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Datasheet for the decision of 6 June 2024

Case Number: T 0235/22 - 3.3.04

Application Number: 14768797.4

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Language of the proceedings: EN

Title of invention:
Methods for achieving therapeutically effective doses of anti-CD47 agents

Patent Proprietor:
The Board of Trustees of the Leland Stanford Junior University

Opponents:
König Szynka Tilmann von Renesse
Genmab A/S

Headword:
Anti-CD47 dosage regimen/LELAND STANFORD JUNIOR UNIVERSITY

Relevant legal provisions:
EPC Art. 123(2), 111(1)
RPBA 2020 Art. 11

This datasheet is not part of the Decision
It can be changed at any time and without notice

Keyword:
Amendments - extension beyond the content of the application as filed (no)
Remittal - special reasons for remittal

This datasheet is not part of the Decisior
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Case Number: T 0235/22 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 6 June 2024

Appellant: (Patent Proprietor)	The Board of Trustees of the Leland Stanford Junior University Office of the General Counsel Building 170, Third Floor, Main Quad P.O. Box 20386 Stanford, CA 94305-2038 (US)
Representative:	Carpmaels & Ransford LLP One Southampton Row London WC1B 5HA (GB)
Respondent I: (Opponent 1)	König Szynka Tilmann von Renesse Patentanwälte Partnerschaft mbB Mönchenwerther Strasse 11 40545 Düsseldorf (DE)
Representative:	König Szynka Tilmann von Renesse Patentanwälte Partnerschaft mbB Düsseldorf Mönchenwerther Straße 11 40545 Düsseldorf (DE)
Respondent II: (Opponent 2)	Genmab A/S Kalvebod Brygge 43 1560 Copenhagen V (DK)
Representative:	J A Kemp LLP 80 Turnmill Street London EC1M 5QU (GB)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 13 January 2022 revoking European patent No. 2 970 493 pursuant to Article 101(3)(b) EPC**

Composition of the Board:

Chairwoman	M. Pregetter
Members:	B. Rutz
	R. Romandini

Summary of Facts and Submissions

I. The appeal by the patent proprietor (appellant) lies from the decision of the opposition division to revoke European patent No. 2 970 493 (the patent), entitled "*Methods for achieving therapeutically effective doses of anti-CD47 agents*", which is based on European patent application No. 14768797.4, published under the PCT as international application WO 2014/149477 (the application).

II. The opposition proceedings were based on the grounds of Article 100(a) EPC, in relation to novelty (Article 54 EPC) and inventive step (Article 56 EPC), and of Article 100(b) and (c) EPC.

III. In the decision under appeal, the opposition division decided that the subject-matter of claim 1 of the main request (first filed as auxiliary request 2 with the patent proprietor's reply to the oppositions on 29 May 2020) and of auxiliary requests 1 to 16 extended beyond the scope of the application as filed.

IV. In its statement of grounds of appeal, the appellant relied on the sets of claims of the main request and of auxiliary requests 1 to 16, i.e. on the claim requests on which the decision under appeal was based.

V. Opponent 2 (respondent II) replied to the appeal.

VI. The board summoned the parties to oral proceedings, as requested, and informed them of its preliminary opinion in a communication under Article 15(1) RPBA.

VII. In this communication, the board indicated that it preliminarily considered that the subject-matter of the claims of the main request did not infringe the requirements of Article 123(2) EPC. The board further indicated that it was inclined to remit the case to the opposition division for further prosecution, as requested by both parties.

VIII. Opponent 1 (respondent I) did not reply to the appeal and indicated with its letter dated 11 April 2024 that it would not be attending the oral proceedings.

