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Datasheet for the decision of 29 July 2021

Case Number: T 0317/20 - 3.3.04

Application Number: 10184427.2

Publication Number: 2305711

IPC: A61K39/395, A61P19/02, A61P29/02, C07K16/22

Language of the proceedings: EN

Title of invention:

Methods for treating osteoarthitis pain by administering a nerve growth factor antagonist and compositions containing the same

Patent Proprietor:

Rinat Neuroscience Corp.

Opponents:

Regeneron Pharmaceuticals, Inc.
Teva Pharmaceutical Industries Ltd.

Headword:

NGF antagonist for treatment of osteoarthritis/RINAT

Relevant legal provisions:

EPC Art. 83, 105
EPC R. 76(2)(c), 89(2)
RPBA 2020 Art. 13(2)

Keyword:

Intervention of assumed infringer - notice of intervention
Intervention of the assumed infringer - admissibility of intervention during appeal proceedings - admissible (yes)
Sufficiency of disclosure - (no)
Amendment after summons - exceptional circumstances (no) - cogent reasons (no) - taken into account (no)

Decisions cited:

G 0001/94, T 1659/07, T 0609/02, T 0347/15, T 1480/16, T 0995/18, T 0482/19

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Case Number: T 0317/20 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 29 July 2021

Appellant I: (Patent Proprietor)	Rinat Neuroscience Corp. 230 East Grand Avenue South San Francisco, CA 94080 (US)
Representative:	Pfizer European Patent Department 23-25 avenue du Docteur Lannelongue 75668 Paris Cedex 14 (FR)
Appellant II: (Opponent 1)	Regeneron Pharmaceuticals, Inc. 777 Old Saw Mill River Road Tarrytown NY 10591 (US)
Representative:	Duffield, Stephen Carpmaels & Ransford LLP One Southampton Row London WC1B 5HA (GB)
Intervener: (Opponent 2)	Teva Pharmaceutical Industries Ltd. 5 Basel Street 49131 Petach Tikva (IL)
Representative:	Wise, Daniel Joseph 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 4 February 2020 concerning maintenance of the European Patent No. 2305711 in amended form**

Composition of the Board:

Chair	G. Alt
Members:	A. Schmitt
	P. de Heij

Summary of Facts and Submissions

I. The appeals lodged by the patent proprietor (appellant I, "proprietor") and opponent 1 (appellant II, "opponent") lie from the opposition division's interlocutory decision that European patent No. 2 305 711 ("patent"), as amended in the form of auxiliary request 2, and the invention to which it relates meet the requirements of the EPC.

II. The patent, entitled "*Methods for treating osteoarth*[r]*itis pain by administering a nerve growth factor antagonist and compositions containing the same*", was granted on European patent application No. 10 184 427.2 ("application"), which is a divisional application of the earlier European patent application No. 06 750 079.3. This earlier application was filed as an international application under the PCT and published as WO 2006/110883 ("earlier application").

Claims 1, 2, 12 and 13 of the patent as granted read:

"1. Use of an effective amount of an anti-NGF antagonist antibody in the manufacture of a medicament for improving physical function in an individual having osteoarthritis.

2. Use of an effective amount of an anti-NGF antagonist antibody in the manufacture of a medicament for treating pain, improving physical function and improving stiffness in an individual having osteoarthritis.

12. The use of any one of the preceding claims, wherein the anti-NGF antibody competes for binding to human NGF

with an antibody comprising the amino acid sequences of SEQ ID NO: 1 and 2.

13. The use of any one of the preceding claims, wherein the anti-NGF antibody binds essentially the same human NGF epitope as an antibody comprising the amino acid sequences of SEQ ID NO: 1 and 2."

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

IV. In the decision under appeal, the opposition division considered, *inter alia*, that the subject-matter of claims 12 and 13 of the patent as granted lacked a basis in the application and the earlier application as filed (Article 123(2) EPC and Article 76(1) EPC) and that the invention as defined in claim 1 of auxiliary request 2 was sufficiently disclosed in the patent because there was "*no evidence on file that an anti-NGF antibody would not improve physical function in the absence of pain*" (point 8.3 of the decision). Claim 1 of auxiliary request 2 was identical to claim 1 as granted (see section II.).

