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Datasheet for the decision of 12 September 2012

Case Number: T 1306/08 - 3.3.02

Application Number: 01962862.7

Publication Number: 1301238

IPC: A61M 37/00

Language of the proceedings: EN

Title of invention:
Needles coated with vaccine

Patentee:
SmithKline Beecham Biologicals S.A.
SMITHKLINE BEECHAM PLC

Opponent:
3M Innovative Properties Company

Headword:
Needles coated with vaccine/SMITHKLINE BEECHAM

Relevant legal provisions:
EPC Art. 123(2), 54, 56
RPBA Art. 13

Keyword:
"Main request, auxiliary requests 1 to 5: allowability of amendments - (no)"
"Auxiliary request 6: novelty (yes): sugar glass not specifically disclosed in the prior art documents"
"Inventive step (no) addition of sugar glass for stabilising the vaccine obvious"

Decisions cited:
G 0009/91

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 1306/08 - 3.3.02

D E C I S I O N
of the Technical Board of Appeal 3.3.02
of 12 September 2012

Appellant: (Opponent)
3M Innovative Properties Company
3M Center
P.O. Box 33427
St. Paul MN 55133-3427 (US)

Representative:
Lawrence, Malcolm Graham
avidity IP
Merlin House
Falconry Court
Baker's Lane
Epping, Essex CM16 5DQ (GB)

Respondents: (Patent Proprietors)
SmithKline Beecham Biologicals S.A.
89 rue de l'Institut
BE-1330 Rixensart (BE)

SMITHKLINE BEECHAM PLC
980 Great West Road
Brentford
Middlesex TW8 9GS (GB)

Representative:
Teuten, Andrew
GlaxoSmithKline
Corporate Intellectual Property (CN9.25.1)
980 Great West Road
Brentford
Middlesex TW8 9GS (GB)

Decision under appeal:
Interlocutory decision of the Opposition Division of the European Patent Office posted 13 May 2008 concerning maintenance of European patent No. 1301238 in amended form.

Composition of the Board:

Chairman: U. Oswald
Members: A. Lindner
L. Bühler

Summary of Facts and Submissions

I. European patent No. 1 301 238 based on application No. 01 962 862.7 was granted on the basis of 14 claims.

II. Two oppositions were filed against the patent. The patent was opposed under Article 100(a) EPC for lack of novelty and inventive step and under Article 100(b) EPC for insufficiency of disclosure.

III. The documents cited during the opposition and appeal proceedings included the following:

(E1b) US-A-3 072 122
(E2) US-A-3 678 150
(E3) US-A-3 123 212
(E4) WO 00/44438
(E6) WO 96/03978
(E8) WO 99/64580
(E14) WO 98/28037
(E17) W. Wang, International Journal of Pharmaceutics (2000), 203, 1-60
(E19) J.F. Carpenter, et al., Pharmaceutical Research (1997), 14(8), 969-975
(E21) G. Walsh and B. Murphy, Biopharmaceuticals, An Industrial Perspective (1999), Chapter 9, Kluwer Academic Publishers
(E26) B. Crystal, New Scientist (1997), 24-27
(E29) Children's Vaccine Initiative, CVI Forum (1999), 18, 1-24
(E34) WO 01/39756
(E56) J. Lloyd, Technologies for Vaccine Delivery in the 21st Century, Department of Vaccines and Biologicals, WHO, December 2000 (print date), 1-25

(E61) C. Cocito and F. Vanlinden, Clin. exp. Immunol. (1986), 66, 262-272

(E62) R.D. Hubbard, et al., Clin. exp. Immunol. (1992), 88, 129-131

(E70) H.S. Gill, et al., Clin. J. Pain (2008), 24(7), 585-594

IV. The appeal lies from an interlocutory decision of the opposition division pronounced on 13 March 2008 and posted on 13 May 2008 maintaining the patent on the basis of the main request filed with the letter dated 3 July 2006.

V. In said decision the opposition division concluded that the subject-matter of the main request met the requirements of Article 123(2) EPC, as all the amendments made in the independent claims were directly derivable from the claims as originally filed. Alternatively, there was also a basis for these claims in the description of the original application. Moreover, the subject-matter of the main request was allowable under Article 123(3) EPC, as all the features of the independent claims could be found in the claims as granted.

