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Datasheet for the decision of 23 December 2009

Case Number: T 0025/09 - 3.3.04

Application Number: 02755452.6

Publication Number: 1401489

IPC: A61K 39/02

Language of the proceedings: EN

Title of invention:
Capsular polysaccharide solubilisation

Patentee:
Novartis AG

Opponent:
GlaxoSmithKline Biologicals SA

Headword:
Capsular polysaccharide/NOVARTIS

Relevant legal provisions:
EPC Art. 56, 113(2)

Keyword:
"Main request - inventive step (no); auxiliary request - added subject-matter (no), clarity, novelty, inventive step (yes)"
"Withdrawal of auxiliary requests (yes); opinion on withdrawn auxiliary requests (no)"

Decisions cited:
G 0002/91, G 0008/91, G 0003/04, J 0019/82, T 0032/84, T 0073/84, T 0060/91, T 0473/98, T 0240/01, T 1033/04, T 1409/05

Catchword:
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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0025/09 - 3.3.04

D E C I S I O N
of the Technical Board of Appeal 3.3.04
of 23 December 2009

Appellant I: (Patent Proprietor)
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Decision under appeal:
Interlocutory decision of the Opposition Division of the European Patent Office posted 8 January 2009 concerning maintenance of European patent No. 1401489 in amended form.

Composition of the Board:

Chair: U. Kinkeldey
Members: M. Wieser
F. Blumer

Summary of Facts and Submissions

I. Appeals were lodged by the Patent Proprietor (Appellant I) and by the Opponent (Appellant II) against the interlocutory decision of the Opposition Division, posted 8 January 2009, according to which the European patent No. 1 401 489 could be maintained in amended form (Article 101(3)(a) EPC).

II. The Opposition Division decided that the subject-matter of the claims of the main request before them was not novel (Article 54 EPC). Auxiliary request 1.1, filed at the oral proceedings before the Opposition Division held on 24 October 2008, was considered as being late filed and was not allowed into the proceedings. However, the Opposition Division decided that the claims of auxiliary request 1.2, also filed at the oral proceedings, met all requirements of the EPC.

III. Appellant II filed a notice of appeal with letter dated 22 December 2008. A statement setting out the grounds for appeal was filed with letter dated 17 April 2009.

Appellant I filed a notice of appeal with letter dated 16 March 2009. A statement setting out the grounds for appeal was filed with letter dated 18 May 2009.

IV. With letter dated 23 December 2008 Appellant II requested accelerated processing of the appeal. This request was repeated in the letter dated 29 May 2009. With letters of 6 August 2009 (Appellant II) and 11 August 2009 (Appellant I) the Board was informed that Appellant I has filed infringement proceedings in Belgium and the UK.

V. In a first communication dated 18 August 2009, the Board declared that it will inform the parties about the timetable in case of accelerated processing only after 13 October 2009, the date on which the time limit for both parties to respond to the other party's grounds for appeal ends.

VI. With letter dated 2 October 2009 addressed to the Vice President DG3, the Hon Mr Justice Arnold, Judge of the High Court, Chancery Division, requested for accelerated processing of the present case, as proceedings for revocation of the UK designation of the patent in suit, commenced by Appellant II, were due to come to trial on 11 January 2010. An application for the infringement proceedings commenced by Appellant I against Appellant II to be tried together with the revocation claim on the same date was being considered.

VII. The Board, in a communication dated 20 October 2009, allowed the request for accelerated processing and summoned the parties for oral proceedings to be held on 22 and 23 December 2009.

VIII. Appellant I, with letter dated 13 October 2009, enclosing its response to Appellant II's grounds for appeal, requested to set aside the decision under appeal and to maintain the patent on the basis of a main request or one of auxiliary requests 1 to 12, all attached to said letter. With letter dated 13 November 2009 Appellant I submitted additional auxiliary requests 1a, 2a, 4a and 8a.

At the oral proceedings the main request and auxiliary requests 1, 5, 6 and 11, all filed with letter dated 13 October 2009, and two auxiliary requests filed during the oral proceedings were considered by the Board.

At the end of the oral proceedings Appellant I withdrew all requests but the main request, filed with letter dated 13 October 2009, and one auxiliary request, filed at the oral proceedings on 23 December 2009.

