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Datasheet for the decision of 11 January 2022

Case Number: T 1435/21 - 3.3.04

Application Number: 15853497.4

Publication Number: 3209676

IPC: C07K14/025, A61K39/00

Language of the proceedings: EN

Title of invention:
Cancer and skin lesion treatment

Applicant:
HPVVAX, LLC

Headword:
Skin cancer/HPVVAX

Relevant legal provisions:
EPC Art. 83
RPBA 2020 Art. 13(2)

Keyword:
Sufficiency of disclosure - main request (no) - auxiliary requests 1 to 3 (no)
Late-filed auxiliary requests 4 and 5 - admitted (no)

Decisions cited:

Catchword:

Europäisches Patentamt
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Case Number: T 1435/21 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 11 January 2022

Appellant: (Applicant)	HPVVAX, LLC 140 SW Chamber Court, Suite 200 Port St. Lucie, FL 34986 (US)
Representative:	Bischoff, Lukas Meissner Bolte Patentanwälte Rechtsanwälte Partnerschaft mbB Postfach 86 06 24 81633 München (DE)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 4 May 2021 refusing European patent application No. 15853497.4 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chair	P. de Heij
Members:	B. Rutz
	D. Luis Alves

Summary of Facts and Submissions

I. The appeal of the applicant (appellant) lies from the decision of the examining division refusing European patent application No. 15853497.4 entitled "*Cancer and skin lesion treatment*" ("the application").

II. In the decision under appeal the examining division held that the main request and the sole auxiliary request did not comply with the requirements of Articles 83, 84 and 123(2) EPC. The auxiliary request in addition did not comply with the requirements of Article 56 EPC.

III. With the statement setting out the grounds of appeal the appellant resubmitted the claims of the main request and of the auxiliary request as main request and auxiliary request 2, respectively. The appellant further submitted new auxiliary requests 1 and 3.

Claim 1 of the main request reads:

"1. A HPV vaccine
wherein the HPV vaccine is a HPV quadrivalent recombinant vaccine against types 6, 11, 16, and 18 comprising HPV L1 proteins and wherein the vaccine is free of host-cell antigens E6 and E7
or wherein the HPV vaccine is a HPV multivalent recombinant vaccine against types 16, 18, 31, 33, 45, 52, and 58 comprising HPV L1 proteins and wherein the vaccine is free of host-cell antigens E6 and E7,
for use in treating or in the prevention of the recurrence of melanoma, squamous cell carcinoma or basal cell carcinoma, by

a) administering to a patient 27 years of age or older or a patient previously not immunized with the HPV vaccine, a first dose of the HPV vaccine;
b) administering to the patient a second dose of the HPV vaccine about one month to about three months after the first administration; and
c) administering to the patient a third dose of the HPV vaccine about five months to about seven months after the first dose."

In claim 1 of auxiliary requests 1 and 3 the wording "in treating or in the prevention of the recurrence" is replaced by "in reducing the incidence of recurrence".

In claim 1 of auxiliary requests 2 "in treating or" and "melanoma" are deleted.

In claim 1 of auxiliary requests 3 "melanoma" is deleted.

IV. The board summoned the appellant to oral proceedings and issued a separate communication pursuant to Article 15(1) RPBA. In point 20 of this communication, the board preliminarily considered a multivalent HPV vaccine against types 16, 18, 31, 33, 45, 52, and 58 comprising HPV L1 proteins for use in treating or in the prevention of recurrence of melanoma, squamous cell carcinoma (SCC) and basal cell carcinoma (BCC) not sufficiently disclosed. In point 22 of this communication, the board considered the treatment or prevention of recurrence of melanoma not sufficiently disclosed.

V. The appellant replied and filed auxiliary requests 4 and 5 in which the alternative "or wherein the HPV vaccine is a HPV multivalent recombinant vaccine

against types 16, 18, 31, 33, 45, 52, and 58 comprising HPV L1 proteins and wherein the vaccine is free of host-cell antigens E6 and E7" was deleted from the claims. In auxiliary request 5, in addition, "melanoma" was deleted from the claims.

VI. Oral proceedings before the board took place on 11 January 2022 by videoconference as requested by the appellant. At the end of the oral proceedings, the Chair announced the board's decision.

