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Datasheet for the decision of 5 April 2022

Case Number: T 0699/19 - 3.3.04

Application Number: 10176627.7

Publication Number: 2270048

IPC: C07K16/22, A61K39/395, A61P25/04

Language of the proceedings: EN

Title of invention:
Anti-NGF antibodies and methods using same

Patent Proprietor:
Rinat Neuroscience Corp.

Opponents:
Regeneron Pharmaceuticals, Inc.
Nexvet Australia Pty Ltd (opposition withdrawn)
James Poole Limited
Teva Pharmaceutical Industries, Ltd.

Headword:
Anti-NGF antibodies/RINAT

Relevant legal provisions:
EPC Art. 54(3), 76(1), 84, 87(1), 100(c), 123(2)

Keyword:

Priority - basis in priority document (no)
Claims - clarity after amendment (no)
Novelty - enabling disclosure
Grounds for opposition - subject-matter extends beyond content of earlier application (yes)
Divisional application - subject-matter extends beyond content of earlier application (yes)

Decisions cited:

G 0001/04, G 0003/04, G 0003/14, T 0609/02, T 1457/09, T 0950/13

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Case Number: T 0699/19 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 5 April 2022

Appellant: (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: (Opponent 1)	Regeneron Pharmaceuticals, Inc. 777 Old Saw Mill River Road Tarrytown NY 10591 (US)
Representative:	Carpmaels & Ransford LLP One Southampton Row London WC1B 5HA (GB)
Intervener: (Opponent 4)	Teva Pharmaceutical Industries, Ltd. 124 Dvora HaNevi'a St. 6944020 Tel Aviv (IL)
Representative:	Carpmaels & Ransford LLP One Southampton Row London WC1B 5HA (GB)
Party as of right: (Opponent 3)	James Poole Limited One Southampton Row London WC1B 5HA (GB)
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 January 2019 concerning maintenance of the European Patent No. 2270048 in amended form**

Composition of the Board:

Chair P. de Heij
Members: A. Schmitt
R. Morawetz

Summary of Facts and Submissions

I. The appeals lodged by the patent proprietor (appellant I; hereinafter "patent proprietor") and opponent 1 (appellant II; hereinafter "opponent 1") lie from the opposition division's interlocutory decision that European patent No. 2 270 048 ("patent"), as amended in the form of auxiliary request 1 filed during the oral proceedings before the opposition division, and the invention to which it relates meet the requirements of the EPC.

Claims 1, 4, 10, 11 and 12 of the patent as granted read as follows:

" 1. An anti-nerve growth factor (NGF) antagonist antibody or antigen binding fragment thereof for use in treating osteoarthritis pain in an individual.

4. An antibody or antigen binding fragment thereof for use of claim 1, comprising (a) three CDRs from a heavy chain variable region of SEQ ID NO:1; and (b) three CDRs from a light chain variable region of SEQ ID NO:2; wherein the CDRs are Kabat CDRs, Chothia CDRs or a combination of Kabat and Chothia CDRs.

10. An antibody or antigen binding fragment thereof for use of any one of claims 4 to 9, wherein the antibody or antigen binding fragment thereof comprises a heavy chain variable region comprising the sequence shown in SEQ ID NO:1 and a light chain variable region comprising the sequence shown in SEQ ID NO:2.

11. An antibody for use of claim 10, wherein the antibody comprises a heavy chain comprising the amino

acid sequence shown in SEQ ID NO:16 and a light chain comprising the amino acid sequence shown in SEQ ID NO:17.

12. An antibody or antigen binding fragment thereof for use of any one of claims 1 to 11, wherein the antibody or antigen binding fragment thereof binds the same human NGF epitope as an antibody as defined in claim 10 or 11."

II. The patent was granted on European patent application No. 10 176 627.7 ("application"), which is a divisional application from European patent application No. 03 800 170.7, which had been filed as an international patent application, published as WO 2004/058184 ("earlier application"). It claims priority of patent applications US 60/436,905 filed on 24 December 2002 ("P1"), US 60/443,522 filed on 28 January 2003 ("P2") and US 60/510,006 filed on 8 October 2003 ("P3"). The title of the patent is "*Anti-NGF antibodies and methods using same*".

III. Three oppositions had been filed against the patent in its entirety. The opposition proceedings were based on the grounds for opposition in Article 100(a) EPC, in relation to novelty (Article 54 EPC) and inventive step (Article 56 EPC), and in Article 100(b) and 100(c) EPC.

IV. Before the appeals were filed, opponent 2 withdrew its opposition. Consequently, it was not a party to the appeal proceedings from the outset.

V. In the decision under appeal, the opposition division considered sets of claims of a main request and an auxiliary request 1. It held, *inter alia*, that the subject-matter of claim 12 of the main request (patent

as granted) extended beyond the content of the application (and the earlier application) as filed. The claims of auxiliary request 1 were considered to meet the requirements of the EPC. In arriving at this conclusion, the opposition division considered *inter alia* that claim 1 of auxiliary request 1 did not validly claim the priority of priority applications P1, P2 and P3 and that the subject-matter of claim 1 was novel over the disclosure in documents D1 and D3.

VI. With the statement of grounds of appeal, the patent proprietor submitted sets of claims of a main request (claims as granted; see section I.) and auxiliary requests 1 to 21 and, *inter alia*, arguments to the effect that the subject-matter of claim 12 as granted did not extend beyond the content of the application (and the earlier application) as filed and that the subject-matter of claim 1 of auxiliary request 3 was entitled to the filing date of priority application P2.

Claim 12 of auxiliary request 1 reads as follows:

"12. An antibody or antigen binding fragment thereof for use of any one of claims 1 to 11, wherein the antibody or antigen binding fragment thereof binds the same human NGF epitope as the antibody MAb 911."

Claim 12 of auxiliary request 2 reads as follows:

"12. An antibody or antigen binding fragment thereof for use of any one of claims 1 to 11, wherein the antibody or antigen binding fragment thereof binds the same human NGF epitope as an antibody comprising CDRH1 of SEQ ID NO:9; CDRH2 of SEQ ID NO:10; CDRH3 of SEQ ID NO:11; CDRL1 of SEQ ID NO:12; CDRL2 of SEQ ID NO:13; and CDRL3 of SEQ ID NO:14."

Claim 1 of auxiliary request 3 is identical to claim 1 of the patent as granted (see section I.).

Claim 12 of each of auxiliary requests 4 to 11 has the same wording as claim 12 of the patent as granted (see section I.).

Claim 1 of auxiliary request 12 reads as follows:

"1. An anti-nerve growth factor (NGF) antagonist antibody or antigen binding fragment thereof for use in treating osteoarthritis pain in an individual, wherein the antibody or antigen binding fragment thereof competes for binding to human NGF with a reference antibody and/or binds the same human NGF epitope as the reference antibody, wherein the reference antibody comprises a heavy chain variable region comprising the sequence shown in SEQ ID NO:1 and a light chain variable region comprising the sequence shown in SEQ ID NO:2."

Claim 1 of auxiliary request 13 reads as follows:

"1. An anti-nerve growth factor (NGF) antagonist antibody or antigen binding fragment thereof for use in treating osteoarthritis pain in an individual, wherein the antibody or antigen binding fragment thereof competes for binding to human NGF with the antibody MAb 911 and/or binds the same human NGF epitope as the antibody MAb 911."

