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Datasheet for the decision of 14 July 2025

Case Number: T 1351/23 - 3.3.07

Application Number: 17159560.6

Publication Number: 3228315

IPC: A61K31/573, A61K39/395, C07K16/28

Language of the proceedings: EN

Title of invention:
PREVENTION OF ADVERSE EFFECTS CAUSED BY CD3 SPECIFIC BINDING DOMAINS

Patent Proprietor:
Amgen Research (Munich) GmbH

Opponents:
James Poole Limited
F. Hoffmann-La Roche AG

Headword:
Blinatumomab/AMGEN

Relevant legal provisions:
RPBA 2020 Art. 12(6), 11
EPC Art. 84, 111

Keyword:
Carry-over requests - admitted (yes)
Clarity (yes)
Remittal (yes)

Decisions cited:
G 0001/24

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Boards of Appeal

Chambres de recours

Boards of Appeal of the
European Patent Office
Richard-Reitzner-Allee 8
85540 Haar
GERMANY
Tel. +49 (0)89 2399-0

Case Number: T 1351/23 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 14 July 2025

Appellant: (Patent Proprietor)	Amgen Research (Munich) GmbH Staffelseestrasse 2 81477 München (DE)
Representative:	Schiweck Weinzierl Koch Patentanwälte Partnerschaft mbB Ganghoferstraße 68 B 80339 München (DE)
Respondent: (Opponent 1)	James Poole Limited One Southampton Row London WC1B 5HA (GB)
Representative:	Carpmaels & Ransford LLP One Southampton Row London WC1B 5HA (GB)
Respondent: (Opponent 2)	F. Hoffmann-La Roche AG Grenzacherstrasse 124 4070 Basel (CH)
Representative:	Mewburn Ellis LLP Aurora Building Counterslip Bristol BS1 6BX (GB)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 19 May 2023 revoking European patent No. 3228315 pursuant to Article 101(3)(b) EPC**

Composition of the Board:

Chairman	A. Usuelli
Members:	J. Molina de Alba
	Y. Podbielski

Summary of Facts and Submissions

I. The decision under appeal is the opposition division's decision revoking the European patent. The decision is based on the claims of a main request and 15 auxiliary requests.

II. In the decision, the opposition division concluded, among other things, the following:

- the subject-matter of the main request was not novel,
- the subject-matter of auxiliary request 1 was not inventive,
- auxiliary requests 2 to 5 and 7 to 15 were not admitted into the proceedings, and
- auxiliary request 6 lacked clarity.

III. The patent proprietor (appellant) filed an appeal against the decision. With its statement of grounds of appeal, the appellant re-filed the claims of the main request and auxiliary requests 1 to 15 on which the decision was based.

IV. In their replies to the statement of grounds of appeal, opponent 1 (respondent 1) and opponent 2 (respondent 2) requested, among other things, that the appeal be dismissed.

V. The Board scheduled oral proceedings, in line with the parties' requests, and issued a communication with its preliminary opinion on the case.

VI. As agreed by the parties, the oral proceedings before the Board were held by videoconference.

At the beginning of the oral proceedings, the appellant withdrew the main request and auxiliary requests 1 and 12 to 15.

At the end of the oral proceedings, the Board announced its decision.

VII. The present decision is based on auxiliary requests 2 to 11 on which the decision under appeal was based. They were filed on 26 January 2023 and re-filed with the statement of grounds of appeal. Although the main request and auxiliary request 1 on which the decision was based were withdrawn by the appellant at the oral proceedings before the Board, their wording has been specified below to make the discussion of the admittance of auxiliary requests 2 to 5 and 7 to 11 easier to understand.

Claim 1 of the main request withdrawn at the oral proceedings before the Board was identical to claim 1 as granted and read as follows:

"*1. A pharmaceutical composition comprising glucocorticoid (GC) for use in the prophylaxis or mitigation of neurological adverse events caused by the administration of a CD3 binding domain, wherein the GC is administered prior to the administration of the CD3 binding domain and the neurological adverse event, wherein said neurological adverse event is one or more of disturbances of the senses, seizures, encephalopathy, cerebral edema, confusion, ataxia, apraxia, speech disorder, paresis, tremor, or*

disorientation, wherein the CD3 binding domain is a CD19xCD3 bispecific antibody."