IX. Claim 1 of the main request reads as follows:

"1. An anti-CD47 agent that can lead to a loss of erythrocytes and anemia when administered at a therapeutic dose, for use in a method of treating cancer in a primate subject, the method comprising:
(a) administering as a primer agent the anti-CD47 agent to the subject at a sub-therapeutic dose that primes the subject for administration of a therapeutically effective dose of the anti-CD47 agent, wherein the sub-therapeutic dose significantly reduces toxicity due to loss of erythrocytes; and
(b) administering a therapeutically effective dose of the anti-CD47 agent to the subject,
wherein the anti-CD47 agent reduces the binding of CD47 to SIRPα and is an anti-CD47 antibody;
wherein step (b) is performed in a range from 3 days to 21 days after beginning step (a)."

X. At the end of the oral proceedings, held by videoconference, as requested by both attending parties, the Chairwoman announced the board's decision.

XI. The appellant's submissions, relevant to the decision, are summarised below. Referenced passages (including claims) are from the application.

Main request
Added subject-matter (Article 123(2) EPC)

The opposition division wrongly decided that there was no textual basis for the combination of the following two features:

(1) the primer agent in step (a) being the anti-CD47 antibody used in step (b), and
(2) step (b) being performed 3 to 21 days after step (a) is begun.

A textual basis for feature (1) could be found in the second alternative of claim 3. A basis for feature (2) could be found in claim 2 as well as at the start of the section entitled "Summary of the Invention" in the description (see paragraph [0005], final sentence). Feature (2) was also disclosed in paragraph [0075].

Example 2 (see paragraph [0127]) reported on the administration of a priming dose of 1 mg/kg or 3 mg/kg of an anti-CD47 antibody (Hu5F9-G4) to a primate, followed seven days later by a therapeutic dose of 10 mg/kg or 30 mg/kg of the same antibody (see also Figure 9B). Furthermore, there were no examples of administering a priming dose of a first anti-CD47 agent prior to a therapeutic dose of a second (different) anti-CD47 agent.

The application as filed seen as a whole favoured priming at a low-dose level followed by maintenance at

a higher dose level with the same anti-CD47 agent, i.e. an anti-CD47 antibody (see, e.g., paragraph [0168] ff.).

The skilled person reading the application as a whole would have regarded feature (2) as a preferred embodiment of the invention (see, e.g., claim 2 and the last sentence of paragraph [0005] at the start of the section entitled “Summary of the Invention”). This was reinforced by the repetition of feature (2) in paragraph [0075]. There was no need for the application as filed to use the word "preferably", because the "application was directed to a technical audience rather that to a philologist or logician" (T 2619/11).

The remaining features (e.g. "cancer", "primates", "anti-CD47 antibodies") were also disclosed as preferred embodiments or were provided as clarifying definitions in the application as filed.

XII. Respondent II's submissions, relevant to the decision, are summarised below. Referenced passages (including claims) are from the application.

Main request
Added- subject-matter (Article 123(2) EPC)

Claim 1 related to a very general method of treatment with no disease indication, no structurally defined primer agent, no structurally defined anti-CD47 agent, and an open-ended treatment regimen. Nine limiting features had been inserted into claim 1 in order to arrive at claim 1 of the main request.

There was no direct and unambiguous disclosure of the complete combination of features of claim 1 of the main request anywhere in the application as filed.

Disease treated

The primary object of claim 1 was not the treatment of a disease *per se*, although a disease was necessarily being treated by virtue of administration of the agent. Instead, the primary object of claim 1 was the treatment of a subject resulting in the effects of anaemia being mitigated.

Claim 17 did not refer to any of claims 2, 3, 18 and 19, and claim 17 did not single out cancer either.

Other passages did not point to cancer as a preferred disease either (see paragraphs [0005], [0007], [0048], [0050] and [0051]).

Example 3 used cancer models only for studying anaemia and concluded that the findings applied both to cancer and to chronic infection.

Anti-CD47 antibody

The claims contained four equally valid alternatives for the anti-CD47 agent: anti-CD47 antibody (claim 19), SIRPα reagent (claim 20), anti-SIRPα antibody (claim 22) and soluble CD47 polypeptide (claim 23). Nowhere in the application was the subject-matter of claim 19 identified as preferred. Furthermore, in paragraphs [0007] and [0033] of the description, the four alternative agents were presented together, with no clear preference for any specific agent.