V. With the statement of grounds of appeal, the proprietor submitted, *inter alia*, sets of claims of a main request and auxiliary requests 1 to 24 and arguments, *inter alia*, to the effect that claims 8 and 9 of the main request did not relate to subject-matter that extended beyond the content of the (earlier) application as filed.

Claims 1, 8 and 9 of the main request are identical to claims 1, 12 and 13 as granted, respectively (see section II.).

Claims 1, 7 and 8 of auxiliary request 11 are identical to claims 2, 12 and 13 as granted, respectively (see section II.).

Claim 1 of auxiliary request 17 is identical to claim 2 as granted except that it comprises the further feature "wherein the anti-NGF antibody is administered once every four weeks". Claims 6 and 7 of auxiliary request 17 are identical to claims 12 and 13 of the patent as granted, respectively (see section II.).

Claim 1 of auxiliary request 18 is identical to claim 2 as granted except that it comprises the further feature "wherein the antibody provides improvement for at least 28 days after a single dose". Claims 7 and 8 of auxiliary request 18 are identical to claims 12 and 13 of the patent as granted, respectively (see section II.).

Claim 1 of auxiliary request 19 is identical to claim 2 as granted except that the individual having osteoarthritis is defined as "an individual having osteoarthritis of the knee". Claims 7 and 8 of auxiliary request 19 are identical to claims 12 and 13 of the patent as granted, respectively (see section II.).

VI. With the statement of grounds of appeal, the opponent submitted eight documents and, *inter alia*, arguments to the effect that the patent did not disclose the invention as defined in claim 1 of the main request in a manner sufficiently clear and complete for it to be

carried out by a person skilled in the art (Article 83 EPC).

VII. The opponent requested acceleration of the appeal proceedings based on ongoing national litigation on the patent and, in a further letter, that the oral proceedings before the board be held before 29 November 2021.

VIII. The board issued a summons to oral proceedings accompanied by a communication informing the parties that the board had decided to accelerate the appeal proceedings.

IX. The proprietor replied to the opponent's statement of grounds of appeal, *inter alia*, by submitting arguments to the effect that the patent sufficiently disclosed the invention as defined in claim 1 of the main request. It requested, *inter alia*, that the documents and new lines of arguments on inventive step submitted by the opponent with its statement of grounds of appeal not be admitted into the proceedings.

X. With a letter dated 28 October 2020, the opponent replied to the proprietor's statement of grounds of appeal, *inter alia*, by submitting arguments to the effect that claims 8 and 9 of the main request related to added subject-matter and that identical claims were also comprised in the sets of claims of auxiliary requests 2 to 4 and 7 to 19. Furthermore, claim 1 of auxiliary requests 1 to 10, 12 to 16 and 20 to 24 did not meet the requirements of Article 83 EPC for the same reasons as claim 1 of the main request.

In a letter dated 18 December 2020, the opponent submitted further considerations on inventive step of claim 1 of the main request.

XI. On 29 January 2021, a notice of intervention was filed by Teva Pharmaceutical Industries, Ltd. ("intervener"). The intervener indicated that it "*adopt*[ed] *the facts, evidence and arguments set out by the existing opponent*" and filed the opponent's statement of grounds of appeal, its submissions dated 28 October 2020 and 18 December 2020 (see section X.), and two new documents, one of them being D39a.

XII. The board issued a communication pursuant to Article 15(1) RPBA in which it set out its preliminary opinion on, *inter alia*, added subject-matter and sufficiency of disclosure.

XIII. In reply, by a letter dated 28 May 2021, the proprietor submitted sets of claims of new auxiliary requests 2 to 19, which replaced auxiliary requests 2 to 19 submitted with the statement of grounds of appeal, and arguments relating to admittance of these requests.

The sets of claims of new auxiliary requests 11, 17, 18 and 19 were identical to the sets of claims of auxiliary requests 11, 17, 18 and 19 submitted with the statement of grounds of appeal (see section V.), respectively, except for the deletion of claims 7 and 8 from auxiliary requests 11, 18 and 19 and the deletion of claims 6 and 7 from auxiliary request 17.

