, and of the documents L19, L20 and L20A. The arguments presented by the Parties in that respect may be summarized as follows:

(b.1) By the Respondent:

(b.1.1) These requests, including new sets of claims, had been submitted about one month before the oral proceedings, and the last modification to the claims was submitted even less than one month before. Reference was made to Article 10b(1) of the Rules of Procedure of the Board of Appeal (RPBA).

(b.1.2) The first goal of the appeal proceedings was to check the validity of the decision under appeal.

(b.1.3) The subject-matter of the claims of the new requests was completely different from that of the claims considered by the Opposition Division.

(b.1.4) The new claims did not contain any reference to the 2 to 10 fold reduction in molecular size.

(b.1.5) Seven years after the beginning of the opposition proceedings, the Appellant was trying to come back to the point at which the opposition proceedings had started.

(b.1.6) Consequently, these requests should be not admitted into the proceedings.

(b.1.7) Documents L19, L20 and L20A had been submitted very late and should not be admitted into the proceedings.

(b.1.8) The Respondent had no possibilities to make counter experiments in response to the tests presented in L20 and L20A.

(b.2) By the Appellant:

(b.2.1) A communication had been issued by the Board on the 9 October 2006.

(b.2.2) The filing of the new requests represented an attempt to respond to the points raised by the Board in its communication. Reference was to Article 10a(1) RPBA in that respect.

(b.2.3) The communication of the Board mentioned the possibility to file amended set of claims.

(b.2.4) The Board had also raised for the first time in its communication the question of temperature dependency of the intrinsic viscosity.

(b.2.5) Experimental work had been necessary to deal with this point. Documents L20 and L20A had been filed as soon as possible in that respect.

(c) The Board, after deliberation, having informed the Parties that the main request and the four auxiliary requests of the Appellant as well as the documents L19, L20 and L20A were introduced into the proceedings, the discussion focussed on the question of the sufficiency of disclosure, in particular in respect of the parameters indicated in Claim 1 of the main request, i.e. molecular weight range, polydispersity, antigenicity index and intrinsic viscosity. The arguments presented by the Parties in that respect may be summarized as follows:

(c.1) By the Respondent:

(c.1.1) A molecular weight range of 1×10^5 to 1×10^6 and the polydispersity of about 1 to about 1.4 were essential parameters in order to characterize the polysaccharide population.

(c.1.2) According to document L2 the weight average molecular weight M_W, the number average molecular weight M_N, or the Z average molecular weight M_Z could be used

for defining the molecular weight of the polysaccharides.

(c.1.3) No method was mentioned in Claim 1 of the main request for the determination of the molecular weight. This implied that any method at the disposal of the skilled person could be used in that respect.

(c.1.4) Table II of the patent in suit showed that the weight average molecular weight and number average molecular indicated therein had been determined with an uncertainty of +/- 20%.

(c.1.5) This would imply a value of 2.1 of the polydispersity should be considered as included by the expression "about 1.4".

(c.1.6) There were huge differences in the measured values of molecular weight for the same polysaccharides up to 200%, determined by different methods, as shown by Tables 1 and 3 of document L6, which compared molecular weight determination by the universal calibration technique and by the MALLS technique.

(c.1.7) Document L1 also acknowledged an overestimation of molecular weight of polysaccharides by the universal calibration technique of up to 53% over MALLS.

(c.1.8) Thus if one would consider a polydispersity value of 1.5 and overestimation of 1.53, a weight average molecular weight in the range of 1×10^5 to 1×10^6 would correspond to a number weight average molecular weight according to MALLS of between 4.3×10^4 to 4.3×10^5, while a number average molecular weight in

the range of 1 x 10^5 to 1 x 10^6 according to MALLS would correspond to a weight average molecular weight in the range of 2.3 x 10^5 to 2.3 x 10^6 according to the universal calibration method. This would imply a very slight overlap between the value of a number average molecular weight determined by MALLS and the value of the weight average molecular weight determined by universal calibration for the same polysaccharide.

(c.1.9) The discrepancy would be even more apparent if one would take the Mz molecular weight which would be in a ratio of 1.5 x 1.5 to the number average molecular weight, and/or if one would consider the huge difference of up to 200% between the determination according to universal calibration and the MALLS technique.

(c.1.10) There was no absolute "true" method for determining molecular weights. There were various methods.

