

Internal distribution code:

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

**Datasheet for the decision
of 21 February 2022**

Case Number: T 2471/17 - 3.3.01

Application Number: 10182213.8

Publication Number: 2322153

IPC: A61K31/00, A61K31/395,
A61K31/165, A61P7/06

Language of the proceedings: EN

Title of invention:

Use of HIF Alpha stabilizers for enhancing erythropoiesis

Patent Proprietor:

Fibrogen, Inc.

Opponents:

Akebia Therapeutics, Inc.
GLAXO GROUP LIMITED
Bayer Intellectual Property GmbH/Bayer Pharma
Aktiengesellschaft/Bayer Animal Health GmbH
GlaxoSmithKline UK Limited

Relevant legal provisions:

EPC Art. 123(2)

Keyword:

Amendments - added subject-matter (yes)
Prohibition of reformatio in peius

Decisions cited:

G 0001/99, T 0061/10



Beschwerdekammern
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
Fax +49 (0)89 2399-4465

Case Number: T 2471/17 - 3.3.01

D E C I S I O N
of Technical Board of Appeal 3.3.01
of 21 February 2022

Appellant: Akebia Therapeutics, Inc.
(Opponent 1) 245 First Street, Suite 1100
Cambridge MA 02142 (US)

Representative: Jones Day
Rechtsanwälte, Attorneys-at-Law, Patentanwälte
Prinzregentenstrasse 11
80538 München (DE)

Respondent: Fibrogen, Inc.
(Patent Proprietor) 409 Illinois Street
San Francisco, CA 94158 (US)

Representative: Carpmaels & Ransford LLP
One Southampton Row
London WC1B 5HA (GB)

Decision under appeal: **Interlocutory decision of the Opposition
Division of the European Patent Office posted on
15 September 2017 concerning maintenance of the
European Patent No. 2322153 in amended form.**

Composition of the Board:

Chairman A. Lindner
Members: R. Hauss
L. Bühler

Summary of Facts and Submissions

- I. European patent No. 2 322 153 (patent in suit) originates from European patent application No. 10 182 213.8, which is a divisional application of European patent application No. 04 754 383.0 (published as WO 2004/108121 A1).
- II. The patent in suit was granted with a set of 11 claims. Claim 1 as granted reads as follows:
- 1. A compound that inhibits hypoxia inducible factor (HIF) hydroxylase activity for use in treating or preventing iron deficiency in a subject, wherein the compound is a structural mimetic of 2-oxoglutarate.*
- III. Three notices of opposition were filed opposing the patent in suit under Article 100(a), (b) and (c) EPC on the grounds that the claimed subject-matter lacked novelty and inventive step, was insufficiently disclosed and extended beyond the content of the application as filed.
- IV. The decision under appeal is the opposition division's interlocutory decision, announced on 1 June 2017 and posted on 15 September 2017, finding that the patent as amended in the form of the main request presented during the oral proceedings before the opposition division (including a set of eight claims and an amended description) met the requirements of the EPC.

V. Claim 1 of the amended main request deemed allowable by the opposition division reads as follows:

1. A compound that inhibits hypoxia inducible factor (HIF) prolyl hydroxylase activity for use in increasing serum iron in treating iron deficiency in a subject, wherein the compound is a structural mimetic of 2-oxoglutarate.

VI. All opponents appealed, requesting the revocation of the patent.

VII. With its reply to the appellants' grounds of appeal (received 11 June 2018), the patent proprietor (respondent) requested that the appeals be dismissed and presented 29 sets of claims as auxiliary requests 1 to 29.

Claim 1 of auxiliary request 1 reads as follows:

1. A compound that inhibits hypoxia inducible factor (HIF) prolyl hydroxylase activity for use in treating or preventing iron deficiency in a subject, wherein the compound is a structural mimetic of 2-oxoglutarate.

VIII. In a submission dated 14 December 2018, appellant-opponent 2 requested that auxiliary requests 1 to 15 of 11 June 2018 not be admitted since upholding the patent on the basis of one of these requests would be contrary to the principle of prohibition of *reformatio in peius* for the following reasons:

(a) Claim 1 of the main request held allowable by the opposition division required that the compound increased serum iron. This requirement was absent from claim 1 of auxiliary requests 1 to 12, 14 and 15.

(b) Claim 1 of the main request was limited to a compound for use in treating iron deficiency and did not encompass preventing iron deficiency. By contrast, auxiliary requests 1 to 15 all claimed preventing iron deficiency.

