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D E C I S I O N
of 11 April 2006

Case Number: T 0423/04 - 3.3.08

Application Number: 93907460.5

Publication Number: 0635132

IPC: G01N 33/569

Language of the proceedings: EN

Title of invention:
Broadly reactive opsonic antibodies that react with common staphylococcal antigens

Patentee:
HENRY M. JACKSON FOUNDATION FOR THE ADVANCEMENT OF MILITARY MEDICINE

Opponent:
Inhibitex Inc.

Headword:
Staphylococcal antigens/JACKSON FOUNDATION

Relevant legal provisions:
EPC Art. 54, 83, 56, 111
EPC R. 57a

Keyword:
"Main request - novelty (no)"
"First auxiliary request - novelty (yes)"
"Inventive step (yes)"
"Sufficiency of disclosure (yes)"
"Remittal to first instance (no)"

Decisions cited:
T 0190/99

Catchword:
-

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Case Number: T 0423/04 - 3.3.08

D E C I S I O N
of the Technical Board of Appeal 3.3.08
of 11 April 2006

Appellant I: (Proprietor of the patent)
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Decision under appeal: **Interlocutory decision of the Opposition Division of the European Patent Office posted 28 January 2004 concerning maintenance of European patent No. 0635132 in amended form.**

Composition of the Board:

Chairman: L. Galligani
Members: F. Davison-Brunel
C. Rennie-Smith

Summary of Facts and Submissions

I. European patent No. 0 635 132 with the title "Broadly reactive opsonic antibodies that react with common staphylococcal antigens" was granted with 5 claims for all Designated Contracting States, on the basis of European patent application No. 93 907 460.5.

Granted claims 1 and 3 read as follows:

"1. An antigen preparation isolatable from *Staphylococcus epidermidis* strain Hay ATCC 55133, wherein said preparation generates broadly reactive opsonic antibody which specifically reacts in an assay with *Staphylococcus epidermidis* serotypes I, II and III.

3. A pharmaceutical composition comprising:

(a) the isolated antigen preparation of claim 1; and

(b) a pharmaceutically acceptable carrier."

Claim 2 related to the antigen preparation of claim 1 further defined by a method for obtaining it. Claim 4 was directed to a purified culture comprising strain Hay and claim 5 related to a method for obtaining broadly reactive opsonic immunoglobulin making use of the antigen preparation of claim 1.

II. An opposition was filed under Article 100(a) to (c) EPC. The opposition division maintained the patent on the basis of auxiliary request B then on file comprising granted claim 4 as the single claim. The main request

comprising granted claims 1 to 3 and 5 and an amended claim 4 was refused because the requirements of Article 84 EPC were not fulfilled. Claims 1 to 4 (granted claims 1 to 3 and 5) of Auxiliary request A were found to be novel but sufficiency of disclosure was denied. The main request and auxiliary request A were not assessed for inventive step.

III. Appellant I (Patentee) and appellant II (Opponent) filed appeals, submitted statements of grounds of appeal and paid appeal fees in due time. Appellant I's appeal was accompanied by a new main claim request and by a request that the case be remitted to the opposition division for a consideration of inventive step if the board was able to acknowledge novelty and sufficiency of disclosure.

IV. Appellant II filed a further submission in answer to appellant I's grounds of appeal.

V. The board sent a communication pursuant to Article 11(1) of the Rules of Procedures of the Boards of appeal, stating its preliminary, non-binding opinion.

VI. Appellants I and II answered to this communication with submissions dated 10 March 2006. Appellant I's submissions were accompanied by new documents (35) to (38)- document (36) being the curriculum vitae of Dr. J.F.Kokai-Kun -, an amended main request and two auxiliary requests for all Designated Contracting States other than Portugal (PT). The corresponding requests were filed for PT. The **amended main request** for all Designated Contracting States other than PT comprised five claims.

Claims 1, 3 and 5 thereof read as follows:

"1. An antigen preparation isolatable from *Staphylococcus epidermidis* strain Hay ATCC 55133, wherein said preparation generates broadly reactive opsonic antibody which specifically reacts in an assay with *Staphylococcus epidermidis* serotypes I, II and III, for use in the prevention, diagnosis or treatment of Staphylococcus infections.

3. A pharmaceutical composition comprising:

(a) an antigen preparation isolatable from Staphylococcus epidermidis strain Hay ATCC 55133, wherein said preparation generates broadly reactive opsonic antibody which specifically reacts in an assay with Staphylococcus epidermidis serotypes I, II and III; and

(b) a pharmaceutically acceptable carrier.

