Internal distribution code:

(A) [-] Publication in OJ
(B) [-] To Chairmen and Members
(C) [-] To Chairmen
(D) [X] No distribution

Datasheet for the decision of 28 January 2025

Case Number: T 0070/23 - 3.3.04

Application Number: 13792601.0

Publication Number: 2903638

IPC: A61K39/09

Language of the proceedings: EN

Title of invention:
Immunogenic Composition

Patent Proprietor:
GlaxoSmithKline Biologicals SA

Opponent:
Pfizer Inc.

Headword:
Immunogenic Composition/GSK

Relevant legal provisions:
EPC Art. 56
RPBA 2020 Art. 13(2)

Keyword:
Inventive step - main and auxiliary requests 2 - 6 (no)
Amendment after notification of Art. 15(1) RPBA communication - auxiliary request 1 (yes)

Decisions cited:
T 0932/99, T 1018/02, T 0674/08, T 0892/08

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

Boards of Appeal

Chambres de recours

Boards of Appeal of the
European Patent Office
Richard-Reitzner-Allee 8
85540 Haar
GERMANY
Tel. +49 (0)89 2399-0

Case Number: T 0070/23 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 28 January 2025

Appellant: (Opponent)	Pfizer Inc. 66 Hudson Boulevard East New York, NY 10001-2192 (US)
Representative:	Dörries, Hans Ulrich df-mp Fünf Höfe Theatinerstrasse 16 80333 München (DE)
Respondent: (Patent Proprietor)	GlaxoSmithKline Biologicals SA Rue de l'Institut 89 1330 Rixensart (BE)
Representative:	Racine, Sophie Christiane Carol GSK Legal & Compliance - Global Patents 79 New Oxford Street London WC1A 1DG (GB)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 11 November 2022 concerning maintenance of the European Patent No. 2903638 in amended form.**

Composition of the Board:

Chairwoman	M. Pregetter
Members:	A. Chakravarty
	A. Bacchin

Summary of Facts and Submissions

I. In an interlocutory decision the opposition division decided to maintain European patent No. 2 903 638 in amended form, on the basis of the main request, where the set of allowable claims was filed on 6 April 2022.

II. In the decision under appeal, the opposition division considered and dismissed objections raised by the opponent under Article 123(2) EPC, Article 83 EPC, Article 54 and Article 56 EPC.

III. The sole opponent (appellant) filed an appeal against this decision and submitted a statement of grounds of appeal to which the patent proprietor (respondent) replied).

IV. With its statement of grounds of appeal the appellant submitted documents D15 to D21.

V. With its reply to the statement of grounds of appeal the respondent re-submitted sets of claims of auxiliary requests 1 to 4. It also submitted documents D22 to D28.

VI. The appellant submitted a further letter dated 6 June 2024 together with documents D29 to D31.

VII. With a further letter dated 5 September 2024, the respondent submitted sets of claims of auxiliary requests 1 to 5. These included two new auxiliary requests 4 and 5. Previous auxiliary request 2 was withdrawn. Former auxiliary requests 3 and 4 became auxiliary requests 2 and 3.

VIII. Finally, the appellant submitted a letter dated 29 October 2024 and document D32.

IX. The board issued a communication under Article 15(1) RPBA in which it informed the parties *inter alia* that it was of the view that "immunogenic composition" of claim 1 the main request was a composition that is suitable for raising an immune response to at least one of the immunogens contained in it but that the level of protection against a specific disease was not a feature of the claim.

X. Oral proceedings before the board were held as scheduled. During these proceedings, the respondent promoted the claim request filed as auxiliary request 2 with the submissions of 5 September 2024 to be the main request. It also submitted a new set of claims as auxiliary request 1. The remaining claim requests were renumbered as follows: the former main request (filed with the reply to the statement of grounds of appeal and held allowable by the opposition division) became auxiliary request 2, the set of claims of former auxiliary requests 1, 3, 4 and 5 filed with the submissions of 5 September 2024 became auxiliary requests 3 to 6, respectively.

