

Internal distribution code:

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

**Datasheet for the decision
of 3 May 2017**

Case Number: T 1138/13 - 3.3.04

Application Number: 05800771.7

Publication Number: 1812059

IPC: A61K39/35

Language of the proceedings: EN

Title of invention:

Method of preventive treatment of allergy by mucosal
administration of an allergy vaccine

Patent Proprietor:

Alk-Abelló A/S

Opponent:

Stallergenes SA

Headword:

Preventive treatment of allergy/ALK-ABELLÓ

Relevant legal provisions:

EPC Art. 84

EPC R. 115(2)

RPBA Art. 15(3)

Keyword:

Main request, auxiliary requests 1 to 3 - clarity (no)

Decisions cited:

G 0009/91, G 0003/14, T 0301/87

Catchword:



Beschwerdekammern
Boards of Appeal
Chambres de recours

European Patent Office
D-80298 MUNICH
GERMANY
Tel. +49 (0) 89 2399-0
Fax +49 (0) 89 2399-4465

Case Number: T 1138/13 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 3 May 2017

Appellant: Stallergenes SA
(Opponent) 6, rue Alexis de Tocqueville
92183 Antony Cedex (FR)

Representative: Lavoix
2, place d'Estienne d'Orves
75441 Paris Cedex 09 (FR)

Respondent: Alk-Abelló A/S
(Patent Proprietor) Bøge Allé 6-8
2970 Hørsholm (DK)

Representative: Inspicos P/S
Kogle Allé 2
2970 Hørsholm (DK)

Decision under appeal: Interlocutory decision of the Opposition
Division of the European Patent Office posted on
7 March 2013 concerning maintenance of the
European Patent No. 1812059 in amended form.

Composition of the Board:

Chairwoman G. Alt
Members: R. Morawetz
L. Bühler

Summary of Facts and Submissions

- I. The appeal of the opponent (hereinafter "the appellant") lies against the decision of the opposition division maintaining European patent No. 1 812 059 in amended form.
- II. The patent at issue has the title "*Method of preventive treatment of allergy by mucosal administration of an allergy vaccine*". It was granted in respect of European patent application No. 05 800 771.7.

Claim 1 as granted read:

"1. An allergen for use in preventive treatment of allergy by administering an allergy vaccine comprising the allergen to a mucosal surface of a subject,

- a) wherein the subject to be treated is sensitised so as to exhibit an IgE response specific to the allergen,
- b) wherein the subject to be treated is free of clinical symptoms of the allergy associated with the allergen, and
- c) wherein the preventive treatment is aimed at preventing or reducing subsequent clinical symptoms of the allergy associated with the allergen."

- III. An opposition was filed invoking the grounds of lack of novelty (Article 54 EPC) and lack of inventive step (Article 56 EPC) under Article 100(a) EPC and the grounds under Article 100(b) and (c) EPC.
- IV. The opposition division maintained the patent on the basis of auxiliary request 2 filed during the oral proceedings before it.

- V. In its statement of grounds of appeal the appellant raised objections under Articles 54, 56, 83 and 84 EPC.
- VI. With its reply to the statement of grounds of appeal the proprietor (hereinafter "the respondent") made the documents on the basis of which the patent was maintained by the opposition division its main request and submitted auxiliary requests 1 to 3.

Claim 1 of the main request reads:

"1. An allergen for use in preventive treatment of allergy by administering an allergy vaccine comprising the allergen to a mucosal surface of a subject,

a) wherein the subject to be treated is sensitised so as to exhibit an IgE response specific to the allergen,

b) wherein the subject to be treated has not yet shown any clinical symptoms of the allergy associated with the allergen, and

c) wherein the preventive treatment is aimed at preventing or reducing subsequent clinical symptoms of the allergy associated with the allergen."

The subject-matter of claim 1 of auxiliary request 1 differs from the subject-matter of claim 1 of the main request in that it further specifies that the allergy vaccine is administered via the oromucosal route.

The subject-matter of claim 1 of auxiliary request 2 differs from the subject-matter of claim 1 of the main request in that the term "*subject*" has been replaced with "*person*".

The subject-matter of claim 1 of auxiliary request 3 differs from the subject-matter of claim 1 of the main request in that it includes both of the above amendments.

- VII. The parties were summoned to oral proceedings and informed of the board's preliminary opinion in a communication pursuant to Article 15(1) RPBA. The board noted *inter alia* that "*it might need to be considered whether the amendment of claim 1 resulted in a lack of clarity of claim 1 itself (see G 9/91, OJ EPO 1993, 408; reasons, point 19). For the clarity requirement of Article 84 EPC to be met, the skilled person who reads the claim against the background of his common general knowledge must be able to unambiguously distinguish subjects that have not yet shown any clinical symptoms of the allergy associated with the allergen to be administered from those which have*" (see point 31 of the communication).
- VIII. Oral proceedings were held on 3 May 2017. The respondent was not present or represented, as announced beforehand in writing. At the end of the oral proceedings the chairwoman announced the board's decision.
- IX. The arguments of the appellant may be summarised as follows:

Main request

Clarity (Article 84 EPC) - claim 1

The appellant agreed with the provisional opinion of the board in its communication that the skilled person

could not differentiate between subjects to be treated and those that should not be treated.

Many of the clinical symptoms associated with an allergy were not specific to allergy but could have other causes, such as an infection or exposure to irritants. For example, sneezing could also be due to a viral infection or exposure to dust.