IX. The final requests of the parties were as follows:

Appellant I requested that the decision under appeal be set aside and that the patent be maintained on the basis of the main request, filed with letter dated 13 October 2009, or, subsidiarily, on the basis of the auxiliary request as filed during the oral proceedings before the Board on 23 December 2009.

Appellant II requested that the decision under appeal be set aside and that the European patent No. 1 401 489 be revoked. Furthermore, it requested that Appellant I was not allowed to withdraw any auxiliary request considered during oral proceedings, or, alternatively, that the Board in its reasoned decision expresses its opinion on auxiliary requests withdrawn during oral proceedings.

X. Claim 1 of Appellant I's main request read as follows:

"A process for conjugating a bacterial capsular polysaccharide to a carrier protein, comprising

purifying the polysaccharide, comprising the steps of (a) precipitation of the polysaccharide using one or more cationic detergents, followed by (b) solubilisation of the precipitated polysaccharide using an alcohol, and

conjugation of the polysaccharide to a carrier protein, wherein the carrier protein is a diphtheria toxoid, a tetanus toxoid or a CRM_{197} diphtheria toxoid,

and wherein the bacterial capsular polysaccharide is from *N.meningitidis*, *Haemophilus influenzae* or *Streptococcus pneumoniae*."

XI. Claims 1 and 11 of Appellant I's auxiliary request read as follows:

"1. A process for conjugating a bacterial capsular polysaccharide to a carrier protein, comprising

purifying the polysaccharide, comprising the steps of (a) precipitation of the polysaccharide using one or more cationic detergents, followed by (b) solubilisation of the precipitated polysaccharide using ethanol at a final concentration of between 75% and 95%, then (c) treating the solubilised polysaccharide obtained in step (b) to remove contaminants, comprising size filtration and/or ultrafiltration,

activation or functionalisation of the polysaccharide, and

conjugation of the polysaccharide to a carrier protein, wherein the carrier protein is a CRM_{197} diphtheria toxoid,

and wherein the bacterial capsular polysaccharide is from *N.meningitidis* serogroup A, W135 or Y and the cationic detergent is cetyltrimethylammonium bromide.

11. A process for conjugating to a carrier protein a capsular polysaccharide that has been precipitated using one or more cationic detergents and then solubilised using ethanol as a solvent at a final concentration of between 75% and 95% and then treated to remove contaminants, comprising size filtration and/or ultrafiltration, and activated or functionalised, wherein the bacterial capsular polysaccharide is from *N.meningitidis* serogroup A, W135 or Y, and wherein the carrier protein is a CRM_{197} diphtheria toxoid and the cationic detergent is cetyltrimethylammonium bromide."

Dependent claims 2 to 10 referred to preferred embodiments of the process of claim 1; dependent claim 12 referred to a preferred embodiment of the process of claim 11.

XII. The following documents are referred to in this decision:

(1) EP-B-0 072 513

(1B) English translation of (1)

(2) WO 00/56 360

(7) Methods in Carbohydrate Chemistry, vol.8, 1965, pages 38 to 44

(11) Methods of Biochemical Analysis, vol. VIII, 1961, pages 145 to 197

(13) WO 97/30 171

(27) Physiochemical Procedures for the Characterisation of Vaccines, Dev. Biol., vol.103, 2000, pages 259 to 264

(29) WO 98/32 873

(29A) English translation of (29)

(30) EP-A-0 528 635

(31) Advances in Biotechnological Processes, Bacterial Vaccines, vol.13, 1990, pages 123 to 145

(33) Exp. Med., vol.129, no.6, 1969, pages 1349 to 1365

XIII. The submissions made by Appellant I, as far as they are relevant to the present decision may be summarised as follows:

The closest prior art for the assessment of inventive step of claim 1 of the main request was represented by document (2) which had more features in common with the claimed subject-matter as any other prior art document of file. Nonetheless document (2) taught away from the

subject-matter of claim 1 and thus the claim met the requirements of Article 56 EPC.

Document (27) which referred to an analytical process was not qualified to represent the closest prior art, as claim 1 was concerned with a vaccine production process comprising purification and conjugation steps. Even if not choosing document (2) as closest prior art, a skilled person would not rely on document (27) but on other prior art documents like, for instance, on document (31).

If, for whatever reason, a skilled person would nevertheless choose document (27) as closest state of the art, the problem to be solved, namely the provision of a suitable purification method for a bacterial capsular polysaccharide could be solved in many different ways. There was no pointer to any specific purification method in document (27), let alone to the purification method of document (1B). Rather the skilled person would have considered the purification methods disclosed in documents (13), (29A), (30), (31) or (33).