Definitions

XI. The patent concerns immunogenic compositions derived from the capsular saccharides of *Streptococcus agalactiae.* This bacterium is also known as ’group B streptococcus’, or simply as ’GBS’ (see paragraph [0003] of the patent). Reference is made to the NeuNAc content of capsular saccharides. NeuNAc is a terminal N-acetyl-neuraminic acid residue, commonly referred to as sialic acid (see paragraph [0015] of the patent).

XII. Claim 1 of the main request reads:

"1. An immunogenic composition comprising: a) a conjugate that is a capsular saccharide from GBS serotype Ia conjugated to a carrier protein; b) a conjugate that is a capsular saccharide from GBS serotype Ib conjugated to a carrier protein; c) a conjugate that is a capsular saccharide from GBS serotype III conjugated to a carrier protein; d) a conjugate that is a capsular saccharide from GBS serotype II conjugated to a carrier protein; and e) a conjugate that is a capsular saccharide from GBS serotype V conjugated to a carrier protein wherein the capsular saccharide from GBS serotype V has a NeuNAc content of greater than 90%, for example greater than 95%, when compared to native GBS serotype V polysaccharide wherein the NeuNAc content is considered to be about 100%".

Claim 1 of auxiliary request 1 differs from claim 1 of the main request in that it includes as a further feature "wherein the composition is a vaccine".

Claim 1 of auxiliary request 2 (the former main request) differs from claim 1 of the main request in that in part e), "90%, for example greater that 95%", is replaced with "75%".

Claim 1 of auxiliary request 3 (former auxiliary request 1) is identical to claim 1 of auxiliary request 2.

Claim 1 of auxiliary request 4 (former auxiliary request 3) differs from claim 1 of the auxiliary request 2 in that, in part e) "greater than 75%", is

replaced by "about 100%".

Claim 1 of auxiliary request 5 (former auxiliary request 4) differs from claim 1 of auxiliary request 2 in that in part e), "greater than 75%", is replaced by "greater than 90%".

Claim 1 of auxiliary request 6 (former auxiliary request 5) differs from claim 1 of auxiliary request 2 in that in part e), "greater than 75%", is replaced by "100%".

Documents

XIII. The following document is referred to in the decision.

D1: WO 2012/035519

The bibliographic data of the other documents mentioned by document number in this decision are not reproduced here because they played no role in the board's considerations on the merits of the case.

XIV. The arguments of the appellant relevant to the present decision are summarised as follows:

Main request - claim 1
Claim construction

The claimed subject-matter was an immunogenic composition. It was claimed as a product *per se* and therapeutic efficacy was not a feature of the claimed subject-matter at all. As to the respondent's submission that the claim had to read as including the content of paragraph [0045] of the description as limiting functional feature, it was established case

law that the description should not be taken into account when constructing the claims (see Case Law of the Boards of Appeal of the European Patent Office, 10th edition 2022, II.A. 6.3.1 and 6.3.4). In any case, the paragraph referred to by the respondent did not support its case, since it did not even name a pathogen that the vaccine was supposed to protect against, let alone state that there was a protective response for all the serotypes of GBS present in the composition.

Inventive step (Article 56 EPC)
In the light of document D1 alone

The opposition division stated that the subject-matter of claim 1 differed from the multivalent composition disclosed in document D1 in that (i) the composition of claim 1 further comprised a conjugate that was a capsular saccharide from GBS serotype II conjugated to a carrier protein, and (ii) it comprised a conjugate that was a capsular saccharide from GBS serotype V with a NeuNAc content of greater than 75% when compared to native GBS serotype V CPS, wherein the NeuNAc content was considered to be about 100%. It was disputed that the claimed composition actually differed from that disclosed in document D1. However, even if the opposition division's view on the differences between the claimed composition and that disclosed in document D1 was accepted, the claimed composition lacked an inventive step.