Furthermore, the invention defined in the main request was sufficiently disclosed, as the term "glass" was well known to the skilled person at the priority date of the contested patent and the examples gave enough guidance as to how to prepare a glass by freeze drying a solution of polyols. Regarding the release rate of ≤5 min, the opposition division, making reference to example 2 of the contested patent, had no doubts that the test described therein was appropriate.

The subject-matter of the main request was novel, as document (E2), combined with the documents incorporated therein by reference, neither disclosed a patch, nor an array, nor that the coating of Old Tuberculin and polyol form a glass, and document (E4) did not disclose glass formation either. Documents (E6), (E8) and (E14) were not relevant for novelty either.

Regarding inventive step, the opposition division defined stabilisation of the vaccine and a rapid release of the vaccine from the device into the skin as the problem to be solved vis-à-vis document (E1b), which was defined as closest prior art. Document (E1b) did not contain any incentive to coat the needles of the delivery device with a glass-forming polyol in order to stabilise the active agent. As a consequence, the skilled person would not have associated the teaching of documents (E6), (E21), (E26) or (E29) with the teaching of document (E1b) in order to arrive at the claimed invention.

VI. The appellant (opponent) lodged an appeal against that decision.

VII. In the course of the appeal proceedings, three third-party submissions were filed with letters dated 9 September 2008, 31 July 2009 and 25 November 2009.

VIII. Oral proceedings were held before the board on 12 September 2012.

IX. The independent claims of the requests on file read as follows:

(i) Main request:

"1. A skin patch for delivery of a pharmaceutical agent comprising an array of microblades or microneedles as skin-piercing members coated with a solid biodegradable reservoir medium containing the pharmaceutical agent wherein the solid biodegradable reservoir medium is a polyol, wherein the solid biodegradable reservoir medium forms a glass and wherein the pharmaceutical agent is a vaccine.

10. A process for the preparation of a skin patch for delivery of a pharmaceutical agent comprising an array of microblades or microneedles as skin-piercing member coated with a solid biodegradable reservoir medium containing the pharmaceutical agent according to any of claims 1 to 7 comprising making a solution of said pharmaceutical agent and said reservoir medium, followed by dipping at least one skin-piercing member into said solution, and allowing the solution to dry onto the skin-piercing member to form said solid biodegradable reservoir medium containing said the pharmaceutical agent.

11. A skin patch for delivery of vaccines comprising an array of microblades or microneedles coated with a glassy sugar reservoir medium containing a vaccine antigen."

(ii) Auxiliary request 1:

"1. A skin patch for delivery of a pharmaceutical agent comprising an array of microblades or microneedles as skin-piercing members coated with a solid biodegradable reservoir medium containing the pharmaceutical agent wherein the solid biodegradable reservoir medium is a polyol, wherein the solid biodegradable reservoir medium forms a glass, wherein the pharmaceutical agent is a vaccine, and wherein the solid biodegradable reservoir medium releases the pharmaceutical agent within 5 minutes after insertion of the skin-piercing member and solid biodegradable reservoir medium into the skin.

9. A process for the preparation of a skin patch for delivery of a pharmaceutical agent comprising an array of microblades or microneedles as skin-piercing member coated with a solid biodegradable reservoir medium containing the pharmaceutical agent according to any of claims 1 to 6 comprising making a solution of said pharmaceutical agent and said reservoir medium, followed by dipping at least one skin-piercing member into said solution, and allowing the solution to dry onto the skin-piercing member to form said solid biodegradable reservoir medium containing said pharmaceutical agent.

10. A skin patch for delivery of vaccines comprising an array of microblades or microneedles coated with a glassy sugar reservoir medium containing a vaccine antigen wherein the reservoir medium releases the vaccine within 5 minutes after insertion of the microblades or microneedles and reservoir medium into the skin."

(iii) Auxiliary request 2:

"1. A skin patch for delivery of a pharmaceuticap agent comprising an array of microblades or microneedles as skin-piercing members coated with a solid biodegradable reservoir medium containing the pharmaceutical agent wherein the solid biodegradable reservoir medium is a polyol, wherein the solid biodegradable reservoir medium forms a glass, wherein the pharmaceutical agent is a vaccine, and wherein the solid biodegradable reservoir medium has a glass transition temperature which is greater than 30 °C that both stabilises the pharmaceutical agent during storage and releases the pharmaceutical agent within 5 minutes after insertion of the skin-piercing member and solid biodegradable reservoir medium into the skin.