In addition, clinical symptoms were also not allergen-specific. High-risk patients who had already developed an allergy against a particular grass pollen might become sensitised against a different grass pollen. As the clinical symptoms caused by both allergens were the same, it was impossible to differentiate between those caused by one or the other.

Accordingly, it could not be determined whether the subject had not yet shown any clinical symptoms of the allergy associated with the allergen to be administered.

Auxiliary requests 1 to 3

Clarity (Article 84 EPC) - claim 1

The objections raised against claim 1 of the main request applied *mutatis mutandis*.

- X. The arguments of the respondent submitted in writing may be summarised as follows:

Main request

Clarity (Article 84 EPC) - claim 1

The limitation in claim 1 simply meant that the treated subject was at present, and had previously been, free of any symptoms relating to the specific allergy treated.

- XI. The appellant requested that the decision under appeal be set aside and that the patent be revoked.

The respondent requested in writing that the appeal be dismissed (main request), or, alternatively, that the patent be maintained according to any one of auxiliary requests 1 to 3 filed with the reply to the statement of grounds of appeal.

Reasons for the Decision

1. The duly summoned respondent was neither present nor represented at the oral proceedings. The board considered it expedient to conduct the scheduled oral proceedings in its absence in order to reach a final decision in this appeal case (Rule 115(2) EPC and Article 15(3) RPBA).

Main request

Clarity (Article 84 EPC) - claim 1

2. Claim 1 of the main request was amended before the opposition division by replacing the feature "*is free*

of clinical symptoms", present in claim 1 as granted (see section II above), with the feature "*has not yet shown any clinical symptoms*". This amendment does not derive from a dependent claim as granted but from the description (see decision under appeal, points 34 to 38). Accordingly, under Article 101(3) EPC the board must consider whether the amendment in any way infringes the Convention, including Article 84 EPC (see T 301/87, OJ EPO 1990, 335, Headnote 1 and G 3/14, OJ EPO 2015, 102, reasons, point 87).

3. Article 84, second sentence, EPC requires the claims to be clear.
4. Claim 1 is directed to a second medical use wherein the subject intended to receive the allergy vaccine is defined as being "*sensitised so as to exhibit an IgE response specific to the allergen*" but "*has not yet shown any clinical symptoms of the allergy associated with the allergen*" (see section VI above for the complete wording of the claim). Thus, in the present case, for the clarity requirement of Article 84 EPC to be met, the skilled person who reads the claim against the background of his common general knowledge must be able to unambiguously distinguish subjects who have not yet shown any clinical symptoms of the allergy associated with the allergen to be administered from those who have. The latter are not eligible for treatment with the allergy vaccine.
5. The claim itself does not define the clinical symptoms of the allergy associated with the allergen to be administered, or indicate any objective measurable criteria for assigning clinical symptoms to the allergen to be administered. The question to be decided is thus whether or not there exists a clear

understanding, i.e. one that is unequivocal and generally accepted, of which clinical symptoms are associated with a given allergen.

6. Conventional clinical symptoms of an allergy include rhinitis, conjunctivitis, rhinorrhea, nasal obstruction, sinusitis, sneezing, atopic dermatitis, itching, watery eyes, watery nose, wheezing and skin irritation (see also paragraph [0056] of the patent).
7. However, these clinical symptoms are not specific for allergies. Indeed, e.g. sneezing can be caused by an allergen, but also by a viral infection or by exposure to dust or other irritants. Accordingly, if a subject, having been sensitised so as to exhibit an IgE response specific to a pollen allergen, sneezes this could be - but is not necessarily - a clinical symptom of an allergy. Thus, it is impossible to determine whether or not the subject *"has not yet shown any clinical symptoms of the allergy associated with the allergen"*.
8. Moreover, clinical symptoms caused by an allergy to allergen A are not necessarily distinguishable from those caused by an allergy to allergen B, as clinical symptoms too are not allergen-specific. Thus, a patient who has already developed an allergy to a particular pollen A, may become sensitised against a different pollen B, i.e. exhibit an IgE response specific to pollen B. If this patient is exposed simultaneously to both allergens A and B and shows clinical symptoms usually associated with a pollen allergy, e.g. nasal obstruction, watery eyes and watery nose, it is impossible to distinguish the clinical symptoms caused by pollen A from those caused by pollen B, because they are the same in both cases. Accordingly, it cannot be unambiguously determined whether the subject has not

yet shown any clinical symptoms of the allergy associated with allergen B.

9. The board concludes from the above that the skilled person cannot unambiguously distinguish subjects who have not yet shown any clinical symptoms of the allergy associated with the allergen to be administered from those which have, and is thus unable to unambiguously distinguish patients who should be treated with the allergy vaccine from those who should not. Consequently, claim 1 does not comply with the clarity requirement of Article 84 EPC.

Auxiliary requests 1 to 3

Clarity (Article 84 EPC) - claim 1

10. The objections set out above for the subject-matter of claim 1 of the main request apply *mutatis mutandis* to the subject-matter of claim 1 of auxiliary requests 1 to 3, because all these claims define the subject/person to be treated as having "*not yet shown any clinical symptoms of the allergy associated with the allergen*". Therefore, claim 1 of these requests likewise fails to comply with Article 84 EPC.
11. In the absence of an allowable claim request, the patent has to be revoked.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The patent is revoked.

The Registrar:

The Chairwoman:



P. Cremona

G. Alt

Decision electronically authenticated