The opposition division was wrong to conclude that the claimed immunogenic composition represented an improvement compared to the compositions disclosed in document D1. The patent contained no data or evidence that showed the immunogenic composition provided improved protection against infection by *Streptococcus*

agalactiae over the entire claimed scope. The results presented in the patent could therefore not be used as evidence for an inventive step. In fact, no improvement in immunogenicity was shown for the claimed composition and so the technical problem had to be formulated less ambitiously as "the provision of an alternative multivalent immunogenic composition". The claimed subject-matter was an obvious solution to this less ambitious problem in view of document D1 alone.

With regard to the first difference, the opposition division held that it would have been obvious to the skilled person to add a further conjugate that was a capsular saccharide from GBS serotype II conjugated to a carrier protein to the tetravalent immunogenic composition of D1, thereby broadening the immunogenic effect of the composition (see item 27 of the Decision). This was correct. As explained in the decision under appeal, document D1 stated that the tetravalent immunogenic compositions of D1 "may comprise a conjugate that is a capsular saccharide from GBS serotype II conjugated to a carrier protein" (see page 3, lines 21-22).

Regarding the second difference, document D1 explicitly suggested using a native (i.e. not desialylated) conjugate at page 13, line 22. This was consistent with the reference to GBS serotype V conjugated to a carrier protein on page 2, lines 2-4 and on page 3, lines 11-16 and was further supported by claim 14 of document D1 which made no mention of sialylisation - "The immunogenic composition according to any one of claims 1 to 12 further comprising: d) a conjugate that is a capsular saccharide from GBS serotype V conjugated to a carrier protein".

Document D1 also disclosed an immunogenic composition comprising four conjugates of serotypes Ia, Ib, III and V (see Table D in pages 7 to 9). There was no mention that the GBS serotype V capsular saccharide was desialylated, or substantially desialylated. Moreover, page 13, lines 31 to 33 explained that the (type V) saccharide used according to the invention may be substantially full-length capsular polysaccharide "as found in nature".

In relation to whether it could be considered that an inventive step lay in the selection of native GBS saccharide from serotype V over desialylated GBS serotype V capsular saccharide, reference was made to decision T 674/08 (see Reasons, 2.7). Here it was held that in cases where the objective technical problem was merely to find an alternative composition, the skilled person would modify an existing product in any way by arbitrary choice.

Analogously, an immunogenic composition as claimed was merely an arbitrary selection of features among equally obvious alternative variations. Hence, in view of document D1 alone, the skilled person would have arrived at the claimed subject-matter without inventive ingenuity. Contrary to the patent proprietor's submissions, there was no teaching away from the native serotype V saccharide conjugate. Moreover, the opposition division was mistaken in concluding that document D1 contained a clear pointer to use a substantially desialylated serotype V saccharide conjugate.

The above arguments on inventive step applied equally to the subject-matter of auxiliary requests 2 to 6.

Auxiliary request 1
Admittance (Article 13 RPBA)

The claim request had been filed at the very latest possible stage of the appeal proceedings and represented an amendment to the respondent's appeal case under Article 13(2) RPBA. There were no exceptional circumstances that justified the admittance of this claim request. The claim construction set out in the board's communication under Article 15(1) RPBA was not the first time this had been raised in the opposition proceedings. The issue of claim construction had already been discussed in the first instance proceedings in the context of Article 83 EPC. Moreover, under Article 13(1) RPBA, the respondent should have reacted to the board's preliminary opinion in a more timely manner. The amendment filed at the oral proceedings, after the board announced a preliminary conclusion on inventive step of the main request, was against procedural economy. On a *prima facie* level it also did not resolve the question of inventive step since it did not change the construction of the claim. In addition it gave rise to new objections, possibly under sufficiency of disclosure.