9. A process for the preparation of a skin patch for delivery of a pharmaceutical agent comprising an array of microblades or microneedles as skin-piercing member coated with a solid biodegradable reservoir medium containing the pharmaceutical agent according to any of claims 1 to 6 comprising making a solution of said pharmaceutical agent and said reservoir medium, followed by dipping at least one skin-piercing member into said solution, and allowing the solution to dry onto the skin-piercing member to form said solid biodegradable reservoir medium containing said pharmaceutical agent.

10. A skin patch for delivery of vaccines comprising an array of microblades or microneedles coated with a glassy sugar reservoir medium containing a vaccine antigen wherein the reservoir medium has a glass transition temperature which is greater than 30 °C that

both stabilises the pharmaceutical agent during storage and releases the vaccine within 5 minutes after insertion of the microblades or microneedles and reservoir medium into the skin."

(iv) Auxiliary request 3:

"1. A process for preparation of a skin patch for delivery of a pharmaceutical agent comprising an array of microblades or microneedles as skin-piercing members coated with a solid biodegradable reservoir medium containing the pharmaceutical agent wherein the solid biodegradable reservoir medium is a polyol, wherein the solid biodegradable reservoir medium forms a glass, and wherein the pharmaceutical agent is a vaccine, which process comprises coating the skin-piercing members by a process comprising making an aqueous solution of vaccine antigen and water soluble polyol, followed by coating the solution onto the skin piercing members by dipping the members into the solution one or more times followed by lyophilisation to give a porous coating."

(v) Auxiliary request 4

"1. A skin patch for delivery of a pharmaceutical agent comprising an array of microblades or microneedles as skin-piercing members coated with a solid biodegradable reservoir medium containing the pharmaceutical agent wherein the solid biodegradable reservoir medium is a polyol, wherein the solid biodegradable reservoir medium forms a glass and wherein the pharmaceutical agent is a DNA vaccine.

8. A process for the preparation of a skin patch for delivery of a pharmaceutical agent comprising an array of microblades or microneedles as skin-piercing member coated with a solid biodegradable reservoir medium containing the pharmaceutical agent according to any of claims 1 to 7 comprising making a solution of said pharmaceutical agent and said reservoir medium, followed by dipping at least one skin-piercing member into said solution and allowing the solution to dry onto the skin-piercing member to form said solid biodegradable reservoir medium containing said pharmaceutical agent."

(vi) Auxiliary request 5

"1. A skin patch for delivery of a pharmaceutical agent comprising a plurality of microblades or microneedles as skin-piercing members coated with a solid biodegradable reservoir medium containing the pharmaceutical agent wherein the solid biodegradable reservoir medium is a polyol, wherein the solid biodegradable reservoir medium forms a glass and wherein the pharmaceutical agent is a vaccine.

5. A skin patch for delivery of vaccines comprising a plurality of microblades or microneedles coated with a glassy sugar reservoir medium containing a vaccine antigen."

(vii) Auxiliary request 6

"1. A skin patch for delivery of vaccines comprising an array of microblades or microneedles coated with a glassy sugar reservoir medium containing a vaccine antigen."

X. The appellant's arguments can be summarised as follows:

The devices according to documents (E1b), (E2) in combination with (E3) and (E4) were skin patches and fell within the definition for skin patches given in paragraph [0016] of the patent in suit. All these documents destroyed the novelty of the claimed subject-matter, as the glassy state was implicitly disclosed there.

Assuming that the glassy state was not implicitly disclosed in the above-mentioned prior art documents, document (E1b) constituted the closest prior art. As the protective effect of sugar glasses on proteins belonged to the general knowledge of the skilled person, the addition of such a glass to the skin patches according to the claims of the requests on file in order to enhance the stability of the vaccine was obvious.

XI. The respondent's arguments can be summarised as follows:

Document (E1b) disclosed devices comprising a backing plate with wing-like projections. There was no adhesive layer. As a consequence, these devices could not be regarded as skin patches. Moreover, the handling was entirely different: the devices according to document (E1b) were pressed against the skin and rotated in a circular motion. In contrast thereto, the application of the skin patches according to the present invention, which was painless due to careful selection of a needle length of up to 1 mm, did not involve any mechanical activity. As a consequence, document (E1b) was not relevant.

Neither document (E4) nor document (E2) in combination with document (E3) related to skin patches.