XIV. By a further letter dated 21 June 2021, the proprietor, *inter alia*, submitted arguments to the effect that the intervention was inadmissible.

XV. The oral proceedings were held on 29 July 2021 by videoconference with the consent of all parties. During the oral proceedings, the proprietor withdrew auxiliary requests 1 to 10, 12 to 16 and 20 to 24. At the end of the oral proceedings, the Chair announced the board's decision.

XVI. The following documents are referred to in this decision:

D5 WOMAC survey form

D6 Roos et al., 1999, Scant J Rheumatol 28, 210-15

D19 Committee for Proprietary Medicinal Products (CPMP) - Points to consider on clinical investigation of medicinal products used in the treatment of osteoarthritis [CPMP/EWP/784/97], July 1998

D26 Second declaration by Rod Junor (2 October 2019)

D35 Proprietor's submission during the opposition proceedings (3 October 2019)

D36 Proprietor's submission during the opposition proceedings (25 September 2018)

D39a Managing Osteoarthritis in Primary Care, 2000 (Blackwell Science), Hosie and Dickson, Chapter 5

XVII. The proprietor's arguments, where relevant to the decision, are summarised as follows.

Admissibility of the intervention (Article 105 EPC)

The intervention was inadmissible because it had not been substantiated and hence did not meet the requirements of Rules 89 and 76 EPC.

First, the intervener only referred to the facts, evidence and arguments set out by the opponent during the appeal proceedings and did not make any reference to the opponent's submissions in the opposition proceedings. The case was therefore not comparable to the one underlying decision T 1659/07, where the intervener had referred to the notice of opposition, grounds of appeal and accompanying citations by the existing opponent.

Second, part of the opponent's arguments and the documents submitted by the opponent in the appeal proceedings were inadmissible. Even if the substantiation requirement were met by reference to existing submissions in appeal proceedings, the reference by the intervener to inadmissible arguments and documents submitted during these proceedings did not meet this requirement.

Main request

Sufficiency of disclosure (Article 83 EPC) - claim 1

In the clinical trial disclosed in Example 9 of the patent, the Western Ontario and MacMaster Universities osteoarthritis index (WOMAC index) was used to assess the effects of treatment with an anti-nerve growth

factor (NGF) antagonist antibody on osteoarthritis patients. For the WOMAC index, the parameters "pain", "physical function" and "stiffness" were assessed (see documents D5 and D6).

These three parameters were separate, independent symptoms of osteoarthritis not correlated to each other in a linear manner. For example, improving stiffness could improve physical function without having an effect on pain, whereas pain relief might even worsen physical function (see section (viii) on page 4 of document D26). It was therefore necessary to assess the improvement of physical function in addition to pain relief in all clinical trials of drugs for osteoarthritis treatment (see document D19, page 3/6, section II).

The patent demonstrated that administration of an anti-NGF antagonist antibody to osteoarthritis patients not only reduced pain but also improved physical function and stiffness irrespective of the patient's baseline level of pain (Example 9, paragraph [0436] and Figure 27). It thus provided convincing evidence that an anti-NGF antagonist antibody could be used for improving physical function in osteoarthritis patients.

In view of this evidence, decision T 609/02 was not relevant for the case at hand, and the burden of proof was on the opponent and the intervener to substantiate their allegation of lack of sufficiency of disclosure by verifiable facts.

The opponent's objection was directed to the exceptional subgroup of osteoarthritis patients who had impaired physical function but did not experience pain. However, it had neither been credibly demonstrated that

the skilled person had serious doubts that physical function could be improved by an anti-NGF antagonist antibody in this rare subgroup of osteoarthritis patients nor that the improved physical function observed in Example 9 of the patent was only due to relief of pain by the treatment with the anti-NGF antagonist antibody. Therefore, the burden of proof had not been discharged.

NGF was not only known for its function in pain, as evident from the chapter "Background of the invention" on page 3 of the patent, and thus another function of NGF could account for its effect on physical function of osteoarthritis patients. The argument that an anti-NGF antagonist antibody only had analgesic function was therefore not correct.