XV. The arguments of the respondent relevant to the present decision are summarised as follows:

Main request - claim 1
Claim construction

The term "immunogenic" in claim 1 of the main request was a functional feature of the claimed subject-matter. When read in conjunction with paragraph [0045] of the

description, it was clear that the term immunogenic implied efficacy as a vaccine, so that each of the antigens present in the claimed composition was effective for both treatment or prevention of disease. The only technically sensible way of reading the claim was to regard each and every constituent of the composition as having an immunogenic effect and a protective/prophylactic effect.

Inventive step (Article 56 EPC)
In the light of document D1 alone

The opposition division's decision on inventive step was correct. It was right that document D1 represented the closest prior art. The opposition division also correctly identified differences between the immunogenic compositions disclosed in document D1 and those claimed. The claimed invention differed from that disclosed in document D1 in two key aspects:
i) it included a GBS serotype II capsular polysaccharide (CPS) conjugate;
ii) the serotype V capsular saccharide had a sialic acid content greater than 75% compared to the wild-type GBS type V capsular saccharide.

The above differences contributed to a technical effect, being that the claimed immunogenic composition was suitable for use as a vaccine against *Streptococcus agalactiae*, as noted in the decision under appeal.

The improved immunogenic effect was supported by evidence in the patent, in particular in Study 8. Here it was shown that the level of sialylation of the saccharide in the conjugate has a different impact on the immunogenicity of the conjugate depending on the serotype. As regards the conjugate of capsular

saccharide from GBS serotype V, study 8 showed that the immunogenicity of this conjugate significantly decreased when the sialic acid (NeuNAc) content was below 75% of the native content.

In view of the above differences and their technical effect, the objective technical problem was "the provision of an improved multivalent immunogenic composition suitable for use as a vaccine against infection by *Streptococcus agalactiae*".

Starting from document D1, based on the remaining disclosure in that document, the skilled person would not have modified the immunogenic compositions disclosed in document D1 to include either i) a GBS serotype II capsular polysaccharide conjugate or ii) a serotype V capsular saccharide with a sialic acid content greater than 75% compared to the wild-type GBS type V capsular saccharide.

Although document D1 at page 3, lines 21 to 22 disclosed that "*For example, the compositions may comprise a conjugate that is a capsular saccharide from GBS serotype II conjugated to a carrier protein*", this did not provide the skilled person with a reasonable expectation of success that the result would be an improved immunogenic composition, suitable for use as a vaccine against infection by *Streptococcus agalactiae.*

In relation to the second difference, i.e. that the GBS serotype V conjugate of claim 1 has a NeuNAc content of greater than 75%, the appellant had argued that document D1 explicitly suggested using native (i.e. fully sialylated) conjugate at page 13, line 22 according to which "*Saccharides used according to the invention may be in their native form*". However, the

skilled person reading D1 would understand that its only teaching was that the capsular saccharides used were preferably substantially desialylated: "*In particular, a serotype V capsular saccharide that has been substantially desialylated (Figure 3) as described in refs. 13 and 14 is specifically envisaged for use in the present invention…*" (see D1, page 13, lines 25-31). Moreover, the immunogenic compositions disclosed in the examples of D1 only used desialylated capsular saccharides. Taken as a whole, document D1 taught away from using non-desialylated/native GBS capsular saccharides in the immunogenic compositions disclosed therein.

The answer to the question of whether improved immunogenicity was a feature of the claimed subject-matter was "yes". This was because the skilled person would understand this from the content of the patent as a whole and from paragraph [0045] of the patent in particular. In that paragraph it was set out that immunogenic compositions within the meaning of the invention were vaccines and that the amount of antigen in such a vaccine was an immunologically effective amount which led to effective treatment or prevention of disease. The skilled person would have read this feature into the claim.

The submissions on inventive step applied equally to the subject-matter of auxiliary requests 2 to 6.