Claim 1 of auxiliary request 1 withdrawn at the oral proceedings before the Board differed from claim 1 as granted in that the GC was specified to be dexamethasone.

Claim 1 of auxiliary request 2 differs from claim 1 as granted in that the following passage has been added at the end of the claim:

"*wherein a first dose of the CD3 binding domain is administered for a first period of time and consecutively a second dose of the CD3 binding domain is administered for a second period of time, wherein the second dose exceeds the first dose, wherein the GC is administered prior to the administration of the first dose of the CD3 binding domain and prior to the administration of the second dose of the CD3 binding domain.*"

Claim 1 of auxiliary request 3 is identical to claim 1 of auxiliary request 2.

Claim 1 of auxiliary request 4 differs from claim 1 of auxiliary request 2 in that the order of the sentences in the added passage has been changed. The added passage in auxiliary request 4 reads as follows:

"*wherein the GC is administered prior to the administration of the first dose of the CD3 binding domain and prior to the administration of the second dose of the CD3 binding domain, wherein a first dose of the CD3 binding domain is administered for a first period of time and consecutively a second dose of the*

CD3 binding domain is administered for a second period of time, wherein the second dose exceeds the first dose."

Claim 1 of auxiliary request 5 differs from claim 1 of auxiliary request 2 in that the GC has been specified to be dexamethasone.

Claim 1 of auxiliary request 6 is identical to claim 1 of auxiliary request 5.

Claim 1 of auxiliary request 7 differs from claim 1 as granted in that the following passage has been added at the end of the claim:

"*wherein a first dose of the CD3 binding domain is administered for a first period of time and consecutively a second dose of the CD3 binding domain is administered for a second period of time, wherein the second dose exceeds the first dose, wherein after a first and second dose of the CD3 binding domain for a first and second period of time, a third dose of the CD3 binding domain is administered, wherein the third dose exceeds the first and second dose, wherein the GC is administered prior to the administration of the first dose of the CD3 binding domain and prior to the administration of the second and third dose of the CD3 binding domain.*"

Claim 1 of each of auxiliary requests 8 and 9 is identical to claim 1 of auxiliary request 7.

Claim 1 of auxiliary request 10 differs from claim 1 of auxiliary request 7 in that the GC has been specified to be dexamethasone.

Claim 1 of auxiliary request 11 is identical to claim 1 of auxiliary request 10.

VIII. The appellant's arguments, where relevant to the present decision, can be summarised as follows.

Admittance of auxiliary requests 2 to 5 and 7 to 11

By not admitting auxiliary requests 2 to 5 and 7 to 11, the opposition division erred in the exercise of its discretion. The auxiliary requests were not late filed. Not only were they identical to auxiliary requests 6 to 9 and 11 to 15 filed with the reply to the notices of opposition, but they had also been filed before the final date fixed under Rule 116 EPC. The respondents had dealt with the auxiliary requests in the written proceedings and the opposition division had indicated in its communication in preparation for the oral proceedings that the requests complied with the EPC. Therefore, auxiliary requests 2 to 5 and 7 to 11 were filed on time and *prima facie* relevant, and the respondents and the opposition division had had sufficient time to deal with them. Furthermore, the requests streamlined the proceedings because they addressed the objections raised against the main request.

Clarity of claim 1 of auxiliary request 2

The condition in claim 1 of auxiliary request 2 that the GC was administered prior to the first dose and prior to the second dose of the CD3 binding domain was clear. The only reasonable interpretation of this condition was that the GC was administered prior to the first dose and between the first and the second dose. The interpretation that this condition encompassed

embodiments in which the GC could be administered exclusively prior to the first dose was artificial and did not reflect the skilled person's understanding.