Furthermore, pain was the main symptom of osteoarthritis, and patients without pain were rare. The patent thus supported a substantial scope of the claim. Moreover, it would not have been possible to conduct a clinical trial with osteoarthritis patients who did not experience pain. Therefore, extrapolation to all osteoarthritis patients encompassed within the scope of the claim was allowable and justified. Besides, an occasional failure of a treatment in a small group of unusual patients could not amount to a lack of sufficient disclosure.

Auxiliary requests 11, 17, 18 and 19

Admittance (Article 13(2) RPBA 2020)

The set of claims of auxiliary request 11 was identical to a set of claims submitted with the statement of grounds of appeal except for the deletion of claims 7

and 8 from this former claim request (see page 2 of the letter dated 28 May 2021).

The deletion of claims 7 and 8 was a direct response to the board's preliminary opinion, in particular the last sentence of point 25 of the board's communication, where the board had provided new reasons why claims 8 and 9 of the main request (to which claims 7 and 8 corresponded) related to added subject-matter. Therefore, exceptional circumstances justified by cogent reasons were present that justified admittance of the amendment.

Moreover, the deletion of claims 7 and 8 only eliminated a point of dispute and therefore corresponded to a situation where an attack of an opponent was abandoned. This improved procedural economy without changing the factual situation. The deletion of claims 7 and 8 did not put other claims in a new light, provide the proprietor with a wrongful advantage or took the opponent and the intervener by surprise since the discussion of inventive step of the remaining independent claim was not changed by the deletion. The situation was thus comparable to the ones underlying decisions T 1480/16 and T 995/18. Auxiliary request 11 should therefore be admitted into the appeal proceedings.

The same arguments applied to auxiliary requests 17, 18 and 19, which should therefore also be admitted into the appeal proceedings.

XVIII. The intervener's arguments concerning the admissibility of the intervention are summarised as follows.

The cross-reference of the intervener to submissions and documents submitted by the opponent in the appeal proceedings was directed to submissions and documents that were "on file", and thus the reasons for the intervention could readily be identified. It was not required to additionally refer to submissions made during the opposition proceedings. The cross-reference thus validly substantiated the intervention, in line with decision T 1659/07.

The proprietor's request not to admit some of the documents and arguments submitted by the opponent in the appeal proceedings had no bearing on whether the intervention had been substantiated as required by Rule 89 EPC since the admissibility of the intervention was to be decided when it was filed, i.e. it was independent of the proprietor's request and the decision on it. Anyhow, as confirmed in decision G 1/94 of the Enlarged Board of Appeal (OJ EPO 1994, 787), an intervener was free to raise any objection.

XIX. The opponent's and the intervener's arguments, were relevant to the decision, are summarised as follows.

Main request

Sufficiency of disclosure (Article 83 EPC) - claim 1

The patent did not sufficiently disclose the invention as defined in claim 1 in so far as it related to the treatment of osteoarthritis patients who did not suffer from pain.

In the study disclosed in Example 9 of the patent, the anti-NGF antagonist antibody was administered to osteoarthritis patients who all experienced pain. It led to a relief of pain, which had a corresponding effect on the patient's physical function (see Figure 27). The observed improvement in physical function thus resulted from the relief of pain.

The effect on physical function observed in osteoarthritis patients who experienced pain could not be generalised to osteoarthritis patients who did not suffer from pain because relief of pain was the only known mechanism of action of an NGF antagonist. Indeed, no functions of NGF or effects of an NGF antagonist were known that could possibly result in an improvement of physical function in osteoarthritis patients independent of pain relief. The common general knowledge could therefore not support the claimed subject-matter for osteoarthritis patients who did not suffer from pain, either (see decision T 609/02, Reasons, point 9).

Consequently, it was not plausible from the teaching in the patent or the common general knowledge that treatment with an anti-NGF antagonist antibody could improve the physical function in osteoarthritis patients who did not suffer from pain. This subgroup of osteoarthritis patients, however, constituted a relevant part of the osteoarthritis patients recited in the claim (see, for example, document D39a, Figure 5.1). The patent, thus, did not sufficiently disclose the claimed invention over the whole claimed scope.