Auxiliary request 1
Admittance (Article 13 RPBA)

The claim request should be admitted into the appeal proceedings. Although it was filed during the oral

proceedings before the board, it met the requirements for admittance set out in Article 13(1) and 13(2) RPBA. There were exceptional circumstances that justified its admittance. These were the board's claim construction presented in the communication under Article 15(1) RPBA. Given that this claim construction had been given only in the board's communication, it was warranted that a set of claims taking this into account be admitted at a late stage. Moreover, the amendments were not complex and the amended feature was already present in claim 13 of the main request. In terms of the requirements of Article 13(1) RPBA the amendments directly addressed and overcame the inventive step problems because they introduced a therapeutic effect as a feature of the claim.

Requests of the parties

XVI. The appellant (opponent) requested that
- the decision under appeal be set aside and that the patent be revoked;
- documents D15 to D21 be admitted into the appeal proceedings;
- documents D22 to D28 be not admitted into the appeal proceedings;
- documents D29 to D32 be admitted into the appeal proceedings;
- auxiliary request 1, filed at the oral proceedings before the board, be not admitted into the proceedings.

XVII. The respondent requested that the decision under appeal be set aside and the patent be maintained on the basis of the set of claims of the main request, filed as auxiliary request 2 with the submissions of 5 September 2024;

- alternatively, that the patent be maintained on the basis of the set of claims of auxiliary request 1, filed at the oral proceedings before the board; or on the basis of the set of claims of auxiliary request 2, filed as main request with the reply to the statement of grounds of appeal (claim request held allowable by the opposition division); or on the basis of the set of claims of any of auxiliary requests 3 to 6 filed as auxiliary requests 1, 3, 4 and 5 with the submissions of 5 September 2024;
- that none of the following be admitted into the proceedings:
i) documents D15, D16, D17, D19, ii) declarations D18 and D21 (and related CV D18a), iii) the comments on the data presented in Study 8 of the patent made in the statement of grounds of appeal, as well as in D18 and D21, the lack of novelty argument vis-à-vis D19; and the lack of inventive step arguments based on D16, D17 and D19, iv) documents D29 to D32.
- that if the arguments relating to Study 8 of the patent, D18 and D21 were admitted into the present proceedings, then document D20 filed by the appellant, as well as documents D22 to D26, filed with the reply to the statement of grounds, be admitted into the proceedings;
- documents D27 and D28 also be admitted into the proceedings.

Reasons for the Decision

Admittance of documents and lines of argument relying on them

1. The board did not need to take a decision on the admittance or otherwise of any of the documents or lines of argument whose admittance was disputed by

either party because they were not relevant to the final decision taken.

2. In particular, the documents submitted by the appellant to support its submissions on novelty and to support lines of argument on inventive step, whose admittance was disputed, were not referred to or adopted by the board. Moreover, the decision on inventive step was taken on the assumption that the claimed subject-matter differed from that disclosed in document D1 (whose admittance was not in dispute) in the manner set out in the decision under appeal (see point 24 of that decision), the respondent is not adversely affected by this way of proceeding. Similarly, given the outcome of the appeal, the appellant is not adversely affected by the fact that the board did not rely on any of the documents or lines of argument that it had requested the admission of.

Main request - claim 1

Claim construction

3. It was common ground that the claim is directed to an immunogenic composition comprising GBS capsular saccharides from serotypes Ia, Ib, II, III and V, each conjugated to a carrier protein and that the capsular saccharide from the GBS serotype V has a NeuNAc content of greater than 90%, which is a product *per se*. There was also no dispute that the claim was not a purpose-limited product claim under Article 54(5) EPC.

4. There was a dispute about whether or not a therapeutic effect was nevertheless a functional feature of the claim and a key question in the case is whether the claim should be interpreted as including therapeutic

efficacy as an implicit functional feature, even though it is not explicitly present in the wording of the claim.