(c.1.11) If the skilled person would use the universal calibration method which appeared to be presented as the preferred method according to the patent in suit, it would not know where the target in terms of "true" molecular weight in order to define the inventive polysaccharide population should be. This would represent an undue burden.

(c.1.12) Polysaccharides were not monodisperse polymers as shown by document L2 (page 65). Thus, it would not be possible to reach a polydispersity of 1.

(c.1.13) According to the patent in suit, the intrinsic viscosity was determined in the course of the SEC or HPSEC (cf. page 4, lines 55 to 57) using the specific viscosity. As shown by document L9 (paragraph 16) and by document L12 (paragraph 14), the value of the intrinsic viscosity was dependent on the value of the concentration used for determining the specific viscosity. As shown by L9, the uncertainty might be as high as 20% depending on the concentration selected.

(c.1.14) The antigenicity index was determined in respect of a "crude" polysaccharide. Even if it would be considered that the crude polysaccharide would be obtained from the ATCC, document L6 showed that there very significant differences between lots of subtypes of polysaccharide in terms of molecular weight and hence in term of starting antigenicity.

(c.1.15) Furthermore, it was not clear which antibody should be used when carrying out the antigenicity index. The results depended on the type of antibody used.

(c.1.16) It should be noted that the crude polysaccharide might contain up to 60% by weight of C-polysaccharide. It would not be possible to distinguish between the antigen-antibody complex precipitate resulting from this part of the crude polysaccharide and the one resulting from the specific Pn-Ps antigen-antibody complex.

(c.2) By the Appellant:

(c.2.1) Distinction should be made between the requirements of Article 84 EPC and those of Article 83 EPC.

(c.2.2) The objections raised by the Respondent in respect of the parameters in Claim 1 amounted however to objections of lack of clarity. Concerning Article 83 EPC, the relevant question would however be whether the patent in suit provide sufficient information which enabled the skilled person to reproduce the invention, i.e. to obtain the claimed polysaccharides. Reference was made in that respect to decisions T 960/98 and T 943/00 of 31 July 2003 (not published in OJ EPO).

(c.2.3) While document L2 referred to the molecular weight M_Z, there was no mention at all of this parameter in the patent in suit.

(c.2.4) In view of paragraph 9 of document L5 it was questionable whether the Respondent had been able to correctly use the universal calibration method.

(c.2.5) Claim 1 of the main request did not require that the molecular weight be determined by a specific method.

(c.2.6) The fact that the universal calibration method was presented as a preferred method in the patent in suit did not prevent the skilled person to use other methods such as those mentioned on page 4, lines 28 to 31 of the patent in suit.

(c.2.7) Claim 1 referred to the true and real molecular weight of the polysaccharide.

(c.2.8) Such molecular weight could be measured by the methods known to the skilled person, such as those mentioned in the patent in suit.

(c.2.9) In that respect, it should be noted that the Opponent (Respondent) had had no difficulty to determine whether polysaccharides of the prior art exhibited a molecular weight within the claimed range.

(c.2.10) While it might be true that a polydispersity of 1 could not be reached with polysaccharides, Claim 1 of the main request however referred to a polydispersity of about 1.

(c.2.11) Concerning the antigenicity index, the crude polysaccharide was obtained from the ATTC. It had not been shown by the Opponent that the variation within lots of crude polysaccharide would lead to different antigenicity.

(c.2.12) The antibody selected for carrying the antigenicity test was specific to the Ps-Pn antigen.

(c.2.13) The presence of C-polysaccharide would hence not affect the outcome of the test. Furthermore the fact that the patent in suit mentioned in 20 fold reduction of the amount of C-polysaccharide did not imply that the crude polysaccharide might contain up to 60% C-polysaccharide.

(c.2.14) Concerning the intrinsic viscosity, documents L20 and L20A showed that there was no significant variation in the range from 20 to 25°C.

(c.2.15) While the patent in suit mentioned the possibility to determine the intrinsic viscosity in the course of the SEC or HPSEC using the specific viscosity, the skilled person would know how to determine this parameter in a conventional way, for example using an the Ubbelhode's viscosimeter.

(c.2.16) In any case, even using the method mentioned in the patent in suit would lead to an uncertainty of 2% as shown in document L12.

XV. The Appellant requested that the decision under appeal be set aside and the case be remitted to the first instance for further prosecution on the basis of the main request consisting of Claims 1 to 2 (part) submitted with letter dated 30 November 2006, and of Claims 2 (part) to 5 as submitted with letter dated 17 November 2006, or, in the alternative, on the basis of one of the auxiliary requests 1 to 4 submitted with letter dated 17 November 2006.

