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Datasheet for the decision of 14 July 2022

Case Number: T 0435/20 - 3.3.08

Application Number: 06802592.3

Publication Number: 1931710

IPC: C07K16/24, C12N15/13, A61K39/395, A61P35/00, A61P37/00

Language of the proceedings: EN

Title of invention:
Engineered anti-IL-23 antibodies

Patent Proprietor:
Merck Sharp & Dohme Corp.

Opponents:
(1) Eli Lilly and Company (opposition withdrawn)
(2) AbbVie Inc.
(3) AbbVie Overseas S.à r.l.

Headword:
Anti-IL-23 antibodies binding at conformational epitope/MERCK SHARP & DOHME

Relevant legal provisions:
EPC Art. 100(b), 83, 114(2)

Keyword:
Grounds for opposition - insufficiency of disclosure (yes)
Sufficiency of disclosure - undue burden (yes)
Late submitted material - correct exercise of discretion (no)

Decisions cited:
T 0431/96, T 1466/05

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Case Number: T 0435/20 - 3.3.08

D E C I S I O N
of Technical Board of Appeal 3.3.08
of 14 July 2022

Appellant: (Patent Proprietor)	Merck Sharp & Dohme Corp. 126 East Lincoln Avenue Rahway, NJ 07065-0907 (US)
Representative:	Mathys & Squire The Shard 32 London Bridge Street London SE1 9SG (GB)
Respondent I: (Opponent 2)	AbbVie Inc. 1 North Waukegan Road North Chicago, IL 60064 (US)
Representative:	König Szynka Tilmann von Renesse Patentanwälte Partnerschaft mbB Düsseldorf Mönchenwerther Straße 11 40545 Düsseldorf (DE)
Respondent II: (Opponent 3)	AbbVie Overseas S.à r.l. 26, Boulevard Royal 2449 Luxembourg (LU)
Representative:	König Szynka Tilmann von Renesse Patentanwälte Partnerschaft mbB Düsseldorf Mönchenwerther Straße 11 40545 Düsseldorf (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 12 December 2019 revoking European patent No. 1931710 pursuant to Article 101(2) and Article 101(3)(b) EPC**

Composition of the Board:

Chair	A. Chakravarty
Members:	R. Morawetz
	M. Blasi

Summary of Facts and Submissions

I. The appeal of the patent proprietor (appellant) lies from the opposition division's decision revoking European patent No. 1 931 710 (the patent), entitled "Engineered anti-IL-23 antibodies".

II. The patent was granted on European patent application No. 06 802 592.3, filed as an international patent application published as WO 2007/027714 (application as filed).

III. Three oppositions were filed. The opposition proceedings were based *inter alia* on the ground for opposition in Article 100(b) EPC. By letter of 10 May 2019, opponent 1 withdrew its opposition. Consequently, it was never a party to the appeal proceedings. Opponent 2 and opponent 3 are respondent I and respondent II in these appeal proceedings.

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

D13 R&D Systems, Product Information Sheet for monoclonal anti-human IL-23 antibody MAB1290, 13 January 2006, pages 1 and 2

D16 G.E. Morris, Methods in Molecular Biology, Epitope Mapping Protocols (1996), Vol. 66, Humana Press, New Jersey, pages 1 to 416

D18 Beyer B.M. et al., J. Mol. Biol. (2008), Vol. 382, pages 942 to 955

D21 Declaration by Dr. D.K. Clawson, 17 October 2017, pages 1 to 11

D32 Chapter 8, Goding, 2008, pages 141 to 191

D33 Chapter 4, Frank, 2002, pages 33 to 56

D37 Langrish C.L. et al., Immunological Reviews (2004), Vol. 202, pages 96 to 105

D43 R&D Systems, Product Information Sheet for anti-human IL-23 p19 antibody AF1716, 2003, page 1

D59 Marks C. and C.M. Deane, Computational and Structural Biotechnology Journal (2017), Vol. 15, pages 222 to 231

D60 Sela-Culang I. et al., Journal of Immunology (2012), Vol. 189, pages 4890 to 4899

D61 Sangar V. et al., BMC Bioinformatics (2007), Vol. 8, pages 294 to 308

D62 Ladner R.C., Biotechnology and Genetic Engineering Reviews (2007), Vol. 24, pages 1 to 30

D80 Declaration by Prof. S.N. Savvides, 21 August 2019, pages 1 to 15

D81 Declaration by Prof. K.-P. Hopfner, 11 October 2019, pages 1 to 15

D82 Curriculum Vitae Prof. K.-P. Hopfner

D83 Annex 2 of document D81

D84 Warren G.L. et al., Drug Discovery Today (2012), Vol. 17, pages 1270 to 1281

D85 Niederfellner G. et al., Blood (2011), Vol. 118(2), pages 358 to 367

D86 Mirschberger C. et al., Cancer Res (2013), Vol. 73(16), pages 5183 to 5194

D87 Grabowski M. et al., J Struct Funct Genomics (2016), Vol. 17(1), pages 1 to 16

D88 Terwilliger T.C. et al., Annu Rev Biophys (2009), Vol. 38, pages 371 to 383

D89 Weitzner B.D. et al., Structure (2015), Vol. 23, pages 302 to 311

D90 Sela-Culang I. et al., Frontiers in Immunology (2013), Vol. 4, Article 302, pages 1 to 13

V. In the decision under appeal, the opposition division considered the patent as granted (main request) and sets of claims of auxiliary requests 1 to 49. It held that the patent did not disclose the invention 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 100(b) EPC). The invention defined in claim 1 of auxiliary requests 1 to 49 was considered not to meet the requirements of Article 83 EPC for the same reasons as given for claim 1 of the main request. Documents D59 to D62 and D81 to D90 were not admitted into the opposition

proceedings.