The condition that the second dose exceeds the first dose was also clear. The skilled person knew that a dose related to the amount administered rather than to the time of administration. Claim 1 was unambiguous in that the amount of the CD3 binding domain administered with the second dose was greater than the amount administered with the first dose. The teaching in paragraph [0064] of the patent was not inconsistent with this understanding and did not render claim 1 unclear. Paragraph [0064] related to a preferred embodiment in which the amount administered in a dose was additionally associated with its time of administration.

Therefore, it was clear to the skilled person that claim 1 defined an escalating dosage regimen as illustrated in the example in paragraph [0088] of the patent.

IX. The respondents' arguments, where relevant to the present decision, can be summarised as follows.

Admittance of auxiliary requests 2 to 5 and 7 to 11

The opposition division was correct not to admit auxiliary requests 2 to 5 and 7 to 11. The requests resulted from a selection and renumbering of the auxiliary requests filed with the reply to the notices of opposition. Therefore, they changed the appellant's case and the opposition division had discretion not to admit them. The new auxiliary requests did not have to be admitted just because they had been filed before the

date fixed under Rule 116 EPC. They were not admissible because they were not convergent with the main request and auxiliary request 1, raised new added subject-matter and clarity issues, and changed the discussion of novelty and inventive step with regard to the previous requests. Consequently, the new auxiliary requests were not *prima facie* allowable and went against the principle of procedural economy. The opposition division's preliminary opinion could not justify their admittance since the opinion was not binding and could change at any time.

Clarity of claim 1 of auxiliary request 2

The condition in claim 1 of auxiliary request 2 that the GC was administered prior to the first dose and prior to the second dose of the CD3 binding domain was unclear. This condition allowed for three different interpretations: the GC could be administered (i) only once before the first dose, (ii) twice before the first dose, or (iii) once before the first dose and once between the first and the second dose. Each of these interpretations was technically sensible and was supported by examples in the patent. The fact that one interpretation looked more likely did not exclude the others.

The condition in claim 1 that the second dose exceeds the first dose was also unclear. In accordance with G 1/24, the description had to be taken into account to interpret claim 1. When claim 1 was read in the light of paragraphs [0063] and [0064] of the description, the term "exceeds" was inconsistent. From the wording of claim 1, which mirrored that of paragraph [0063], the skilled person would understand that a dose related to the administered amount. The term "exceeds" in claim 1

would then require the amount of CD3 binding domain administered with the second dose to be greater than the amount administered with the first dose. However, paragraph [0064] stated that the term "exceeds" meant that the time of administration was at least one day longer, i.e. it related not to the administered amount but to the time of administration. As both interpretations of the term "exceeds" were technically sensible in the context of the invention, it was uncertain whether the term in claim 1 had to be interpreted as relating to amounts, times or both.

X. The parties' final requests, as far as relevant to the present decision, were as follows.

- The appellant requested that the decision under appeal be set aside, that auxiliary requests 2 to 5 and 7 to 11 be admitted into the proceedings, and that the case be remitted to the opposition division if one of auxiliary requests 2 to 11 was found to comply with Article 84 EPC.

  As an auxiliary measure the appellant requested that the patent be maintained in amended form on the basis of the claims of one of auxiliary requests 2 to 11.

- Respondent 1 requested that the appeal be dismissed.

  It also requested that auxiliary requests 2 to 5 and 7 to 15 not be admitted into the proceedings. Furthermore, respondent 1 requested that the case be remitted to the opposition division if any of auxiliary requests 2 to 5 and 7 to 11 were admitted into the proceedings and if any of auxiliary

requests 2 to 11 were found to meet the requirements of Article 84 EPC.

- Respondent 2 requested that the appeal be dismissed.

  In addition, it requested that the case be remitted to the opposition division if either the opposition division's decision not to admit auxiliary requests 2 to 5 and 7 to 15 was reversed or auxiliary request 6 was found to meet the requirements of Article 84 EPC.