The Respondent requested that the appeal be dismissed.

Reasons for the Decision

1. The appeal is admissible.

2. *Procedural matters*

2.1 As can be seen from the Facts and Submissions the Board has been confronted with the following procedural issues:

(i) the question as to whether or not the ground of opposition under Article 100(c) EPC had been introduced into the proceedings by the Opposition Division and the procedural consequences of the introduction or of the non introduction of this ground into the proceedings,

(ii) the question as to whether the requests submitted by the Appellant with its letters dated 17 and 30 November 2006 should be admitted into the proceedings, and

(iii) the question as to whether documents L19, L20 and L20A should admitted into the proceedings.

2.2 Concerning point (i):

2.2.1 As indicated above in Section III, the first auxiliary request submitted by the Patent Proprietor at the oral proceedings before the Opposition Division has been refused because Claim 1 thereof did not meet the requirements of Article 123(2) EPC.

2.2.2 According to the decision of the Opposition Division, there was no basis in the application as originally filed for the feature in Claim 1 of that request that the lower limit of the molecular weight Mw of the polysaccharide derived from Streptococcus pneumoniae 4 be 2×10^5.

2.2.3 In that respect, the Board however notes that Claim 1 of the first auxiliary request was based on a combination of Claims 1, 2 and 3 as granted, and that

Claim 3 as granted already contained the objected feature.

2.2.4 This implies, in the Board's view, that the presence of this feature in Claim 1 of the first auxiliary request could only have been open to an objection under Article 123(2) EPC, provided the ground of opposition under Article 100(c) EPC would have been in the opposition proceedings.

2.2.5 In this connection, the Board, however, observes that, in the Notice of Opposition dated 15 April 1999, only the grounds of opposition under Article 100(a) and 100(b) EPC were mentioned.

2.2.6 While in its letter dated 14 February 2003, the Opponent (Respondent) requested that "due to the claim **amendments** made by the Patentee as a main request in their submission of 23 December 1999 and retained in their main request as submitted on 11 September 2002, the claims are revoked under new grounds of Article 100(c)" (emphasis by the Board), the Board can only state that no objection under Article 100(c) EPC has been raised in substance by the Opponent (Respondent) against the claims as granted.

2.2.7 In view of the minutes of the oral proceedings before the Opposition Division and the decision of the Opposition Division, it is further not apparent as to whether a discussion and a decision on the admission of this new ground of opposition had taken place.

2.2.8 In this connection, the Board also observes there would have been no need for the Opposition Division to introduce this new ground of opposition, in order, as requested by the Opponent, to check the allowability of amendments made in the course of the opposition proceedings by the Patent Proprietor under Article 123(2) EPC, since, as stated in the decision G 09/91 (OJ EPO 1993, 408; Reasons point 19) in case of amendments of the claims or other parts of a patent in the course of opposition or appeal proceedings, such amendments are to be fully examined as to their compatibility with the requirements of the EPC e.g. with regard to the provisions of Article 123(2) and (3) EPC.

2.2.9 The Board further observes that the Opposition Division had taken the view that the main request on which its decision was based met the requirements of Article 123(2) EPC (cf. minutes of the oral proceedings of 15 April 2003, page 2, lines 1 to 2), although Claim 3 of this request, which corresponded to Claim 3 as granted, already contained the feature which had led to the refusal of the first auxiliary request. This suggests, in the Board's view, that the ground of opposition under Article 100(c) EPC had not been introduced into the opposition proceedings by the Opposition Division, otherwise the main request should also have been refused on the grounds of Article 123(2) EPC by the Opposition Division.

2.2.10 The Board also notes that the Appellant has submitted that there was no discussion concerning the admission of the ground of opposition under Article 100(c) EPC into the proceedings at the oral proceedings before the

Opposition Division (cf. letter dated 17 November 2006, page 4, second paragraph) and that this had not been disputed by the Respondent.

2.2.11 Under these circumstances, it is hence more than likely, in the Board's view, that the ground of opposition under Article 100(c) EPC had not been introduced into the opposition proceedings by the Opposition Division, but that the Opposition Division had erroneously handled the combination of granted Claims 1, 2 and 3 which resulted in Claim 1 of the first auxiliary request as representing an amendment open to objection under Article 123(2) EPC in accordance with Article 102(3) EPC. Thus, the Board comes to the conclusion that Article 100(c) EPC does not form part of the opposition/appeal proceedings.