Claim 1 of auxiliary request 14 reads as follows:

"1. An anti-nerve growth factor (NGF) antagonist antibody or antigen binding fragment thereof for use in

treating osteoarthritis pain in an individual, wherein the antibody or antigen binding fragment thereof competes for binding to human NGF with an antibody comprising CDRH1 of SEQ ID NO:9; CDRH2 of SEQ ID NO:10; CDRH3 of SEQ ID NO:11; CDRL1 of SEQ ID NO:12; CDRL2 of SEQ ID NO:13; and CDRL3 of SEQ ID NO:14 and/or binds the same human NGF epitope as an antibody comprising CDRH1 of SEQ ID NO:9; CDRH2 of SEQ ID NO:10; CDRH3 of SEQ ID NO:11; CDRL1 of SEQ ID NO:12; CDRL2 of SEQ ID NO:13; and CDRL3 of SEQ ID NO:14."

Claim 1 of auxiliary request 15 reads as follows:

"1. An anti-nerve growth factor (NGF) antagonist antibody or antigen binding fragment thereof for use in treating osteoarthritis pain in an individual, wherein the antibody or antigen binding fragment thereof binds the same human NGF epitope as an antibody comprising a heavy chain variable region comprising the sequence shown in SEQ ID NO:1 and a light chain variable region comprising the sequence shown in SEQ ID NO:2."

Claim 1 of auxiliary request 16 reads as follows:

"1. An anti-nerve growth factor (NGF) antagonist antibody or antigen binding fragment thereof for use in treating osteoarthritis pain in an individual, wherein the antibody or antigen binding fragment thereof binds the same human NGF epitope as the antibody MAb 911."

Claim 1 of auxiliary request 17 reads as follows:

"1. An anti-nerve growth factor (NGF) antagonist antibody or antigen binding fragment thereof for use in treating osteoarthritis pain in an individual, wherein the antibody or antigen binding fragment thereof binds

the same human NGF epitope as an antibody comprising CDRH1 of SEQ ID NO:9; CDRH2 of SEQ ID NO:10; CDRH3 of SEQ ID NO:11; CDRL1 of SEQ ID NO:12; CDRL2 of SEQ ID NO:13; and CDRL3 of SEQ ID NO:14."

Claim 11 of auxiliary request 18 reads as follows:

"11. An antibody or antigen binding fragment thereof for use of any one of claims 1 to 10, wherein the antibody or antigen binding fragment thereof binds the same human NGF epitope as an antibody as defined in claim 9 or 10."

Claim 10 of auxiliary request 19 reads as follows:

"10. An antibody or antigen binding fragment thereof for use of any one of claims 1 to 9, wherein the antibody or antigen binding fragment thereof binds the same human NGF epitope as an antibody as defined in claim 8 or 9."

Claims 1, 3, 4 and 5 of auxiliary request 20 read as follows:

"1. An anti-nerve growth factor (NGF) antagonist antibody or antigen binding fragment thereof for use in treating osteoarthritis pain in an individual, wherein the antibody or antigen binding fragment thereof comprises (a) three CDRs from a heavy chain variable region of SEQ ID NO:1; and (b) three CDRs from a light chain variable region of SEQ ID NO:2; wherein the CDRs are Kabat CDRs, Chothia CDRs or a combination of Kabat and Chothia CDRs.

3. An antibody for use of claim 1 or 2, wherein the antibody further comprises a human heavy chain IgG2a constant region.

4. An antibody for use of claim 3, wherein the antibody further comprises a human light chain kappa constant region.

5. An antibody for use of claim 3 or 4, wherein the human heavy chain IgG2a constant region is modified."

VII. With the statement of grounds of appeal, opponent 1 contested the opposition division's decision on the set of claims of auxiliary request 1 (identical to auxiliary request 3 on appeal) *inter alia* with respect to novelty over the disclosure in documents D1 and D3.

VIII. With the reply to opponent 1's statement of grounds of appeal, the patent proprietor submitted, *inter alia*, document D73 and arguments on the novelty of the claims of auxiliary request 3.

IX. With the reply to the patent proprietor's statement of grounds of appeal, opponent 1 submitted comments on the sets of claims of the main request and auxiliary requests 1 to 20 with respect to *inter alia* amendments, lack of novelty and/or lack of clarity of the claimed subject-matter. The only objection raised against the set of claims of auxiliary request 20 was that claims 3 to 5 of auxiliary request 20 lacked novelty over document D3 (see point 22.1 on page 51 of opponent 1's reply).

X. On 21 October 2020, a notice of intervention was filed by Teva Pharmaceutical Industries, Ltd. ("intervener") and the opposition and appeal fees were paid. The

intervener indicated that it was adopting the arguments made by opponent 1 in the appeal proceedings. Furthermore, it submitted seven documents as well as arguments to the effect that the subject-matter of claim 1 as granted and claim 1 of each of auxiliary requests 1 to 19 lacked inventive step. No additional comments were submitted on the set of claims of auxiliary request 20.

XI. The board summoned the parties to oral proceedings, as per their requests. It subsequently issued a communication pursuant to Article 15(1) RPBA setting out its preliminary opinion that, i*nter alia*, claim 12 of both the main request and auxiliary request 2 contained subject-matter going beyond the content of the application (and the earlier application) as filed, the subject-matter of claim 1 of auxiliary request 1 lacked clarity, the priority claim of claim 1 of auxiliary request 3 was not valid and the novelty of this claim over documents D1 and D3 hinged on whether these documents contained an enabling disclosure of the claimed subject-matter.

XII. The patent proprietor replied to the board's preliminary opinion by submitting, *inter alia*, comments on claim 12 of auxiliary request 2 in respect of amendments, the disclosure in priority application P2 and the novelty of the claims of auxiliary request 3 over the disclosure in documents D1 and D3.

XIII. The oral proceedings were held as scheduled. At the end of the oral proceedings, the Chair announced the board's decision.

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

D1 WO 2005/019266

D2 US 60/487,431 filed on 15 July 2003

D3 WO 2004/096122

D8 WO 02/096458

D30 Hongo et al., Hybridoma 19, 2000, 215-227

D49 Creamer and Hochberg, The Lancet 350, 1997, 503-509

D73 Brennan et al., Pain 64, 1996, 493-501

XV. The patent proprietor's arguments relevant to the decision are summarised as follows.

Main request - patent as granted - claim 12
Amendments (Article 100(c) EPC)

Support for the claim was provided in paragraphs [0259] and [0265] of the application (and the earlier application), which disclosed that in an embodiment the antibody bound the same (human) NGF epitope as the mouse monoclonal antibody MAb 911. The antibody E3 was a humanised antibody derived by library scanning mutagenesis from MAb 911 (see Example 1 of the application (and the earlier application)). It had improved affinity but maintained the NGF binding and blocking specificity of MAb 911, as evident from paragraph [0333] and Example 3 (paragraphs [0383] to

[0385]) of the application (and the earlier application).

Furthermore, paragraph [0290] of the application (and the earlier application) stated that "*the binding assay is a competitive binding assay, where the ability of a candidate antibody to compete with a known anti-NGF antagonist for NGF binding is evaluated*". This passage could serve as a basis for claim 12 as granted because antibodies identified in a competition assay bound the same epitope. Moreover, in the context of the application (and the earlier application), the reference to a known anti-NGF antagonist in said passage included the antibody E3, so paragraph [0290] disclosed antibodies binding the same epitope as the antibody E3.