IX. With a submission dated 30 April 2019, the respondent filed amended versions of auxiliary requests 1 to 15 in which the words "or preventing" had been deleted.

Claim 1 of auxiliary request 1 of 30 April 2019 reads as follows:

1. A compound that inhibits hypoxia inducible factor (HIF) prolyl hydroxylase activity for use in treating iron deficiency in a subject, wherein the compound is a structural mimetic of 2-oxoglutarate.

X. A notice of intervention under Article 105 EPC was filed requesting that the decision under appeal be set aside and that the patent be revoked.

XI. Subsequently, opponents 2 and 3 and the intervener withdrew from the appeal proceedings by withdrawing their oppositions. Opponent 1 remained as the sole appellant.

XII. In a communication under Article 15(1) RPBA issued in preparation for oral proceedings and advising the parties of its preliminary opinion, the board mentioned, *inter alia*, the following points:

(a) The board had some difficulty in identifying, in the text passages cited by the respondent, a specific disclosure of the combination of technical features of claim 1 of the main request requiring a compound as defined in claim 1

for use in increasing serum iron (see point 2.5 of the communication of 7 April 2020).

(b) *Reformatio in peius* was an issue to be discussed also with regard to the deletion of the feature "for use in increasing serum iron" in claims 1 of auxiliary requests 1 to 12, 14 and 15 (see section 7 of the communication). In the board's preliminary opinion, the criteria of Enlarged Board of Appeal decision G 1/99 for exception from the prohibition of *reformatio in peius* were not met.

XIII. With a submission dated 19 January 2022, the respondent filed, *inter alia*, document D208 (Günzler/Weidmann: Prolyl 4-Hydroxylase Inhibitors, textbook extract without publication date, 65-95,).

XIV. Oral proceedings before the board took place on 21 February 2022.

XV. The appellant's arguments may be summarised as follows:

Claim construction

In claim 1 of the main request in the passage

"for use in increasing serum iron in treating iron deficiency in a subject"

the feature "in treating iron deficiency" was isolated from "for use" and did not belong to the second medical use designation. The common meaning of the second "in" in the context of the claim could be considered to be either "thereby" or "during". This resulted in two alternative meanings with different scope.

Admittance - document D208

The appellant objected to the admittance of, *inter alia*, document D208.

Amendments - main request

The feature "for use in increasing serum iron in treating iron deficiency" was not originally disclosed. Furthermore, no link between inhibition of HIF prolyl hydroxylase and 2-oxoglutarate mimetics, or between either of these two descriptions of the compound and increasing serum iron, was provided in the application as filed.

Admittance, prohibition of "reformatio in peius"

The appellant objected to the admittance of, *inter alia*, auxiliary request 1 of 30 April 2019. This request should have been filed at an earlier stage of the proceedings and should also be rejected because it still contravened the principle of prohibition of *reformatio in peius* on account of the deletion of the limiting feature "for use in increasing serum iron".

XVI. The respondent's arguments may be summarised as follows:

Claim construction

Claim 1 according to the main request required that the compound be capable of increasing serum iron while also treating iron deficiency. Both of these actions followed the term "for use in". In accordance with the well-established way of interpreting a claim formulated under Article 54(5) EPC, medical uses and effects after the words "for use in" were functional features in the claim.

Admittance - document D208

Document D208 had been filed in response to the appellant's submission of May 2020 and was relevant to illustrate common general knowledge. The appellant was

familiar with the content of D208 from earlier litigation in the UK.

Amendments - main request

The subject-matter of claim 1 found basis in the following passages of the application as filed: paragraph [0038] combined with paragraph [0051]; paragraphs [0064], [0082], [0122], [0157], [0161], [0162] and [0258]; and embodiments 36 and 40.

Admittance, prohibition of "reformatio in peius"

Auxiliary request 1 in the version of 30 April 2019 had been filed promptly in response to the objection raised by appellant-opponent 2, in its submission of 14 December 2018, regarding the prohibition of *reformatio in peius*. This request should be accepted since the conditions for an exception to the prohibition of *reformatio in peius* in accordance with Enlarged Board of Appeal decision G 1/99 were met.

XVII. The appellant (opponent 1) requested that the decision under appeal be set aside and that the patent be revoked.

The appellant also requested that auxiliary requests 1 to 15 of 30 April 2019 and auxiliary requests 1 to 29 of 11 June 2018 not be admitted into the appeal proceedings and, furthermore, that documents D133 and D207 to D216 not be admitted.