The examples did not establish a preference either, for the same reasons as discussed in relation to the disease to be treated.

Primer agent being the same agent as the therapeutic agent

The selection of the (same) anti-CD47 agent was a selection from a list of some length, because claim 3 mentioned three alternatives as well as combinations thereof.

The description did not provide any indication that any specific primer agent (or combination of primer agents) was preferred. Examples 4 and 5, at most, only hinted at the primer agent being the same anti-CD47 agent as that being used at a therapeutic dose. Example 5 used a number of different primer agents, such as erythropoietin ((EPO), sometimes in combination with an anti-CD47 antibody). Paragraph [00125] in Example 2 also provided an example of the use of EPO as a primer agent.

There was no pointer in the application as filed for the selection of a primer agent that was the same anti-CD47 agent as the therapeutic agent.

Separating steps (a) and (b) by 3 to 21 days

While this feature was present in claim 2, it was not a preferred option, because an alternative was mentioned in claim 5 with equal prominence ("6 days to 8 days"). Paragraph [0075] presented further alternative timescales. The feature was therefore selected from a long list of possibilities without any pointer.

Primates

In the context of the application as a whole, it was doubtful whether paragraph [0060], which mentioned that the "[*s*]*ubject methods that use a primer agent are particularly relevant when treating primates*", would be applicable to the subject-matter of claim 1. This could be seen from the following paragraph [0061] which further described the primer agents mentioned in paragraph [0060], but only discussed the use of erythropoiesis-stimulating agents (ESAs) as the primer agent. A statement that methods may be "relevant" to primates was not a statement that primates were a preferred group of subjects. In contrast, paragraph [0053] disclosed that the "*terms* […] *'subject'* […] *refer to any mammalian subject for whom diagnosis, treatment, or therapy is desired, particularly humans.* […] *Preferably, the mammal is human.*" If any preference was expressed in the application as filed, it was for the species "human", not the genus "primate".

Combination of features

Claim 1 of the main request presented new technical information to the skilled reader, because the amendments created a new combination involving, *inter alia*, the following:

- a selected primer agent(the same agent as the anti-CD47 agent)
- a selected anti-CD47 agent (anti-CD47 antibody)
- a selected dosage regimen (where (a) and (b) are separated by 3 to 21 days)
- for the treatment of a particular disease (cancer);
- in a particular subject (primates)

Each of the features was selected from lists of distinct alternatives, with none of the features being explicitly preferred, let alone being disclosed in combination with all of the other selected features.

XIII. The appellant (patent proprietor) requested that the decision under appeal be set aside and the case be remitted to the opposition division for further prosecution.

The appellant requested that - in the event that the board decided not to remit the case - the patent be maintained based on the claims of the main request, or, alternatively, based on the claims of auxiliary requests 1 to 16 and an appropriately amended description.

Respondent I (opponent 1) did not reply to the appeal and made no requests in the appeal proceedings.

Respondent II (opponent 2) requested that the appeal be dismissed and the patent be revoked. Respondent II requested that - in the event that the board allowed the appeal - the case be remitted to the opposition division for discussion of the remaining grounds of opposition, namely those raised under Article 100 (a) and (b) EPC.

Reasons for the Decision

Absence of a duly summoned party (Rule 115(2) EPC and Article 15(3) RPBA)

1. Respondent I (opponent 1) had been duly summoned to the oral proceedings, but had indicated with its letter dated 11 April 2024 that it would not be attending.

Main request
Added subject-matter (Article 123(2) EPC) - claim 1

2. When deciding whether claimed subject-matter extends beyond the content of the application as filed (Article 123(2) EPC), it has to be established what a skilled person would derive directly and unambiguously, using common general knowledge, and seen objectively and relative to the date of filing, from the whole of the documents as filed (G 3/89, OJ 1993, 117; G 11/91, OJ 1993, 125; G 2/10, OJ 2012, 376; referring to this test as the "gold standard").