XII. The appellant requested that the decision under appeal be set aside and the European patent No. 1 301 238 be revoked.

XIII. The respondent requested that the appeal be dismissed (main request) or, alternatively, that the patent be maintained on the basis of one of auxiliary requests 1 and 2, filed with letter dated 9 February 2010, auxiliary requests 3 to 5, filed with letter dated 31 March 2009, and auxiliary request 6, submitted during oral proceedings of 12 September 2012.

Reasons for the Decision

1. The appeal is admissible.

2. Admission of late-filed requests and evidence

2.1 Auxiliary request 6

This request was filed at a late stage of the oral proceedings before the board. Its admissibility is therefore at the board's discretion and depends upon the overall circumstances of the case under consideration. As the amendments made concerned only the deletion of claims resulting in a single claim which is identical to claim 11 of the main request, the respondent could not have been taken by surprise. As a consequence, the board

decided to admit auxiliary request 6 into the proceedings (Article 13 RPBA).

2.2 Documents (E61) and (E62)

Documents (E61) and (E62) were submitted by the appellant with letter dated 20 April 2010. According to Article 13(1) RPBA, any amendment to a party's case after it has filed its grounds of appeal or reply may be admitted and considered at the board's discretion. The board notes that the respondent had contested OT's suitability as a vaccine already in its reply to the notices of opposition dated 3 July 2006 (see first complete paragraph on page 4) so that said documents could have been filed much earlier. As a consequence, the board decided not to admit documents (E61) and (E62) into the proceedings.

2.3 Document (E70) was submitted by the respondent with letter dated 8 September 2010 in order to demonstrate that microneedles of length 1450 µm cause more pain and bleeding than shorter microneedles (see paragraph bridging pages 5 and 6 of the respondent's letter dated 8 September 2010). At the oral proceedings before the board, the respondent cited document (E70) during the discussion of novelty of auxiliary request 6. As the single claim of said auxiliary request 6 does not contain any definition of the needle length, the board concluded that document (E70) was not relevant and decided not to admit it into the proceedings.

2.4 Document (E56) was submitted by the appellant with letter dated 20 April 2010 as a potentially important document for inventive step setting out scientific facts

about sugar glasses which would motivate the skilled person to use them in microneedle skin patch technology (see table on page 7 of the letter dated 20 April 2010). The board notes that the use of sugar glasses in microneedle skin patch technology has been an issue since the beginning of the opposition proceedings, so that document (E56) could have been filed already during the first-instance proceedings. In view of this fact and taking into consideration that the function of sugar glasses as stabiliser for proteins is also known from other documents on file (e.g. documents (E17) and (E26)), the board decided not to admit document (E56) into the proceedings.

3. Main request - amendments

3.1 Competence of the board to examine the amendments made in claim 1

The respondent argued that Article 100(c) EPC had not been cited as a ground for opposition and, making reference to decision G 09/91 (OJ EPO 1993, 408), concluded that the board was not competent to examine whether or not the amendments are in accordance with the requirements of Article 123(2) EPC. The board wishes to emphasise that, in so far as subject-matter of the European patent extending beyond the content of the application as filed is concerned, a distinction has to be made between the ground for opposition according to Article 100(c) EPC, which concerns amendments made in the pre-grant phase, and amendments made in the course of opposition or appeal proceedings. Regarding the latter alternative, decision G 09/91 notes in point 19: "In order to avoid any misunderstanding, it should

finally be confirmed that in case of amendments of the claims or other parts of a patent in the course of opposition or appeal proceedings, such amendments are to be fully examined as to their compatibility with the requirements of the EPC (e.g. with regard to the provisions of Article 123(2) and (3) EPC)." As the objections raised by the appellant concern subject-matter amended in the course of the opposition and appeal proceedings, the board concludes that it is competent to examine them.

3.2 The subject-matter of claim 1 relates to a skin patch comprising an array of microblades or microneedles. The board notes that the term "array" implies a certain ordered or structured arrangement of elements. An array of microblades or microneedles is therefore more specific than a mere plurality of microblades or microneedles, as in the latter case said microblades or microneedles can be arranged in any form. As a consequence, the passage on page 5, lines 20-21 of the original application, relating to a plurality of piercing protrusions, cannot serve as a basis for the array according to claim 1 of the main request.