XVIII. The respondent (patent proprietor) requested that the appeal be dismissed and that the patent be maintained in the version of the main request deemed allowable in the decision under appeal,
or, in the alternative, that the patent be maintained according to one of the sets of claims filed as

auxiliary requests 1 to 15 with the letter of 30 April 2019,

or, if the auxiliary requests of 30 April 2019 were not admitted, that the patent be maintained according to one of the sets of claims filed as auxiliary requests 1 to 15 with the reply to the statements setting out the grounds of appeal (of 11 June 2018),

or in the further alternative, that the patent be maintained according to one of the sets of claims filed as auxiliary requests 16 to 29 with the reply to the statements setting out the grounds of appeal.

The respondent also requested that documents D125B-D132, D136-D152, D156, D157 and D159-D198 not be admitted.

Reasons for the Decision

1. Claim construction
 - 1.1 Claim 1 of the main request is drafted in the format according to Article 54(5) EPC. The medical use targeted by this claim is treating iron deficiency in a subject. The pharmaceutically active agent is the compound defined in claim 1.
 - 1.2 The person skilled in the art would understand the claim in the straightforward sense that the feature "increasing serum iron" is for, or contributes to, the therapeutic purpose of treating iron deficiency.
 - 1.3 The appellant's interpretation that "increasing serum iron" may be a non-therapeutic treatment that happens concomitantly to an unrelated therapeutic treatment of iron deficiency appears artificial. This meaning would not suggest itself in the absence of a more explicit

indication of the context of such a separate therapeutic treatment.

2. Amendments - main request (Article 123(2) EPC)

2.1 The question to be decided with regard to added subject-matter is whether the application as filed, directly and unambiguously, discloses the technical features of claim 1 in combination.

2.2 The passages in the application as filed mentioned by the respondent in this context (see point XVI. above) are assessed as follows.

2.3 Embodiment 40 combined with embodiment 36

Embodiment 36 mentioned on page 88 of the application as filed is a method of treating or preventing iron deficiency which comprises administering to a subject an effective amount of a compound that stabilises HIF α . Embodiment 40 is the method according to any of embodiments 36 to 39 in which the method increases serum iron in the subject. (Embodiments 37 to 39 relate to subgroups of iron deficiency.)

By linking the features of increasing serum iron and treating iron deficiency, the disclosure of embodiment 40 corresponds to the medical indication in claim 1 of the main request.

In embodiments 36 and 40, the pharmacologically active compound is defined as a compound that stabilises HIF α . This differs from the definition of the compound in claim 1 of the current main request (i.e. a compound that inhibits HIF prolyl hydroxylase activity and is a structural mimetic of 2-oxoglutarate).

2.4 Paragraphs [0038], [0051] and [0064]

A method for treating and preventing iron deficiency is also mentioned in paragraphs [0038], and a method for increasing serum iron is mentioned in paragraphs [0051] and [0064]. However, there is no reference linking the content of paragraphs [0051] and/or [0064] with that of paragraph [0038]. While paragraph [0064] refers to a method of increasing serum iron "in a subject having iron deficiency", this does not necessarily imply treating iron deficiency.

The respondent argued that, based on paragraph [0038], it would still be clear that a preferred method of paragraph [0064] would be one in which the iron deficiency is treated. This argument does not succeed because it relates to what might be inferred as obvious from the information provided in separate passages of the application rather than to showing a direct and unambiguous disclosure of the required combination of features.

In these passages, the pharmacologically active compound is defined as a compound that stabilises HIF α .

2.5 Paragraph [0258]

Example 19, in paragraphs [0257] and [0258], describes an experiment in which rats were treated with various concentrations of "compound A" ([1-Chloro-4-hydroxy-isoquinoline-3-carbonyl)-amino]-acetic acid, see paragraph [0083]) for 93 days. Total serum iron levels were determined. The treatment increased serum iron levels in the animals. Paragraph [0258] concludes

"These results indicated that the methods and compounds of the present invention are useful for increasing serum iron levels, thereby useful for

treating disorders associated with iron deficiency."

Treating "disorders associated with" iron deficiency is different from treating iron deficiency.

2.6 To summarise, treatment increasing serum iron levels is disclosed in the application as filed and is linked, in embodiment 40 when combined with embodiment 36 (but not in the other cited passages), to the treatment of iron deficiency. This therapeutic use is, however, not disclosed together with a class of compounds defined as structural mimetics of 2-oxoglutarate that inhibit HIF prolyl hydroxylase activity.