5. The use of an antigen preparation isolatable from Staphylococcus epidermidis strain Hay ATCC 55133, wherein said preparation generates broadly reactive opsonic antibody which specifically reacts in an assay with Staphylococcus epidermidis serotypes I, II and III, in the manufacture of an agent for use in the prevention, diagnosis or treatment of Staphylococcus infections."

VII. Appellant II filed a further submission requesting that the documents (35), (37) and (38) filed by Appellant I be disregarded.

VIII. Further submissions on this point were made by both appellants.

IX. Oral proceedings took place on 11 April 2006. During oral proceedings, the first auxiliary request filed on 10 March 2006 was replaced by an **amended first auxiliary request** which in the version for all Designated Contracting States other than PT comprised three claims.

Claims 1 and 3 read as follows:

"1. The use of an antigen preparation isolatable from Staphylococcus epidermidis strain Hay ATCC 55133, wherein said preparation generates broadly reactive opsonic antibody which specifically reacts in an assay with Staphylococcus epidermidis serotypes I, II and III, in the manufacture of an agent comprising said antigen preparation for use in the prevention or treatment of Staphylococcus infections.

3. A pharmaceutical composition comprising :

(a) a prophylactically or therapeutically effective amount of an antigen preparation isolatable from Staphylococcus epidermidis strain Hay ATCC 55133, wherein said preparation generates broadly reactive opsonic antibody which specifically reacts in an assay with Staphylococcus epidermidis serotypes I, II and III; and

(b) a pharmaceutically acceptable carrier."

Claim 2 related to the use as claimed in claimed 1 wherein the antigen preparation was further characterised by the method for obtaining it.

The amended first auxiliary request for the Designated Contracting State PT consisted of granted claims 1 to 3 and 5 (renumbered as 1 to 4), the only amendment being the insertion of the qualifier "non-human" before the term "mammal".

Appellant I withdrew its request that the case be remitted to the first instance for assessment of inventive step whereas appellant II made this same request for the first time.

X. The following documents are mentioned in this decision:

(1) WO 93/17044 published on 2 September 1993 claiming priority from US 804 317 filed on 25 February 1992;

(17) Ohshima, Y. et al., Ann. Microbiol. (Inst. Pasteur), Vol. 135A, pages 353 to 365, 1984;

(32) Ichiman, Y. et al., J. of Applied Bacteriology, Vol. 56, pages 311 to 316, 1984;

(35) Fischer, G.W. et al., The J. of Infectious Diseases, Vol. 169, pages 324 to 329, 1994;

(37) Oshima, Y. et al., Zbl.Bakt., Vol. 274, pages 417 to 425, 1990;

(38) Oshima, Y., Zbl.Bakt.Hyg.A, Vol. 270, pages 219 to 227, 1988.

XI. Appellant I's submissions in writing and during oral proceedings insofar as relevant to the present decision may be summarised as follows:

Admissibility of documents (35), (37) and (38)

Documents (35), (37) and (38) were brief and relevant. Document (35) provided further support for the fact that strain Hay had, as stated in the patent in suit, a type II capsule. Documents (37) and (38) were simply cited to show that serotype II and III strains could be readily identified at the priority date on the basis of their carbohydrate constituents. These documents should be admitted in the proceedings.

Main request for all Designated Contracting States other than PT.

Articles 123(2) and 84 EPC; claim 1

A basis was found on page 1, lines 11 to 14 of the application as filed for re-drafting claim 1 as a first medical use claim (Article 123(2) EPC).

In accordance with the case law (T 190/99 of 6 March 2001), a claim was to be construed by the mind of a person willing to understand. In the present case, the skilled person would have no problems in understanding what the term "for use in the prevention, diagnosis or treatment of Staphylococcus infections" meant, nor would he/she be in doubt after reading the description

that this use was intended to be carried out with, in particular, strain Hay (Article 84 EPC).

Article 123(3) EPC; claim 5

Granted claim 1 was a product claim directed to the Hay antigen preparation per se and, therefore, protected the use of the antigen for any purpose including, of course, the use of the antigen preparation in the manufacture of an agent for diagnostic purposes as claimed in claim 5. The scope of protection had, thus, not been extended.