VI. With the statement setting out the grounds of appeal, the appellant re-submitted sets of claims of auxiliary requests 1 to 49 which are identical to the corresponding requests underlying the decision under appeal.

Claims 1 and 2 of the main request (patent as granted) read as follows:

"1. An antibody, or antigen binding fragment thereof, that binds to human IL-23p19 at an epitope comprising residues 82-95 and residues 133-140 of SEQ ID NO: 29.

2. The antibody, or antigen binding fragment thereof, of Claim 1, that binds to an epitope comprising residues E82, G86, S87, D88, T91, G92, E93, P94, S95, H106, P133, S134, Q135, P136, W137, R139 and L140 of SEQ ID NO: 29."

Claim 1 of auxiliary request 1 is identical to claim 1 of the main request.

For the following auxiliary requests amendments compared to claim 1 as granted are indicated by underlining or strikethrough by the board.

Claim 1 of auxiliary requests 2 and 3 is based on claim 1 of the main request, amended to specify that binding is "as determined by a structural method".

Claim 1 of auxiliary requests 4 and 5 is based on claim 1 of the main request amended to recite "~~A~~ humanized or chimeric antibody".

Claim 1 of auxiliary request 6 is based on claim 1 of the main request amended to additionally recite "wherein the antibody or antigen binding fragment is capable of blocking the binding of IL-23 to its receptor".

Claim 1 of auxiliary request 7 is based on claim 1 of the main request amended to additionally recite "wherein the antibody or antigen fragment is capable of blocking the binding of a reference antibody to IL-23p19 in a cross-blocking assay, wherein the reference antibody comprises a light chain comprising residues 20-233 of SEQ ID NO:4; and a heavy chain comprising residues 20-464 of SEQ ID NO:3".

Claim 1 of auxiliary request 8 is based on claim 1 of the main request amended to specify that binding is "as determined by X-ray crystallography".

Claim 1 of auxiliary request 9 combines the amendments of claim 1 of auxiliary requests 6 and 8.

Claim 1 of auxiliary request 10 combines the amendments of claim 1 of auxiliary requests 7 and 8.

Claim 1 of auxiliary request 11 is based on claim 1 of the main request amended to additionally recite "wherein at least 50% of amino acid residues 82-95 are within 5Å of residues on the antibody or antigen binding fragment, and at least 50% of amino acid residues 133-140 are within 5Å of residues on the antibody or antigen binding fragment, as determined by X-ray crystallography".

Claim 1 of auxiliary request 12 combines the amendments of claim 1 of auxiliary requests 6 and 11.

Claim 1 of auxiliary request 13 combines the amendments of claim 1 of auxiliary requests 7 and 11.

Claim 1 of auxiliary request 14 is based on claim 1 of the main request amended to additionally recite "wherein at least 50% of amino acid residues 82-95 are within 4Å of residues on the antibody or antigen binding fragment, and at least 50% of amino acid residues 133-140 are within 4Å of residues on the antibody or antigen binding fragment, as determined by X-ray crystallography".

Claim 1 of auxiliary request 15 combines the amendments of claim 1 of auxiliary requests 6 and 14.

Claim 1 of auxiliary request 16 combines the amendments of claim 1 of auxiliary requests 7 and 14.

Claim 1 of auxiliary requests 17 to 27 are based on claim 1 of auxiliary requests 6 to 16 further amended to recite "A~~n~~ humanized or chimeric antibody".

Claim 1 of auxiliary requests 28 to 49 is identical to claim 1 of auxiliary requests 6 to 27.

VII. Respondents I and II filed replies to the appellant's statement of grounds of appeal. In the course of the appeal proceedings, the board, on the basis of corresponding information, supported by appropriate evidence, accepted that Abbvie Overseas S.à.r.l. was party to the appeal proceedings as the universal legal successor of Abbvie S.à.r.l., the latter being former opponent 3 and having ceased to exist.

VIII. The board scheduled oral proceedings, as requested by the parties, and issued a communication under Article 15(1) RPBA, in which it indicated its preliminary opinion with respect to, *inter alia*, the construction of claim 1 of the main request and sufficiency of disclosure of the invention defined in claim 1 of the main request.

IX. In response, respondent I provided further comments regarding, *inter alia*, insufficiency of disclosure.

X. Oral proceedings were held as scheduled. At the end of the oral proceedings the Chair announced the decision of the board.

XI. The appellant's submissions are summarised below.

The respondents' request to set aside the opposition division's decision not to admit documents D59 to D62 and D81 to D90 into the proceedings

Documents D59 to D62 and D81 to D90 had been filed late. The opposition division had discretion to admit these documents and it had exercised its discretion correctly.