Auxiliary requests 11, 17, 18 and 19

Admittance (Article 13(2) RPBA 2020)

Auxiliary requests 11, 17, 18 and 19 should not be admitted into the appeal proceedings under Article 13(2) RPBA 2020 because there were no exceptional circumstances which could justify their submission after the summons to oral proceedings had been issued. Indeed, in the decision under appeal in point 1.4.3, the opposition division considered that the subject-matter of claims 12 and 13 as granted contained subject-matter which extended beyond the (earlier) application as filed. However, despite this finding in the decision under appeal, the proprietor did not submit auxiliary requests dealing with this objection when submitting the statement of grounds of appeal.

Furthermore, the board's preliminary opinion did not contain any new surprising facts. The last sentence of point 25 of the board's preliminary opinion was not a new argument of the board but had been present in section 1.4.3 of the decision under appeal.

XX. The proprietor's requests, as far as relevant for the decision, were that the decision under appeal be set aside and that the patent be maintained on the basis of the set of claims of the main request, filed with the statement of grounds of appeal, or the set of claims of auxiliary requests 11 or 17 to 19, filed with the letter dated 28 May 2021, each claim set with an adapted description according to auxiliary request A; that the intervention be held inadmissible; and that the submissions in documents D35 and D36, filed by the

patent proprietor during the opposition proceedings, be considered.

XXI. The opponent's requests, as far as relevant for the decision, were that the decision under appeal be set aside and that the patent be revoked, and that auxiliary requests 11 and 17 to 19 not be admitted into the proceedings.

XXII. The intervener requested that the decision under appeal be set aside and that the patent be revoked.

Reasons for the Decision

1. The appeals of the proprietor and the opponent comply with Articles 106 to 108 and Rule 99 EPC and are admissible.

Admissibility of the intervention (Article 105 EPC)

2. Under Rule 89(2) EPC in conjunction with Rule 76(2)(c) EPC, the notice of intervention must be filed in a written reasoned statement that indicates the extent of and grounds for opposition and the facts and evidence presented in support of these grounds.

3. In decision T 1659/07, the entrusted board held that the reference to the statement of grounds of appeal and the notice of opposition of the existing opponent met the substantiation requirement. The purpose of this requirement was to ensure that the intervener's reasons and arguments could be identified and understood. This was achieved by reference to the grounds and arguments set forth by the existing opponent (see Reasons, point 2.3 and also a translated summary quoted in the

Case Law of the Boards of Appeal of the European Patent Office, 9th edition, 2019, III.P.1.7.).

4. In the notice of intervention (see section XI.), the intervener indicated that it "*adopted the facts, evidence and arguments set out by the existing opponent*" and enclosed the opponent's statement of grounds of appeal (see section VI.) and the opponent's letters dated 28 October 2020 and 18 December 2020 (see section X.).

5. The proprietor argued that the intervention was inadmissible because the intervener had only referred to the opponent's submissions made during the appeal proceedings and not also to those in the opposition proceedings as was the case in decision T 1659/07.

6. However, the opponent's submissions made during the appeal proceedings and re-submitted by the intervener with the notice of intervention identify the opponent's grounds for opposition, arguments, facts and evidence on which the objections are based, in particular lack of inventive step (see section 3 of the statement of grounds of appeal and the letter dated 18 December 2020), insufficiency of disclosure (see section 4 of the statement of grounds of appeal and the letter dated 28 October 2020) and added subject-matter (see section 5 of the statement of grounds of appeal and the letter dated 28 October 2020).

7. These submissions are therefore sufficient for identifying and understanding the grounds on which the intervention is based, and a reference to submissions made during the opposition proceedings is not necessary.

8. The proprietor further argued that even if it were accepted that a mere reference to the opponent's submissions in appeal proceedings was a sufficient substantiation, the intervention was nevertheless inadmissible since a part of these submissions was inadmissible.

9. However, the opponent's submissions to which the intervener referred need not be admissible to allow the proprietor and the board to understand the grounds on which the intervention is based. The admissibility of the opponent's submissions is therefore irrelevant for the assessment of the admissibility of the intervention. Moreover, in accordance with decision G 1/94 of the Enlarged Board of Appeal, an intervener may anyhow raise any objections under any grounds for opposition, irrespective of whether these grounds and objections had been raised by an existing opponent.