5. The respondent submitted that, contrary to the board's preliminary view expressed in the communication under Article 15(1) RPBA, the skilled person would understand that the claimed immunogenic compositions were suitable to be "*used as vaccines [that] comprise an immunologically effective amount of antigen(s), as well as any other components, as needed*", as set out in [0045] of the patent. Thus efficacy of the claimed immunogenic composition as a vaccine against infection with each of the serotypes recited in the claim, in particular also against serotype V, was a feature of the claim. In short, it submitted that the skilled person would understand that claim 1 was to be read as including the content of paragraph [0045] of the patent as a feature.

6. The appellant on the other hand, submitted that the claimed subject-matter was an immunogenic composition that was not defined or limited by therapeutic efficacy at all. It submitted that, according to established case law, the description should not be taken into account when interpreting the claims, especially in cases where the claims were clear on their own (see section XIV. above).

7. The board's approach to claim construction is in line with that adopted in decisions T 932/99 (see Reasons, 4.3.3) and T 1018/02 (see Reasons 3.8), which is that the description cannot be used to give a different meaning to features in a claim, which themselves impart a clear, credible technical teaching to the skilled reader and that no limitations derived from the

description can be read into claims in order to avoid objections based on lack of novelty or inventive step.

8. In the case at hand, the claim is not drafted as purpose-limited product under Article 54(5) EPC, meaning that a therapeutic purpose or effect is not a feature of the claim. Nor can such a purpose or effect be considered an inherent feature of the claimed immunogenic composition at least because the claim does not define amounts for any of its constituents or define the carrier proteins for any of the conjugates.

9. In view of the case law on claim construction cited above, the board cannot agree with the respondent that the claim should be read as including the functional features set out in paragraph [0045] of the description.

10. In any case, even if it were taken into account as suggested by the respondent, the disclosure in paragraph [0045] does not support the respondent's arguments. The paragraph reads as follows : "*Immunogenic compositions used as vaccines comprise an immunologically effective amount of antigen(s), as well as any other components, as needed. By 'immunologically effective amount', it is meant that the administration of that amount to an individual, either in a single dose or as part of a series, is effective for treatment or prevention. Commonly, the desired result is the production of an antigen (e.g., pathogen)-specific immune response that is capable of or contributes to protecting the subject against the pathogen. This amount varies depending upon the health and physical condition of the individual to be treated, age, the taxonomic group of individual to be treated (e.g. non-human primate, primate, etc.), the capacity of the*

individual's immune system to synthesise antibodies, the degree of protection desired, the formulation of the vaccine, the treating doctor's assessment of the medical situation, and other relevant factors. It is expected that the amount will fall in a relatively broad range that can be determined through routine trials".

11. It is apparent that this paragraph contains an explanation of immunogenic compositions used as vaccines but not a definition of all immunogenic compositions that fall within the ambit of the claim, which are not necessarily vaccines. Even in relation to vaccines, it does contain a clear statement of which pathogen the vaccine might protect against, or even if GBS is taken as the pathogen, there is no indication of which serotypes are protected against. Thus, contrary to the respondent's submissions, the paragraph relied on does not support its claim construction.

12. In view of these considerations, the board did not find that a decision in the present case necessarily depends on the questions referred to the Enlarged Board of Appeal in case G 1/24, so that a stay of the proceedings to receive a clarification on those requests was not necessary.

13. It should be noted that the following considerations on inventive step are based on the wording of the claim. Since the claim is not limited to the subject-matter in the examples, in particular not to the compositions that are the subject of Study 8, no decision had to be taken on whether or not the results reported therein justified the recognition of an inventive step for that, more limited subject-matter.