Main request (patent as granted) - claim 1

Claim construction

The claim extended to all antibodies that bound hIL-23p19 at a conformational epitope that comprised residues 82 to 95 and residues 133 to 140 of SEQ ID NO: 29. Additional residues from outside these two regions could contribute to the epitope.

An interpretation where the antibody bound at least one amino acid in both groups of residues was the broadest technical sensible interpretation and was consistent with the teaching of the patent as regards antibody G710, the antibody from which the epitope in claim 1 originated. Detection of binding by X-ray crystallography (X-RC) was the method of choice for the skilled person when putting the claim into effect but was not an absolute requirement of the claim.

Disclosure of the invention (Article 100(b) EPC)

Generation and screening of additional antibodies

At the priority date of the patent, the generation and screening of antibodies that bind to the p19 subunit of hIL-23 (hIL-23p19) did not amount to an undue burden of experimentation for a person skilled in the art, see T 431/96.

The teaching in the patent, taking into account the common general knowledge would have led the skilled person to use (i) a hIL-23 heterodimer (composed of two subunits, p19 and p40) as the immunogen to raise antibodies that bind to the hIL-23p19 subunit at the claimed conformational epitope and to (ii) screen the resulting antibodies by conventional specificity-screening assays for antibodies that bind specifically at the IL-23p19 subunit, followed by optional further screening to arrive at a subset of antibodies that was most likely to bind the claimed epitope, which the skilled person would have taken forward for analysis by X-RC, thus arriving at antibodies that bind to human IL-23p19 at the claimed conformational epitope without an undue burden of experimentation.

Choice of immunogen

The patent identified suitable immunogens in paragraphs [0079] and [0080]. While the patent also mentioned that antibodies of the disclosure may be raised by immunisation with an epitope or peptide fragment of hIL-23, the skilled person understood that this approach was unsuitable for raising antibodies that bind a conformational epitope. The skilled person would not have considered the p19 monomer to be an appropriate antigen for raising antibodies to the claimed conformational epitope because this strategy carried the risk of generating antibodies that do not bind the p19 in the context of the hIL-23 heterodimer. The skilled person would have understood that the heterodimer was the most appropriate immunogen for raising antibodies that bind to a conformational epitope on one of its subunits. Hence, common general knowledge, combined with the teaching in the patent, would have led the skilled person to use a hIL-23 heterodimer (linked or unlinked) as the immunogen to raise antibodies that bind to hIL-23p19 at the claimed conformational epitope.

Screening process for p19-specificity

Having raised a pool of antibodies against hIL-23 heterodimer (comprising the p19 and p40 subunit), the skilled person seeking to put the claimed invention into practice would screen the pool for p19-specificity using any conventional assay available in the art. The skilled person would focus on p19 binding antibodies in the pool because the claim was to an anti-p19 antibody.

The patent directed the skilled person to routine techniques for screening for target specificity, i.e.

ELISAs and routine bioassays for determining specific inhibition of IL-23 activity (see paragraph [0082], page 13, lines 48 to 49; paragraphs [0084], [0118], [0119] citing Langrish *et al.*, which was document D37 in these proceedings).

Conventional specificity-screening assays were part of the common general knowledge and were described in e.g. document D32, a textbook (see pages 166 to 168, which described ELISAs). Documents D13 and D43 confirmed that the ELISA test described in document D32 was used in the specific context of determining p19-specificity. The skilled person could thus have used a routine ELISA to identify antibodies that bound to p19.

Alternatively, or in addition, a routine ELISA could have been used to screen for antibodies that bind to hIL-23 heterodimer but did not bind to the related IL-12 heterodimer (which lacks the p19 subunit) or to p40 alone. As a further alternative, the skilled person could have used a conventional bioassay to screen the antibodies for inhibition of IL-23 activity but not IL-12 activity.

Optional additional pre-screening to narrow down the pool of anti-IL-23p19 antibodies

If the skilled person wished to narrow down an initial pool of anti-IL23p19 antibodies to a smaller group of candidates to be analysed by X-RC, optional additional pre-screening assays such as a conventional cross-blocking assay to eliminate any p19-specific antibodies that did not block the binding of the exemplary antibody 7G10 to hIL-23p19 could be performed.

The epitope footprint of 7G10 on p19 was relatively

small as compared to the total exposed surface area of p19 in the hIL-23 heterodimer (see document D18, page 948). This meant that the pool of antibodies raised against hIL-23 heterodimer was expected to include many p19-specific antibodies that bound accessible regions of p19 that were distant from the 7G10 footprint. These other p19-specific antibodies would not cross-block 7G10 and therefore were highly unlikely to bind to hIL-23p19 at either of the epitope regions recited in claim 1. A suitable routine cross blocking assay was taught in the patent at paragraph [0110]. Further evidence that such cross-blocking assays were part of the common general knowledge was provided in document D16 (pages 47-53 and 55-56) and document D80 confirmed it.

Alternative (or additional) strategies that the skilled person could have used, if desired, to reduce the pool of anti-p19 antibodies included, dividing the antibody pool into 'sub-classes' based on e.g. CDR sequence similarity (see document D80, points 20 to 21).