Reasons for the Decision

1. The opposition division's decision not to admit auxiliary requests 2 to 5 and 7 to 11

1.1 Auxiliary requests 2 to 5 and 7 to 11 were filed on 26 January 2023, i.e. one day before the final date fixed by the opposition division under Rule 116 EPC. They were identical to auxiliary requests 6 to 9 and 11 to 15 filed with the reply to the notices of opposition. Auxiliary requests 2 to 5 and 7 to 10 contained dependent claims of the patent as granted that had been deleted in the main request and auxiliary request 1 filed on the same date. In addition, claim 1 of each of auxiliary requests 2 to 4 and 7 to 9 was broader than claim 1 of auxiliary request 1 in that the glucocorticoid (GC) was not limited to dexamethasone.

1.2 In its communication in preparation for the oral proceedings, the opposition division conveyed the

preliminary opinion that auxiliary requests 6 to 15, now auxiliary requests 2 to 11, complied with the EPC (see page 1, point 3.3 and page 17, fifth line from the bottom). Nevertheless, at the oral proceedings, the opposition division decided not to admit auxiliary requests 2 to 5 and 7 to 11 for three reasons (decision, points 25.2, 26 and 30): (i) auxiliary requests 2 to 5 and 7 to 10 reinstated dependent claims that were not present in the main request and auxiliary request 1; (ii) auxiliary requests 2 to 4 and 7 to 9 were not convergent with auxiliary request 1 because they did not limit the GC to dexamethasone; and (iii) auxiliary requests 7 to 11 raised a clarity issue that had already been discussed for auxiliary request 6 at the oral proceedings.

1.3 In accordance with Article 12(6) RPBA, the Board should not admit requests which were not admitted in the proceedings leading to the decision under appeal, unless the decision not to admit them suffered from an error in the use of discretion or unless the circumstances of the appeal case justify their admittance.

1.4 It is established case law of the Boards of Appeal that the primary facts to be considered by an opposition division when admitting or disregarding claim requests filed at late stages of the opposition proceedings are the point in time at which the claim requests were filed and whether they *prima facie* overcome the outstanding objections. In relation to the point in time at which the claim requests were filed, the opposition division may also need to assess whether the claim requests were filed in response to a change in the proceedings, whether the opponents and the opposition division had sufficient time to consider the

amendments and whether the late filing of the claim requests could constitute an abuse of procedure (Case Law, 10th ed., 2022, IV.C.5.1.4(d) and 11th ed., 2025, IV.C.5.1.7).

In the Board's view, the opposition division did not correctly apply these principles when it decided not to admit auxiliary requests 2 to 5 and 7 to 11 into the proceedings.

1.4.1 The opposition division failed to take proper account of the circumstances at the point in time at which the claim requests were filed.

In point 25.2 of the decision, the opposition division correctly acknowledged that auxiliary request 2 could not be considered late filed. The Board agrees with this conclusion and holds that the same is true for auxiliary requests 3 to 5 and 7 to 11.

Auxiliary requests 2 to 5 and 7 to 11 had been initially filed as auxiliary requests 6 to 9 and 11 to 15 with the reply to the notices of opposition. This was the earliest possible opportunity for the appellant to file amendments in the opposition proceedings. The day before the final date fixed under Rule 116 EPC, the appellant promoted initial auxiliary requests 6 to 9 and 11 to 15 to auxiliary requests 2 to 5 and 7 to 11. This change of the appellant's case constituted an adequate response to the opposition division's preliminary opinion that initial auxiliary requests 6 to 9 and 11 to 15 complied with the EPC. In addition, the change streamlined the proceedings as they stood on the date at which said change was submitted since it involved withdrawing several higher-ranking requests

and promoting claim requests that the opposition division had preliminarily considered allowable.

Under such circumstances, the position that auxiliary requests 2 to 5 and 7 to 11 were late filed can hardly be defended. The Board also notes that the opposition division and the respondents have never argued that the number or nature of the amendments in auxiliary requests 2 to 5 and 7 to 11 constitute an abuse of proceedings, nor that they did not have enough time to deal with the amendments before the oral proceedings.