2.2.12 Furthermore, it also follows from the above that the error in law which led to the refusal of the first auxiliary request has to be regarded, in the Board's view, as an error of judgement but not as a substantial procedural violation which might have justified setting aside the decision under appeal.

2.3 Concerning point (ii):

2.3.1 As indicated above in paragraph IX the Appellant has submitted with its letter dated 17 November 2006 a new main request, and four auxiliary requests. Claim 1 of the main request was further amended as indicated in the letter dated 30 November 2006 (cf. paragraph XIII above).

2.3.2 In the Board's view, it is firstly clear that the filing of the new requests represents an attempt to deal with the objections under Article 123(2) and 84 EPC mentioned by the Board in its communication dated 9 October 2006 in view of the requests then on file. Secondly, these requests have been filed shortly before the deadline set out by the Board in its communication (i.e. one month before the date scheduled for oral proceedings) for filing further submissions e.g. amended set of claims. This consideration is not altered by the fact that a slight amendment has been carried out in Claim 1 of the main request as filed in the letter dated 30 November 2006, since it was clearly the intention of the Appellant to delete the reference to subtype 7F in Claim 1 of the main request submitted on 17 November 2006 (cf. letter dated 17 November 2006; page 2, paragraph No. 1).

2.3.3 Since the Board has clearly informed the Parties in that communication that it did not intend to deal with the issues of novelty and inventive step at the oral proceedings, and since the subject-matter of these new claims does not raise new issues under Article 83 EPC, which have not been yet considered in the course of the opposition and appeal proceedings, the introduction of these late filed requests cannot, in the Board's view, cause any disadvantage to the Respondent. Consequently, the Board, making use of its discretion under Article 10b RPBA, decides to admit them into the proceedings.

2.4 Concerning point (iii):

2.4.1 In its communication dated 9 October 2006, the Board questioned the dependency of the intrinsic viscosity on the temperature.

2.4.2 Two experimental reports have been submitted by the Appellant, one (L20) with its letter of 17 November 2006, i.e. before the deadline set out in the communication of the Board of 9 October 2006 for the filing of further submissions, and the other (L20A) with its letter dated 21 November 2006.

2.4.3 On the one hand, it is clear, in the Board's view, that the filing of document L20 represents a response to the observations made by the Board in its communication dated 9 October 2006 concerning the dependency of the intrinsic viscosity on the temperature, and that document L20A merely aims to confirm the conclusions drawn by the Appellant in L20 according to which the intrinsic viscosity does not significantly vary at room temperature, i.e., according to the Appellant at temperatures between 20°C and 25°C.

2.4.4 Furthermore, it could have been reasonably expected, in view of the communication of the Board of 9 October 2006, that comparative data aiming to show an insignificant influence (Appellant) or a significant influence (Respondent) of the temperature on the intrinsic viscosity of the claimed polysaccharides might be of relevance for the assessment of sufficiency of disclosure.

2.4.5 In this connection, the Respondent was thus free either to submit its own tests before the deadline set out in the communication of the Board, or to prepare itself in order to be able to submit counter examples in a short period (one month).

2.4.6 It thus follows, in the Board's view, that the filing of the experimental reports L20 and L20A by the Appellant does not represent unfair behaviour but, on the contrary, corresponds to a diligent and foreseeable handling of its case.

2.4.7 Thus, the Board sees no reason not to admit these experimental reports into the proceedings.

2.4.8 Concerning document L19 also submitted with the letter dated 17 November 2006 of the Appellant, it merely presents, in the Board's view, counterarguments of the technical expert of the Appellant concerning the documents L9, L10 and L10b submitted by the Respondent with its letters dated 7 October 2005 and 2 November 2005.

2.4.9 As indicated in decision T 92/92 of 21 September 1993 (not published in OJ EPO), Article 114(2) EPC did not however provide a legal basis for disregarding late filed arguments.

2.4.10 Consequently, document L19 is admitted into the proceedings.

Main request

3. *Wording of the claims*

3.1 Claim 1 of the main request corresponds to a combination of granted Claims 1 and 2 with the exception that the reference to the subtype 7F has been deleted.