Undue burden

In sum, it was within the routine ability of the skilled person at the priority date to raise antibodies to hIL-23 heterodimer and to screen the resulting antibodies for p19-specificity and, if desired, to perform further screening to arrive at a subset of antibodies that was most likely to bind the claimed epitope, to take forward for analysis by X-ray crystallography.

The opposition division's reliance on T 1466/05 was inappropriate given the significant factual (technical) differences between the present case and the case

underlying T 1466/05. In contrast to the case underlying T 1466/05, the patent disclosed the epitope that was targeted by the exemplary antibody 7G10 as determined by the gold standard technique, X-RC. The skilled person also had at their disposal (i) a suitable immunogen (hIL-23 heterodimer); and (ii) conventional assays to screen for p19-specificity. Furthermore, the common general knowledge at the priority date of the patent was greatly advanced as compared to the common general knowledge at the 1998 filing date of the application in T 1466/05.

The respondents had not cast "serious doubts, substantiated by verifiable facts" on the ability of the skilled person to generate an antibody or antigen binding fragment thereof that was determined by X-RC to bind to hIL-23p19 at a conformational epitope as defined in granted claim 1 of the patent.

Auxiliary requests 1 to 49
Disclosure of the invention (Article 83 EPC)

The skilled person would arrive at the antibodies defined in claim 1 of auxiliary requests 1 to 49 without an undue burden of experimentation for the same reasons as given for the subject-matter of claim 1 of the main request.

XII. The respondents' submissions are summarised below.

The respondents' request to set aside the opposition division's decision not to admit documents D59 to D62 and D81 to D90 into the proceedings

Documents D59 to D62 were filed by the final date for making written submissions under Rule 116 EPC in

response to arguments raised by the appellant or the opposition division.

Documents D81 to D90 were filed in direct and immediate response to new evidence submitted by the appellant on the last day of making written submissions under Rule 116 EPC. In admitting the appellant's documents D64 to D78 and D80 but not the respondents' counter-evidence the opposition disregarded the principles of procedural fairness and equal treatment.

Main request (patent as granted) - claim 1

Claim construction

The "epitope" bound by an antibody depended on and was defined by said antibody. The spatial extent of the epitope was ambiguous because of the "comprising" language and the claim therefore needed interpretation.

According to a first possible interpretation, the claim required that the antibody contacted all residues recited in the claim. This interpretation appeared not to be correct in view of dependent claim 2. According to a second interpretation, binding could occur entirely outside of the recited epitope stretches. This interpretation appeared not to be correct in view of the description of the patent. Pursuant to a third and correct interpretation, the claimed antibodies had to bind at both epitope stretches defined in the claim and a substantial interaction with them was required.

The claim did not specify binding to at least one amino acid per stretch and there was no basis for such an interpretation in the patent either. Antibody 7G10 contacted the majority of the amino acids in these

stretches. The broadest technical meaningful interpretation had to be used, this was that at least 50% of the amino acids were bound per stretch (see paragraph [0019]).

Binding at the discontinuous epitope was to be determined by X-RC. The epitope of 7G10 had been determined by X-RC and paragraph [0019] of the patent defined that the epitope "may be determined by X-RC".

Disclosure of the invention (Article 100(b) EPC)

Generation and screening of additional antibodies

The patent did not disclose a suitable antigen and a reliable screening process that would lead the skilled person necessarily and directly, with a reasonable amount of trial and error, towards structurally unrelated antibodies that bind to the discontinuous epitope defined in claim 1.

Choice of immunogen

No specific antigen was disclosed in the patent for raising antibodies that bound to the claimed discontinuous conformational epitope. The patent not only referred to the complete hIL-23 heterodimer, but also suggested using fragments thereof as immunogens (see e.g. paragraphs [0079] and [0080]). The appellant's arguments that the skilled person would necessarily have used the complete IL-23 heterodimer and would not have used the p19 monomer or other large fragments of hIL-23 were not supported by any evidence.

A large antigen such as hIL-23 had many different epitopes (see e.g. document D33) and the result of the

immunisation with hIL-23 were antibodies which bound to IL-23 anywhere on its surface, including antibodies directed to the subunit p40 and antibodies directed to any epitope on the subunit p19. Whether immunisation with the hIL-23 heterodimer generated antibodies having the desired specificity was also dependent on chance and was therefore unpredictable, even if the skilled person had used hIL-23 for immunisation. The patent provided no guidance as to which epitopes were bound by antibodies raised in this manner. Furthermore, even if such an antibody were raised, it would be buried among a myriad of other antibodies raised including those directed to the p40 subunit and those directed to any epitope on the p19 subunit.

Screening process for p19 specificity

The patent was silent on any of the screening steps suggested by the appellant. There was no document on file that qualified as common general knowledge and demonstrated that such screening steps belonged to the common general knowledge of the skilled person.

The appellant had not explained why the skilled person would have considered screening for p19 specificity of the generated antibodies and from where the skilled person would have taken the knowledge how to set up such a screening.

The opposed patent did not disclose that in order to generate functional antibodies against p19, immunisation had to be performed with the whole hIL-23 protein and then antibodies directed against p40 had to be eliminated from the antibody pool as a first screening step. Accordingly, the opposed patent also failed to teach by which screening method this could be

accomplished. A respective screening assay was furthermore not taught by the common general knowledge, as also noted by the opposition division.