3. Claim 1 differs from claim 1 as filed by the following additional features (see also decision under appeal, point 22.4):

(i) "treating cancer"
(ii) "in a primate subject"
(iii) "as a primer agent the anti-CD47 agent", i.e. identical to the agent in step (b)
(iv) "sub-therapeutic dose" in step (a)
(v) the sub-therapeutic dose "primes the subject for administration of a therapeutically effective dose of the anti-CD47 agent"

(vi) the sub-therapeutic dose "significantly reduces toxicity due to loss of erythrocytes"

(vii) the anti-CD47 agent "reduces the binding of CD47 to SIRPα"

(viii) the anti-CD47 agent "is an anti-CD47 antibody"

(ix) "step (b) is performed in a range from 3 days to 21 days after beginning step (a)"

4. In the present case it is necessary to determine whether the features of claim 1 of the main request can be found in combination in the application as filed. As there is no *verbatim* disclosure of that combination, it has to be determined whether that combination of features can be derived directly and unambiguously, taking into account the skilled person's common general knowledge, from the application as filed. One approach suggested by the appellant was to start with the disclosure of claim 1 as filed.

5. In doing so, it is necessary to analyse whether the additional features of claim 1 of the main request (see point 3. above) are disclosed in the application as filed and also whether the skilled person would derive the combination of those additional features with the subject-matter of claim 1 as filed in a direct and unambiguous manner from the application as filed. According to the case law of the boards of appeal the content of an application must not be treated as a reservoir from which features pertaining to separate embodiments of the application can be taken and combined in order to artificially create a particular embodiment. Instead, a pointer to a particular combination is required. This can, for example, be an explicit indication that a particular embodiment is

preferred or an implicit pointer through the preferential use of an embodiment in the examples (see Case Law of the Boards of Appeal of the EPO, 10th edition 2022, II.E.1.6.1).

6. In the following paragraphs, the disclosure in the application as filed for each of the limiting features (i) to (ix) will be discussed in turn, together with an analysis of how this disclosure would be perceived by the skilled reader when consulting the application as a whole.

6.1 Feature (i) "treating cancer" represents one of the two specified therapeutic applications of the invention, the other being treating "*infection with an intracellular pathogen*"(see paragraph [0005] in the "*Summary of the Invention*"). Paragraph [0050] further discloses that "*symptoms, illnesses, and/or diseases that can be treated with an anti-CD47 agent include, but are not limited to cancer and infection*". In claim 17 as filed, which is dependent on claim 1 as filed, "*the subject has cancer or an intracellular pathogen infection*". The skilled person would therefore infer that "cancer" and "infection" are the two main disease groups to be treated.

6.1.1 The skilled person would, however, also consult the examples. In doing so, they would realise that none of the examples relates to infection. Example 3 is performed on diseased animals carrying xenografts of various cancer cell lines. Mice carrying xenografts of a human bladder cancer cell line were treated with human anti-CD47 antibody hu5F9-G4 and shown to remain tumour-free in contrast with mice treated with buffered saline (see Figure 11). Further experiments established the effect on metastasis using engrafted human

metastatic prostate tumour specimens (see Figure 11B) and a xenograft model of human breast cancer (see Figure 12). All other examples were carried out in healthy animals (mice or monkeys) to test different dosage regimens and to evaluate safety and toxicity of the anti-CD47 antibody (see Examples 1, 2, 4 and 5).

6.1.2 The skilled person would therefore conclude that the application as filed showed a preference for the treatment of cancer by performing the respective experiments while not testing anti-CD47 agents for other diseases, e.g. infection.