The original application contains three passages relating to arrays:

(a) the passage on page 5, lines 20 et seq., making reference to a list of 11 documents, mentions "methods of manufacture of the microblade arrays being incorporated by reference". This unspecific reference to microblade arrays disclosed in a multitude of documents is much too vague to be able to serve as a basis for the specific arrays of microneedles of microblades according

to claim 1 of the main request. Moreover, said passage is completely silent about arrays of microneedles.

(b) The first complete paragraph on page 8 discloses as a preferred embodiment a skin patch for delivery of pharmaceutical agents or vaccines comprising an array of microblades or microneedles coated with a solid biodegradable reservoir medium containing the pharmaceutical agent or vaccine. Compared to this disclosure, the subject-matter of claim 1 comprises the additional features that the biodegradable reservoir medium is a polyol which forms a glass. Furthermore, the active agent is now a vaccine. The board notes that all these features are individually disclosed in the original application. Vaccines are disclosed throughout the application as filed and polyol glasses are disclosed on page 9, lines 12-17. However, when it comes to the question whether there is a basis for the combination of these features in the original application, the board notes that the above-mentioned passage on page 9, lines 12-17, links the polyol glasses or simply dried polyol to antigens or agents, wherein agents in the context of the application means pharmaceutical agents. As the term vaccine is not limited to antigens but includes additional compounds such as DNA vaccines, which are structurally different from protein-based antigens, this passage does not provide a basis for the combination of glass-forming polyol plus vaccine.

(c) The passage on page 10, lines 20-22, as well as independent claim 16 concern a skin patch for delivery of vaccines comprising an array of microblades or microneedles coated with a glassy sugar reservoir medium

containing the vaccine. As "glassy sugar reservoir medium" is identical to "wherein the reservoir medium is a sugar that forms a glass", this passage provides a basis for glass-forming sugar plus vaccine.

To summarise:
The passages cited above disclose arrays comprising either a glass-forming polyol in combination with an antigen or a glassy sugar in combination with a vaccine. Arrays comprising a glass-forming polyol in combination with a vaccine are not specifically disclosed there.

The respondent also cited the original claims, in particular claims 1 to 3, 7, 11 and 12, as a basis for the amendments made in claim 1 of the main request. However, original claims 1 to 15 are not relevant as they disclose neither arrays nor skin patches.

As a consequence, the subject-matter of claim 1 of the main request is not allowable under Article 123(2) EPC.

4. Auxiliary request 1 - amendments

Compared to claim 1 of the main request, the skin patch according to claim 1 of auxiliary request 1 is further defined by the release rate of the vaccine. This additional feature does not change the fact that arrays comprising a glass-forming polyol in combination with a vaccine are not specifically disclosed in the original application, so that the reasoning according to point 3.2 above applies *mutatis mutandis* to claim 1 of auxiliary request 1. As a consequence, the requirements of Article 123(2) EPC are not met.

5. Auxiliary request 2 - amendments

Compared to claim 1 of the main request, the skin patch according to claim 1 of auxiliary request 2 is further defined by the release rate of the vaccine and the glass transition temperature of the polyol. These additional features do not change the fact that arrays comprising a glass-forming polyol having a defined glass transition temperature in combination with a vaccine are not specifically disclosed in the original application, so that the reasoning according to point 3.2 above applies *mutatis mutandis* to claim 1 of auxiliary request 2. As a consequence, the requirements of Article 123(2) EPC are not met.

6. Auxiliary request 3 - amendments

Claim 1 of auxiliary request 3 concerns the preparation of a skin patch as defined in claim 1 of the main request. This change of claim category plus the introduction of process features does not change the fact that arrays comprising a glass-forming polyol in combination with a vaccine, which are prepared by said process, are not specifically disclosed in the original application, so that the reasoning according to point 3.2 above applies *mutatis mutandis* to claim 1 of auxiliary request 3. As a consequence, the requirements of Article 123(2) EPC are not met.

7. Auxiliary request 4 - amendments

Claim 1 of auxiliary request 4 differs from claim 1 of the main request in that the vaccine is limited to DNA vaccine. This limitation does, however, not change the

fact that arrays comprising a glass-forming polyol in combination with a vaccine are not specifically disclosed in the original application, so that the reasoning according to point 3.2 above applies *mutatis mutandis* to claim 1 of auxiliary request 4. As a consequence, the requirements of Article 123(2) EPC are not met.