Article 54(3)(4) EPC; claims 1 and 5

Document (1) did not teach in a clear and unambiguous manner the use of an antigen preparation isolatable from strain Hay in the prevention, diagnosis or treatment of staphylococcus infections as required by claims 1 and 5. It had to be kept in mind that the whole thrust of the document was not towards isolating an antigenic preparation for medical purposes but rather towards using the preparation for screening immunoglobulin samples for the presence of broadly reactive opsonic antibodies. Even if the data described on pages 19 and 22 related to a *S.epidermidis* vaccine, it was not clear that this vaccine had been made from strain Hay, nor whether it was in the form of an antigenic preparation rather than in the form of whole cells. Furthermore, the sentence on page 22 mentioning that *"... S.epidermidis vaccine induced antibody could be used for prevention and treatment of S.epidermidis infections..."* could not be interpreted as disclosing a first or second medical use because it did not relate

to the use of the vaccine per se for prevention and treatment, but to its use for inducing an antibody which could then be used for prevention and treatment.

The subject-matter of claims 1 and 5 was, thus, novel.

First auxiliary request for all Designated Contracting States other than PT.

Rule 57a EPC, Articles 123(2) and 84 EPC; claim 3

The expression *"a prophylactically and therapeutically effective amount.."* had been introduced in claim 3 to make it unambiguous that the claimed pharmaceutical composition did not comprise the *S. epidermidis* vaccine disclosed in document (1) for injection into rabbits for the purpose making Directed Immune Globulin. The claim was, thus, admissible pursuant to Rule 57a EPC. Furthermore, the claimed subject-matter found a basis in the passage bridging pages 27 and 28 of the application as filed (Article 123(2) EPC). The skilled person willing to understand would have no doubts as to the significance of the expression "A pharmaceutical composition comprising a prophylactically and therapeutically effective amount of an antigen preparation..." (Article 84 EPC).

Article 54(3)(4) EPC

The passage on page 22 of document (1) argued by appellant II to be novelty destroying disclosed the use of a vaccine for the manufacture of an agent comprising an antibody ("*S.epidermidis* vaccine induced antibody") for use for medical purposes but it did not disclose

the use of a vaccine in the manufacture of an agent comprising said vaccine for said purposes. Therefore, document (1) did not affect the novelty of claim 1. In the same manner, there was no disclosure in document (1) of a pharmaceutical composition falling within the scope of claim 3. Novelty was to be acknowledged.

Article 83 EPC, sufficiency of disclosure in relation to claim 1

– Claim 1 extended to antigenic preparations made from other strains than strain Hay. This generalisation simply reflected the scientific contribution made to the art by the invention, namely that there existed an antigen common to Staphylococcus strains in general. Example 13 showed that the common antigen could be obtained from another strain than the Hay strain. A protocol was, thus, described which could be followed to extract said antigen from any Staphylococcus strains.

– Starting from the claimed antigenic preparation, the skilled person would have achieved a better characterisation (purification) of the relevant specific antigen without undue burden.

– Strains of serotypes I, II and III were either available to the public or identifiable anew on the basis of the teachings of document (17). A serotype I strain was on deposit (ATCC 31432). As shown by the declarations on file, at least three different scientists had been able to obtain a serotype III strain from their colleagues either

before or well after the effective date of the patent.

In document (17) a comparison of the cell wall structure of three serologically different strains of *S.epidermidis* designated as capsular types I, II and III was carried out. The biochemical and serological properties of the cell walls were said to correlate with the capsular types of these organisms. Accordingly, the skilled person would have no problem in identifying the serotype of a given strain via its biochemical properties.

For these reasons, sufficiency of disclosure could be acknowledged.

Article 56 EPC

The problem to be solved could be defined as how to prevent or treat Staphylococcus infections. In this framework, document (32) could be regarded as the most relevant piece of prior art as it was concerned with *S.epidermidis* capsular antigens, teaching that the three strains representative of the capsular types I, II and III were serologically different and that their protection-inducing capacity was capsular-type specific.

Starting from this knowledge, the obvious route to take to solve the above mentioned problem would be to produce a polyvalent vaccine comprising a mixture of antigens from the three capsular types.

The provided solution was completely different as it relied on the finding that there existed one antigen common not only to the three *S.epidermidis* serotypes but also to other Staphylococcus species, and that antibodies against it were broadly reactive and also opsonic ie. protective against many of the tested Staphylococci.

There was no suggestion in the art that an antigen other than those characterising the three serotypes could be of medical use. The argument that an antigenic preparation obtained from strains with a mixed polyvalent capsular type (I/II/III) would serve the same purpose as the claimed preparation was not convincing because it had not been shown that antibodies against it would be opsonic nor that their protecting effect would extend to protecting against other species than *S.epidermidis*.

In summary, the state of the art did not mention other antigens than those linked to the serotype and, furthermore, the properties of the antigenic preparation obtained from strain Hay were fully unexpected.

For these reasons, inventive step could be acknowledged.