The subject-matter of the claims of the auxiliary request met all requirements of the EPC. It could not be derived in an obvious way from the disclosure in the prior art documents on file, either when taken alone or in any combination.

According to Article 113(2) EPC the EPO should examine and decide upon a European patent only in the text agreed by the proprietor of the patent. The EPC contained no provision which could serve as legal basis

to prohibit the patent proprietor from withdrawing a request on which no final decision has been taken by the Board. Also a request, that the Board should express its opinion on auxiliary requests withdrawn during oral proceedings has no basis in any Article or Rule of the EPC.

XIV. The submissions made by Appellant II, as far as they are relevant to the present decision may be summarised as follows:

Document (27) represented the closest prior art for the assessment of inventive step of the subject-matter of claim 1 of the main request. The problem to be solved in the light of the disclosure in document (27) was to decide which purification method should be used for the bacterial capsular polysaccharide. The skilled person would turn to document (1B) and would arrive at the claimed subject-matter in an obvious way by combining the teaching in documents (27) and (1B).

No submissions were made with regard to the subject-matter of any of the 12 claims of Appellant I's auxiliary request.

Appellant I should not be allowed to withdraw any auxiliary request considered by the Board during oral proceedings as this would have various unfavourable effects. It would deprive the public of learning the Board's negative opinion on requests pursued by the Patent Proprietor and thus lead to an impoverishment of the case law of the Boards of Appeal. Moreover, the situation could arise that the same or another Board would be confronted with identical requests, for

instance in the case of a divisional application. To prevent these and other disadvantageous situations the Board, in its reasoned decision, should at least express its opinion on auxiliary requests withdrawn during oral proceedings.

Reasons for the Decision

Main request

1. During the written procedure Appellant II has raised several objections under Articles 84 and 123 EPC and under Rule 80 EPC (see Appellant II's letter dated 22 September 2009).

   In the light of the findings below, concerning the requirements of Article 56 EPC, the Board sees no necessity to decide these issues.

2. Novelty of the subject-matter of claims 1 to 23 of the main request was not put into question by Appellant II during the entire procedure. Also the Board has no objection under Article 54 EPC.

3. To assess inventive step (Article 56 EPC), the Boards apply the "problem and solution approach" which, as a first step requires the identification of the "closest prior art". The Boards have developed certain criteria for carrying out this first step. After the relevant prior art has been identified, careful consideration must be given to the question whether, in the case concerned, the skilled person, taking into account all the available information on the technical context of

the claimed invention, would have had good reason to take a specific prior art document as the starting point for further development. The Boards have repeatedly pointed out that the closest prior art for assessing inventive step is normally a prior art document disclosing subject-matter conceived for the same purpose or aiming at the same objective as the claimed invention and having the most relevant technical features in common, i.e. requiring the minimum of structural modifications.

4. Claim 1 refers to a process for treating a bacterial capsular polysaccharide. The process comprises purification and conjugation of the polysaccharide to a carrier protein.

Thus, although the claim in its preamble refers to a "[P]rocess for conjugating a capsular polysaccharide to a carrier protein, ..." it is not restricted to the conjugation step but rather relates to a process for producing a conjugate vaccine containing a bacterial capsular polysaccharide, which process comprises purification and conjugation.

5. Document (27) refers to the quantification of free polysaccharide in meningococcal polysaccharide-diphtheria toxoid conjugate vaccines. The material on which the disclosed analytical method is performed is described in the introduction on page 259, last paragraph, as being meningococcal polysaccharide-diphtheria toxoid (Mn-Dt) conjugate vaccines. It is said that "[I]n these vaccines, purified polysaccharide from *N.meningitidis* serotypes A, C, W and Y are individually linked to diphtheria toxoid and are mixed to form tetravalent Mn-Dt conjugate vaccine." Page 260,

second paragraph, first sentence reads: "Purified meningococcal polysaccharide powders of serotypes A, C, W135 and Y and meningococcal conjugate vaccines were produced by Aventis Pasteur."

6. In the written procedure Appellant I argued that "... the closest prior art must necessarily be directed to a process for making bacterial capsular polysaccharide conjugates". In the following sentences he indicated twenty-three cited documents, including document (27), as "candidates for the closest prior art" (see Appellant I's letter dated 13 October 2009, page 2, point 2.3).