8. Auxiliary request 5 - amendments

Claim 1 of auxiliary request 5 differs from claim 1 of the main request in that "array of microblades or microneedles" is replaced by "plurality of microblades or microneedles", which is disclosed on page 5, lines 20-21 of the original application. However, this substitution does not change the fact that the combination of glass-forming polyol plus vaccine is not disclosed in the description of the original application (see point 3.2 above).

In view of the fact that present claim 1 is no longer directed to arrays, it is necessary to investigate whether the original claims, possibly in combination with the description, provide a basis for the subject-matter claimed therein. As was mentioned above (see penultimate paragraph of point 3.2 above), the originally filed claims 1 to 14 do not disclose skin patches but refer to the more general feature "pharmaceutical delivery device". Moreover, on account of the multiple back-references in the dependent claims, the combination of a plurality of microblades or microneedles plus glass-forming polyol plus vaccine is not specifically disclosed there either. Dependent claim 12, which indicates that the active agent is a

vaccine, refers to any one of claims 1 to 11 rather than specifically to claim 11, which discloses microblades or microneedles. Claim 11 in its turn refers to any one of claims 1 to 10 rather than specifically to claim 7 where the glass-forming property of the biodegradable reservoir medium is disclosed, which according to claim 3 is a polyol but which according to claim 5 may also be a sugar or, according to claim 6, a specific sugar selected from lactose, sucrose raffinose or trehalose. Claim 7 does not specifically refer to claim 3 but to any of claims 1 to 5. In addition, the feature "skin patch" would have to be added from the description or from original claim 16, which is an independent claim and therefore separate from original claims 1 to 14. As a consequence, the original claims in combination with the description do not provide a basis for the subject-matter of claim 1 of auxiliary request 5 either.

The requirements of Article 123(2) EPC are therefore not met.

9. Auxiliary request 6

The sole independent claim is identical to independent claim 14 as granted. In view of the fact that Article 100(c) EPC was not cited as ground for opposition and the patentee did not give its approval to discuss objections raised on the basis of Article 100(c) EPC, the board has no competence for examining this issue (see decision G 09/91, point 3 of the opinion). Nor is the board competent to examine whether or not said claim 1 meets the requirements of Article 84 EPC.

9.1 Novelty

Document (E2) concerns a process for improving the stability of Old Tuberculin (OT) or Tuberculin Purified Protein Derivative (PPD) comprising dipping the tines of an intracutaneous injector into a preparation comprising in addition to OT or PPD a mixture of acacia and a sugar selected from lactose and glucose (see column 1, lines 13-16 and 66-75; column 2, lines 31-40; examples 1 and 2). Document (E2) does not disclose whether or not the reservoir medium thus obtained has a glassy structure. As a consequence, irrespective of whether or not OT and PPD have antigenic activity and the injectors disclosed in document (E3) and incorporated by reference into document (E2) (see column 2, lines 37-40 and examples 1 and 2 of document (2)) can be considered as skin patches, the subject-matter of claim 1 of auxiliary request 6 is novel over document (E2). In this context, it is noted that the board is not convinced by the appellant's assertion that the above-mentioned mixture of document (E2) inevitably has a glassy state after drying and it therefore concluded that a glassy sugar reservoir medium containing a vaccine antigen is not implicitly disclosed in document (E2).

Document (E4) discloses a plate with precoated electrodes for delivering macromolecules such as DNA vaccines. The macromolecules are preloaded onto the needle electrodes having a length which allows penetration of the stratum corneum of the skin (see figure 2, page 17, lines 14-17; page 19, lines 26-27; page 29, lines 13-23). The coating involves dipping the electrodes into a solution or suspension of the DNA vaccine which may additionally comprise sugars as

protectants and/or other carrier molecules (see page 25, lines 28-36, and page 28, lines 1-4). Document (E4) does not specifically disclose, either explicitly or implicitly, that a mixture of DNA vaccine and sugar is inevitably in a glassy state upon drying.

As a consequence, the subject-matter of claim 1 of auxiliary request 6 meets the requirements of Article 54 EPC.

9.2 Inventive step

The invention defined in claim 1 of auxiliary request 6 concerns storage-stable devices for vaccination into the skin, in particular skin patches which allow vaccination without the dangers and fear often associated with conventional needles and devices (see paragraphs [0001] and [0012] of the patent in suit).