2.7 The board furthermore considers that the description as filed does not specifically disclose a class of compounds defined as structural mimetics of 2-oxoglutarate which inhibit HIF prolyl hydroxylase activity for the following reasons.

2.7.1 The application as filed refers to several alternative classes of compounds described in different ways by functional or structural features.

According to paragraph [0082], the compounds of the invention are defined as compounds that stabilise HIF α . The stabilisation occurs, for instance, through inhibition of HIF hydroxylase activity, preferably HIF prolyl hydroxylase activity.

Independently of this, paragraph [0082] also states that in various embodiments, a compound of the invention is selected from the group consisting of 2-oxoglutarate mimetics, iron chelators and proline analogues.

According to paragraph [0121], the term "prolyl hydroxylase inhibitor" refers to any compound that reduces or otherwise modulates the activity of an

enzyme that hydroxylates amino acid residues. This statement is not linked to the subsequent statement that "[c]ompounds that can be used in the methods of the invention include, for example, iron chelators, 2-oxoglutarate mimetics, and modified amino acid, e.g. proline, analogs".

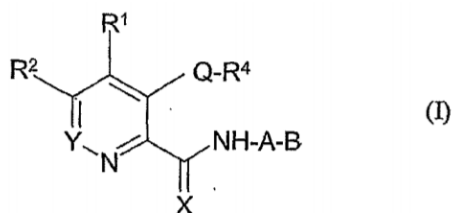
According to paragraph [0122], in particular embodiments, the invention provides for use of structural mimetics of 2-oxoglutarate. The passage goes on to state that PHIs (i.e. prolyl hydroxylase inhibitors) specifically contemplated for use in the methods of the invention are described in various literature references (given in the text).

According to paragraph [0157], in certain embodiments, a compound of the invention is a compound that inhibits HIF hydroxylase activity, preferably HIF prolyl hydroxylase activity.

According to paragraph [0158]: "In one aspect, a compound of the invention is any compound that inhibits or otherwise modulates the activity of a 2-oxoglutarate dioxygenase enzyme. 2-oxoglutarate dioxygenase enzymes include, but are not limited to, hydroxylase enzymes."

According to paragraph [0162]: "In some aspects, compounds of the invention include, for example, structural mimetics of 2-oxoglutarate."

According to paragraph [0163], "[i]n certain embodiments, compounds used in the methods of the invention are selected from a compound of the formula (I)",



followed by a definition of the residues of the Markush formula (pages 39 to 49 of the application).

2.7.2 It appears from this that the compounds of the invention may be:

- compounds that stabilise HIF α
- compounds that inhibit HIF hydroxylase activity, preferably HIF prolyl hydroxylase activity
- compounds that inhibit or otherwise modulate the activity of a 2-oxoglutarate dioxygenase enzyme
- 2-oxoglutarate mimetics
- structural mimetics of 2-oxoglutarate
- compounds of formula (I)
- iron chelators
- proline analogues

2.7.3 As set out above (see point 2.7.1), these different descriptions of compounds by their structural or functional properties are juxtaposed in the application as filed, but the relationship and potential overlap between these definitions is not fully explained, nor is it self-explanatory in most instances. It is not possible to conclude that the compound classes and functionalities are synonymous or can be freely combined.

2.7.4 In particular, no specific disclosure of a class of compounds defined as structural mimetics of 2-oxoglutarate that inhibit HIF prolyl hydroxylase can be derived from the language used in any of the cited passages.

2.7.5 This is also the case for embodiment 40, which (by reference to embodiment 36) describes the compound as a *"compound that stabilises HIF α "*, i.e. a rather general functional description of suitable compounds.

In any case, it cannot be directly and unambiguously derived from the information provided that the "*compound that stabilises HIF α* " mentioned in embodiment 36 is, more specifically, a structural mimetic of 2-oxoglutarate that inhibits HIF prolyl hydroxylase (i.e. a compound as defined in granted claim 1), in particular because:

- according to paragraph [0082], compounds that inhibit HIF prolyl hydroxylase are only a subgroup of compounds that stabilise HIF α ;
- the application does not provide a definition of "structural mimetics of 2-oxoglutarate" and does not explain the relationship between these compounds and HIF prolyl hydroxylase inhibitors.