At the oral proceedings Appellant I argued that document (27) referred to an analytical process and could not therefore be considered as representing the closest prior art for the subject-matter of claim 1 which was directed to a production process.

The Board does not agree. The teaching of a prior art document cannot be reduced to its title or to specific parts of its disclosure. In case of document (27) the production of meningococcal conjugate (Mn-Dt) vaccines comprising a purified polysaccharide from *N.meningitidis* serotypes A, C, W and Y is explicitly stated in the passages cited in point (5) above and forms therefore an integral part of its disclosure, which cannot be reduced to a purely analytical issue.

7. Furthermore, Appellant I argued that there were other prior art documents on file which had more technical features in common with the subject-matter of claim 1 than document (27) and which therefore qualified better

as the closest prior art. Mainly Appellant I considered document (2) as being a better starting point for the assessment of inventive step than document (27), but also document (31) had to be taken into consideration.

8. Document (2) relates to the field of bacterial polysaccharide antigen vaccines. In particular it relates to bacterial polysaccharides conjugated to Protein D from *H.influenzae* (see abstract). The document discloses that carriers used previously for polysaccharide based vaccines had many disadvantages, particularly in case of combination vaccines. Diphtheria toxoid and tetanus toxoid are explicitly mentioned as examples of such previously used carrier proteins on page 6, lines 26 to 29. It is stated that, in order to overcome these disadvantages, a new carrier is disclosed, namely protein D from *H.influenzae,* for use in the preparation of polysaccharide/polypeptide-based immunogenic conjugates (see page 7, line 29 to page 8, line 11). Example 7 describes the manufacture of *N.meningitidis* C polysaccharide - Protein D conjugate (PSC-PD). Purification of the polysaccharide, comprising its precipitation using cetyltrimethyl-ammoniumbromide, and solubilisation with ethanol, and its conjugation to Protein D is described on page 61, line 19 to page 64, line 2.

Considering, that document (2), although using a purification step corresponding to the one of present claim 1, focuses on a conjugation step using a new carrier protein which is explicitly chosen in order to avoid disadvantages which are said to arise from the conjugation step according to claim 1, the Board does

not agree that document (2) represents the closest state of the art for assessing inventive step.

9. Document (31) is a review article referring to the production and control of *N.meningitidis* vaccines. Chapter II.B on pages 125 to 127 describes the various production phases comprising precipitation of meningococcal polysaccharides by use of a cationic detergent and solubilisation of the precipitated polysaccharide using calcium chloride (see figure 1 on page 126). In chapter V, on pages 133 to 134, several references, published between 1981 and 1987, are mentioned which are said to disclose the conjugation of meningococcal polysaccharides to tetanus toxoid and bovine serum albumin. Section II.B of document (31) does not contain any information concerning the purification of the polysaccharides before the conjugation step.

Accordingly, the Board does not agree that document (31) represents the closest state of the art.

10. In the light of the above, the Board decides that the closest state of the art is represented by document (27).

The problem to be solved by the patent is therefore to decide which purification process to use in the manufacture of the meningococcal polysaccharide-diphtheria toxoid conjugate vaccines disclosed in document (27).

11. Document (1) is a European patent published in French language. The parties, during the entire procedure,

have relied on the English translation of document (1) which is document (1B) in the present procedure. The Board in this decision will therefore also refer to document (1B).

Document (1B) refers to a process for the preparation of an antigenic capsular polysaccharide, comprising the isolation of the polysaccharide from a solution containing it by precipitation in the form of a complex with a quaternary ammonium salt in the presence of an inert support and the solubilisation of the precipitate with an aqueous ethanol solution of up to 60% v/v ethanol in such a manner that the final salt solution is between 0.1 and 0.6 N (see page 7, lines 12 to 25; examples; claims 1 to 4). The polysaccharides used are identical to those of the patent in suit. The process is described as being a large scale process, which is said to be relatively simple and to be suitable to produce polysaccharides of remarkable purity for the preparation of vaccines (see page 5, lines 1 to 7; page 7, lines 12 to 14; page 9, lines 22 to 24).

12. Although claim 1 of the main request does not require the presence of an inert support at the precipitation step and does not define the salt concentration during the solubilisation step, the broad wording of the claim is such that the purification process disclosed in document (1B) has all features of the purification process according to claim 1.