3.2 Claims 2 to 5 correspond to granted Claims 3 to 6 as granted.

3.3 As indicated above Article 100(c) EPC does not form part of the present opposition/appeal proceedings.

3.4 No objection under Article 123(2) EPC arises from the amendment made in Claim 1, i.e. the deletion of the reference to the subtype 7F. The same is also true in respect to Article 84 EPC.

3.5 No objection has been raised under Article 123(3) EPC against the claims of the main request. The Board is also satisfied that the requirements of that Article are met.

4. *Sufficiency of disclosure*

4.1 Claim 1 of the main request is directed to a population of polysaccharides characterized in particular by a molecular weight in the range of 1×10^5 to 1×10^6, a polydispersity between about 1.0 and 1.4, an intrinsic viscosity in the range of 0.6 to 3 dl/g, an antigenicity index between 0.7 and 1.1 and a level of contamination by C-polysaccharides of below 3%.

4.2 Although one of the essential features of the claimed polysaccharides is that they must exhibit a molecular weight in the range 1 x 10^5 to 1 x 10^6, it is however evident that Claim 1 does not specify which type of molecular weight must be in that range or according to which method this molecular weight should be determined.

4.3 While in view of the lack of indication of the specific molecular weight and of its method of determination, it might have been questionable as to whether the claimed invention was correctly defined in accordance with Article 84 EPC, Claim 1 of the main request is not open to objection of lack of clarity in that respect, since this essential feature was already present as such in granted Claim 1.

4.4 Nevertheless, it is indisputable that the claimed polysaccharides must exhibit a specific molecular weight i.e. a "true and real" molecular weight as submitted by the Appellant in a specific range in order to be able to solve the technical problem underlying the patent in suit i.e. providing polysaccharides having improved properties for the preparation of conjugate immunogens. In other words, the necessity of identifying a population of polysaccharides exhibiting this specific molecular weight belongs to the core of the claimed invention.

4.5 In this connection, the Board firstly concurs with the submissions of the Appellant that a distinction should be made between the requirements of Article 84 EPC and those of Article 83 EPC, and that with respect to sufficiency the relevant question is whether the patent

in suit provides sufficient information which enables the skilled person when taking account common general knowledge to reproduce the invention (cf. also decisions T 943/00; Reasons point 10.4; and T 960/98; Reasons point 3.2.1) both relied on by the Appellant).

4.6 In that respect, the Board also concurs with the considerations made in the decision T 943/00 in respect of the decision T 256/87 of 26 July 1988 (not published in OJ EPO; reasons point 17) according to which a person skilled in the art has to know "when he is working within the forbidden area of the claims", would appear to be rather associated with the boundaries of the claimed subject-matter, i.e. Article 84 EPC than to sufficiency of disclosure.

4.7 However, the question at stake in the present case is not the question of the boundaries of the claimed subject-matter, but whether the lack of indications in Claim 1 in respect to the core of the claimed invention does not amount to an undue burden for the skilled person trying to reproduce the invention (cf. also decision T 225/93 of 13 May 1997 (not published in OJ EPO; Reasons points 2 and 2.3; also cited in the decision T 943/00 relied on by the Appellant).

4.8 In the present case, it is clear that the reproduction of the invention presupposes that the skilled person must have access to the "true and real" molecular weight of the polysaccharide, i.e. that he will know how to identify a population of polysaccharides exhibiting this specific molecular weight range for the purpose of solving the technical problem.

4.9 In this connection the Board observes that polymeric compounds like polysaccharides might be characterized by several molecular weights, such the weight average molecular weight, the number average molecular weight or the Z-average molecular weight (cf. L2, page 69, last paragraph).

4.10 Even if it would be accepted, as argued by the Appellant, that, due to the absence of any reference to the Z-average molecular weight in the patent in suit, the skilled person would consider that the Z-average molecular weight cannot be the "true" measure of molecular weight referred to in Claim 1, it still remains that the patent in suit does not indicate which one of the weight average molecular weight or of the number average molecular weight should be considered as representing the "true" measure of molecular weight.

4.11 It is also evident that each of these average molecular weights may be determined by different methods such as those disclosed in the patent in suit (page 4, line 28 to page 5, line 3) or further known to the skilled person such as the MALLS technique.

4.12 In that context, it is however noted by the Board that the value of the weight average molecular weight of pneumococcal polysaccharides is highly dependent on the method used for its determination, since, as shown by document L6, there might be a more than 2.7 fold difference between the value of the weight average molecular weight of polysaccharides by the universal calibration method and the one determined by the MALLS technique (cf. Table 1, sized PS 6A, 7F, 9N, 14, 19F

and 23F, and Table III sized PS 6A, 7F, 9N, 14, 19F and 23F).