Auxiliary request 1 - claim 12
Clarity (Article 84 EPC)

The reference to "MAb 911" in claim 12 of auxiliary request 1 was clear because this antibody was described in the state of the art (see document D30, to which paragraphs [0259] and [0265] referred, and document D8 cited in paragraph [0009] of the application). Furthermore, the complementarity-determining region (CDR) sequences of MAb 911 were disclosed on page 70, line 52 to page 71, line 2 of the patent.

Auxiliary request 2 - claim 12
Amendments (Article 76(1) EPC and Article 123(2) EPC)

Support for the claim was provided in paragraphs [0259] and [0265] of the application (and the earlier application), which disclosed that in an embodiment the antibody bound the same human NGF epitope as MAb 911,

and in the passage at the top of page 148 of the application (and the earlier application), which disclosed the CDR sequences of the antibody MAb 911, i.e. the CDRs recited in the claim.

Auxiliary request 3 - claim 1
Priority (Article 87(1) EPC)

The disclosure in priority application P2 was not restricted to treating pain (including osteoarthritis pain) with the E3 antibody or a humanised anti-NGF antibody. The fourth paragraph of page 6 of priority application P2 referred to treating pain by administering a composition comprising the antibody E3 "*or any of the antibody or polynucleotide embodiments described herein*". The last full paragraph of page 24 of priority application P2 also emphasised that the methods "*appl*[ied] *to any of the NGF binding embodiments described herein*". Moreover, the first full paragraph on page 26 of priority application P2 stated that the clinician "*will administer an anti-NGF antagonist antibody (such as E3)*". This passage hence also referred to any anti-NGF antagonist antibody.

Furthermore, the last paragraph on page 10 and the third paragraph on page 16 of priority application P2 disclosed that antibodies of the invention might have any one or more of particular characteristics of the antibody E3, and therefore also disclosed other NGF antibodies. The disclosure in priority application P2 hence concerned anti-NGF antibodies in general and therefore directly and unambiguously disclosed the claimed subject-matter.

Novelty (Article 54(3) EPC)
Document D3

The experimental data disclosed in document D3 related to the administration of an anti-NGF antibody to a rat animal model of post-surgical pain (see Example 1 on pages 54 to 57). This animal model assessed the effect of an anti-NGF antagonist antibody on resting pain based on a local inflammation, which was different from chronic joint pain in osteoarthritis. Hence, the experimental data of document D3 could not provide any conclusions on the treatment of osteoarthritis pain with an anti-NGF antagonist antibody. This deficiency was not remedied by the disclosure in paragraphs [0007] and [0008] of document D3, which did not mention osteoarthritis or correlate NGF levels with osteoarthritis pain and hence did not disclose a mechanism underlying the treatment recited in the claim. Document D3 therefore did not disclose that an anti-NGF antagonist antibody was suitable for use in treating osteoarthritis pain.

Moreover, from the common general knowledge at the priority date of the patent the skilled person was not aware that an anti-NGF antibody could treat osteoarthritis pain.

Consequently, it was not credible from either the data disclosed in document D3 or the common general knowledge that osteoarthritis pain could be treated with an anti-NGF antagonist antibody. Document D3 therefore did not contain an enabling disclosure of the claimed second medical use (see T 609/02, Reasons 9). For this reason, in line with established case law (see T 1457/09, Reasons 36), it was not prejudicial to the novelty of claim 1.

Document D1

Document D1 did not disclose treating osteoarthritis "pain" with an anti-NGF antagonist antibody and could not be prejudicial to the novelty of claim 1 for this reason alone. The list of NGF-mediated diseases and conditions disclosed in the paragraph bridging pages 40 and 41 included conditions linked to pain (e.g. "inflammatory pain", "neuropathic pain", "diabetic neuropathy pain") and conditions not linked to pain, including diabetes and osteoarthritis. Document D1 therefore only disclosed "osteoarthritis" as an NGF-mediated disease to be treated with an anti-NGF antagonist antibody. It was also clear from the paragraph bridging pages 16 and 17 that the treatment disclosed in document D1 was not solely in the context of pain.

Moreover, document D1 only contained experimental data on functional properties of an anti-NGF antibody in a neutralisation assay. From the data in document D1, the skilled person would therefore not consider it credible that the described anti-NGF antibodies could be effective in treating osteoarthritis pain. Consequently, document D1 did not contain an enabling disclosure of treating osteoarthritis pain with an anti-NGF antagonist antibody and was therefore not prejudicial to the novelty of the subject-matter of claim 1 for this additional reason.

Auxiliary requests 4 to 12, 15, 18 and 19
Amendments (Article 76(1) EPC and Article 123(2) EPC)

The patent proprietor did not submit any arguments concerning amendments with respect to claim 12 of each

of auxiliary requests 4 to 11, claim 1 of each of auxiliary requests 12 and 15, claim 11 of auxiliary request 18 and claim 10 of auxiliary request 19.

Auxiliary requests 13 and 16 - claim 1
Clarity (Article 84 EPC)

The patent proprietor did not submit any arguments concerning the clarity of claim 1 of each of auxiliary requests 13 and 16.

Auxiliary requests 14 and 17 - claim 1
Amendments (Article 76(1) EPC and Article 123(2) EPC)

The patent proprietor did not submit any arguments concerning amendments with respect to claim 1 of each of auxiliary requests 14 and 17.

Auxiliary request 20
Article 13(2) RPBA 2020

The set of claims of auxiliary request 20 was first submitted as auxiliary request 13 on 28 September 2018 during the opposition proceedings. Claim 1 was amended to include the subject-matter of claim 4 of the patent as granted, against which opponent 1 had not raised any novelty objection during the proceedings. The only objection submitted by opponent 1 against auxiliary request 20 was that the subject-matter of claims 3 to 5 lacked novelty in view of the disclosure in document D3 – a document that was found, in the context of the main request, not to contain an enabling disclosure of the claimed invention. It was therefore not a change of case to rely on auxiliary request 20 to overcome objections raised by opponent 1 against the novelty of the claims of the main request.

Novelty (Article 54(3) EPC) - claims 3, 4 and 5
Document D3

The subject-matter of claims 3, 4 and 5 was novel over document D3 because document D3 did not contain an enabling disclosure of the claimed subject-matter and could therefore not be prejudicial to the novelty of the claimed subject-matter.

XVI. Opponent 1's arguments relevant to the decision are summarised as follows.

Main request - patent as granted - claim 12
Amendments (Article 100(c) EPC)

The application (and the earlier application) did not disclose an antibody for use in treating osteoarthritis pain that bound the same epitope as the E3 antibody. Paragraphs [0259] and [0265] cited by the patent proprietor in support of this claim only referred to an antibody that bound the same epitope as "MAb 911", the murine precursor of the E3 antibody. The application (and the earlier application) did not disclose that MAb 911 and E3 bound the same epitope.

Furthermore, paragraph [0333] of the application (and the earlier application) only stated that the described humanisation and affinity maturation methods were useful for improving affinity while retaining the binding specificity of the starting antibody. However, the application (and the earlier application) did not disclose that retaining the binding specificity meant binding the same epitope.