However, despite considering that auxiliary request 2 was not late filed, the opposition division held that this was immaterial for the issue of admittance. This conclusion is surprising since neither Article 114(2) EPC nor Rule 116 EPC gives the opposition division discretion to disregard submissions that were filed in due time. For this reason alone, the decision not to admit auxiliary requests 2 to 5 and 7 to 11 was flawed.

1.4.2 With regard to the question of whether auxiliary requests 2 to 5 and 7 to 11 were *prima facie* suitable to overcome the objections raised up to the time of their filing, the decision under appeal does not provide any reasons. However, it is clear that the requests had to be regarded as *prima facie* suitable to overcome those objections since the opposition division had considered in its preliminary opinion that they complied with the EPC.

1.4.3 The reasons put forward by the opposition division for disregarding auxiliary requests 2 to 5 and 7 to 11 were set out in points 25.2, 26 and 30 of the decision under appeal. These were also the reasons raised by the respondents in these appeal proceedings. First, it was

argued that auxiliary requests 2 to 5 and 7 to 10 contained dependent claims that had been removed in the main request and auxiliary request 1. Second, it was argued that auxiliary requests 2 to 4 and 7 to 9 were not convergent with auxiliary request 1 because they did not contain the limitation that the GC was dexamethasone.

Neither of these reasons can prevail over the consideration that the auxiliary requests were filed in due time and *prima facie* relevant.

In point 30 of the decision, an additional reason was mentioned against auxiliary requests 7 to 11, namely that they contained a feature that had been found unclear in the discussion of auxiliary request 6 at the oral proceedings. This reason does not take account of the fact that auxiliary requests 7 to 11 were filed in due time - not at the oral proceedings. The discussion of auxiliary request 6 at the oral proceedings could not retroactively render auxiliary requests 7 to 11 inadmissible.

1.5 Therefore, the Board decided to set aside the opposition division's decision not to admit auxiliary requests 2 to 5 and 7 to 11 and admitted the requests in accordance with Article 12(6), first paragraph, RPBA.

2. Remittal (Article 111 EPC)

The patent proprietor and respondent 1 requested that the case be remitted if any of auxiliary requests 2 to 5 and 7 to 11 were admitted and any of auxiliary requests 2 to 11 were found to meet the requirements of Article 84 EPC.

Respondent 2 requested that the case be remitted if the opposition division's decision not to admit auxiliary requests 2 to 5 and 7 to 15 was reversed, i.e. even before assessing whether the auxiliary requests comply with Article 84 EPC.

The issue of the clarity of auxiliary request 6 decided by the opposition division was identical to that raised against auxiliary request 2. Therefore, the Board concluded at the oral proceedings that the issue of clarity had to be discussed before remittal and that if any of auxiliary requests 2 to 11 were found to comply with Article 84 EPC, there were special reasons within the meaning of Article 11(1) RPBA to remit the case to the opposition division for further prosecution.

3. Auxiliary request 2 - clarity (Article 84 EPC)

The respondents raised two points against the clarity of claim 1 of auxiliary request 2. First, the interpretation of the time at which the GC is administered with respect to the CD3 binding domain, namely that "*the GC is administered prior to the administration of the first dose of the CD3 binding domain and prior to the administration of the second dose of the CD3 binding domain*". Second, the meaning of the phrase "*the second dose exceeds the first dose*".

3.1 With regard to the time of administration of the GC in relation to the administration of the CD3 binding domain, the respondents considered that claim 1 could be interpreted in three different ways. The GC was administered:

(i) only once before the first dose of the CD3 binding domain,
(ii) twice before the first dose of the CD3 binding domain, and
(iii) once before the fist dose and once between the first and the second dose of the CD3 binding domain.