The appellant did not cite any document which could demonstrate that elimination of the antibodies binding to p40 was part of the skilled person's common general knowledge. Especially, documents D13 and D43 referred to by the appellant did not form part of the common general knowledge of the skilled person.
That ELISAs were known in the art did not help the appellant's case. There was no guidance how to use them to screen and identify the claimed antibodies. Document D32 did not help in this respect as it did not contain any relevant disclosure. Even the paragraphs of the opposed patent cited by the appellant only referred to IL-23 in general but not to determining p19 specificity (see, e.g., paragraphs [0084] and [0118]).

A screening assay for IL-23 neutralising activity of the candidate antibodies such as described in Example 5 of the patent also identified antibodies which bound to p40 of IL-23 and blocked binding to IL-12Rβ1.
Accordingly, this screen would not have significantly reduced the number of potential antibody candidates.

Optional additional pre-screening to narrow down the pool of anti-IL-23p19 antibodies

A cross-blocking assay would not significantly reduce the number of candidate antibodies, even if done on a preselected pool of anti-p19 antibodies from which antibodies binding to p40 of IL-23 had been eliminated (which was not disclosed in the patent). Most of these candidate antibodies would, however, bind to an epitope on p19 which did not correspond to the discontinuous

epitope defined in claim 1.

The patent did not teach that CDR grouping had to be included in a screening process for identifying antibodies binding at the discontinuous epitope and no evidence was presented that it represented common general knowledge and was routine for the skilled person.

X-RC did not represent a suitable screening tool because it only gave an answer at which epitope a specific antibody bound, which could be the epitope of interest or an entirely different epitope. This was different from screening for binding to a desired (antigen) epitope in which e.g. the epitope was offered as a binding partner and the screening assay automatically selected from a large pool of antibodies those candidates that bound to the antigen epitope. In the present case, this was not feasible since the desired discontinuous epitope as such could not be offered as binding partner in a screening assay.

Undue burden

In summary, the opposed patent failed to disclose a suitable antigen and a clear and complete screening process that would lead the skilled person necessarily and directly, with a reasonable amount of trial and error, towards further monoclonal antibodies that bind to the discontinuous epitope defined in claim 1 but which are structurally unrelated to the only example provided in the opposed patent. Due to the lack of technical details and guidance provided, the experimentation needed for generating, screening and selecting antibodies to identify any further antibodies that bound at the discontinuous epitope claimed

remained a trial and error based research project that was moreover, the outcome relied on chance and which overall amounted to an undue burden.

The principles established in T 1466/05 were relevant and the fact that the discontinuous epitope to be bound was defined in the claim did not provide any relevant distinction over T 1466/05 because the epitope merely defined a functional desideratum but without any teaching in the patent as how to achieve this desired specificity (see also T 716/01, T 405/06, T 760/12, T 2416/18).

At least to the extent that claim 1 covered antibodies other than the specific monoclonal antibody 7G10 or very close structural variants thereof, it did not fulfil the requirement of sufficiency of disclosure.

Auxiliary requests 1 to 49
Disclosure of the invention (Article 83 EPC)

The amended claims did not address the core objections that the patent provided insufficient guidance on how to arrive at other antibodies with the claimed properties. Especially, none of these requests defined structural features of the claimed antibody that enabled binding to the discontinuous epitope claimed. None of the requests therefore met the requirements of Article 83 EPC.

XIII. The appellant requested that the decision under appeal be set aside and that the patent be maintained as granted (implying the rejection of the oppositions) or, alternatively, that the patent be maintained in amended form on the basis of the set of claims of one of auxiliary requests 1 to 5, filed on 1 June 2018, or on

the basis of the set of claims of one of auxiliary requests 6 to 49, filed on 21 August 2019, together with an appropriately amended description; with copies of the claims of auxiliary request 1 to 49 resubmitted with the statement of grounds of appeal and that the documents which had not been admitted by the opposition division not be admitted into the appeal proceedings.

XIV. Respondent I and respondent II requested that the appeal be dismissed and that the documents not admitted by the opposition division be admitted into the appeal proceedings.

Reasons for the Decision

1. The appeal complies with Articles 106 to 108 and Rule 99 EPC and is admissible.

The respondents' request to overrule the decision of the opposition division not to admit documents D59 to D62 and D81 to D90 into the proceedings

2. It is established case law that if an opposition division is required under the EPC to exercise its discretion in certain circumstances, it should have a certain degree of freedom when exercising that discretion, without interference from the Boards of Appeal and, consequently, if a discretionary decision of the opposition division is challenged on appeal, it is not the task of the board to review all the facts and circumstances as if it were in the place of the opposition division and to decide whether or not it would have exercised discretion in the same way. The board should therefore overrule the way in which the opposition division exercised its discretion only if it concludes that the opposition division did so according

to the wrong principles or without taking into account the right principles, or that it exercised its discretion in an unreasonable way and thus exceeded the proper limit of its discretion (see Case Law of the Boards of Appeal, 9th edition 2019, ("CLBA"), V.A.3.5.1 b)). Article 12(6) RPBA reflects this case law by referring to "an error in the use of discretion".