10. In view of these considerations, the intervention is admissible.

Main request

Sufficiency of disclosure (Article 83 EPC) - claim 1

11. The requirements of Article 83 EPC of a medical use claim are complied with if, at the relevant date of the application, the skilled person is able to prepare the claimed product, here an anti-nerve growth factor (NGF) antagonist antibody, and if the application discloses that the claimed product is suitable for the claimed therapeutic application, here for improving physical function in an individual having osteoarthritis, unless this is already known to the skilled person at the priority date (see Case Law of the Boards of Appeal of

the European Patent Office, 9th edition, 2019, II.C.7.2., in particular decision T 609/02 discussed there).

12. In the case at hand, the opponent and the intervener considered that the second requirement was not met, i.e. an anti-NGF antagonist antibody was not suitable for the improvement of physical function in osteoarthritis patients who did not experience pain. The proprietor argued that the invention as claimed was supported by Example 9 and Figure 27 of the patent. The burden of proof was therefore on the opponent and the intervener to substantiate their allegation by verifiable facts or evidence, which they had failed to do.

13. The board notes that it was not disputed between the parties that, even if rare, osteoarthritis patients with impaired physical function who did not suffer from pain existed (see, for example, Figure 5.1 of document D39a). It was also not disputed that all osteoarthritis patients treated with an anti-NGF antagonistic antibody in the clinical study disclosed in Example 9 of the patent suffered from pain. The patent therefore does not contain experimental proof that physical function could be improved in osteoarthritis patients who do not suffer from pain.

14. In the absence of experimental proof of treatment of these patients, comprehensible and plausible arguments can substantiate serious doubts as to whether the skilled person could carry out the invention as claimed, and evidence in the form of experimental data is not necessarily required (see, for example, decision T 347/15, Reasons 2.2.2).

15. The opponent and the intervener argued that the improvement of physical function observed in Example 9 of the patent was only due to the relief of pain caused by the anti-NGF antagonist antibody. Indeed, Example 9 of the patent relates to a study on the analgesic effects of anti-NGF antibody E3 in patients with moderate to severe pain from osteoarthritis of the knee (see the title of Example 9 on page 74, lines 6 to 7 and paragraph [0426] of the patent). The Visual Analogue Scale (VAS) and the Western Ontario and MacMaster Universities osteoarthritis (WOMAC) questionnaire were employed to assess arthritis pain after single intravenous doses of anti-NGF antibody E3 (paragraphs [0429] and [0431]).

16. Also, effects on physical function were assessed with the WOMAC questionnaire, which contains separate questions for the three domains of pain, physical function and stiffness (see paragraph [0431] of the patent and documents D5 and D6). Single administration of the anti-NGF antibody reduced pain and improved physical function and stiffness (see paragraph [0436] and Figure 27 of the patent).

17. However, all osteoarthritis patients treated in the study of Example 9 suffered from pain (see points 13. and 15. above), and the observed effects on physical activity were solely based on the WOMAC questionnaire. Four of the five questions in the pain-related domain of the WOMAC questionnaire relate to use-related pain. Difficulties in, *inter alia*, doing the same physical activities affected by pain are again assessed in the physical-function domain of the WOMAC questionnaire (walking on flat surfaces, going up and down stairs, sitting, lying, and standing upright; see documents D5 and D6 (Table I)).

18. In view of this interrelation of use-related pain and physical function as assessed by the WOMAC questionnaire, a lower score in the pain-related domain of the WOMAC questionnaire is expected to also result in a lower score for difficulties in physical activities, as was reported in Example 9 of the patent. However, Example 9 of the patent cannot demonstrate the suitability of an anti-NGF antagonist antibody for the improvement of physical function in osteoarthritis patients who do not suffer from pain.

19. The suitability of an anti-NGF antagonist antibody for improving physical function in these patients could also be demonstrated by the common general knowledge at the filing date of the patent (see point 11. above).

