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Datasheet for the decision of 30 April 2019

Case Number: T 1702/15 - 3.3.04

Application Number: 11162713.9

Publication Number: 2377551

IPC: A61K39/145, A61K39/39

Language of the proceedings: EN

Title of invention:
Adjuvanted influenza vaccines including cytokine-inducing agents

Applicant:
Novartis AG

Headword:
Influenza vaccines against pandemic strains/NOVARTIS

Relevant legal provisions:
EPC Art. 84

Keyword:
Clarity - sole request (no)

Decisions cited:

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

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Case Number: T 1702/15 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 30 April 2019

Appellant: (Applicant)	Novartis AG Lichtstrasse 35 4056 Basel (CH)
Representative:	Marshall, Cameron John Carpmaels & Ransford LLP One Southampton Row London WC1B 5HA (GB)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 25 February 2015 refusing European patent application No. 11162713.9 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairwoman	G. Alt
Members:	D. Luis Alves
	L. Bühler

Summary of Facts and Submissions

I. The appeal by the applicant (appellant) concerns the decision of the examining division to refuse the European patent application No. 11 162 713.9, entitled "*Adjuvanted influenza vaccines including cytokine-inducing agents*". The present application is a divisional application of the European application No. 06 808 426.8.

II. In the decision under appeal the examining division held that the sole claim request on file lacked novelty (Article 54 EPC) and did not involve an inventive step (Article 56 EPC).

In particular, the examining division found that claim 1 lacked novelty over a prior-art document disclosing a composition comprising a strain of influenza subtype H3N2. The examining division referred in this respect to a second document, which cited influenza subtype H3N2 as "*responsible for the 1975 pandemic*".

III. With the statement of grounds of appeal the appellant maintained the claims on the basis of which the decision under appeal was taken. Oral proceedings were requested on an auxiliary basis.

Independent claim 1 read as follows:

"1. An immunogenic composition comprising: (i) an influenza virus antigen; (ii) an oil-in-water emulsion adjuvant; and (iii) a cytokine-inducing agent, wherein the cytokine inducing agent is an agonist of human TLR4, wherein the composition is free from ovalbumin, ovomucoid and chicken DNA and wherein the composition

is a monovalent vaccine against a pandemic influenza virus strain."

IV. The board appointed oral proceedings and subsequently issued a communication pursuant to Article 15(1) RPBA indicating its preliminary opinion on the sole claim request on file with respect to Articles 54 and 56 EPC.

Additionally, with reference to Article 111(1) EPC and decision G 10/93, the board raised new objections under Article 84 EPC, one of them being that it was not clear which virus strains were encompassed by the expression "pandemic influenza virus strain" in claim 1.

Furthermore, the board introduced the document Taubenberger, J.K. and Morens, D.M., Public Health Reports, 2010, Suppl.3, vol.125, pages 16-26, numbered as D11.

V. The appellant withdrew the request for oral proceedings and indicated its intention not to attend the oral proceedings should they take place.

No substantive submissions were made in reply to the board's communication.

VI. Oral proceedings were held as scheduled in the absence of the appellant. At the end of the oral proceedings the chair announced the board's decision.

VII. Given that the appellant did not attend the oral proceedings their substantive submissions are restricted to those filed with the statement of grounds of appeal in relation to novelty and inventive step. Insofar as relevant for the present decision, they may be summarised as follows:

The strain of subtype H3N2 disclosed in the cited prior-art document was not a "pandemic influenza virus strain", as required by claim 1.

The meaning of "pandemic influenza virus strain" was as stated in the application, on page 15, lines 25 to 31: "*The characteristics of an influenza strain that give it the potential to cause a pandemic outbreak are: (a) it contains a new hemagglutinin compared to the hemagglutinins in currently-circulating human strains, i.e. one that has not been evident in the human population for over a decade (e.g. H2), or has not previously been seen at all in the human population (e.g. H5, H6 or H9, that have generally been found only in bird populations), such that the human population will be immunologically naive to the strain's hemagglutinin; (b) it is capable of being transmitted horizontally in the human population; and (c) it is pathogenic to humans.*"

Thus, the subtype H3N2 was not referred to in this passage and the human population would not be immunologically naive to it. In fact, haemagglutinin from H3N2 was used in seasonal vaccines instead.