2.8 For the sake of completeness, the following remarks on the claims in the application as filed may be added:

2.8.1 As mentioned in the decision under appeal (Reasons, point 7.2), the descriptions of the application as filed and the parent application as filed are identical with the exception of embodiments 1 to 90 of the application, which are, however, identical to the claims of the parent application.

2.8.2 In addition, the (divisional) application as filed contains a set of 18 claims. Claim 1 relates to a compound that inhibits hydroxylation of HIF α for use in treating or preventing iron deficiency in a subject. Claim 10 relates to the compound of claim 1 for the use of claim 1, wherein the compound is for use in, *inter alia*, increasing serum iron, as part of a list of five possible purposes. Claim 11 relates to the compound of any preceding claim for the use of that claim, where the compound inhibits HIF prolyl hydroxylase activity. Claim 12 relates to the compound of any preceding claim

for the use of that claim, where the compound is a structural mimetic of 2-oxoglutarate.

2.8.3 The claims in question do not provide specific disclosure of the combination of technical features as defined in claim 1 of the current main request, because

- "increasing serum iron" must be selected from several possibilities in claim 10;
- the subsequent claims refer back to "any preceding" claim, i.e. there is no direct and unambiguous line of back-reference from claim 12 to claim 11 and from claim 11 to claim 10.

2.9 Taking these considerations into account, the subject-matter of claim 1 of the main request extends beyond the content of the application as filed (Article 123(2) EPC).

3. Admittance - document D208 (Article 13(2) RPBA)

3.1 In the discussion regarding added subject-matter, the respondent stated that it wished to rely on document D208 in support of certain arguments regarding common general knowledge. The appellant objected to the document's admittance.

3.2 The board did not admit D208 for the following reasons:

3.2.1 The respondent submitted document D208 only one month before the oral proceedings in appeal. The accompanying letter (dated 19 January 2022) stated that the document was relevant to the issue of sufficiency of disclosure (rather than added subject-matter).

3.2.2 The objection that there was no clear and unambiguous link between the compound definitions of HIF prolyl hydroxylase inhibitor and 2-oxoglutarate mimetic was known, as it had been included in the appellant's

statement setting out the grounds of appeal (section 6) and raised in the proceedings before the opposition division (see the decision under appeal, Reasons 7.2.1. (ii)).

- 3.2.3 The respondent argued that the content of D208 (information regarding the geometry of the prolyl 4-hydroxylase active site and examples of prolyl 4-hydroxylase inhibitors) should be admitted to illustrate common general knowledge, in response to the appellant's new objection that "compound A" or compounds of formula (I) according to the application as filed would not be recognised by the person skilled in the art as 2-oxoglutarate mimetics.
- 3.2.4 The board considered that this issue would not be decisive for the assessment regarding added subject-matter (see point 2.5 above).
- 3.2.5 Hence, the introduction of D208 in support of the respondent's reasoning under Article 123(2) EPC on the day of the oral proceedings before the board was regarded as an amendment of the respondent's case not justified by exceptional circumstances.
4. Admittance, principle of prohibition of *reformatio in peius* - auxiliary request 1 of 30 April 2019
 - 4.1 As established by Enlarged Board of Appeal Decision G 4/93, if the opponent is the sole appellant against an interlocutory decision maintaining a patent in amended form, the patent proprietor is primarily restricted on appeal to defending the claims held allowable by the opposition division.
 - 4.2 If these claims are not allowable, the principle of prohibition of *reformatio in peius* applies, i.e. an amended claim which would put the opponent and sole

appellant in a worse situation than if it had not appealed must be rejected.

- 4.3 The scope of claim 1 of auxiliary request 1 is broader than that of claim 1 of the main request held allowable by the opposition division due to the deletion of the limiting feature "increasing serum iron".
- 4.4 For this reason, auxiliary request 1 runs counter to the principle of prohibition of *reformatio in peius*. To decide on its admissibility, it must be established whether compelling reasons exist for departing from this principle.
- 4.5 In G 1/99 (OJ 2001, 381), the Enlarged Board of Appeal considered it equitable, under certain circumstances, to deviate from the prohibition of *reformatio in peius* to give the patent proprietor the opportunity to mitigate the effects of an error of judgement made by the opposition division that would have the revocation of the patent as a direct consequence. The error of judgement of the opposition division dealt with in G 1/99 was to allow an amendment which had the effect of limiting the scope of the claims that was objected to in appeal (see point 14 of the Reasons).
- 4.6 In the current case, the respondent argued that it was not obliged to retain the term "increasing serum iron" in all its requests since the appellants/opponents had, in the course of the appeal proceedings, raised objections against this specific term on several grounds (including at least Articles 123(2), 123(3), 84 and 83 EPC). The respondent was therefore entitled to address the objections by pursuing claim requests from which this term had been deleted, in particular as the appellants/opponents had not suggested ways in which

the objections could be addressed by limiting or amending the term.

