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Datasheet for the decision of 27 September 2021

Case Number: T 2395/16 - 3.3.02

Application Number: 14150998.4

Publication Number: 2719395

IPC: A61K39/00, A61K39/095, C07D487/04, C07D471/04, C07D239/48

Language of the proceedings: EN

Title of invention:
Adsorption of immunopotentiators to insoluble metal salts

Applicant:
GlaxoSmithKline Biologicals SA

Headword:

Relevant legal provisions:
EPC Art. 84

Keyword:
Claims - clarity

Decisions cited:

Catchword:

Europäisches Patentamt
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Beschwerdekammern

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Case Number: T 2395/16 - 3.3.02

D E C I S I O N
of Technical Board of Appeal 3.3.02
of 27 September 2021

Appellant: (Applicant)	GlaxoSmithKline Biologicals SA Rue de l'Institut 89 1330 Rixensart (BE)
Representative:	Furstoss, Olivia Aline GlaxoSmithKline Global Patents (CN925.1) 980 Great West Road Brentford, Middlesex, TW8 9GS (GB)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 2 June 2016 refusing European patent application No. 14150998.4 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman	M. O. Müller
Members:	A. Lenzen
	L. Bühler

Summary of Facts and Submissions

I. This decision concerns the appeal filed by the patent applicant (appellant) against the decision of the examining division (decision under appeal) to refuse European patent application No. 14 150 998.4 (application).

II. The decision under appeal is based on a request of which the set of claims was filed in electronic form on 31 March 2016. The examining division decided, *inter alia*, that this set of claims lacked clarity.

III. The appellant requested that the decision under appeal be set aside and that a patent be granted based on the set of claims on which the decision under appeal is based (main request).

IV. In preparation for the oral proceedings scheduled at the appellant's request, the board issued a communication pursuant to Article 15(1) RPBA 2020 observing, *inter alia*, that the claims of the main request lacked clarity.

V. By letter of 10 September 2021, the appellant announced that it would not attend the oral proceedings. The board then cancelled the oral proceedings.

VI. The appellant's appeal case, where relevant for the present decision, can be summarised as follows:

The examining division's clarity objections in the decision under appeal were not convincing. The claim

language made perfect sense and was perfectly clear to the skilled person, when properly interpreted.

Reasons for the Decision

Main request - clarity (Article 84 EPC)

1. Claims 1 to 5 of the main request read as follows:

Claim 1

"*A composition comprising a TLR agonist and an insoluble metal salt, wherein the TLR agonist comprises at least one adsorptive moiety, wherein the isoluble* [sic] *metal salt is an insoluble aluminium salt or an insoluble calcium salt and the adsorptive moiety comprises a phosphate, a phosphonate, a phosphinate, a phosphonite or a phosphinite, and wherein the TLR agonist is adsorbed onto the insoluble metal salt, with the proviso that the TLR agonist:*

(a) is not a TLR4 agonist;
(b) is not a TLR9 agonist;
(c) is not a compound according to formula (I) or (II) ...;
(d) is not a compound according to formula (III) ...;
(e) is not a compound according to formula (I-A) ... ."

Claim 2

"*The composition of claim 1, wherein at least 80% of the total TLR agonist in the composition is adsorbed onto insoluble metal salt.*"

Claim 3

"*The composition of claim 1 or claim 2, wherein the adsorbed TLR agonist is, when injected intramuscularly, still present in the injected muscle at least 12 hours later.*"

Claim 4

"*The composition of claim 1 or claim 3, wherein the adsorbed TLR agonist, when injected intramuscularly, has a lower peak serum concentration (Cmax) than the same TLR agonist when injected intramuscularly in non-adsorbed form.*"

Claim 5

"*A composition comprising: (a) an adjuvant complex comprising a TLR agonist adsorbed to an insoluble metal salt, according to claim 1; and (b) at least two different immunogens.*"

2. As explained by the board in its communication pursuant to Article 15(1) RPBA 2020, claims 1 to 5 lack clarity for the following reasons:

2.1 Claim 1 stipulates that "*the TLR agonist comprises at least one adsorptive moiety*" and further that "*the adsorptive moiety comprises a phosphate, a phosphonate, a phosphinate, a phosphonite or a phosphinite*".

By way of the "comprising language", claim 1 is not formulated in such a way that the adsorptive moiety is necessarily to be equated to a phosphate, phosphonate, phosphinate, phosphonite or phosphinite group. Instead,

the adsorptive moiety can also comprise a much larger part of the TLR agonist than just these phosphorous-containing functional groups. However, it is completely unclear which parts of the TLR agonist actually constitute the adsorptive moiety.

2.2 Claim 1 also relates to "*A composition comprising ... an insoluble metal salt, ... wherein the isoluble* [sic] *metal salt is an insoluble aluminium salt or an insoluble calcium salt*".

Claim 1 does not specify a solubility threshold according to which a particular salt could be qualified as "*insoluble*". Furthermore, the solubility of salts in general and also the solubility of a particular aluminium/calcium salt depend not only on the chemical composition of the salt itself but also on that of the composition comprising it. For instance, the application in the present case gives aluminium hydroxide as an example for an insoluble aluminium salt (page 36, line 5). Due to its amphoteric nature, the solubility of this salt is highly dependent on the pH of the composition containing it. Consequently, it is unclear when a salt is to be considered "*insoluble*" within the meaning of claim 1 and when it is not.

2.3 Claim 2 requires that "*at least 80% of the total TLR agonist in the composition is adsorbed onto insoluble metal salt*".

However, claim 2 does not specify whether the percentages are meant to be wt.-% or mol-%. It does not specify how the amount of adsorbed TLR is to be determined either. This renders claim 2 unclear.

2.4 Claims 3 and 4 are formulated as results to be achieved

- claim 3: "*wherein the adsorbed TLR agonist is, when injected intramuscularly, still present in the injected muscle at least 12 hours later*",
- claim 4: "*wherein the adsorbed TLR agonist, when injected intramuscularly, has a lower peak serum concentration (Cmax) than the same TLR agonist when injected intramuscularly in non-adsorbed form*".

However, both claims lack the measures necessary to achieve the indicated results. Claims 3 and 4 are thus unclear.

2.5 In claim 5 it is unclear whether the "*according to claim 1*" relates to "*an adjuvant complex*", "*a TLR agonist*" or "*an insoluble metal salt*". The comma before "*according to claim 1*" seems to suggest that it refers to "*an adjuvant complex*". However, no such "*adjuvant complex*" is mentioned in claim 1.

3. Following the board's communication pursuant to Article 15(1) RPBA 2020, the appellant did not challenge the board's preliminary view. Instead, by letter of 10 September 2021, it announced that it would not attend the oral proceedings and that written submissions were to be relied upon.

The appellant's only written substantive submission in the present case was its statement of grounds of appeal. In it, the appellant had addressed the clarity objections contained in the decision under appeal. However, these clarity objections differ from those raised by the board (for details, see the decision under appeal, points 26 to 28). The arguments put forward by the appellant in its statement of grounds of

appeal, therefore, have no bearing on the above assessment.

4. For the reasons given above, claims 1 to 5 of the main request lack clarity and the main request is not allowable.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

G. Nachtigall M. O. Müller

Decision electronically authenticated