13. Appellant I argued that the skilled person trying to solve the problem as defined in point (10) above, would not turn to document (1B) for several reasons.

He stated that, at the relevant date, a number of different purification methods were at the skilled person's disposition. Among those were processes using a cationic detergent for precipitation and an organic solvent for solubilisation, as for instance described in document (13), processes using an anionic detergent and ethanol (document (29A)) and processes using ultrafiltration and no detergents at all (document (30)). Since the closest state of the art, document (27), did not contain a pointer to document (1B), a combination of the teaching in exactly these two documents could only be made with hindsight.

On the other hand, the skilled person had several reasons not to turn to document (1B). Firstly, the use of the method disclosed therein was the intellectual property of the Patent Proprietor of document (1B). A skilled person, knowing that other purification processes were not protected by patent law, would not have chosen the process of document (1B).

Document (1B) did not contain any experimental data showing that the produced capsular polysaccharides were indeed immunogenic in humans and thus functional as vaccines. The skilled person, however, was aware of the so-called "Gotschlich-process" which was approved by the World Health Organisation (WHO) as a standard process for the preparation of immunogenic products for vaccine use, and which was described in documents (31) and (33).

14. With regard to Appellant I's argument that the skilled person would not have considered the teaching of document (1B) because patent rights to be observed

would have prevented him to do so, the Board firstly remarks that it is not aware of any legal basis, neither in the EPC nor in any other national or international law, which could form a basis for the conclusion that the disclosure in a patent should be disregarded for the assessment of inventive step, and secondly is convinced that this view is not supported by the usual and common approach how to consider the state of the art. To intellectually consider a certain teaching in a piece of prior art for the technical solution of a given technical problem is not hampered by the fact that carrying out commercially this teaching might be forbidden by patent rights, which furthermore might not even be valid. It is also to be noted that the priority date of document (1B) is 1981 whereas the priority date of the patent in suit is 2001.

Document (1B) contains a statement on page 9, lines 22 to 24 that the capsular polysaccharides produced can be readily used for the production of vaccines. This implies their immunogenic activity. No evidence, whatsoever, has been provided by Appellant I that this statement is not correct and that the products of the purification process according to document (1B) are not functionally suitable as vaccines.

The Board agrees with Appellant I in so far as the skilled person at the relevant date was aware of the "Gotschlich-process" approved by the WHO and of other purification processes for bacterial polysaccharides in the preparation of vaccines. This, however, does not mean that he/she would have considered one of these prior art processes as being a preferred, or even the

only possible choice for the purification of bacterial capsular polysaccharides. Rather the skilled person, also having knowledge of the disclosure in document (1B), would have considered these different and well known prior art purification methods as being obvious alternative choices for solving the technical problem underlying the patent in suit.

15. Furthermore, Appellant I argued that a skilled person, when considering the disclosure in document (1B), would have read it in the light of the disclosure in document (2), an international patent application from the same Applicant as document (1B) and published seventeen years later.

Document (2) in example 7, starting on page 60, describes the production and purification of *N.meningitidis* C polysaccharide by using the method of document (1B). However, document (2) contains a strong message not to use commonly used carrier proteins for the production of conjugated vaccines as they are highly immunogenic and suffer from various disadvantages. Document (2) instead discloses Protein D from *Haemophilus influenzae,* as a new carrier for use in polysaccharide based immunogenic conjugates. The three carrier proteins used according to the process of present claim 1 are explicitly named in the list of carrier proteins to be avoided (see page 6, line 21 to page 8, line 11). Thus, the skilled person would learn from document (2) not to use the purification process of document (1) in combination with a conjugation step using diphtheria toxoid, tetanus toxoid or CRM_{197} diphtheria toxoid as carrier molecule. It was the present patent which found that document (2) in this

respect was wrong and that a functional human vaccine can be produced by the method disclosed in claim 1.

16. The Board does not agree to Appellant I's interpretation of the disclosure of document (2). Although it is correct that it discloses a new carrier protein which is said to be advantageous over certain commonly used carriers, this does not equate to the message not to use the traditional carriers, like diphtheria toxoid, tetanus toxoid or CRM_{197} diphtheria toxoid, anymore. A situation that would force a skilled worker to avoid these traditional carriers in the production of conjugated vaccines would be present only if the existence of a prejudice to that effect could be recognised.