VII. The following documents are cited in the present decision:

D4 T.-Y. Liu et al., "Advances in Peptide-based Human Papillomavirus Therapeutic Vaccines", Current Topics in Medicinal Chemistry 12(14), August 2012, 1581-92, NL ISSN: 1568-0266, DOI:10.2174/156802612802652402

D6 S. E. Vinzón et al., "HPV vaccination for prevention of skin cancer", Human Vaccines and Immunotherapeutics 11(2), February 2015, 353-7, US ISSN: 2164-5515, DOI:10.4161/21645515.2014.983858

D13 Declaration of Dr. Tim Ioannides, dated 6 July 2018

VIII. The appellant's arguments, as far as relevant to the decision, are summarised as follows:

Main request and auxiliary request 1
Sufficiency of disclosure (Article 83 EPC)

The invention was not limited to HPV-related cancers (such as SCC), as evidenced by the results shown for preventing the recurrence of BCC, which was likely not HPV-related (see e.g. document D3). In particular paragraph [00077] of the application, which stated that "[t]*he method of the present invention has been shown to treat and prevent recurrence of SCC, and to significantly reduce recurrence of BCC. It is also possible that the increase in immune surveillance, as a result of the treatment method, will concomitantly decrease the incidence of malignant melanoma*", rendered the treatment of melanoma plausible and sufficiently disclosed. Supported by the supplementary experimental data (see document D13), the requirements of Article 83 EPC were met.

Auxiliary requests 2 and 3
Sufficiency of disclosure (Article 83 EPC)

During oral proceedings the applicant argued as follows:
The multivalent vaccine referred to in the claims overlapped in two valencies (16 and 18) with the quadrivalent vaccine which had been successfully tested in the application. These were exactly the HPV types which were known in the art to be high-risk and responsible for the occurrence of cancers (reference was made to document D4, page 1581, left-hand column, first paragraph, and document D6, page 354, right-hand column, first paragraph, and the application,

paragraphs 3 and 6), while the other two types present in the quadrivalent vaccine (6 and 11) were commonly known to be low-risk and only responsible for warts (see document D6, page 354, right-hand column, first paragraph). The skilled person, based on their common general knowledge, would therefore have considered it plausible that a multivalent vaccine which covered the two most relevant HPV types for cancer (16 and 18) would have a similar therapeutic effect to the quadrivalent vaccine.

Admission of auxiliary requests 4 and 5 (Article 13(2) RPBA)

With the preliminary opinion of the Board of Appeal, the applicant was confronted with a completely new interpretation of claim 1 with respect to the feature "comprising HPV L1 proteins". Such a claim interpretation had never been discussed before the examining division and constituted an exceptional circumstance justifying the admittance of the requests. Moreover, the deletion of one alternative from the claims of auxiliary request 5 could not be considered an amendment to the appeal case as the remaining subject matter had been fully addressed in the decision under appeal and also covered in the grounds of appeal. The requests should therefore be admitted.

IX. The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the set of claims of the main request or alternatively on the basis of one of auxiliary requests 1 to 5.

Reasons for the Decision

1. The appeal complies with Articles 106 to 108 and Rule 99 EPC and is admissible.

Main request and auxiliary request 1
Sufficiency of disclosure (Article 83 EPC)

2. The decision under appeal found that treatment and prevention of recurrence of melanoma was not rendered plausible by the data in the patent or by any prior art.

3. The appellant argued that the application as filed rendered the prevention of recurrence of melanoma plausible and sufficiently disclosed because it showed results for BCC which, like melanoma, was not related to HPV. Moreover, the application in paragraph [00077] provided a physiological explanation for the treatment of melanoma: "*It is also possible that the increase in immune surveillance, as a result of the treatment method, will concomitantly decrease the incidence of malignant melanoma.*"

4. The board cannot agree with this reasoning because the treatment of BCC together with the fact that BCC is likely not related to HPV is not sufficient to demonstrate that other diseases which are equally not related to HPV would be amenable to treatment. Also a general increase in immune surveillance is not a sufficient reason to render the treatment of melanoma plausible. The mere possibility of "*decreas*[ing] *the incidence of malignant melanoma*" as stated in the application is not a sufficient disclosure for a medical treatment. The (post-published) experimental data in document D13 do not support the applicant's

position either because the experiments do not concern melanoma.

5. In conclusion, the invention to which claim 1 of the main request relates is not sufficiently disclosed. The main request is therefore not allowable.