In the Board's view, option (iii) is the only reasonable interpretation. If all three options or either of options (i) and (ii) were meant as possible embodiments, then the claim did not need to specify that the GC was administered before the second dose of the CD3 binding domain. The specification that the GC is administered not only prior to the first dose of the CD3 binding domain but also prior to the second dose can only be reasonably construed as meaning that the GC is administered once before the first dose and once between the first and the second dose. Interpreting claim 1 as encompassing options (i) and (ii) is more of a semantic exercise than an interpretation of what the skilled person would realistically understand when reading the claim.

The fact that the patent contains examples in which the GC is administered only prior to the first dose does not change this conclusion. Claim 1 of auxiliary request 2 is limited with regard to claim 1 as granted, which did not refer to a second dose. The embodiments in which the CD3 binding domain is administered only prior to the first dose could be covered by claim 1 as granted but are no longer claimed by auxiliary request 2.

Therefore, the Board holds that the feature relating to the time of administration of the GC in claim 1 of auxiliary request 2 is clear and means option (iii).

3.2 With regard to the meaning of the phrase "the second dose exceeds the first dose", the wording of claim 1 is in itself clear. The skilled person in the field of therapeutic uses understands that the dose of an active ingredient is the amount of that active ingredient that is administered to the patient at one time or within a specified period of time. Although a dose can be administered in shorter or longer periods of time, it is unambiguous that a second dose that exceeds a first dose means that the amount administered with the second dose is greater than the amount administered with the first dose.

3.2.1 The respondents argued that paragraphs [0063] and [0064] of the patent rendered the meaning of the phrase unclear because, within the meaning of the patent, they taught that a second dose that exceeds a first dose meant that the second dose was administered for a longer period of time than the first dose rather than in a greater amount. In this context, the respondents referred to the recent decision of the Enlarged Board of Appeal G 1/24, which establishes how to use the description to interpret the claims. The order of G 1/24 states that:

"*The claims are the starting point and the basis for assessing the patentability of an invention under Articles 52 to 57 EPC. The description and drawings shall always be consulted to interpret the claims when assessing the patentability of an invention under Articles 52 to 57 EPC, and not only if the person*

skilled in the art finds a claim to be unclear or ambiguous when read in isolation."

3.2.2 In line with G 1/24, the Board has consulted the description when interpreting claim 1, in particular the paragraphs discussed by the parties, which read as follows:

"*[0063] In a preferred embodiment, a first dose of the CD3 binding domain is administered for a first period of time; and optionally consecutively a second dose of the CD3 binding domain is administered for a second period of time, wherein the second dose exceeds the first dose.*

[0064] The term 'exceeds' means that the second period of time is at least one day longer than the first period of time."

Paragraphs [0063] and [0064] refer to a preferred embodiment in which the second dose is greater than the first dose, a greater dose meaning that it is administered for a longer period of time. Such a preferred embodiment is not incompatible with the clear meaning of claim 1 indicated in point 3.2 above, which is the starting point and the basis for assessing the patentability of an invention in accordance with G 1/24. The teaching of paragraphs [0063] and [0064] does not raise doubts as to the overarching understanding that when a second dose exceeds a first dose, the amount administered with the second dose is greater than that administered with the first dose. The time aspect in paragraph [0064] has to be understood as relating to a preferred embodiment which contains an additional limitation as to the time within which the doses are administered relative to each other. Such a

limitation is merely preferred and remains within the bounds of the prevailing meaning of claim 1 that the amount administered with the second dose is greater than that administered with the first dose. Therefore, paragraphs [0063] and [0064] do not change the clear meaning of claim 1 or render it ambiguous.

As noted by the appellant, the interpretation that claim 1 describes a dose escalation regimen in which the amount administered with the second dose is greater than the amount administered with the first dose is confirmed by the dependent claims, which are also silent on the length of the administration period.

4. In view of the conclusions in points 2 and 3 above, the Board decided to remit the case to the opposition division for further prosecution on the basis of auxiliary request 2.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the opposition division for further prosecution.

The Registrar: The Chairman:

A. Vottner A. Usuelli

Decision electronically authenticated