Documents D59 to D62

3. Documents D59 to D62 were filed by the respondents on the final date for making written submissions fixed by the opposition division pursuant to Rule 116(1) EPC. Documents D59 and D60 were cited as technical evidence for the relevance of the HCDR3 in antigen binding. Document D61 was cited as technical evidence for similarity of proteins with homologous sequences and document D62 was cited as technical evidence for epitope mapping methods.

4. The opposition division held that these documents were filed after expiry of the nine-month period stipulated in Article 99(1) EPC and hence late. In relation to these documents, the opposition division stated that it was of the "opinion that in view of the preliminary opinion of the OD, being in favour of O2/O3 [the respondents] and in view of the fact that said documents are not prima facie more relevant then [sic] the documents already submitted by the opponents with their notices of opposition" and decided not to admit them into the opposition proceedings in the exercise of its discretion under Article 114(2) EPC (see decision under appeal, page 4, first and fourth paragraph).

Documents D81 to D90

5. On the final date for making written submissions fixed by the opposition division pursuant to Rule 116(1) EPC, the appellant filed a declaration of a technical expert (document D80) and documents referred to in that declaration.

6. Ten days prior to the date of oral proceedings and hence after the date fixed by the opposition division pursuant to Rule 116(1) EPC and in reaction to the above mentioned filing by the appellant, the respondents filed a declaration of a technical expert (document D81) and documents referred to in therein (documents D82 to D90).

7. The opposition division held that documents D81 to D90 were filed late in view of the nine-month period stipulated in Article 99(1) EPC. Considering that "the arguments of the declaration ... (D81) as a reply to the declaration ... (D80) are reflected in the representative's arguments in the [accompanying] letter" and that documents D82 to D90 "were published years after the priority date of the present application and are prima facie not suitable to establish the general knowledge and the skills of the skilled person required at the date of filing which is discussed in this declaration" it decided not to admit documents D81 to D90 into the opposition proceedings in the exercise of its discretion under Article 114(2) EPC.

8. On the other hand, considering that the appellant's documents D64 to D80 had been filed in "reaction to the negative preliminary opinion of the OD" and further, that the declaration D80 "can be seen as a reply to the

declaration ... (D21, filed by O1 with the notice of opposition)", and also that "the documents [D64 to D79 cited in D80] were published at the latest in the priority year", the opposition division admitted D64 to D80 into the opposition proceedings in the exercise of its discretion under Article 114(2) EPC.

9. The board considers that the opposition division decided according to the wrong principles and disregarded the principles of procedural fairness and of equal treatment of the parties in not admitting documents D59 to D62 and D81 to D90. The reasons are as follows.

10. Firstly, the mere fact that the opposition division's preliminary opinion was positive for one party (see point 4. above) cannot in itself justify not admitting any further documents by this party which are filed by the final date set by the opposition division for making written submission under Rule 116(1) EPC. Furthermore, *prima facie* relevance is to be assessed with taking into account the outcome of the proceedings (see CLBA, IV.C.4.5.3) and the opposition division gave no reasons why this criterion was not fulfilled for documents D59 to D62. Accordingly, the board cannot assess whether the opposition division has exercised its discretion in this respect correctly.

11. Secondly, arguments submitted by a party's professional representative do not qualify as means of giving evidence under Article 117(1) EPC and may therefore have a different weight depending on whether or not they are supported by evidence in the form of a declaration by a technical expert accompanied by evidentiary documents supporting the content of the declaration. Accordingly, the opposition division was

mistaken in holding that the declaration D81 with supporting documents on the one hand, and the representative's arguments on the other were equivalent and that this could justify non-admittance of documents D81 to D90.

12. Thirdly, consideration of a document submitted in substantiation of an allegation of fact does not depend on whether or not the document forms part of the state of the art (see CLBA, section III.G.4.1). The board therefore does not agree with the opposition division that, as a matter of principle, post-published evidence is *prima facie* unsuitable for the substantiation of allegations of verifiable facts in the context of sufficiency of disclosure.

13. Fourthly, as noted above, documents D81 to D90 had been filed as direct and immediate response to new evidence, submitted by the appellant on the last day for making written submissions under Rule 116 EPC. In admitting the late filed documents D80 and its supporting documents D64 to D79 into the proceedings but not admitting documents D81 to D90 filed by the respondents in direct response, the opposition division did not respect the principles of procedural fairness and of equal treatment of parties.

14. Finally, the fact that the opposition division's preliminary opinion was negative for the appellant but positive for the respondents cannot justify a different treatment of the parties, since a preliminary opinion is neither binding nor definitive.

15. Since the opposition division's decision not to admit documents D59 to D62 and documents D81 to D90 into the opposition proceedings suffered from an error in the

use of discretion, the board decided to admit documents D59 to D62 and D81 to D90 into the appeal proceedings (Article 12(6) RPBA).

Main request (patent as granted) - claim 1

The claimed invention - claim construction

16. Claim 1 is directed to antibodies (or antigen binding fragment thereof) that bind to subunit p19 of human interleukin-23 (hIL-23p19) at an epitope comprising amino acid residues 82 to 95 and amino acid residues 133 to 140 of the amino acid sequence of mature hIL-23p19 (SEQ ID NO: 29). The claim is not for a single antibody but for a pool of antibodies each of which binds human interleukin-23 at an epitope as defined in the claim.