XII. Appellant II's submissions in writing and during oral proceedings insofar as relevant to the present decision may be summarised as follows:

Admissibility of documents (35), (37) and (38)

The contents of these documents should be disregarded. Document (35) did not go any further than the prior art on file in identifying strain Hay as a type II strain. Documents (37) and (38) did not provide reliable information on the carbohydrate contents of the serotypes I, II and III and were, thus, irrelevant for the purpose of demonstrating that a given serotype strain could be identified on the basis of its carbohydrate constituents.

Main request for all designated Contracting States other than PT.

Article 84 EPC; claim 1

Claim 1 had been re-worded in the first medical indication format by adding the words "for use in the prevention, diagnosis or treatment of Staphylococcus infections". The sentence on page 1, line 5 of the patent: *"This invention relates to antigens used to prevent, diagnose or treat Staphylococcus infections"* was inadequate to support the amended claim because, firstly, it did not constitute anything of substance as regard the technical disclosure in the specification and, secondly, it did not specifically refer to the claimed antigenic preparation.

Article 123(3) EPC; claim 5

Being formulated as a use claim, claim 5 covered eg. directed standard intravenous immunoglobulin (IVIG) as the end product of said use. None of the granted claim

related to IVIG and, therefore, the scope of protection had been extended.

Article 54(3)(4) EPC; claims 1 and 5

Document (1) disclosed a *S.epidermidis* vaccine on page 19. As the document only referred to three strains of *S.epidermidis* including strain Hay, the skilled person would readily understand that the generic term *"S.epidermidis* vaccine" covered, in particular, a *S.epidermidis* strain Hay vaccine. Furthermore, being aware that whole cells from a pathogen would not be used for immunisation purposes, he/she would also understand the *S.epidermidis* vaccine as being an antigenic preparation such as the one described on page 14 of document (1). The extraction protocol for the antigenic preparation therein described was the same as in the patent in suit, which left no doubt that the antigenic preparations were the same, ie that they had the same property of being capable of generating broadly reactive opsonic antibody specifically reacting in an assay with *S.epidermidis* serotypes I, II and III.

On page 19, the *S.epidermidis* vaccine was said to be used for producing Directed Immune Globulin in rabbits which produced survival similar to Directed Human Immune Globulin produced by screening immunoglobulin for antibody to *S.epidermidis*. These data were interpreted on page 22, in particular, as showing that *S.epidermidis* vaccine-induced antibody could be used for prevention and treatment of *S. epidermidis* infections. Document (1) thus taught the use of an *S.epidermidis* antigenic preparation made from strain Hay for preventive treatment of Staphylococcus

infections. Consequently, the subject-matter of claims 1 and 5 was not novel.

First auxiliary request for all designated Contracting States other than PT.

Article 84 EPC; claim 3

The subject-matter of claim 3 was unclear insofar as the term *"... effective amount"* only made sense in relation to a method of treatment and not in relation to a pharmaceutical composition.

Article 54(3)(4) EPC

Document (1) disclosed on page 22 the use of the antigenic preparation as a vaccine against Staphylococcus infections. Otherwise stated, it disclosed the use of the antigenic preparation in the manufacture of an agent comprising said preparation for use in the treatment of Staphylococcus infections, thus destroying the novelty of claim 1. Claim 3 also lacked novelty as the vaccine disclosed on page 22 was a pharmaceutical composition which by definition contained a prophylactically effective amount for the purpose of immunisation.

Article 83 EPC; sufficiency of disclosure in relation to claim 1

Sufficiency of disclosure was lacking in three respects:

– Claim 1 extended to antigenic preparations from other strains than strain Hay by virtue of the use of the term "isolatable". In contrast, the patent in suit provided no guidance on how to identify these further antigenic preparations.

– Claim 1 extended to single antigens in addition to the TCA-produced antigenic preparation. There again, the patent in suit did not provide any guidance for isolating such antigens; it did not even show that one such antigen existed.

– Strains of serotype II and III which were needed in order to identify the claimed antigenic preparation were not available. The evidence on file showed that it required an undue amount of effort to obtain the capsular type III strain SE-10. SE-360; a representative of capsular type II could not be obtained at all.

Furthermore, there was no evidence in the prior art on file that strains representing each of the serotypes could be re-isolated without undue burden. Document (17) defined the carbohydrate contents of three specific strains said to represent capsular types I, II and III; yet, it did not disclose the relationship between a given carbohydrate content and a given capsular type (serotype), in general. Before a strain of a given serotype could be identified by its carbohydrate contents, the link between the two would have to be established without ambiguity. This implied that the carbohydrate content of the different capsular types would have to be exactly identified, ie that it should have been determined for many strains of each

type. Otherwise stated, the results shown in document (17) were insufficient to provide a reliable, albeit indirect test for serotyping. Consequently, *S.epidermidis* strains of the three serotypes could not be identified without undue burden, which was all the more true of serotype III strains which were quite rare. It also followed that antigenic preparations such as claimed could also not be obtained without undue burden.