Paragraph [0290] described that an NGF antagonist antibody could be identified in a competitive binding assay, in which the ability of a candidate antibody to "compete with a known anti-NGF antagonist" was evaluated. However, it did not refer to the E3 antibody, and therefore, for this reason alone, could not provide a direct an unambiguous basis for an antibody binding the same epitope as E3. The assaying of antibodies in a cross-competition assay did not mean that these antibodies bound the same epitope either.

The study described in paragraphs [0383] to [0385] concerned the testing of the E3 and MAb 911 antibodies in neuron survival assays and did not lead to any conclusions on the respective epitopes bound by these antibodies.

Auxiliary request 1 - claim 12
Clarity (Article 84 EPC)

The term "MAb 911" introduced into claim 12 of auxiliary request 1 was not clear because it was an internal designation that did not provide the skilled person with sufficient information for identifying whether or not they were working within the scope of the claim. Documents D30, cited in paragraphs [0259] and [0265] of the application, and D8, cited in paragraph [0009] of the application, could not remedy this deficiency because they did not provide any sequences or a deposit of MAb 911. Page 70 of the patent (page 148 of the application) only disclosed the CDRs of MAb 911, not the complete sequences, so this was also insufficient for clearly defining the claimed subject-matter.

Auxiliary request 2 - claim 12
Amendments (Article 76(1) EPC and Article 123(2) EPC)

The disclosure in paragraphs [0259] and [0265] of the application was restricted to an antibody that bound the same epitope as MAb 911. It could therefore not provide a basis for an antibody that bound the same human NGF epitope as an antibody comprising only the CDR sequences of MAb 911.

Auxiliary request 3 - claim 1
Priority (Article 87(1) EPC)

The priority application P2 only disclosed "humanised" anti-NGF antibodies and in particular the antibody E3 (see the chapter "*Field of the invention*" on page 1; the first two sentences of the chapter "*Brief summary of the invention*" on page 3; the first paragraph of the chapter "*Detailed description of the invention*" on page 8). No anti-NGF antibodies other than the humanised anti-NGF antibody E3 or humanised anti-NGF antibodies closely related to E3 were disclosed in priority application P2, and thus any references to antibodies "of the invention" or antibodies "described herein" also only referred to these humanised anti-NGF antibodies. The subject-matter of claim 1, which related to any anti-NGF antagonist antibody, therefore did not validly claim priority from priority application P2.

Novelty (Article 54(3) EPC)
Document D3

D3 provided a clear and unambiguous disclosure of the use of an anti-NGF antibody in treating osteoarthritis pain. There was nothing in document D3 to suggest that

an anti-NGF antibody would not work in the treatment of osteoarthritis pain.

The technical concept underlying the treatment of osteoarthritis pain with an anti-NGF antagonist antibody disclosed in document D3 was that increased NGF levels were associated with hyperalgesia and inflammation in various forms of arthritis (see page 2, paragraphs [0007] and [0008] of document D3). Osteoarthritis pain had an inflammatory component, as acknowledged by the patent proprietor.

Document D3 furthermore disclosed that an anti-NGF antagonist antibody could alleviate pain in an *in vivo* model of post-surgical pain. It therefore credibly disclosed that an anti-NGF antagonist antibody could be used for treating all types of pain. On the basis of the technical concept disclosed in paragraphs [0007] and [0008] of document D3, the data on the treatment of post-surgical pain could be extrapolated to the treatment of osteoarthritis pain.

The patent proprietor had not provided any reasonable doubts, substantiated by verifiable facts, that this was not the case. Document D3 contained all the information that was needed for an enabling disclosure of the possibility of treating osteoarthritis pain with an anti-NGF antagonist antibody.

Document D1

Document D1 related to the treatment of pain and pain-related disorders with an anti-NGF antagonist antibody, as evident from its overall content (see e.g. page 1, lines 8 to 10; page 2, last full paragraph, in particular lines 28 and 29; page 3, lines 18 to 26).

Claim 27 and the paragraph bridging pages 40 and 41 provided a list of NGF-mediated diseases or conditions linked to pain, which included pain resulting from osteoarthritis. It did not make technical sense to read the list of conditions recited in claim 27 and on pages 40 and 41 such that the expression "*pain resulting from* ..." only referred to amputation or abscess. This was further confirmed by the fact that the list also referred to toxins and chemotherapy, which were not medical conditions and hence only made technical sense when read in conjunction with the expression "pain resulting from". Document D1 therefore disclosed the subject-matter of claim 1.

Moreover, document D1 specifically disclosed that persons afflicted with an inflammatory condition, "*such as ... osteoarthritis*", often experienced enhanced sensations of pain (page 2, lines 8 to 15), i.e. it linked osteoarthritis with inflammation as well as linking increased levels of NGF with osteoarthritis. It was therefore credible for the skilled person from the disclosure in document D1 alone that osteoarthritis pain could be treated with an anti-NGF antagonist antibody. The disclosure in document D1 was thus enabling for the claimed subject-matter, which was therefore not novel over document D1.

Auxiliary requests 4 to 12, 15 and 19
Amendments (Article 76(1) EPC and Article 123(2) EPC)

Claim 12 of each of auxiliary requests 4 to 11, claim 1 of auxiliary requests 12 and 15 and claim 10 of auxiliary request 19 contained subject-matter that extended beyond the application (and the earlier application) as filed for the same reasons as claim 12 of the main request.

Auxiliary requests 13 and 16 - claim 1
Clarity (Article 84 EPC)

The subject-matter of claim 1 of each of auxiliary requests 13 and 16 lacked clarity for the same reasons as claim 12 of auxiliary request 1.

Auxiliary request 14 - claim 1
Amendments (Article 76(1) EPC and Article 123(2) EPC)

Claim 1 of auxiliary request 14 contained subject-matter that extended beyond the application (and the earlier application) as filed for the same reasons as claim 12 of auxiliary request 2.

Auxiliary request 20
Article 13(2) RPBA 2020

The patent proprietor could not rely on auxiliary request 20 to overcome the novelty objections raised against the main request because auxiliary request 20 had only been substantiated to overcome inventive step objections. Relying on this auxiliary request to overcome a novelty objection was a change of case, which should not be admitted pursuant to Article 13(2) RPBA.

Novelty (Article 54(3) EPC) - claims 3, 4 and 5
Document D3

The subject-matter of claims 3, 4 and 5 was only entitled to an effective date of 24 December 2003. It was not novel over the disclosure of the E3 antibody for use in treating osteoarthritis pain in document D3 because the E3 antibody had the properties of the

antibody recited in said claims (see paragraph [0073] of document D3).

XVII. The intervener's arguments submitted in writing are irrelevant for the decision because they only concerned inventive step, with the exception of those arguments adopted from opponent 1 (see section X.). During the oral proceedings, opponent 1, the intervener and the party as of right (opponent 3) were represented by the same representatives and made the same arguments. The intervener, opponent 1 and opponent 3 are referred to as "opponents" in the "Reasons for the Decision" when reference is made to one or more of these arguments.