17. A prejudice in any particular field relates to an opinion or preconceived idea widely or universally held by experts in that field. The existence of such prejudice is normally demonstrated by reference to the literature or to encyclopaedias published before the priority date. The case law of the Boards of Appeal is **very strict** on recognising the existence of a prejudice. A solution put forward as overcoming a prejudice must clash with the prevailing teaching of experts in the field, i.e. their unanimous experience and notions. A prejudice **cannot** be demonstrated by a statement in a single patent specification, since the technical information in a patent specification or a scientific article might be based on special premises or on the personal view of the author (see case Law of the Boards of Appeal at the EPO, 5th edition, 2006, chapter I.D.9.2).

18. In the present case the existence of a prejudice has to be answered in the negative as document (2) is the only prior art document on file suggesting to replace the so-called "currently commonly used" carriers by another protein, namely Protein D from *Haemophilus influenzae*.

On the other hand, the document representing the closest state of the art, document (27), published in the same year as document (2), explicitly discloses meningococcal polysaccharide - diphtheria toxoid (Mn-Dt) conjugate vaccines.

19. In the light of the findings above, the Board arrives at the decision that a skilled person trying to solve the problem underlying the patent in suit, would combine the teaching in the closest prior art, document (27), with the disclosure in document (1) and would arrive at the subject-matter of claim 1 of Appellant I's main request in an obvious way.

The subject-matter of claim 1 does not involve an inventive step and does not therefore meet the requirements of Article 56 EPC.

Auxiliary request

20. Claim 1 is based on claims 1, 2, 3, 4, 6, 10 and 14 and on page 2, lines 1 to 2 and 33 to 35 and page 4, line 27 of the International Patent Application as published. The same applies to claim 11.

Dependent claims 2 to 10 are based on claims 11 to 13, 16 to 21 respectively and dependent claim 12 is based

on claim 4 of the International Patent Application as published.

By more precisely defining the technical features of the claimed process, the scope of protection of the claims has been reduced with regard to the claims as granted.

The claims are clear and supported by the description.

The requirements of Articles 84, 123(2) and 123(3) EPC are met.

21. The process according to claims 1 and 11 is not disclosed in any of the prior art documents on file.

The subject-matter of the claims is novel within the meaning of Article 54 EPC.

22. Appellant II, at the oral proceedings before the Board, has not raised an objection under Article 56 EPC against the subject-matter of claims 1 to 12 of the auxiliary request.

23. Document (27) is considered to represent the closest state of the art for assessing inventive step of the subject-matter of claims 1 and 11 (see point (5) above).

As for claim 1 of the main request, the problem to be solved by the patent according to claims 1 and 11 is to decide which purification process to use in the manufacture of the vaccines disclosed in document (27).

24. The purification process according to steps (a), (b) and (c) of claim 1 is distinguished from the purification process disclosed in document (1B) in that the solubilisation of the precipitatd polysaccharide is carried out by using ethanol at a final concentration of between 75% and 95%.

25. The polysaccharide/cationic detergent precipitate formed during step (a) can be solubilised in different ways. The addition of salt solutions breaks the ionic bonds holding together the anionic polysaccharide and the cationic detergent. The precipitate is disrupted and the polysaccharide itself is solubilised. When high percentages of an alcohol and no salt is used to solubilise the precipitate, the ionic bonds between the polysaccharide and the detergent stay intact and the polysaccharide is solubilised as a complex with the cationic detergent.

The general principle of both these processes for the recovery of polysaccharides (polyanions) from their insoluble complexes with cationic detergents are known and are described, for instance, in document (7), page 39 and document (11), pages 172 to 173.

26. The patent describes in paragraph [0013], on page 3 (corresponding to page 2, lines 27 to 28 of the International Patent application as published), that after precipitation, the polysaccharide is typically re-solubilised in the form of a complex with the cationic detergent.

27. Document (1B) discloses the solubilisation of the precipitate with an aqueous ethanol solution of up to

60% v/v ethanol in such a manner that the final salt solution is between 0.1 and 0.6 N (see point (11) above).

Page 6, lines 23 to 28 of document (1B) reads: "..., the principle of the process being based on the specificity of the salt concentrations which regulates either the formation or the decomposition of the complexes between a quaternary ammonium salt and different polyionic compounds."