6.1.3 Respondent II argued in this respect that Example 3 also referred to infection in its conclusion (see paragraph [00132]) and did not therefore establish any preference for cancer. The board does not accept this argument, because the cited passage merely concludes that, as regards disease, the tested humanised antibody had the same general properties as non-humanised antibodies (i.e. as used in Example 1) and could therefore also be effective for other diseases. This, however, does not render irrelevant the fact that only cancer treatments using dedicated cancer models for human bladder, prostate and and breast cancer were tested in the application, thus indicating a preference to the skilled person.

6.1.4 Respondent II further argued that, due to the wording of claim 1 as filed, which required "treating a subject with a therapeutic dose of an anti-CD47 agent", and the specification of claim 17 "wherein the subject has cancer", no actual treatment of cancer was disclosed but only the treatment of a subject having cancer in which the effects of anaemia were mitigated. The board does not agree, because treating a subject with a

therapeutic dose of an agent is a therapeutic treatment of the underlying disease in the subject with that agent. The fact that the invention relates to a specific dosage regimen that mitigates side effects of said treatment does not change this.

6.2 Feature (ii) "in a primate subject" is explicitly mentioned in paragraph [0060] ("*particularly relevant when treating primates*") with links to features (v) ("*methods that use a primer agent*") and (vi) ("*primates are sensitive to RBC [red blood cell] count and prone to develop anemia*"). Moreover, Examples 2, 4 and 5 were performed in non-human primates, namely rhesus or cynomolgus monkeys.

6.2.1 Respondent II argued by reference to paragraph [0053] that, despite the particular relevance mentioned, humans were a more preferred subset in the application. The board does not agree with this reasoning, because the disclosure of a more preferred subset, e.g. humans, does not invalidate the explicit indication that primates, as a target group, are of particular interest. Therefore, the skilled person would have considered the claimed treatment in this subject group as directly and unambiguously derivable.

6.2.2 Respondent II furthermore argued that, as the following paragraph [0061] was limited to ESAs as primer agents, the particular relevance of primates was also limited to this embodiment. The board does not agree, because the next paragraph [0062] discloses that "*the primer agent comprises a sub-therapeutic dose of an anti-CD47 agent*", thus making clear that the subject group primates was particularly relevant also for the use of anti-CD47 agents.

6.2.3 The skilled person would therefore have concluded that primate subjects were preferred.

6.3 Feature (iii) "as a primer agent the anti-CD47 agent", i.e. the identical agent to that in step (b), is disclosed in claim 3 as filed, which is directly dependent on claim 1 as filed. It is disclosed as one of three options and combinations thereof: "*an erythropoiesis-stimulating agent (ESA), a priming dose of the anti-CD47 agent, a priming dose of a second anti-CD47 agent, and combinations thereof*".

6.3.1 The appellant argued that using the anti-CD47 agent of step b) as the primer agent was a preferred embodiment, as could be seen from the examples in which escalating doses of anti-CD47 antibodies were tested (see, e.g., Examples 2, 4 and 5).

6.3.2 Respondent II argued that EPO, dexamethasone and benadryl were also used as primer agents in the examples (see Example 5, paragraph [00152] and Table 3). EPO was further used as a primer agent in Example 2 (see paragraph 00125]). Moreover, Table 6 in Example 5 showed that effects on red blood cell morphologies were less pronounced when EPO was used as a primer agent. The skilled person would not therefore recognise a preference for using the same anti-CD47 agent in both steps.

6.3.3 Furthermore, the decision under appeal (see point 22.4.3), referring to paragraph [00152], Table 3, paragraphs [0159] to [0167], and Tables 4 to 6, also considered the use of alternative primer agents (dexamethasone and benadryl or EPO) in the examples as evidence that the skilled person would not have

regarded the use of the same anti-CD47 agent as a preferred embodiment.

6.3.4 Taking into account the application as a whole, including the remaining examples (see paragraph [0168] ff.), the board comes to a different conclusion, for the following reasons.