XVIII. The parties' requests relevant for the decision were as follows.

The patent proprietor requested that the decision under appeal be set aside and the patent be maintained as granted (main request) or, as an auxiliary measure, on the basis of the set of claims of one of auxiliary requests 1 to 2. In the alternative, it requested that opponent 1's appeal be dismissed (i.e. the patent be maintained on the basis of auxiliary request 3, which is identical to auxiliary request 1 considered allowable in the decision under appeal) or, as a further alternative, that the patent be maintained as amended on the basis of the set of claims of one of auxiliary requests 4 to 21, all claim requests submitted with the statement of grounds of appeal, and that document D73 be admitted into the appeal proceedings.

Opponent 1 and the intervener requested that the decision under appeal be set aside and that the patent be revoked. The intervener furthermore requested

reimbursement of the appeal fee in the event that payment of that fee was not required.

Opponent 3, a party as of right in the appeal proceedings, did not formulate any requests.

Reasons for the Decision

Admissibility

1. The appeals comply with Articles 106 to 108 and Rule 99 EPC and are admissible. The intervention complies with Article 105 and Rule 89 EPC and is admissible. Pursuant to Article 105(2) EPC, an admissible intervention is treated as an opposition.

Admittance of document D73

2. The patent proprietor requested that document D73 be admitted into the appeal proceedings. The board decided not to admit document D73 into the appeal proceedings but in view of the board's decision that document D3 does not contain an enabling disclosure of treating osteoarthritis pain with an anti-nerve growth factor (NGF) antagonist antibody (see points 26. to 35. below), it is not necessary to provide reasons for this decision.

Main request - patent as granted - claim 12
Amendments (Article 100(c) EPC)

3. Claim 12 as granted concerns an antibody or antigen binding fragment thereof for use in treating osteoarthritis pain in an individual, the antibody or antigen binding fragment thereof being defined in that

it "binds the same human NGF epitope as an antibody as defined in claim 10 or 11". Claim 10 defines an antibody comprising the amino acid sequences of the heavy chain (SEQ ID NO:1) and light chain (SEQ ID NO:2) variable regions of the antibody "E3"; claim 11 defines an antibody comprising the amino acid sequences of the heavy chain (SEQ ID NO:16) and light chain (SEQ ID NO:17) of the antibody "E3" (see section I.).

4. The passages of the application and the earlier application which concern antibodies binding the same epitope as another antibody are paragraphs [0259] and [0265]. These paragraphs are identical in both applications. Paragraph [0259] discloses an anti-NGF antagonist antibody that "*binds essentially the same NGF epitope 6 as an antibody selected from any one or more of the following: MAb 911, MAb 912 and MAb 938*". Paragraph [0265] discloses an antibody that "*binds essentially the same hNGF epitopes as an antibody selected from the group consisting of MAb 911, MAb 912, and MAb 938*". Both passages furthermore single out an antibody that binds the same epitope as the antibody "MAb 911" but neither passage refers to the E3 antibody or any other antibody comprising the amino acid sequences recited in the claim. The same is true for document D30 cited in paragraphs [0259] and [0265] as a reference for the anti-NGF antibodies MAb 911, MAb 912 and MAb 938.

5. According to the patent proprietor, the reference to an antibody binding the same epitope as MAb 911 provided the basis for the claimed subject-matter because the E3 antibody was a humanised version of MAb 911 and bound the same epitope as MAb 911, as evident from paragraph [0333] and Example 3 (paragraphs [0383] to [0385]) of the application (and the earlier

application), which showed that the humanisation and affinity maturation process performed on MAb 911 to obtain the E3 antibody retained the binding specificity and activity of MAb 911 while improving the affinity.

6. However, considerations as regards the epitope which the E3 antibody might bind do not have any bearing on the fact that the application (and the earlier application) does not disclose an anti-NGF antagonist antibody for treating osteoarthritis pain that binds the same epitope as the E3 antibody (see point 4. above). Moreover, paragraph [0333] and Example 3 of the application (and the earlier application) do not disclose that the E3 antibody indeed binds the same epitope as the MAb 911. This line of argument therefore fails to persuade the board.

7. Paragraph [0290] of the application (and the earlier application) discloses that in an embodiment, "*the binding assay is a competitive binding assay, where the ability of a candidate antibody to compete with a known anti-NGF antagonist for NGF binding is evaluated*". This paragraph hence only contains a general reference to "a known anti-NGF antagonist", i.e. it does not directly and unambiguously refer to the E3 antibody, even if the E3 antibody was an anti-NGF antagonist known in the prior art. For this reason alone, this paragraph does not provide a basis for the claimed subject-matter.

8. Consequently, none of the passages in the application (and the earlier application) relied on by the patent proprietor provide a basis for the claimed subject-matter. Claim 12 as granted therefore contains subject-matter that extends beyond the content of the application (and the earlier application) as filed (Article 100(c) EPC).

Auxiliary request 1 - claim 12
Clarity (Article 84 EPC)

9. Claim 12 of auxiliary request 1 concerns an antibody or antigen binding fragment thereof for use in treating osteoarthritis pain in an individual, the antibody or antigen binding fragment thereof being defined in that it "binds the same human NGF epitope as the antibody MAb 911" (see section VI.). The expression "antibody MAb 911" was not present in the claims as granted. Claim 12 may therefore be examined for compliance with the requirements of Article 84 EPC to the extent that this amendment introduces non-compliance with Article 84 EPC (see decision G 3/14 of the Enlarged Board of Appeal, OJ EPO 2015, A102, Order). Under Article 84 EPC, the claims must define the subject-matter for which patent protection is sought and must be clear.

10. Since the antibody of claim 12 is defined as binding the same epitope as the antibody "MAb 911", the identity of this antibody is essential for the definition of the claimed subject-matter. In G 1/04 (OJ EPO 2006, 334; Reasons 6.2), the Enlarged Board of Appeal held that the meaning of the essential features should be clear for the person skilled in the art from the wording of the claim alone.

11. No structural or functional features of "MAb 911" are defined in the claim, other than the fact that it binds an epitope of human NGF. This feature, however, does not provide any information on the amino acid sequence(s) of the antibody "MAb 911". The meaning of the term "MAb 911" is therefore not clear from the wording of the claim alone.

12. Furthermore, the description and drawings of the application do not disclose the entire amino acid sequence(s) of "MAb 911". Only the amino acid sequences of the complementarity-determining regions (CDRs) of MAb 911 are disclosed (see lines 1 to 9 on page 148 and SEQ ID NO:9 to SEQ ID NO:14). These are, however, only small fragments of the antibody's complete amino acid sequence(s) and are therefore insufficient for clearly defining this antibody.

13. Paragraphs [0259] and [0265] cite document D30 as a reference for the "MAb 911" antibody. However, document D30 neither discloses the amino acid sequence(s) of "MAb 911" nor refers to a deposited hybridoma cell line producing this antibody. The same is true for the disclosure in document D8, cited by the patent proprietor as a further reference for the "MAb 911" antibody and in paragraph [0009] of the application. Hence, even when documents D8 and D30 are taken into account, the antibody to which the term "MAb 911" refers is unclear.

14. Consequently, the term "MAb 911" leaves the person skilled in the art in doubt as to the structural identity of the antibody. The subject-matter for which protection is sought therefore cannot be determined and claim 12 lacks clarity (Article 84 EPC).

Auxiliary request 2 - claim 12
Amendments (Article 76(1) EPC and Article 123(2) EPC)

15. The antibody or antigen binding fragment recited in claim 12 of auxiliary request 2 is defined by the feature whereby it binds the same human NGF epitope as an antibody comprising the CDRs defined by SEQ ID NO:9

to SEQ ID NO:14, which are the CDRs of the antibody "MAb 911" (see section VI., and page 148, lines 1 to 10 of the application (and earlier application)).