Thus, while the technical features of claim 1 are chosen such as to allow the re-solubilisation of the precipitated polysaccharide in the form of a complex with the cationic detergent, the conditions of the process of document (1B) result in the polysaccharide itself being solubilised by breaking the ionic bonds holding together the anionic polysaccharide and the cationic detergent.

28. Neither document (1B) nor any other prior art document on file describes the purification of bacterial capsular polysaccharides from *N.meningitidis* wherein the precipitated polysaccharides are solubilised according to step (b) of claim 1, namely by using ethanol at a final concentration between 75% and 95%.

29. Thus, contrary to the main request, a combination of the teaching in document (27) with the disclosure in document (1B), or any other prior art document on file, would not allow a skilled person to arrive at the claimed subject-matter in an obvious way.

Therefore, the subject-matter of claims 1 to 12 involves an inventive step and meets the requirements of Article 56 EPC.

Appellant II's request that Appellant I is not allowed to withdraw any auxiliary request considered during oral proceedings - Article 113(2) EPC

30. Proceedings before the Boards of Appeal are governed by the principle of party disposition under which a public authority or court normally may not continue proceedings if the procedural act which gave rise to the proceedings (such as the filing of an appeal) has been retracted, unless procedural laws specifically permit continuation (decision G 8/91, OJ EPO 1993, 346, point (5)). Such exceptions are set forth, in particular, in Rule 70(1) EPC (no withdrawal of the request for examination) and in Rule 84(2) EPC (possible continuation of opposition proceedings after withdrawal of the opposition). There is no similar exception that would allow the continuation of the appeal proceedings with respect to claim requests withdrawn in appeal proceedings.

The principle of party disposition is of particular relevance for inter partes proceedings (see, e.g., decision T 240/01 of 24 September 2002, point (6)). It means, for example, that a department of the EPO is not allowed to decide on a non-pending application (decision T 1409/05, OJ EPO 2007, 113, point (3.2.26)). The Boards of Appeal do not intervene of their own motion, but only at the request of the appellants (decision T 60/91, OJ EPO 1993, 551, point (9.3)). Referring to the principle of party disposition, the

Enlarged Board of Appeal confirmed that the appeal proceedings are terminated after the appeal is withdrawn in so far as the substantive issues are concerned (decision G 8/91, OJ EPO 1993, 346, points (4), (5), see also decision G 2/91, OJ EPO 1992, 206, point (6.1)). This applies also in cases where a third party who intervened during appeal proceedings is interested in the continuation of the proceedings (decision G 3/04, OJ EPO 2006, 118, point (10)). The principle of party disposition (in German "Verfügungsgrundsatz" or "Dispositionsmaxime") also allows that the patent proprietor changes the order of auxiliary claim requests or introduces new claim requests and thereby avoids that certain requests are examined. Such changes of the order of auxiliary requests were made – and were not contested – during the oral proceedings in the present case.

31. Not only an appeal in its entirety but also part of an appeal can be withdrawn if the appeal could initially have been accordingly limited in conformity with Rules 99(1)(c) and 99(2) EPC (see decision J 19/82, EPO 1984, 6, point 4). In the present case, Appellant I could have refrained from filing the auxiliary requests in question. Consequently, Appellant I should be allowed to withdraw individual auxiliary requests filed in the course of the appeal proceedings. For the Board, it is not relevant whether the Board has discussed the relevant requests with the parties and/or whether the Board has given its opinion on such requests as long as the debate has not been closed in accordance with Article 15(5) of the Rules of Procedure of the Board of Appeal and no decision has been announced (see below point (35)). Opinions given by the Board in appeal

proceedings regularly trigger the filing of new requests, the admissibility of which will then be examined under Article 13 of the Rules of Procedure. Likewise, the withdrawal of requests – which normally does not raise any issues under Article 13 of the Rules of Procedure – must be possible as a reaction to an opinion given by the Board.

32. In the Board's view, it does not matter whether Appellant I filed the auxiliary requests in question as appellant or as respondent to the appeal filed by Appellant II. In *inter partes* proceedings, the principle of party disposition applies to the procedural acts of both parties (see also decision T 240/01 of 24 September 2002, point (6)).