Inventive step (Article 56 EPC)

The closest prior art and the differences thereto

14. The parties agreed with the opposition division in the decision under appeal (see point 23) that document D1 represented a suitable starting for the assessment of inventive step. While the appellant has submitted that the claimed subject matter is not novel in the light of the disclosure in document D1, the board has for the sake of procedural efficiency assessed inventive step based on the assumption that the differences between the claimed subject matter and that disclosed in document D1 are essentially those set out in the decision under appeal in point 24, i.e. that "*the subject-matter of claim 1 differs from the multivalent composition disclosed in document D1 (page 13, lines 11-16) in that (A) it further comprises a conjugate that is a capsular saccharide from GBS serotype II conjugated to a carrier protein, and (B) it comprises a conjugate that is a capsular saccharide from GBS serotype V conjugated to a carrier protein, wherein the capsular saccharide from GBS serotype V has a NeuNAc content of greater than 75% when compared to native GBS serotype V polysaccharide wherein the NeuNAc content is considered to be about 100%*". The only difference between the main request considered in the decision under appeal and the present main request is the NeuNAc content of the capsular saccharide from GBS serotype V, which is now greater than 90%, instead of the "greater than 75%" specified in claim 1 as granted. In view of the board's decision on inventive step (see point 25., below), the appellant is not disadvantaged by this approach.

15. The technical effect brought about by these differences must, in view the board's construction of the claim, be considered to be that the claim composition remains immunogenic. Technical effects such as improved immunogenicity are neither a feature of the claim nor inherent in the composition as defined therein.

The objective technical problem

16. In view of the above identified differences between the claimed immunogenic composition and the immunogenic compositions disclosed in document D1 and taking into account the technical effect thereof, the objective technical problem is considered to have been 'the provision of a further immunogenic GBS composition'. The problem formulated in the decision under appeal (see point 26) and also put forward by the respondent (see point 2.5.2.2 of its reply to the statement of ground of appeal) of "*the provision of an improved immunogenic composition that is suitable for use as a vaccine against infection by Streptococcus agalactiae*" is not adopted because it is based on an incorrect claim construction.

Obviousness

17. The question to be asked in assessing obviousness of the presently claimed subject-matter is whether or not the person skilled in the art starting from the disclosure in document D1 of immunogenic compositions tetravalent for conjugates of capsular saccharides from GBS serotypes Ia, Ib, III or V with a carrier protein (see page 1, lines 22 to 25 and page 3, lines 11 to 16), and faced with the technical problem formulated above, would have arrived at the presently claimed immunogenic compositions. In particular, it must be

asked whether the skilled person at the relevant date would have included carrier protein-capsular saccharide conjugates where the GBS saccharide derived from serotype II and whether they would have used native capsular saccharide for the serotype V saccharide.

18. Document D1 suggests the addition of capsular saccharide from GBS serotype II conjugated to a carrier protein (see page 3, lines 21 to 22) to the immunogenic compositions disclosed therein. This part of the claimed solution was therefore directly suggested in document D1 and cannot be seen as non-obvious.

19. The inclusion of a non-desialylated/native GBS serotype V conjugated to a carrier protein was also presented as an alternative in document D1, see page 13, line 23 which reads as follows: "*Saccharides used according to the invention may be in their native form, or may have been modified*". In the board's view, this line clearly presents the skilled reader with two alternatives from which to choose. In accordance with established jurisprudence, as also cited by the appellant (e.g. T 892/08, Reasons 1.7, T 674/08, Reasons 2.7), no inventive step can be recognised for the arbitrary selection of one of these equally suggested alternatives.

20. The respondent argued that the skilled person would not have considered including carrier conjugated native GBS saccharide from serotype V as a solution to the objective technical problem because document D1 taught away from using non-desialylated saccharides, as could be seen from the disclosure on page 13, which focused on the preparation of desialylated saccharide. Moreover, all examples in document D1 used desialylated saccharide.

21. The board is not persuaded that document D1 teaches away from the use of native GBS saccharide. Instead, it presents native and desialylated GBS saccharides as alternatives, without expressing a preference between them (*ibid*). It is true that the examples in D1 all use desialylated GBS saccharide. However, this on its own does not amount to a teaching away from the use of the native version, especially when the latter was explicitly disclosed as an alternative.