For these reasons, the requirements of Article 83 EPC were not fulfilled.

Article 56 EPC

– The case should be sent back to the first instance for the assessment of inventive step as the now claimed subject-matter was quite different from that considered by the opposition division.

– The problem to be solved was to provide something useful in the prevention, treatment and diagnosis of Staphylococcus infections.

Document (32) could be regarded as the closest prior art. In its introductory part, it reminded the skilled person that Staphylococcus strains were divided in three groups on the basis of their capsular types. Each of the three groups was serologically different and the protection-inducing capacity was capsular-type specific. Document (32) also reported the occurrence of "polyvalent" capsular type strains ie broadly reactive across all three serotypes. Even if it

did not disclose that antibodies raised against a polyvalent strain were opsonic, it must be so, since they were protective and the opsonic activity of anti-peptidoglycan antibodies had been demonstrated. Accordingly, *S.epidermidis strains* capable of generating broadly reactive opsonic antibody which specifically reacted in an assay against *S.epidermidis* serotypes I, II and III were already known at the priority date, as was, by necessary implication, their use in diagnosis and treatment. The properties exhibited by antigenic preparations made from strain Hay as regards the generation of antibodies as specified in the claim were not obviously different from those of antibodies raised against antigenic preparations made from the polyvalent strains. Therefore, the basis underlying the current claims lacked inventive step.

XIII. 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 on 10 March 2006 or the first auxiliary request filed at the oral proceedings or the second auxiliary request filed on 10 March 2006, all with corresponding sets of claims for the Contracting State PT.

Appellant II requested that the decision under appeal be set aside and that the patent be revoked.

Reasons for the Decision

Admissibility of documents (35), (37) and (38) in the proceedings

1. It is within the board's discretionary power pursuant to Article 114(2) EPC to admit in the proceedings documents which are filed at a late stage, the prime consideration being their prima facie relevance. In the present case, documents (35), (37) and (38) were produced one month before the oral proceedings. Document (35) teaches that strain Hay is a capsular type II strain, a property which is already mentioned in the patent in suit. Documents (37) and (38) are concerned with protective antigens of strains representative of the capsular types III and II, respectively. They both disclose, in particular, that the carbohydrate moieties present on a cell surface antigen are closely correlated to antigenicity and that the antigen per se is specific of the capsular type studied. The equivalent information is already found in document (17), a document of the state of the art already on file, albeit expressed in a somewhat different way because of the time interval separating its publication (1984) from that of documents (37) and (38) (1990 and 1988, respectively). In the board's judgment, documents (35), (37) and (38) do not bring any new information which would prima facie be so relevant that they must be introduced in the proceedings. For this reason, they are not admitted.

Main request for all Designated Contracting States other than PT (Section VI supra).

Articles 123(2)(3) and 84 EPC; claims 1 and 5

2. Compared to granted claim 1, claim 1 of the main request was redrafted as a first medical use claim. Appellant I cited as a basis for the amendment the passage on page 1, lines 11 to 14 of the application as filed: "This invention ... relates to an isolated antigen used to prevent, diagnose, or treat Staphylococcus infections." The production of an antigenic preparation starting from Strain Hay is described on page 31. In the board's judgment, the skilled person would understand the disclosure provided by the patent specification as a whole as a teaching of a strain Hay antigenic preparation for medical uses. Furthermore, he/she would have no problems in figuring out the technical implications of said uses.

The scope of the claim is narrower than that of granted claim 1 directed to the antigenic preparation per se. The requirements of Articles 123(2)(3) and 84 EPC are fulfilled.

3. Claim 5 is drafted as a second medical use claim, i.e. to the use of the antigenic preparation for the manufacture of an agent and, inasmuch as this use may be regarded as a manufacturing process, the claim provides protection via Article 64(2) EPC for the agent directly obtained thereby. Granted claim 1 to the antigenic preparation is a product claim which provides absolute protection, including the use of the antigenic preparation in the manufacture of an agent for medical

use, and, by the same rationale, the agent directly obtained thereby. Thus, the scope of claim 5 is not broader than that of granted claim 1. The requirements of Article 123(3) EPC are fulfilled.