4.13 Consequently, the skilled person wishing to have access to the relevant "true and real" molecular weight of the polysaccharides according to the invention is hence inevitably confronted with a combined uncertainty linked to the choice of the "true" measure of molecular weight to be determined and to the choice of the method of determining the "real" value of this "true" measure.

4.14 In that respect the present case substantially differs from the case considered in the decision T 492/92 (cf. Reasons point 3.3) relied on by the Appellant, where it was considered that the fact that two methods suggested by the Appellant did not necessarily lead to identical results when measuring a specific parameter (i.e. the electrolyte contents of a composition) was no sufficient evidence that a skilled person could not determine this parameter of the claimed compositions with the required accuracy, in that the skilled person in the present case does not even know which parameter (i.e. which measure of the molecular weight) of the claimed polysaccharide should be determined.

4.15 Since the polydispersity of the claimed polysaccharide is according to Claim 1 up to 1.4, this implies that the number average molecular weight can be 1.4 fold lower than the weight average molecular weight, and that hence there could be difference of about 280 % between a weight molecular weight determined by the universal calibration method and a number average molecular weight determined by the MALLS technique.

4.16 This level of uncertainty in the determination of the "true and real" molecular weight is, in the Board's view, much more than what the skilled person would normally have expected from a determination of a specified molecular weight by a specific method, e.g. the level of experimental error mentioned in Table II of the patent in suit (i.e. +/-20%).

4.17 The level of uncertainty which affects in the present case the core of the claimed invention is such that there would have to have been available adequate instructions in the patent specification or on the basis of the general knowledge of the skilled person in order to reduce this level of uncertainty to a level which could be reasonably expected by the person skilled in measurements of molecular weight of polysaccharides.

4.18 The Board can however only state that this is not the case here, since this level of uncertainty cannot be reduced by relying on the further features of the claimed polysaccharides mentioned in Claim 1, i.e. their intrinsic viscosity, their antigenicity index, and their level of contamination by C-polysaccharides.

4.19 This is because, although the skilled person would assume that there is some relationship between intrinsic viscosity and molecular weight, the patent in suit is totally silent on the specific relationship between the intrinsic viscosity of the claimed polysaccharides and their "true and real" molecular weight.

4.20 Nor could the level of antigenicity provide any information on the "true and real" molecular weight of the polysaccharide, on the one hand, since the antigenicity index is a mere relative value calculated in respect to a crude polysaccharide whose molecular weight is not specified in the patent in suit and which might further vary considerably from lot to lot as shown by document L6 (Table II, PS 18C) and, on the other hand, since no direct link is discernable in the patent in suit between the antigenicity index and the "true and real" molecular weight.

4.21 The degree of contamination by C-polysaccharide is, in the Board's view, even less relevant to provide instructions as to reduce the level of uncertainty concerning the "true and real" molecular weight since it merely reflects the degree of purity of the claimed polysaccharide.

4.22 Thus, the Board comes to the conclusion that the skilled person can only establish by trial and error whether or not it has indeed acceded to the "true and real" molecular weight of the claimed polysaccharides, and that hence the determination of the "true and real" molecular weight which is compulsory to identify the population of polysaccharides according to Claim 1 of the main request involves an undue burden.

4.23 Consequently, in accordance with the considerations made in the decision T 225/93, the subject-matter of present Claim 1 must be regarded as insufficiently disclosed to be reproduced by a skilled person. For these reasons, the main request of the Appellant does

not comply with the requirements of Article 83 EPC, and therefore it must be refused.

4.24 Under these circumstances there is no need for the Board to deal with the further objections of lack of sufficiency which have been raised in respect to the determination of the intrinsic viscosity, the determination of the antigenicity index, the Kd coefficient, and the target end-point viscosity.

5. The same conclusion as in paragraph 4.23 above would apply to the subject-matter of Claim 1 of the auxiliary requests 1 to 4, since they all contain a reference to the molecular weight, i.e. the "true and real" molecular weight either of the claimed polysaccharides (Auxiliary requests 1, 2), or of the polysaccharides to be obtained (Auxiliary requests 3 and 4).

6. Since none of the requests of the Appellant is allowable, the appeal must be dismissed.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

E. Görgmaier R. Young