20. In this context, the proprietor submitted, with reference to documents D19 and D26, that some physical activities in osteoarthritis might be affected and could therefore be treated independently of pain. However, document D19 only discusses that functional disability was an "*important additional primary endpoint for symptom modifying drugs*" (see page 2/6, section II a)) but does not refer to an anti-NGF antagonist antibody. Document D26 likewise merely discusses that drugs could have an effect on stiffness and physical function without affecting pain but does not disclose that an anti-NGF antagonist antibody would or could have this effect (see section (viii) on page 4). Hence, documents D19 and D26 do not provide the skilled person with the knowledge of whether an anti-NGF antagonist antibody was suitable for a pain-independent improvement of physical activity.

21. The proprietor also argued that, as evident from the background section of the invention on page 3 of the patent, NGF had various other functions unrelated to pain which could also account for its effect on physical function. However, the proprietor did not point to any specific function of NGF, nor could the board identify an NGF function in the cited passages of the patent, that would support the suitability of an anti-NGF antagonist antibody for improving physical function and that was independent of its known activity as an analgesic. This argument therefore also fails to persuade the board.

22. In a further line of argument, the proprietor submitted that an occasional failure in the treatment of a small patient subgroup did not result in an insufficiency of disclosure.

23. However, the disclosure of a patent must allow an invention to be performed in the whole range claimed (see also Case Law of the Boards of Appeal of the European Patent Office, 9th edition, 2019, II.C.5.4). The improvement of physical function of an osteoarthritis patient is a limiting purpose-feature of the claim, and therefore the invention as defined in the claim is only sufficiently disclosed if this improvement is achieved for all osteoarthritis patients.

24. Therefore, the failure of treating an entire patient subgroup, albeit small, which is distinguished from the patient group as a whole by its pathological status, is not equivalent to an occasional failure in treating some patients within the patient group. The size of the patient subgroup is not decisive for the assessment of sufficiency of disclosure of the invention as defined

in the claim. This argument therefore does not persuade the board, either.

25. The proprietor further requested the board to consider its submissions in the procedure before the opposition division (documents D35 and D36). Apart from the obligation of the proprietor to present its complete case in appeal (Article 12(3) RPBA 2020), these submissions do not add any relevant argument to the above assessment.

26. Consequently, in view of the above considerations, it is concluded that the opponent's arguments substantiate serious doubt that the skilled person could carry out the invention as claimed. Neither the teaching in the patent nor the skilled person's common general knowledge at the filing date of the patent discloses the suitability of an anti-NGF antagonist antibody to improve the physical function of an osteoarthritis patient in the absence and independent of pain relief.

27. Therefore, the invention as defined in claim 1 of the main request is not disclosed in the application such as to meet the requirements of Article 83 EPC.

Auxiliary requests 11, 17, 18 and 19

Admittance (Article 13(2) RPBA 2020)

28. In the case at hand, a summons to oral proceedings was notified after 1 January 2020, and auxiliary requests 11, 17, 18 and 19 were submitted after notification of the summons to oral proceedings with the letter dated 28 May 2021.

29. These new claim requests are identical to claim requests 11, 17, 18 and 19 filed with the statement of grounds of appeal except for the deletion of claims 7 and 8 from auxiliary requests 11, 18 and 19 and claims 6 and 7 from auxiliary request 17. The wording of the deleted claims is identical to that of claims 12 and 13 as granted (see sections II., V. and XIII.).

30. Under Article 13(2) RPBA 2020, any amendment to a party's appeal case after notification of a summons to oral proceedings must in principle not be taken into account unless there are exceptional circumstances justified with cogent reasons by the party concerned.

31. The proprietor submitted two lines of argument why the new auxiliary requests 11, 17, 18 and 19 should be admitted into the appeal proceedings. First, the amendment was a direct response to the board's preliminary opinion that claims 8 and 9 of the main request contained subject-matter that extended beyond the content of the (earlier) application. Second, the amendment improved procedural economy without changing the factual situation. This latter circumstance was similar to those underlying decisions T 1480/16 and T 995/18 where the entrusted boards had admitted newly filed requests resulting from the deletion of claims.

32. As regards the proprietor's first line of argument, the board notes that in the opposition proceedings, an objection on the ground in Article 100(c) EPC had been raised against claims 12 and 13 as granted, and the opposition division found that claims 12 and 13 as granted related to subject-matter which extended beyond the disclosure of the application and the earlier application as filed (see point 1.4.3 of the decision

under appeal). In fact, the proprietor's appeal was on this issue only.