Article 54(3)(4) EPC; claim 5

4. Document (1) is an International patent application with an earlier priority date (25 February 1992) than the earliest priority date (19 March 1992) of the patent in suit. Thus, it is relevant for the assessment of novelty under Article 54(3)(4) EPC insofar as it designates the same European Contracting States as the patent in suit (all Contracting States designated in the patent in suit other than PT). The invention described in said document concerns the identification of human immune globulins for preventing or treating staphylococcal infections. This is achieved by screening samples of human plasma for the presence of high levels of *S.epidermidis* antibody with an antigenic preparation which is described on page 14 as being obtainable from, in particular, strain Hay. On pages 19, 20 and 22, mention is made of immunoglobulins (antibodies) which may be produced starting from an *S.epidermidis* vaccine and which could be used for prevention and treatment of *S.epidermidis* infections.

5. It is fair to say that the sum total of that information does not amount to an expressis verbis disclosure of the subject-matter of claim 5. Yet, the question which arises is whether the skilled person would have understood it as an unambiguous albeit implicit disclosure thereof. It is, thus, helpful to

proceed to a detailed analysis of the contents of document (1).

6. The method for isolating the antigenic preparation described on pages 14 and 15 does not differ in any relevant manner from the method for the same purpose disclosed in the patent in suit. Strain Hay is one of three specific strains mentioned as sources of the antigenic preparations. It follows therefrom that document (1) teaches an antigenic preparation made from strain Hay which has the same properties as the now claimed antigenic preparation, including that of generating broadly active opsonic antibodies which specifically react in an assay with *S. epidermidis* serotypes I, II and III.

7. On pages 19 and 20, reference is made to a *S.epidermidis* vaccine which is used for generating Directed Immune Globulin in rabbits which, in turn, is said to induce survival. And, it is mentioned on page 22 that *"These data show that S.epidermidis vaccine induced antibody could be used for the prevention and treatment of S.epidermidis infections..."* Admittedly, the nature of the vaccine is not specified. Yet, it certainly was a matter of common general knowledge at the relevant date that not only killed whole cells but also antigenic preparations could be used for triggering an immune response (ie the production of immunoglobulins). Taking into account that killed whole cells are not mentioned in document (1) whereas the antigenic preparation, the extraction of which is described in detail (cf point 6 supra), is fundamental for putting into practice the concept underlying the invention therein described, the board

has no hesitation in concluding that the term *"S.epidermidis* vaccine" was intended to mean, in particular if not exclusively, "antigenic preparation".

8. It is, thus, concluded from this analysis that document (1) teaches unambiguously albeit implicitly an antigenic preparation isolatable from Hay, having the now claimed property (see point 6, supra), for use in the manufacture of an agent (the directed immune globulin, see point 7 supra) for use in the prevention or treatment of staphylococcus infections. Accordingly, the subject-matter of claim 5 is not novel and the main request is rejected for failing to fulfil the requirements of Article 54 EPC.

First auxiliary request for all Designated Contracting States other than PT (Section IX, supra)

Rule 57a EPC, Articles 123(2) and 84 EPC; claim 3

9. Claim 3 was amended to relate to a pharmaceutical composition comprising "a prophylactically or therapeutically effective amount" of an antigen preparation isolatable from strain Hay. Appellant I argued that the amendment had been introduced to ward off a possible objection of lack of novelty on the basis of document (1) which disclosed the immunization of rabbits with an S.epidermidis vaccine. The amended claim is, thus, admissible pursuant to Rule 57(a) EPC.

Furthermore, there is a basis for it in the passage bridging pages 27 and 28 of the application as filed (Article 123(2) EPC). Whereas it is true that the added expression is more appropriate to define a method of

treatment than a composition, if the claim is read as instructed by the case law (T 190/99 supra), i.e. with a mind willing to understand, there is no doubt as to the characteristics of the pharmaceutical composition (Article 84 EPC).

Article 54(3)(4) EPC

10. Claim 1 corresponds to claim 5 of the main request insofar as it is drafted as a second medical use claim. Yet, the claimed use of the antigenic preparation is now for the manufacture of an agent comprising **said antigenic preparation** for use in the prevention and treatment of staphylococcus infections. Claim 3 relates to a pharmaceutical composition comprising an effective amount of the antigenic preparation.

11. Document (1) which is concerned with the production of immunoglobulin to be used for passive immunisation for prevention and treatment of *S.epidermidis* infections, discloses neither such a use nor such a pharmaceutical composition. In particular, it is the board's opinion that the sentence on page 22: "... *S.epidermidis vaccine* ***induced antibody*** *could be used for prevention and treatment of S.epidermidis infections..."* (emphasis added by the board) cannot be interpreted as meaning that an *S.epidermidis* vaccine could be used directly for prevention and treatment. It is clear that it is only the antibodies retrieved from an immunisation with the antigenic preparation which are disclosed for such uses. The subject-matter of claim 1, dependent claim 2 and claim 3 is, thus, novel. The requirements of Article 54 EPC are fulfilled.