- 4.7 The board does not come to the same conclusion for the following reasons.
- 4.7.1 In G 1/99 the Enlarged Board recognises, in point 9.1 of the Reasons, that it is primarily the patent proprietor that is responsible for its claims and bears the risk when submitting amended claims as its main request. In such a situation, the patent proprietor is aware that if the opposition division allows its main request, it will lose the right to file an appeal (because the opposition division's decision does not adversely affect it).
- 4.7.2 G 1/99 cannot be understood as meaning that this risk is simply removed in just any situation where the opposition division decided in favour of the patent proprietor but the board subsequently disagrees with this assessment.
- 4.7.3 Rather, the exception to the prohibition of *reformatio in peius* must be based on a new situation in the appeal proceedings (see G 1/99, Reasons point 12, "reasons which were not raised at the first instance"), which must be causal for the board's divergent opinion (see also T 61/10).
- 4.7.4 This condition is not met in the case at issue. The objection under Article 123(2) and 76(1) EPC that the features of claim 1 were not specifically disclosed in combination in the application and in the parent application as filed (including the combination of increasing serum iron with the remaining features) was already an issue in the proceedings before the opposition division (see the decision under appeal, point 7.2.1 summarising the opponents' arguments,

especially points ii, iv and v). So were further objections under, *inter alia*, Articles 123(3), 84 and 83 EPC.

4.7.5 The respondent did not show, and it was not established, that new reasons against claim 1 of the main request, on account of the feature "increasing serum iron", arose on appeal which would have caused the revocation of the patent.

4.8 For these reasons, the circumstances of this case do not justify an exception to the prohibition of *reformatio in peius*, and auxiliary request 1 must be rejected.

5. Further auxiliary requests

5.1 Prohibition of *Reformatio in peius*

5.1.1 Claim 1 in each of auxiliary requests 1 to 12, 14 and 15 of 30 April 2019 and auxiliary requests 1 to 12, 14 and 15 of 11 June 2018 relates to a compound as defined in claim 1 of the main request (or further limited as being a compound of formula (I)) for second medical use, but the feature of "increasing serum iron" is absent.

5.1.2 The further limiting features present in these claims relate to the type of iron deficiency (functional iron deficiency, iron deficiency associated with anemia or anemia of chronic disease) or the subjects to be treated (mammalian, having iron-restricted or iron-deficient erythropoiesis, having a transferrin saturation of less than 20%, adults with a transferrin saturation of less than 16%). These features do not restrict the scope in such a way as to compensate for the deletion of the feature "increasing serum iron".

5.1.3 As a consequence, the same conclusion as in point 4.8 above also applies to auxiliary requests 1 to 12, 14 and 15 of 30 April 2019 and auxiliary requests 1 to 12, 14 and 15 of 11 June 2018.

5.2 Amendments (Article 123(2) EPC)

5.2.1 As far as auxiliary requests 13 and 16 to 29 of 11 June 2018 and auxiliary request 13 of 30 April 2019 are concerned, each of these requests contains the combination of features according to claim 1 of the main request and would not be allowable under Article 123(2) EPC for the same reasons as set out in section 2 above.

5.2.2 The further limiting features present in these claims relate to the type of iron deficiency (functional iron deficiency, iron deficiency associated with anemia or anemia of chronic disease) or the subjects to be treated (mammalian, having iron-restricted or iron-deficient erythropoiesis, having a transferrin saturation of less than 20%, adults with a transferrin saturation of less than 16%). The presence of further limiting features would not change the negative conclusions reached under Article 123(2) EPC.

5.3 In view of these considerations, a decision on the admittance of the respondent's lower-ranking auxiliary requests is not required.

5.4 Admission of evidence

Since documents D125B-D132, D133, D136-D152, D156, D157, D159-D198, D207 or D209 to D216 were not pertinent to the issues in this decision, a ruling on their admittance is not required.

Order

For these reasons it is decided that:

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

The Registrar:

The Chairman:



M. Schalow

A. Lindner

Decision electronically authenticated