33. Under Article 113(2) EPC, the EPO shall examine, and decide upon, the European patent application or the European patent only in the text submitted to it, or agreed, by the applicant or the proprietor of the patent. This provision not only specifies an aspect of the right to be heard; it is also relevant in the context of party disposition. It has been concluded from Article 113(2) EPC that a Board of Appeal has no authority to order the grant of a patent containing claims which are different from those submitted by the applicant (decision T 32/84, OJ EPO 1984, 354, point (19)). The principle that a patent may not be granted or maintained with claims to which the proprietor has never consented or to which the consent has been withdrawn applies to all procedural situations. If the patent proprietor in appeal proceedings withdraws its approval of the text of the patent as granted and declares that he will not be submitting an amended text,

the appeal proceedings have to be terminated and the patent has to be revoked without any substantive examination (decision T 73/84, OJ EPO 1985, 242, points (3), (5)). Accordingly, the withdrawal of the approval with respect to individual claim sets (filed as auxiliary requests) must result in the termination of the proceedings with respect to such claim sets. Appellant I, by withdrawing his requests, withdrew his consent to the respective claim wording. In this context, any decision of the Board on the allowability of requests withdrawn by the patent proprietor would be completely pointless since a withdrawn request could never form the basis of a maintained patent.

34. The principle of party disposition (which implies the right to withdraw an appeal in its entirety or in part) and the provision of Article 113(2) EPC imply, in the Board's judgment, that Appellant I, being the patent proprietor, must have the right to withdraw any of its claim requests filed in the course of appeals proceedings.

35. A withdrawal of an appeal cannot have any effect on the decision if the appeal is withdrawn after the decision has been announced by the Board at oral proceedings in accordance with Rule 111(1) EPC (see decision T 1033/04 of 21 September 2006, point (3)). *E contrario*, an appeal may be withdrawn at any time before the decision is announced. When Appellant I (proprietor) withdrew part of its requests during the oral proceedings, no formal decision had been announced yet on these requests. This fact was pointed out by the chair – and was not disputed – when the request was discussed. Appellant I was therefore allowed to withdraw part of

its auxiliary requests in view of the status of the proceedings. The Board has to reject the request of Appellant II that the withdrawal of claim requests of Appellant I considered during oral proceedings shall not be allowed.

Appellant II's request that the Board expresses its opinion on auxiliary requests withdrawn during oral proceedings

36. If Appellant I (Proprietor) is allowed to withdraw auxiliary requests before a final decision is taken, there is no room for any opinion or reasoning given by the Board on such withdrawn requests in the written decision. In view of Rule 111(1) EPC, decisions need to be given and reasoned only on admissible requests which are pending after the debate is closed.

37. Any opinion or reasoning given by the Board on claim requests withdrawn during the proceedings would, in effect, constitute declaratory judgments or *obiter dicta* (i.e., findings which do not support the formula of the decision, see decision T 473/98, OJ EPO 2001, 231). There is no basis in the EPC for any declaratory judgment. Appellant II (opponent) may therefore not request any formal decision on any claims which are not part of a pending request. The Board agrees with Appellant II that the Board may give comments or *obiter dicta* on points which need not to be decided in order to arrive at the final decision. The Board would not exclude that such *obiter dicta* may even comment on claims which do not form part of a pending request.

However, it lies within the discretion of the Board to include or not to include such *obiter dicta* in the

written decision. Any interest of Appellant II in such *obiter dicta* which may arise in the course of pending or future application, opposition, infringement or invalidity proceedings cannot justify that *obiter dicta* (which may not have any relevance for any proceedings on the present patent before the EPO) are included in the final decision of the present proceedings. Even if a divisional application contains claims identical to claims forming part of withdrawn requests in the present proceedings, such claims in a divisional application could not be accepted or rejected on the basis of *res iudicata* if they were commented only in *obiter dicta* in the present proceedings. Likewise, the Board does not accept the position of Appellant II that the public interest would require the requested opinions on withdrawn claim requests. Third parties may not claim any right to learn about the Board's opinion on claims that are not part of a pending request.

38. For these reasons, the request that the Board expresses its opinion on withdrawn auxiliary requests has to be rejected.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the department of first instance with the order to maintain the patent on the basis of the auxiliary request as filed during the oral proceedings before the Board on 23 December 2009 and a description yet to be adapted thereto.

3. The request of Appellant II not to allow Appellant I to withdraw any of its auxiliary requests considered during oral proceedings is rejected.

4. The request of Appellant II that the Board expresses its opinion on auxiliary requests withdrawn during oral proceedings is rejected.

Registrar: Chair:

P. Cremona U. Kinkeldey