Article 83 EPC, sufficiency of disclosure in relation to the subject-matter of claim 1

12. The objection was raised that identical antigenic preparations from other strains than the Hay strain (comprised within claim 1 in view of the word "isolatable" used in its formulation) could not be isolated without undue burden. In the board's judgment, producing antigenic preparations of various staphylococcal origins can be done in a straightforward manner by following the protocol described in Example 1 of the patent in suit. Testing their property of generating antibodies such as mentioned in claim 1 may require much work but it cannot be considered as undue burden because it can be carried out by well known methods (eg. patent in suit, Example 2) as long as strains representative of the three *S.epidermidis* serotypes are accessible (see points 15 to 17, infra).

13. A second objection was that claim 1 encompassed single antigens as well as mixtures of antigens, (cf description of the patent in suit, page 4, lines 11 to 14) and no guidance was provided for purifying them. It is true that the patent in suit does not describe an experimental protocol for purifying the "common antigen" said to be present in an antigenic preparation from strain Hay. Yet, references to documents representing the common general knowledge on protein or polysaccharide (ie. antigens) purification are given on page 8 and the purification of relevant antigen could be followed by testing for its claimed property (see points 15 to 17, infra). In the absence of any evidence to the contrary, the board is prepared to accept that

enough information is provided by the patent in suit to be able to reproduce this aspect of the invention.

14. Finally, it was argued that the skilled person had no means to identify an antigenic preparation as capable of generating broadly active opsonic antibodies which specifically reacted in an assay with *Staphylococcus epidermidis serotypes* II and III because these strains could not be reproduced without undue burden, nor were they available - the availability of a type I strain was never challenged.

15. Document (17) teaches the carbohydrate contents of capsular I, II and III types of *S.epidermidis* (page 353). On page 362, it discloses that the immunological properties of the three capsular types are different, the differences being attributed to different carbohydrates being present (capsular types I and II) or if the same carbohydrates are present - but in different relative quantities - (capsular types I and III) to variations in their configuration. On page 363, it is concluded: *"..., our results suggest that .... the biochemical and serological properties of CWTA (cell wall techoic acid) correlated with the capsular types of these organisms".* Document (17), thus, discloses the link between the serotype and the polysaccharide composition of the cell wall for each capsular type and, in doing so, provides a means to identify strains representative of each serotype. For this reason, it is accepted that, at the priority date, the skilled person would have been able either to obtain (in case of serotype I) or to reproduce without undue burden (in case of serotypes II and III) strains representative of the three serotypes on the basis of

the carbohydrate compositions and, consequently, that he/she would have been able to reproduce the claimed antigenic preparation.

16. Appellant II pointed out that strains of capsular type III were rare. In this respect, the board will make the same remark as in point 12 supra, that it may require some work to identify a serotype III/capsular type III strain, yet this work cannot be regarded as undue burden insofar as methods for determining carbohydrate compositions were part of the common general knowledge at the relevant date (see patent in suit, page 8).

17. Furthermore, it was submitted by appellant II that document (17) did not establish the carbohydrate contents characteristic of each of the three capsular types in a reliable manner because these contents were only determined for one strain of each serotype. Accordingly, in its view, strains could not be attributed a given serotype on the basis of a comparison of their carbohydrate contents with those determined in document (17) which, in turn, implied that the claimed subject-matter could not be reproduced without undue burden. The board is not convinced by this argument. Document (17) is a scientific article which was undoubtedly submitted to peers review before publication. For this reason, there is no room for challenging the validity of the results it describes. More specifically, there is no room to challenge that it identifies a capsular type at the same time by a certain carbohydrate composition and by its unique antigenicity; otherwise stated, that it provides a straightforward albeit indirect means to determine the

serotype of any given *S.epidermidis* strain on the basis of its carbohydrate content.

18. In the course of the proceedings, three affidavits were filed reporting that a strain representative of serotype III was available at the priority date and also well after that date. Appellant II challenged that it was easily available. In view of the above mentioned findings, no decision needs to be made on the issue of the availability of serotypes II and III strains.