16. As a basis for the subject-matter of the claim, the patent proprietor pointed to lines 1 to 10 of page 148 and paragraphs [0259] and [0265] of the application (and the earlier application). However, as discussed above (see point 4.), paragraphs [0259] and [0265] of the application (and the earlier application) disclose an antibody that binds the same NGF epitope as "*an antibody selected from any one or more of the following: MAb 911, MAb 912 and MAb 938*". The disclosure in paragraphs [0259] and [0265] is therefore limited to antibodies binding the same NGF epitope as one of the three antibodies listed there. There is, however, no disclosure of antibodies binding the same epitope as an antibody that comprises only the CDRs of one of said three antibodies. It is therefore irrelevant that the CDRs listed in the claim are the same CDRs contained in "MAb 911".

17. Consequently, claim 12 of auxiliary request 2 contains subject-matter which extends beyond the content of the application (and the earlier application) as filed (Article 76(1) EPC and Article 123(2) EPC).

Auxiliary request 3 - claim 1
Priority (Article 87(1) EPC)

18. The opposition division decided that the subject-matter of claim 1 was not entitled to the filing date of any of the priority applications P1, P2 and P3 (see sections II. and V.). The patent proprietor challenged this decision in respect of priority application P2 only (see section VI.). According to the opposition

division, the priority application P2 only disclosed humanised anti-NGF antibodies, and in particular the humanised anti-NGF antibody E3, but did not teach "any" anti-NGF antagonist antibody for treating osteoarthritis pain.

19. The priority application P2 states, in the section "*Field of the invention*", that the invention "*concerns humanized anti-NGF antibodies*" and the "*use of such antibodies in the treatment and/or prevention of pain*" (see the first sentence on page 1). In the section "*Brief summary of the invention*", it is indicated that "*the invention disclosed herein concerns humanized antibodies to nerve growth factor*" and that "*in one aspect, the invention is a humanized and affinity matured antibody, E3, that specifically binds human and rodent nerve growth factor*" (see page 3, last full paragraph from the bottom). A similar disclosure can be found in the first paragraph of the section "*Detailed description of the invention*", where it is stated that "[t]*he invention disclosed herein provides a humanized antibody, E3*" (see the first full paragraph on page 8). The overall disclosure of the priority application P2 therefore explicitly teaches that the "antibodies of the invention" are humanised anti-NGF antibodies, in particular the antibody E3, and not "any" anti-NGF antagonist antibody.

20. The board is also not persuaded that passages on pages 6, 10, 16, 24 and 26 of the priority application P2 demonstrated that the disclosure in P2 was not restricted to treating pain (including osteoarthritis pain) with a humanised anti-NGF antibody or the E3 antibody. The fourth full paragraph on page 6 of the priority application P2 pointed out by the patent proprietor discloses that the "*invention is a method of*

treating pain by administering an effective amount of a composition comprising the antibody E3 or any of the antibody or polynucleotide embodiments described herein". This passage therefore merely refers to antibody embodiments explicitly described in the priority application P2 and hence does not itself disclose "any" anti-NGF antibody.

21. The last paragraph on page 10 of the priority application P2 discloses amino acid sequences and biological functions of the "E3" antibody and that "*antibodies of the invention may have any one or more of these characteristics*". This passage hence does not teach that the antibody of the invention could be "any" anti-NGF antagonistic antibody; it merely teaches that the antibodies of the invention, which, according to the general teaching in the priority application P2, are humanised anti-NGF antibodies and in particular E3 (see point 19. above), could have one or more of particular characteristics of the E3 antibody.

22. The third paragraph on page 16 also refers to particular characteristics of the "*antibodies of the invention*". In the two preceding paragraphs on page 16 it is stated that "[T]*his invention encompasses compositions, including pharmaceutical compositions, comprising the E3 antibody ...*" and that "[T]*he present invention also encompasses various formulations of E3 and equivalent antibodies or polypeptide fragments (e.g., Fab, Fab', F(ab')$_2$, Fv, Fc, etc.), single chain (ScFv), mutants thereof, fusion proteins comprising an antibody portion, and any other modified configuration of E3 that comprises an antigen (NGF) recognition site of the required specificity*". Moreover, in the subsequent paragraph on page 16, it is concluded that "[A]*ccordingly, the invention provides antibodies ...*

comprising any of the following polypeptides: (a) antibody E3; (b) an antibody comprising a fragment or a region of the antibody E3; ..." or other modified antibody variants or fragments, but these are all derived from the E3 antibody. It is therefore clear from this context on page 16 that the mentioned "*antibodies of the invention*" are the E3 antibody and antibodies or polypeptide fragments related to E3, not "any" anti-NGF antagonist antibody.

23. The last full paragraph on page 24 of the priority application P2 also refers to "*any of the NGF binding embodiments herein*", which are, as established above, the E3 antibody, antibodies related to E3 or, possibly, other "humanised" anti-NGF antibodies. The same considerations apply to the disclosure in the first full paragraph on page 26 of the priority application P2, which states that the clinician "*will administer an anti-NGF antagonist antibody (such as E3)*". This section is part of the chapter "*Methods of using E3 for therapeutic purposes*", the first paragraph of which clarifies that the treatment is with a "humanised" E3 antibody or "*any ... modified configuration of E3*" (see the first two paragraphs of this chapter on page 24 and the paragraph bridging pages 24 and 25).

24. Consequently, the opposition division was correct in that the priority application P2 does not disclose "any" antagonistic anti-NGF antibody for use in treating pain (including osteoarthritis pain) in an individual and that the claimed subject-matter is therefore not entitled to the filing date of the priority application P2 (Article 87(1) EPC). Since the patent proprietor has not challenged the opposition division's decision that the claimed subject-matter is not entitled to the filing date of the priority

applications P1 and P3, the effective date of the claimed subject-matter is 24 December 2003.

25. As a consequence, the content of document D3 as filed is within the state of the art as per Article 54(3) EPC. The content of document D1 as filed is within the state of the art as per Article 54(3) EPC in so far as it is entitled to priority (document D2).

Novelty (Article 54(3) EPC)
Document D3

26. In line with established case law, a disclosure destroys novelty only if its teaching is reproducible, i.e. is disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art (see e.g. Case Law of the Boards of Appeal of the European Patent Office, 10th edition 2022, I.C.4.11). A second medical use claim is sufficiently disclosed only if the disclosure in the prior art document makes it credible that the therapeutic effect on which the disclosed treatment relies can be achieved (see decision T 609/02, Reasons 9). Therefore, document D3 is only novelty destroying to the claimed subject-matter if it discloses that an anti-NGF antagonist antibody is indeed suitable for the treatment of osteoarthritis pain.

27. In the decision under appeal, the opposition division considered that document D3 lacked any such disclosure because it contained data on treating post-surgical pain, but not osteoarthritis pain, with an anti-NGF antagonist antibody.

28. Document D3 investigated the effect of an anti-NGF antagonist antibody on post-surgical resting pain based

on a local inflammation in a rat animal model. The local inflammation was caused by an incision through skin and fascia in the hind paw of the rat (see Example 1 on pages 54 to 57). The post-surgical pain experienced in this animal model is therefore caused by an injury to soft tissue and an associated inflammation.