17. The two amino acid stretches recited in the claim are not contiguous along the primary sequence of the hIL-23p19 protein chain, thus the epitope defined in the claim is a so-called discontinuous or conformational epitope.

18. While the epitope bound by the claimed antibodies must include both stretches of amino acids, the claim does not unambiguously delimit the spatial extent of the epitope. Interpretation is therefore required to determine its extent. The board does this according to the normal rules of claim construction, in which the terms used in the claim are given their broadest technically sensible meaning in the context in which they appear and having regard to the common general knowledge and the teaching in the patent (see also CLBA, II.A.6.1).

19. The broadest technically sensible construction of the epitope defined in the claim is one where the epitope includes amino acid residues outside the two recited stretches of amino acids, recited in claim 1. Firstly, this is in keeping with the claim wording "comprising". Secondly, it is supported by dependent claim 2, according to which the bound epitope comprises 16 residues located within the recited stretches and 1 additional residue, H106, that is located outside these stretches. Indeed, the claimed antibodies need not bind exactly the amino acid residues recited in the claim as long as their epitope comprises these amino acid residues.

20. The appellant's submission that binding at least one amino acid residue in each stretch would be the broadest technically sensible interpretation is not found persuasive for the following reasons. First, the appellant's interpretation is not supported by the teaching of the patent in the general part of the description (see paragraph [0019] of the patent) and second, it is also no supported by antibody 7G10, relied on in this context by the appellant. Indeed, antibody 7G10 was determined by X-ray crystallography (X-RC) to be within 4.0 Å of the antibody (i.e. to "bind") at 9 of the 14 amino acid residues in stretch 82 to 95 of SEQ ID NO: 29 and 7 of the 8 amino acid residues in stretch 133 to 140 of SEQ ID NO: 29 (see paragraph [0180] of the patent).

21. Contrary to the decision under appeal, a technically meaningful interpretation of claim 1 does not require that it be implied that X-RC must be used to determine binding of the antibody at the target epitope. First, the use of X-RC is not a necessary consequence of the express language of the claim and thus not an implicit

feature. Second, construction of the claim in light of the teaching of the patent does not imply the use of X-RC either. While the patent discloses that binding may be determined by X-RC (see paragraph [0019] of the patent), it discloses further methods for determining binding of the antibody at the epitope, (see e.g. paragraphs [0110], [0111] and [0113]).

22. Accordingly, in an embodiment, although the claim is not limited to this embodiment, the claim encompasses antibodies that are functionally defined by their ability to bind to human IL-23p19 and contact several of the amino acid residues within both amino acid stretches recited in the claim, i.e. antibodies with the same specificity as the exemplified antibody 7G10, but which are not structurally related to it. Binding to the conformational epitope may be determined by X-RC, but this is not mandatory.

Disclosure of the invention (Article 100(b) EPC)

23. According to the established case law of the Boards of Appeal, a patent complies with the requirement of sufficiency of disclosure if the skilled person, on the basis of the information provided in the patent and taking into account the common general knowledge, is able to perform the invention as claimed in the whole range claimed without undue burden, i.e. with reasonable effort (see CLBA, II.C.1).

24. The patent discloses, *inter alia*, a mouse anti-human IL-23p19 antibody termed 7G10 (see Tables 2 and 3), and a humanised version of this antibody, hum7G10 (see Example 2 and Tables 2 and 3). As mentioned in point 20. above, antibody 7G10 was determined by X-RC to bind 9 of the 14 amino acid residues in stretch 82

to 95 of SEQ ID NO: 29 and 7 of the 8 amino acid residues in stretch 133 to 140 of SEQ ID NO: 29 (see Example 6).

25. Antibody 7G10 is therefore one way of performing the claimed invention. However, claim 1 is not limited to antibody 7G10 and structural related variants but encompasses antibodies which are solely defined by the functional feature that they have the same specificity as the exemplified antibody 7G10 (see also point 22. above).

26. For meeting the requirement of sufficiency of disclosure it is required that the patent, when considered in combination with the common general knowledge at the priority date, provides technical guidance which is sufficiently clear and complete to allow the skilled person to reliably obtain the above mentioned, functionally defined antibodies without an undue burden.

27. In a first line of argument the appellant submitted that, at the priority date of the patent, the generation and screening of antibodies that bind to the p19 subunit of hIL-23 did not amount to an undue burden of experimentation for a skilled person and that according to the case law of the Boards of Appeal, it was a matter of routine to raise and screen antibodies to a known antigen (see decision T 431/96).

28. The board acknowledges that raising and screening antibodies involves only routine experimentation. However, this is the case only if the skilled person knows from the disclosure in the patent or from common general knowledge (i) which antigens are suitable for raising antibodies having the desired properties and

(ii) which screening process should be used to select these antibodies without undue burden (see also decision T 431/96, Reasons, points 6, 7, 10, 11, 12).

29. Indeed, the generation and screening of antibodies that bind (anywhere) to the p19 subunit of hIL-23 would not involve an undue burden for the skilled person.