19. For the reasons given in points 12 to 17 supra, sufficiency of disclosure is acknowledged.

Appellant II's request to remit the case to the first instance

20. When, towards the end of the oral proceedings, the board was about to consider the issue of the inventive step of appellant I's first auxiliary request, appellant II requested that the case be remitted to the first instance. Appellant I, which had at an earlier point in the oral proceedings withdrawn its own request for such remittal, wanted the board to proceed to deal with inventive step. Under Article 111(1) EPC the board has complete discretion either to exercise any power of the first instance or to remit a case to that instance. In considering a request to exercise a discretion in favour of one party the board must of course seek to make a decision which is fair and equitable. One matter which must be considered is the behaviour of the parties and, in particular, the relevant behaviour of the party requesting the exercise of discretion in its favour, sometimes expressed by the legal maxim "He who comes to equity must come with clean hands".

21. Appellant II had, throughout the appeal proceedings up to this point, argued its case on inventive step as if expecting the board to deal with this issue (see page 5 of appellant II's reply of 31 December 2004 to appellant I's grounds of appeal and page 2 of its submissions of 10 March 2006 in answer to the board's communication). It was in fact appellant I which had requested remittal to deal with inventive step (see its grounds of appeal of 7 June 2004, paragraph 2.1(8), and its submissions of 10 March 2006 in answer to the board's communication, paragraph 2.4). During the morning session of the oral proceedings before the board, appellant I withdrew this request and indicated it was content for the board to deal with all issues, including inventive step. If appellant II wished to change its previous position, that was the natural point in the oral proceedings for it to do so but at that time it remained silent on the issue.

22. It was only when inventive step was about to be considered, well into the afternoon session, that appellant II announced its change of position. It admitted very candidly that its intention in doing so was to gain further time to prepare its case. While the request of appellant I then under consideration was only filed during the oral proceedings, its claims were not so different from earlier requests that either it was held inadmissible or that an adjournment or postponement of the oral proceedings was necessary. Indeed, appellant II did not request any such adjournment or postponement when the new request was filed. In those circumstances, if other issues could be dealt with there and then in relation to a new request,

and if appellant I was now prepared to deal with inventive step before the board as appellant II had been previously, it would have been unreasonable to reward appellant II's last-minute volte-face by granting it, in effect, the adjournment or postponement it could have but did not request, and would not have obtained if requested, plus a further possible appeal. Appellant II's request for remittal was therefore refused and the board proceeded to consider inventive step.

Article 56 EPC, inventive step

23. The purpose of the presently claimed invention is to prevent or treat Staphylococcus infections. None of the prior art on file relevant for the assessment of inventive step shares or suggests this purpose. Several documents, however, relate to *S.epidermidis* capsular antigens and, thus, as agreed by both parties either of them may come into consideration when attempting to solve the problem of preventing or treating Staphylococcus infections. Amongst them, document (32) was chosen as the "closest" prior art.

24. In its introductory part, document (32) reminds the reader that three serologically different capsular type strains of *S.epidermidis* had been reported and that the protection-inducing activity of these strains was considered to be capsular type specific. There follows a study of the capsular types of many *S.epidermidis* strains which shows, in particular, that most of them fall within either of the three capsular types defined earlier on - capsular type II being the most frequent -

while some of them are found to be of mixed polyvalent capsular types (I/II, II/III; Table 3).

25. In the board's judgment, this teaching would render obvious an antigenic preparation isolatable from a mixture of strains representative of each capsular type or, alternatively, an antigenic preparation isolatable from a a polyvalent strain for the purpose of preventing, treating or diagnosing Staphylococcus infections.

26. The solution provided by the instant invention, however, does not follow this obvious approach. On the contrary, what is claimed is an antigenic preparation from a capsular type II strain which is nonetheless capable of generating protective antibodies reacting with the three capsular types/serotypes. This property is also shown in the patent in suit to extend to further Staphylococcus species.

27. An antigenic preparation with such properties was wholly unexpected on the basis of document (32) or of any other documents of the state of the art which are essentially preoccupied with establishing capsular type and serotype specificities and the links existing between them. For these reasons, inventive step is acknowledged.

First auxiliary request for the Designated Contracting State PT

28. This request contains the granted claims 1 to 3 and 5. Document (1) is not state of the art pursuant to Article 54(3)(4) EPC since PT is not one of the

Contracting States which it designates. None of the other documents on file are relevant for the assessment of novelty. The claimed subject-matter is, thus, novel.

29. Inventive step and sufficiency of disclosure may also be acknowledged for the same reasons as they were acknowledged for the first auxiliary request for all other Designated Contracting States.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the first instance with the order to maintain the patent on the basis of the first auxiliary request filed at the oral proceedings and a corresponding set of claims for the Contracting State PT, and a description and figures to be adapted thereto.

The Registrar: The Chairman:

A. Wolinski L. Galligani