29. In contrast, osteoarthritis is a chronic disease which affects the joints. Pain in the affected joint is one of the major symptoms, but it can have various possible sources (see e.g. the paragraph bridging pages 505 and 506 in the review article D49). Osteoarthritis pain therefore does not have a mechanism in common with the post-surgical pain experimentally induced in the animal model in document D3. Consequently, the data obtained in document D3 on the treatment of post-surgical pain does not provide any conclusions on the treatment of osteoarthritis pain with an anti-NGF antagonist antibody. Document D3 therefore does not contain any experimental evidence for the treatment recited in the claim.

30. Experimental results need not always be disclosed in an application in order to establish sufficiency. Therefore, a lack of experimental data as such is not a reason to conclude that a claimed invention is not sufficiently disclosed. Suitable evidence for a claimed therapeutic effect may also be derivable from the common general knowledge or a plausible technical concept disclosed in the application (see e.g. decision T 950/13, Reasons 3.2 and 3.6).

31. The opponents considered that paragraphs [0007] and [0008] of document D3 disclosed a plausible technical concept for the claimed therapeutic effect. These

paragraphs disclose that a link between increased NGF levels and inflammatory conditions (including "*a number of forms of arthritis*") has been observed in the prior art. Paragraph [0008] then specifies that high levels of NGF were observed in the synovium of patients affected by rheumatoid arthritis and in rats with experimentally induced rheumatoid arthritis but not in non-inflamed synovium.

32. Hence, paragraphs [0007] and [0008] of document D3 only disclose a plausible concept for rheumatoid arthritis as a condition associated with inflammation and elevated NGF levels. Unlike the disclosure in document D1 (see points 40. to 43. below), there is no information on osteoarthritis, a disease with an aetiology different from that of rheumatoid arthritis. Therefore, the teaching in paragraphs [0007] and [0008] of document D3 does not on its own lead to any conclusions on a link between osteoarthritis and elevated NGF levels or inflammation. Consequently, document D3 does not disclose a technical concept which would plausibly show that osteoarthritis pain could be treated with an anti-NGF antagonist antibody.

33. The opponents did not submit any evidence of common general knowledge which would support the notion that the skilled person, taking note of the disclosure in document D3, would accept that osteoarthritis pain could be treated with an anti-NGF antagonist antibody. Instead, they argued that the patent proprietor had not provided any prior art raising reasonable doubts, substantiated by verifiable facts, that the treatment disclosed in document D3 could not be carried out, asserting also that the patent proprietor itself had acknowledged that osteoarthritis had an inflammatory component.

34. However, the opposition division had decided that document D3 did not contain an enabling disclosure of treating osteoarthritis pain with an anti-NGF antagonist antibody. The opponents challenged this finding. It was therefore on the opponents to demonstrate that the opposition division's decision was incorrect, and why; it was not down to the patent proprietor to raise additional doubts. The opponents did not submit any further evidence or arguments, e.g. to the effect that the skilled person, on the basis of their common general knowledge, would have considered the claimed therapeutic effect plausible at the effective filing date of document D3. Moreover, in order to assess whether or not the treatment of osteoarthritis pain with an anti-NGF antagonist antibody was sufficiently disclosed in document D3, the only relevant factor is what the skilled person understood from the disclosure in document D3 when reading it, and not what the patent proprietor may or may not have acknowledged in the course of the appeal proceedings.

35. Consequently, on the basis of the arguments and evidence submitted by the opponents, the board is not persuaded that the opposition division's decision that document D3 did not sufficiently disclose that osteoarthritis pain could be treated with an anti-NGF antagonistic antibody was incorrect. As a consequence, in line with established case law (see point 26. above and decision T 1457/09, Reasons 36), the disclosure in document D3 is not prejudicial to the novelty of the claimed subject-matter (Article 54(3) EPC).

Document D1

36. In the decision under appeal, the opposition division considered that document D1 did not disclose treating osteoarthritis "pain" with an anti-NGF antibody because it only disclosed treating osteoarthritis as such (see page 40, line 26 and claim 27 of document D1).

37. However, document D1 as a whole is concerned with treating pain, as is evident, for example, from lines 8 to 10 of page 1, describing the field of the invention: "*The invention relates to human monoclonal antibodies that bind nerve growth factor (NGF). Compositions and methods for treating pain and pain-related disorders are also described.*" Furthermore, in the chapter "*Background of the invention*" (see pages 1 to 3 of document D1), various forms, causes and treatments of chronic pain are discussed, with the technical problem being defined as "*a need for new safe and effective treatments for pain*" (see page 3, lines 14 and 15). In the chapter "*Summary of the invention*", the invention is defined as providing "*novel human monoclonal antibodies that are therapeutically useful for managing pain*" (see page 3, lines 18 and 19). It is hence evident from these passages that the medical conditions described in document D1 are pain-related and that the treatment is aimed at reducing this pain.

38. Moreover, claim 27 of document D1 relates to treating a condition caused by increased NGF expression with a human NGF signalling-inhibiting (i.e. antagonistic) anti-NGF antibody (see claims 25 and 26, to which claim 27 refers). The conditions are further defined in claim 27 as "*acute pain, dental pain, pain from trauma, surgical pain, pain resulting from amputation or abscess, causalgia, demyelinating diseases, trigeminal*

neuralgia, cancer, chronic, alcoholism, stroke, thalamic pain syndrome, diabetes, acquired immune deficiency syndrome ("AIDS"), toxins, chemotherapy, general headache, migraine, cluster headache, mixed-vascular or non-vascular syndromes, tension headache, general inflammation, arthritis, rheumatic diseases, lupus, osteoarthritis, ..." (emphasis added by the board).

39. In view of the overall disclosure in document D1 in relation to treating pain-related conditions with an NGF antibody, the board agrees with the opponents that it would not make technical sense to read the list of conditions in claim 27 such that the expression "*pain resulting from ...*" (see the first underlined expression in point 38. above) referred only to amputation or abscess and not to each of the pain-related disorders listed subsequently, including osteoarthritis. Therefore, the skilled person understands that treating pain related to each of the conditions listed in claim 27 is implicitly disclosed within this list. Consequently, document D1 discloses treating osteoarthritis pain with an anti-NGF antagonistic antibody (see claim 27 in conjunction with claims 26, 25 and 1). Next, it has to be addressed whether D1 also credibly discloses that an anti-NGF antagonist antibody is suitable for treating osteoarthritis pain (see point 26. above).

40. As correctly pointed out by the patent proprietor, the experimental data disclosed in document D1 do not relate to treating osteoarthritis pain with an anti-NGF antagonist antibody. However, experimental data are not always required in order to establish sufficiency of disclosure (see point 30. above). Sufficiency could also be established if, for example, in line with the

standard set in decision T 609/02 (Reasons 9; see point 34. above), document D1 provides some information to the effect that an anti-NGF antibody has a direct effect on a mechanism involved in osteoarthritis pain.

41. In this context, document D1 discloses that persons afflicted with an inflammatory condition, "*such as ... osteoarthritis*", "*often experience enhanced sensations of pain*" (see page 2, lines 8 to 15). Hence, unlike document D3 (see point 32. above), document D1 discloses that osteoarthritis is an inflammatory condition and that inflammation enhances pain. The patent proprietor has not submitted any arguments or evidence to the effect that this teaching in document D1 was incorrect.