Document (E1b), which constitutes the closest prior art, discloses a device for vaccination comprising a substantially rigid backing member having secured thereto a thin metal plate having a plurality of needle-like projections punched therefrom, and with a dried antigenic substance on each of the needle-like projections (see column 2, lines 5-10). Figures 8 and 9 show that these needle-like projections, which are identical to microneedles or microblades, are arranged in a structured form and therefore constitute an array. The figures also show that the backing member is angled on both the left and the right ends (see wing-like projections 13 and 14 in figures 5, 6 and 7). An important point to be clarified in this context is whether or not the devices according to document (E1b)

constitute skin patches, which was contested by the respondent.

Regarding a definition for the term skin patch, the patent in suit states that the patch generally comprises a backing plate from which depends a plurality of piercing protrusions such as microneedles or microblades (see page 3, lines 41-42). The devices according to document (E1b) would fall within this definition. The respondent argued that this definition was not exhaustive and that the skilled person would associate additional features to it. In particular, he would know that an important property of skin patches is that they are attached to and worn by a host, as described on page 1, lines 19-20, of document (E34).

These properties, however, are important only if the patch, as in document (E34), is worn for a longer period of time. There, attachment to the skin (see page 6, lines 1-3), effected by an adhesive layer (see paragraph bridging pages 9 and 10) and, in general, comfort for the host wearing the device (see page 1, lines 11-15) are essential and wing-like projections as described in document (E1b), which are uncomfortable and therefore not suitable for long-term treatment, would be contra-indicated.

In contrast thereto, the skin patches according to the patent in suit are destined for short-term treatment, which in its most preferred embodiment is effected within 30 seconds (see paragraph [0033] of the patent). For such a brief contact with the skin, comfort is not important. Adhesive layers are not required, as the patch can manually be pressed onto the skin. They may

even be harmful, as they can cause discomfort during removal from the skin or mucuous membrane. For such a short application period, wing-like projections according to document (E1b) are not only not contra-indicated but may even be advantageous as they facilitate the handling of the skin patch during the process of manually fixing it onto the skin or mucuous membrane. The board concludes therefrom that the definition of the term skin patch depends on its mode of application and that the devices disclosed in document (E1b) constitute skin patches which are suitable for the short-term application envisaged in the patent in suit.

This means that the devices according to document (E1b) comprise all the features of present claim 1 except for the glassy sugar. Accordingly, the problem to be solved can be defined as the provision of a skin patch comprising a vaccine and a plurality of microblades or microneedles, wherein the stability of the vaccine is improved.

As a solution to this problem, the subject-matter according to the sole claim of auxiliary request 6 proposes a glassy sugar reservoir medium containing the antigenic vaccine.

Regarding the question whether or not this problem has been plausibly solved, the board notes that the patent in suit itself does not contain any evidence demonstrating such an improvement over a device according to the closest state of the art. Despite this fact, the board is nevertheless convinced that it has indeed been plausibly solved, as it was generally known

before the effective filing date of the patent in suit that sugar glasses stabilise proteins. Reference is made to documents (E19), which states that "if a protein-based drug is mixed with a sugar-based solution and then freeze-dried, the sugars - which turn glassy as they dry - pull the proteins into a stable state (see page 1923, third complete paragraph of the left-hand column), (E21), according to which it is generally accepted that immobilisation of a protein within a glassy matrix is essential for achieving good stability during storage and that trehalose, glucose and other monosaccharides form glassy matrices (see page 236), or (E26), which mentions on page 24 (see right-hand column) that sugar molecules can protect drug molecules by "propping up" the active structure, preventing it from denaturing when the water molecules are removed. As a consequence, the protective effect was foreseeable to the skilled person so that, as mentioned above, the problem was plausibly solved.

However, in view of the fact that its plausibility is based on the general knowledge of the skilled person, the solution to the problem defined above is obvious and therefore does not involve an inventive step. In this context, the board wishes to emphasise that it cannot follow the respondent's argument that the above-mentioned general knowledge does not mention stabilisation of proteins in connection with vaccination via skin patches and is therefore not relevant to the present case. The stabilising effect described in documents (E19), (E21) and (E26) is of a general nature and not limited to specific applications. The skilled person could therefore reasonably expect said stabilising effect in connection with vaccination via

skin patches. The board also notes that the alleged painless administration due to careful selection of needle length cannot be taken into consideration, as this feature is not comprised in the claim. As a consequence, the requirements of Article 56 EPC are not met.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

The Registrar: The Chairman:

N. Maslin U. Oswald