22. The respondent also made extensive submissions to the effect that an inventive step should be recognised for the claimed immunogenic composition in view of the results shown *inter alia* in Study 8 of the patent that there is a technical effect associated with the sialic acid content being greater than 75%, i.e. the improvement of protection against serotype V GBS.

23. While the board has noted the effects shown in Study 8 of the patent, the results in Study 8 are not aligned with the present claim wording. Thus the respondent's arguments already fail because therapeutic efficacy is not a feature of the claimed compositions, as set out above.

24. In summary, the board is convinced that the skilled person seeking a solution to the problem of provision of a further immunogenic GBS composition would have adapted the immunogenic composition disclosed in D1 by including GBS serotype II saccharide-carrier protein conjugates, as well as selecting native GBS serotype V conjugated to a carrier protein because both of these adaptations were directly suggested in document D1 itself.

25. The claimed immunogenic composition therefore lacks inventive step in the light of the disclosure in document D1 alone.

Auxiliary request 1

Admittance (Article 13 RPBA)

26. At the oral proceedings, the board decided not to admit this claim request into the appeal proceedings under Article 13(2) RPBA. The reasons for this were as follows.

27. The claim request was filed during the oral proceedings before the board. It therefore represents an amendment to the proprietor's case in the sense of Article 13 RPBA, so its admission is at the discretion of the board. Article 13(2) RPBA provides that the board should in principle not take such an amendment into account unless there are exceptional circumstances which have been justified with cogent reasons.

28. The justification submitted by the respondent was that the claim construction set out in the board's communication under Article 15(1) RPBA had been surprising and therefore represented exceptional circumstances. In addition the amendment did not introduce any new issues, or add complexity to the case. Rather it directly addressed and overcame the problems with inventive steps.

29. This submission is not convincing because, as noted by the appellant, the question of whether a therapeutic effect was a feature of the claim (as granted) had been topic during the proceedings before the opposition division, in the context of sufficiency of disclosure,

and resulted in the deletion of medical use claims (see minutes of the oral proceedings before the opposition division, point 2.2). Moreover, the timing of filing of the claim request (after the board had given a negative opinion on the main request during oral proceedings) must also be taken into account. Even if it were, for the sake of argument, accepted that the claim construction in the communication under Article 15(1) RPBA had been surprising for the respondent, it should have submitted claim requests responding to this claim construction in writing as soon as possible, after having received the board's communication. That is to say, it should have submitted them in writing in advance of the oral proceedings so as to give the other party and the board sufficient time to consider them.

30. Furthermore, the amendments made to the appeal case do not comply with the criteria set out in Article 13(1) RPBA either, on which the board, at the third level of the convergent approach pursuant to Article 13(2) RPBA, may also rely (see explanatory remarks to Article 13(2) RPBA in Supplementary publication 2, OJ EPO 2020, pages 59 and 60). The respondent has not demonstrated that the amendments introduced to claim 1 are suitable to resolve the issue of lack of inventive step raised by the appellant. In particular, a *prima facie* reading of claim 1 leads to the conclusion that it suffers from the same lack of inventive step as claim 1 of the main request because the protective immune response against all of GBS serotypes present in the vaccine is still not a feature of the claim.

Auxiliary requests 2 to 6 - claim 1

31. The finding of obviousness set out above for the subject-matter claim 1 of the main request applies

equally to the subject-matter of each of auxiliary requests 2 to 6. This is because the amendments made are not suitable to address the lack of inventive step finding which is the result of a claim construction that therapeutic efficacy is not a feature of the claimed immunogenic composition.

32. In view of the above considerations, no claim request is allowable and the patent must be revoked

Order

For these reasons it is decided that:

The decision under appeal is set aside.

The patent is revoked.

The Registrar: The Chairwoman:

I. Aperribay M. Pregetter

Decision electronically authenticated