6. The board decided to admit auxiliary request 1 into the proceedings for reasons of procedural economy. However, this claim request is equally not allowable for the same reasons as for the main request.

Auxiliary requests 2 and 3
Sufficiency of disclosure (Article 83 EPC)

7. The decision under appeal states that "*the data in the examples support only a quadrivalent vaccine comprising L1 from all of HPV types 6, 11, 16, and 18. Consequently, the medical use of the multivalent vaccine in treating and preventing the recited medical conditions is not supported*".

8. The applicant argued that HPV types 16 and 18, which were contained in both vaccines, the quadrivalent and the multivalent, were commonly known as high-risk and responsible for cancer. The applicant referred to documents D4 and D6.

9. The board, however, notes that documents D4 and D6 (and in fact all the evidence on file) with regard to types 16 and 18 refer to cervical cancer and not to skin cancer (e.g. SCC or BCC). This was confirmed by the appellant during the oral proceedings. The skilled person thus had no indication from the application as filed or from the common general knowledge as to which types of HPV were responsible for SCC and/or BCC and

had to be targeted by an effective vaccine. No more can be concluded from the data in the patent than that all four types in the quadrivalent vaccine could in principle be relevant. It was therefore not plausible that a multivalent vaccine which shared only two HPV types of a total of seven types with the quadrivalent vaccine that had been tested would have the same therapeutic effect. Even if the post-published document D13 was taken into account this would not change this conclusion. In "Case Study #1" and "Case Study #2" the patients were treated with Gardasil, the quadrivalent vaccine. In "Case Study #3" one patient having a history of SCC was treated with Gardasil 9, i.e. a multivalent vaccine including all four HPV types of the quadrivalent vaccine. This is, however, different from the multivalent vaccine referred to in claim 1, which lacks HPV types 6 and 11. The post-published evidence therefore does not allow any conclusion about the therapeutic effect of a multivalent vaccine as claimed either.

10. The board thus agrees with the decision under appeal that a multivalent HPV vaccine against types 16, 18, 31, 33, 45, 52, and 58 comprising HPV L1 proteins for use in the prevention of or for reducing the incidence of recurrence of SCC or BCC is not sufficiently disclosed. Auxiliary requests 2 and 3 are therefore not allowable.

Admission of auxiliary requests 4 and 5 (Article 13(2) RPBA)

11. Auxiliary requests 4 and 5 were filed in response to the communication by the board and after the summons to oral proceedings. Article 13(2) RPBA, which requires that "*Any amendment to a party's appeal case made [...] after notification of a summons to oral proceedings*

shall, in principle, not be taken into account unless there are exceptional circumstances, which have been justified with cogent reasons by the party concerned", therefore applies.

12. The appellant argued that the deletion of an alternative in a claim was not an amendment to its appeal case because the alternative remaining in the claim ("HPV quadrivalent recombinant vaccine") had been addressed in the decision under appeal and in the statement of grounds of appeal and therefore did not represent new subject-matter which would require separate consideration.

13. The board does not agree with this argument because the wording of Article 13(2) RPBA already makes it clear that "any amendment to a party's appeal case" (highlighting added by the board) is not limited to amendments which would introduce new subject-matter into the claims. A new claim request will usually represent a change of the party's case because it necessitates an assessment of the allowability of subject-matter which has not been the subject of the applicant's appeal case before. In the case at hand the allowability of subject-matter involving the claimed use of the quadrivalent vaccine only had not been the subject of the appeal before the summons to the oral proceedings. The board therefore considers the deletion of the multivalent vaccine from the claims an amendment to the appeal case.

14. The appellant further referred to the claim construction proposed by the board in its communication under Article 15(1) RPBA as exceptional circumstances justifying the submission of new claim requests. The board does not agree because the issue of sufficiency

of disclosure for "HPV multivalent recombinant vaccine" or for the indication melanoma, issues that auxiliary requests 4 and 5 address, cannot be regarded as being linked to the interpretation of the term "comprising L1 proteins". The board furthermore notes that the lack of sufficiency of disclosure of a multivalent HPV vaccine was already part of the decision under appeal and thus should have been addressed at least in the statement of grounds of appeal.

15. The board therefore found that no exceptional circumstances as required by Article 13(2) RPBA existed for the filing of auxiliary requests 4 and 5, and did not admit these requests into the proceedings.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chair:

I. Aperribay P. de Heij

Decision electronically authenticated