6.3.5 Example 1 using mice finds that "*repeated administration of anti-CD47 antibodies does not exacerbate the initial anemia*", thereby providing "*the basis of the subsequent experiments in non-human primates*" (see paragraph [00120]).

6.3.6 Example 2 confirms this finding in non-human primates with or without EPO: "*Escalating concentrations of anti-CD47 antibodies do not exacerbate anemia*" (see paragraph [00125]) and establishes that a "[s]*ingle loading dose of anti-CD47 antibodies enables higher maintenance doses*" (see paragraph [00127]).

6.3.7 This then leads to the only therapeutic experiment, Example 3, in which mice with different xenografts receive anti-CD47 antibody, but without a priming dose.

6.3.8 Example 4 using cynomolgus monkeys confirms that "*the priming/maintenance dosing strategy allows Hu5F9-G4 to be clinically well-tolerated, even at doses as high as 300 mg/kg*" (see paragraphs [00133] and [00134] as well as Figures 13 to 15).

6.3.9 Example 5 first performs *in vitro* and *in vivo* tests of humanised anti-CD47 antibody in monkeys. It then tests a single or repeated low dose (1 or 3 mg/kg) of humanised anti-CD47 antibody either alone or with dexamethasone/benadryl in parallel or EPO as a primer

agent (minus 5 days) (see Table 3). It concludes that "*administration of Hu5F9-G4 as a single dose at 1 mg/kg or once weekly doses for 4 weeks at a dose of 3 mg/kg (alone or with pre-treatment with EPO or in combination with administration of Dexamethasone/Benadryl) was well-tolerated in male cynomolgus monkeys*" (see paragraph [00158]).

6.3.10 Respondent II argued that the use of dexamethasone and benadryl or EPO in these experiments would have indicated to the skilled person that those agents were equally preferred agents. The board disagrees. The doses of anti-CD47 antibody used in this study are sub-therapeutic and are also too low to cause anaemia. The skilled person would therefore have considered this experiment to be only an initial test but not a test for the priming/maintenance regimen of the invention. Moreover, dexamethasone and benadryl are commonly known as being neither an ESA nor an anti-CD47 agent, i.e. they do not fall within the two groups of primer agents listed in claim 3 as filed.

6.3.11 In the subsequent experiments of Example 5, monkeys receive escalating doses of anti-CD47 antibody with or without EPO (see paragraphs [00159] ff.). In both parts of the study this leads to good maintenance of the red blood cell count (RBC) even with therapeutic doses of up to 100 mg/kg (see Tables 4 and 5).

6.3.12 The fact that some red blood cell morphologies changed in this study (see Table 6), as pointed out by respondent II, is not seen as an indication that EPO was equally preferred as a primer agent. First of all, EPO is present together with the priming/maintenance dose of the same anti-CD47 antibody, i.e. it represents only an optional additional primer agent, which -

according to the claim wording ("comprising") - can be present in the method referred to in the claim. Secondly, the study conducted in the absence of EPO was followed up for a longer period (for 37 days compared to 5 days - see Table 6) and is therefore not directly comparable over the whole period. Thirdly, the red blood cell count (RBC), as the most relevant measure, was even slightly better in the absence of EPO (see Table 5).

6.3.13 The following paragraph [00168] states that "*initial administration of Hu5F9-G4 at lower doses enables subsequent administration of higher doses that are tolerated in cynomolgus monkeys*" and, based on this, sets out "*to evaluate the potential toxicity and toxicokinetics of Hu5F9-G4 when administered as a priming dose at a low dose level followed by multiple maintenance doses at higher dose levels*" in order "*to model the potential clinical dosing schedule using a priming/maintenance-dosing regimen*". This paragraph thus summarises the results of the preceding experiments and presents the aim of using the priming/maintenance regimen with the same anti-CD47 agent (anti-CD47 antibody) in a clinical setting.