33. The proprietor therefore had to expect that the board might uphold the opposition division's decision. Under these circumstances, the fact that the board, in its preliminary opinion, had endorsed the decision under appeal in this respect does not qualify as exceptional circumstances pursuant to Article 13(2) RPBA 2020.

34. The proprietor also argued that the last sentence of point 25 in the board's preliminary opinion referred to reasons going beyond those provided in the decision under appeal. However, first, the board indicated in point 25 that it was not persuaded by the proprietor's arguments "*for essentially the same reasons as set out in the decision under appeal*". Second, the same reasoning provided in the last sentence of point 25, that *"a disclosure of the specific E3 antibody does not directly and unambiguously disclose other antibodies comprising SEQ ID NO:1 and 2*", is reflected in point 1.4.3 of the decision under appeal where the opposition division considered that none of the passages cited by the proprietor in support of the claims disclosed the E3 antibody, "*let alone any of the VH and VL of SEQ ID 1 and 2*".

35. The board's preliminary opinion therefore did not contain any new surprising facts that could justify the proprietor's late reaction to the opposition division's decision on added subject-matter.

36. The board is also not persuaded by the proprietor's second line of argument that the deletion of two claims from the claim requests improved procedural economy

without changing the factual situation (see point 31. above).

37. The deletion of dependent claims 7 and 8 from auxiliary requests 11, 18 and 19, filed with the statement of grounds of appeal, and dependent claims 6 and 7 from auxiliary request 17, filed with the statement of grounds of appeal, resulted in sets of claims covering subject-matter which had not been decisive prior to the filing of the new auxiliary requests. This is so because although the subject-matter of new auxiliary requests 11, 17, 18 and 19 had been present also in the previous auxiliary requests 11, 17, 18 and 19 filed with the statement of grounds of appeal, it was never in focus since these previous auxiliary requests all comprised the objected to claims 7 and 8 or 6 and 7, respectively.

38. Thus, as a consequence of the deletion of two claims, the other parties and the board were confronted with a new line of defence which had not been part of the proprietor's original appeal case.

39. For these reasons, the board is not persuaded by the proprietor's submission that the deletion of claims 7 and 8 from auxiliary requests 11, 18 and 19 and claims 6 and 7 from auxiliary request 17 improves procedural economy without changing the factual situation.

40. Furthermore, the board has not seen any exceptional circumstances justifying not having presented this line of defence earlier in the appeal proceedings.

41. The case at hand is different from that underlying decision T 1480/16 where Article 13(2) RPBA 2020 did

not apply and the entrusted board exercised its discretion under Article 13(1) RPBA 2020 to admit an auxiliary request submitted during the oral proceedings. In the case at issue, Article 13(2) RPBA 2020 applies, which does not confer any such discretion to the board but stipulates that as a rule the amendment of a case must not be taken into account.

42. The reference to the decision in case T 995/18 also cannot persuade the board to come to a different conclusion. In this decision, the deletion of a dependent claim was considered not to constitute an amendment of the proprietor's case (Reasons, point 2). However, this consideration depended on the circumstances of the case and therefore cannot be applied as a general rule. The assessment of this board of the circumstances of this case is different.

43. The case at hand resembles the one underlying decision T 482/19, where the deletion of a claim resulted in a set of claims for which features of a claim would have to be considered that thus far had not played any role in the appeal proceedings, and this "*would result in a substantial and unexpected change in the discussion at the oral proceedings*", and where the board therefore decided not to admit the auxiliary requests (Reasons, point 5.7).

44. Consequently, the board could not identify exceptional circumstances which would justify the amendment of the proprietor's case by filing auxiliary requests 11, 17, 18 and 19 after the board had summoned the parties to oral proceedings and issued its preliminary opinion. The board thus decided not to admit auxiliary

requests 11, 17, 18 and 19 into the appeal proceedings pursuant to Article 13(2) RPBA 2020.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

The Registrar: The Chair:

I. Aperribay G. Alt

Decision electronically authenticated