VIII. The appellant requested in writing that the decision under appeal be set aside and that the case be remitted to the examining division for further prosecution on the basis of the set of claims filed on 16 June 2014, or that the case be remitted to the examining division with the order to grant a patent on that basis.

Reasons for the Decision

Main request

Clarity of the claims - Article 84 EPC

1. Article 84 EPC requires that the claims shall define the matter for which protection is sought, and they shall do so in a clear manner.

   In accordance with the established case law of the boards of appeal, a claim cannot be considered clear within the meaning of Article 84 EPC if it comprises a technical feature for which no unequivocal generally accepted meaning exists in the relevant art. This applies all the more if the unclear feature is essential for delimiting the subject-matter claimed from the prior art (see Case Law of the Boards of Appeal of the European Patent Office, 8th edition 2016, II.A.3.1).

2. In the present case, the meaning of the expression "pandemic influenza virus strain" in claim 1 was decisive for the assessment of novelty of the claimed subject-matter in the decision under appeal, this expression defining the influenza virus antigen in the composition (see part (i) of claim 1).

   Thus, it must be established what the meaning of the expression "pandemic influenza virus strain" is and whether it is unambiguous.

3. With the statement of grounds of appeal, the appellant relied on the meaning that is given to this expression on page 15 of the application.

In this respect, a first point to be addressed in view of the appellant's argument is whether, and if so, to what extent the description can be used to determine the meaning of the expression "pandemic influenza virus strain".

In the following analysis the board assumes, in favour of the appellant, that the expression "pandemic influenza virus strain" can in the present case be interpreted taking into account the definition given in the description.

4. The appellant refers to the definition of "pandemic strain" given on page 15, lines 25 to 31 of the application. The whole paragraph containing the passage in question reads as follows: "*The characteristics of an influenza strain that give it the potential to cause a pandemic outbreak are: (a) it contains a new hemagglutinin compared to the hemagglutinins in currently-circulating human strains, i.e. one that has not been evident in the human population for over a decade (e.g. H2), or has not previously been seen at all in the human population (e.g. H5, H6 or H9, that have generally been found only in bird populations), such that the human population will be immunologically naive to the strain's hemagglutinin; (b) it is capable of being transmitted horizontally in the human population; and (c) it is pathogenic to humans. A virus with H5 haemagglutinin type is preferred for immunising against pandemic influenza, such as a H5N1 strain. Other possible strains include H5N3, H9N2, H2N2, H7N1 and H7N7, and any other emerging potentially pandemic strains.*"

This paragraph does not provide an exhaustive list of influenza strains that are influenza pandemic strains.

Rather, it expressly states that possible strains include *"any other emerging potentially pandemic strains"*. Due to this definition - which is functional and open - the definition of pandemic strains according to the description includes future, unknown developments.

In the board's view, the skilled person cannot know at a given point in time which strains will be "pandemic" in the future on the basis of their common general knowledge. This is illustrated by document D11, published in 2010 and entitled: "*Influenza: The Once and Future Pandemic*", in which the authors state: "*[...] we are still unable to predict future pandemics, as evidenced by the completely unexpected emergence of the 2009 swine-origin H1N1 virus.*" (see page 22, left-hand column, third paragraph, last sentence). This is also illustrated by the disclosure in the present application, with effective date 2005, which identifies, on page 15, line 11, subtype H1N1 as one used in inter-pandemic periods, whereas this subtype was in fact the one causing the 2009 influenza pandemic (see document D11).

5. Thus, the meaning of the expression "pandemic influenza virus strain" in claim 1 depends on the point in time at which the claims are assessed.

6. In light of all the above, the expression "pandemic influenza virus strain" does not have an unequivocal generally accepted meaning and thus lacks clarity. The subject-matter of claim 1 does not comply with the requirements of Article 84 EPC.

7. In the board's view, the expression "pandemic influenza virus strain" is unclear regardless of how widely used

the expression might be in the research and public health domain.

8. Consequently, the sole request on file is not allowable.

Order

For these reasons it is decided that:

1. The appeal is dismissed.

The Registrar: The Chair:

I. Aperribay G. Alt

Decision electronically authenticated