6.3.14 In conclusion, the experiments consistently develop a priming/maintenance regimen using the (same) anti-CD47 antibody, which is envisaged for clinical use. The skilled person would thus have considered the use of the same anti-CD47 agent in the form of an anti-CD47 antibody to be a preferred embodiment.

6.4 Feature (iv) "sub-therapeutic dose" is disclosed in paragraphs [0057] and [0062] (also named "priming dose"). It is linked to the use of "the same anti-CD47 agent" throughout the application (see point 6.3 above)

and in the examples (see, e.g., Examples 2, 4 and 5), and can thus be seen as generally disclosed in this context.

6.5 Feature (v) "primes the subject for administration of a therapeutically effective dose of the anti-CD47 agent" is a definition pertaining to the terms "primer" and "anti-CD47 agent" (see paragraphs [0033], [0057] and [0059]). It is thus generally applicable.

6.6 Feature (vi) "significantly reduces toxicity due to loss of erythrocytes" reflects the object of the invention by identifying the context for the priming regimen (see paragraphs [0004], [0008], [0059]) and is thus also generally applicable.

6.7 Feature (vii) "reduces the binding of CD47 to SIRPa" is a definition of the term "anti-CD47 agent" (see paragraphs [0033], [0057] and [0059]) and is thus generally applicable.

6.8 Feature (viii) "an anti-CD47 antibody" is disclosed in dependent claim 19 as filed, which is dependent on claim 1 via claim 18. It is also disclosed in paragraphs [0039] and [0007] of the application as filed. Anti-CD47 antibodies are the only anti-CD47 agents which are used in the examples (MIAP410 and MIAP740 in mice, Hu5F9-G4 in primates, see points 6.3.5 to 6.3.11 above). The skilled person would therefore conclude that an anti-CD47 antibody is the preferred embodiment of an anti-CD47 agent mentioned in claim 1 as filed.

6.9 Feature (ix) "in a range from 3 days to 21 days" and the combination thereof with the features in claim 1 as filed is disclosed in paragraph [0005].

6.9.1 Respondent II argued that other more limited ranges were disclosed in the application as filed (see, e.g., claim 5, which is directly dependent on claim 1, and the list of ranges in paragraph [0075]) and were at least equally preferred. The board does not agree, because the range of "from about 3 days to about 21 days" is the only range disclosed at the beginning of the "*Summary of the Invention*" (see end of paragraph [0005]). It would therefore have been considered by the skilled person as the generally applicable dosage range to be combined with the other features.

7. In conclusion, the board finds that each of the features inserted into claim 1 as filed represents either a general definition (features (iv) to (vii) and (ix)) or a preferred embodiment of the invention (features (i) to (iii), (viii)). The skilled person would therefore have derived the combination of these features with the subject-matter of claim 1 as filed in a direct and unambiguous manner.

8. The subject-matter of claim 1 does not infringe the requirements of Article 123(2) EPC.

Added subject-matter (Article 123(2) EPC) - claims 2 to 8

9. Respondent II considered that claims 2 to 8 infringed Article 123(2) EPC for the same reasons as claim 1.

10. The board has not been presented with any additional reasons to support the view that the subject-matter of claims 2 to 8 extends beyond the content of the application as filed.

11. The board concludes that claims 2 to 8 do not infringe Article 123(2) EPC.

Remittal to the opposition division (Article 111(1) EPC and Article 11 RPBA)

12. There are special reasons in the present proceedings for remitting the case to the opposition division for further prosecution. Firstly, both parties requested remittal if the board concluded that the claims did not infringe Article 123(2) EPC. Additionally, the decision under appeal did not address the other grounds of opposition, particularly novelty and inventive step. The board found it inappropriate to initiate this examination for the first time during the appeal proceedings. This might have required a continuation of the proceedings in written form, possibly followed by further oral proceedings, if deemed appropriate or if requested.

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 Chairwoman:

I. Aperribay M. Pregetter

Decision electronically authenticated