42. Document D1 furthermore discloses that "*there is considerable evidence implicating endogenous NGF in conditions in which pain is a prominent feature*" (see page 2, lines 8 and 29), that "*it has been demonstrated that antagonism of NGF function prevents hyperalgesia and allodynia in models of neuropathic and chronic inflammatory pain*" (see page 3, lines 4 to 6), and that pain resulting from osteoarthritis "*is associated with increased levels of NGF or increased sensitivity to NGF*" (see paragraph bridging pages 40 and 41).

43. Therefore, document D1 teaches the skilled person that osteoarthritis is an inflammatory condition with enhanced pain experience, that osteoarthritis pain is associated with increased endogenous NGF levels, and that antagonism of NGF function prevents hyperalgesia in models of *inter alia* chronic inflammatory pain. In view of this teaching, the skilled person would have considered it credible that osteoarthritis pain could be treated with an anti-NGF antagonist antibody.

Consequently, document D1 discloses an anti-NGF antagonist antibody for treating osteoarthritis pain in a manner sufficiently clear and complete for it to be carried out by the skilled person.

44. The same disclosure is present in priority document D2; see page 1, lines 5 to 6; page 2, lines 2 to 6, 23, 24, 30 and 31; page 3, lines 5 to 6, 9 and 10; paragraph bridging pages 28 and 29; claims 14, 15 and 16 of document D2). This was not contested by the patent proprietor.

45. The subject-matter of claim 1 is thus not novel over the disclosure in document D1 (Article 54(3) EPC).

Auxiliary requests 4 to 12, 15, 18 and 19
Amendments (Article 76(1) EPC and Article 123(2) EPC)

46. Claim 12 of each of auxiliary requests 4 to 11, claim 1 of auxiliary requests 12 and 15, claim 11 of auxiliary request 18 and claim 10 of auxiliary request 19 relate to an anti-NGF antagonist antibody or antigen binding fragment thereof which is, *inter alia*, defined in that it binds the same human NGF epitope as an antibody comprising a heavy chain variable region comprising the sequence shown in SEQ ID NO:1 and a light chain variable region comprising the sequence shown in SEQ ID NO:2 or an antibody comprising a heavy chain comprising the amino acid sequence shown in SEQ ID NO:16 and a light chain comprising the amino acid sequence shown in SEQ ID NO:17 (see section VI.).

47. As assessed in the context of claim 12 as granted, an antibody defined in this manner lacks a basis in the application (and the earlier application) (see points 4. to 8. above).

48. Consequently, claim 12 of each of auxiliary requests 4 to 11, claim 1 of auxiliary requests 12 and 15, claim 11 of auxiliary request 18 and claim 10 of auxiliary request 19 contain subject-matter that extends beyond the application (and the earlier application) as filed for the same reasons as claim 12 of the main request (Article 76(1) EPC and Article 123(2) EPC).

Auxiliary requests 13 and 16 - claim 1
Clarity (Article 84 EPC)

49. Claim 1 of each of auxiliary requests 13 and 16, as amended during the appeal proceedings, refers to the antibody "MAb 911" to characterise the claimed subject-matter (see section VI.). As assessed in the context of claim 12 of auxiliary request 1, the term "MAb 911" does not have a clear meaning in the art and therefore does not make it possible to ascertain the technical features of this antibody (see points 9. to 14. above).

50. Consequently, claim 1 of each of auxiliary requests 13 and 16 lacks clarity for the same reasons as claim 12 of auxiliary request 1 (Article 84 EPC).

Auxiliary requests 14 and 17 - claim 1
Amendments (Article 76(1) EPC and Article 123(2) EPC)

51. Claim 1 of each of auxiliary requests 14 and 17 relates to an anti-NGF antagonist antibody or antigen binding fragment thereof which is, *inter alia*, defined in that it binds the same human NGF epitope as an antibody comprising CDRH1 of SEQ ID NO:9; CDRH2 of SEQ ID NO:10; CDRH3 of SEQ ID NO:11; CDRL1 of SEQ ID NO:12; CDRL2 of SEQ ID NO:13; and CDRL3 of SEQ ID NO:14 (see section VI.).

52. As assessed in the context of claim 12 of auxiliary request 2, an antibody defined in this manner lacks a basis in the application (and the earlier application) as filed (see points 15. to 17. above).

53. Consequently, claim 1 of each of auxiliary requests 14 and 17 contains subject-matter that extends beyond the application (and the earlier application) as filed for the same reasons as claim 12 of auxiliary request 2 (Article 76(1) EPC and Article 123(2) EPC).

Auxiliary request 20
Admittance (Article 13(2) RPBA)

54. In its reply to opponent 1's statement of grounds of appeal, the patent proprietor stated that auxiliary request 20 had been occasioned by the opposition division's preliminary opinion concerning inventive step. During the oral proceedings the patent proprietor relied on auxiliary request 20 to overcome added-matter and novelty objections that the board had found convincing. Therefore, the question was raised whether relying on auxiliary request 20 represented an amendment to the patent proprietor's appeal case.

55. However, in its reply to opponent 1's statement of grounds of appeal, the patent proprietor also indicated that, *inter alia*, claim 12 had been deleted, implying that the claim set overcame the added-matter objections against the main request. On the issue of novelty, the patent proprietor referred to its comments regarding auxiliary request 3. These comments included the view that document D3 was not novelty-destroying because it was a non-enabling disclosure. In view of this implicit substantiation, the board concluded that the patent

proprietor's reliance on auxiliary request 20 did not constitute an amendment to its appeal case.

Novelty (Article 54(3) EPC)

56. The only objection against the set of claims of auxiliary request 20 raised by opponent 1 was that claims 3 to 5 lacked novelty over document D3 (see section IX.). The intervener did not raise any objections against the set of claims of auxiliary request 20 other than by adopting opponent 1's arguments (see section X.).

57. As analysed above in the context of claim 1 of auxiliary request 3 (see points 26. to 35.), document D3 does not sufficiently disclose that osteoarthritis pain could be treated with an anti-NGF antagonist antibody and is therefore not prejudicial to the novelty of that subject-matter. As a consequence, the subject-matter of claims 3 to 5 of auxiliary request 20 is novel over document D3 (Article 54(3) EPC).

58. No further objections were submitted by the opponents against the claims of auxiliary request 20.

Reimbursement of the appeal fee

59. The intervener paid both the opposition fee and appeal fee (see section X.) and requested reimbursement of the appeal fee in the event that payment of that fee was not required (see section XVIII.).

60. In G 3/04 (OJ EPO 2006, 118) the Enlarged Board of Appeal held that there was no legal basis for demanding

payment of the appeal fee from an intervener in appeal proceedings (see Reasons 11).

61. Since fees paid by way of precaution but without a legal basis are reimbursed, the board decided that the appeal fee is to be reimbursed to the intervener.

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 with the order to maintain the patent with the following claims and the description and drawings to be adapted thereto, if need be:

   Claims 1 to 10 of auxiliary request 20 filed with the statement of grounds of appeal.

3. The appeal fee is to be reimbursed to the intervener.

The Registrar: The Chair:

I. Aperribay P. de Heij

Decision electronically authenticated