30. However, the patent in suit discloses neither a suitable antigen nor a screening process that would ensure the reliable generation and selection of antibodies having the required properties (see point 22. above) by applying routine methodology and a reasonable amount of experimentation. It is common ground that peptides consisting of the primary sequence of the claimed conformational epitope are unsuitable for raising the claimed antibodies or screening for them.

31. It is moreover undisputed that the patent does not disclose how antibody 7G10 was prepared, i.e. which antigen/immunogen was used for its generation or the screening process that was used to select for it. The board must therefore conclude that the patent contains no guidance regarding a suitable antigen or screening process for the generation and selection of antibodies that are structurally unrelated to antibody 7G10. For these reasons, the conclusion reached in decision T 431/96 that generation of antibodies to known antigens is routine, does not apply.

32. In a further line of argument the appellant maintained that the process of generating antibodies to hIL-23p19 involved immunisation with hIL-23 heterodimer to raise a pool of antibodies, and then identifying those antibodies that bind specifically to the p19 subunit.

Selected anti-hIL-23p19 antibodies could then be analysed by X-RC to determine their epitopes. Since suitable methods for raising and screening antibodies were part of the skilled person's common general knowledge at the priority date, the requirement of sufficiency of disclosure was met.

33. The board is not persuaded by this this line of argument for the following reasons.

Choice of immunogen

34. The patent does not teach that the complete hIL-23 heterodimer should be used for the generation of antibodies that bind to hIL-23p19 at the claimed conformational epitope (see paragraphs [0079] and [0080] of the patent).

35. The appellant asserted that the common general knowledge would have led the skilled person to understand that not any fragment or the p19 monomer but the complete hIL-23 heterodimer (composed of a p19 and a p40 subunit) was the most suitable immunogen to raise antibodies that bind to hIL-23p19 at the claimed conformational epitope. No evidence supporting the pertinent common general knowledge was provided by the appellant.

36. Since p19 is one of the two subunits of hIL-23, the board accepts, for the sake of argument, that the skilled person might consider that the complete hIL-23 heterodimer was a suitable immunogen to raise the claimed antibodies.

37. It is common ground that in using the hIL-23 heterodimer for immunisation, the skilled person would

obtain a pool of antibodies recognising (linear and conformational) epitopes anywhere on the surface of the hIL-23 heterodimer and its subunits, p19 and p40.

38. Moreover, since the generation of antibodies to the claimed epitope on p19 cannot be controlled by using the hIL-23 heterodimer, it is a matter of chance whether the antibody pool comprises an antibody that has the same specificity as the exemplified antibody 7G10 (see point 22. above).

39. Therefore, if the skilled person were to choose the hIL-23 heterodimer for raising antibodies, they would obtain a pool of antibodies, which may or may not comprise antibodies having the required properties.

40. However, the board holds that starting from the above mentioned pool of antibodies, the skilled person would not be able to arrive at the claimed antibodies without an undue burden of experimentation for the following reasons.

Screening antibodies for p19 specificity

41. The appellant submitted that, having raised a pool of antibodies against the hIL-23 heterodimer, the skilled person, seeking to put the claimed invention into practice, would have screened the pool to identify those antibodies that bind an epitope on the p19 subunit using any conventional assay available in the art, e.g. an enzyme-linked immunosorbent assay (ELISA).

42. The board acknowledges that at the priority date of the patent, the skilled person was familiar with ELISAs, e.g., for screening hybridoma supernatants for

antibodies that bind to a given antigen. For this, the antigen is offered in an ELISA as a binding partner allowing the selection from a pool of antibodies those candidates that bind the antigen.

43. The patent does not disclose which antigen should be used in an ELISA to screen the pool of antibodies raised by immunisation with the hIL-23 heterodimer to obtain those antibodies that bind a conformational epitope on the p19 subunit of hIL-23 (see paragraphs [0082] and [0084]). The only ELISA mentioned in the patent refers to testing of antibodies "*for specificity of binding by comparing binding to IL-23 to binding to irrelevant antigen or antigen mixture under a given set of conditions*" (see paragraph [0118]).

44. Document D32, relied on by the appellant as evidence that ELISAs were well known in the state of the art, merely confirms that an ELISA can be set up, provided an antigen suitable to screen for the desired property is available (see page 168, second and third paragraph). However, document D32 provides no information as regards antigens or screening steps, e.g. positive and/or negative, which would be suitable to select antibodies that bind an epitope on the p19 subunit, nor does it address the difficulties in selecting an antibody as claimed from a pool of antibodies raised against hIL-23 and without missing antibodies that bind at p19 in the conformation that this subunit adopts in the presence of p40.

45. Documents D13 and D43, relied on by the appellant to confirm that ELISA tests were commonly used in the field at the priority date, and in the "*specific context of determining p19-specificity*" are production information sheets for commercially available anti-

IL-23p19 antibodies. These documents do not constitute what is commonly understood to represent the common general knowledge of the person skilled in the art (see CLBA I.C.2.8.1).

46. Furthermore, document D13 discloses an anti-p19 antibody that was selected for its ability to neutralise the bioactivity of human IL-23. As regards ELISA tests, document D13 discloses that the selected antibody detects the human IL-23 heterodimer and does not cross-react with rhIL-12 p35, rhIL-12 heterodimer, rmIL-23 p40, or rmIL-23 heterodimer. Document D13 does not disclose that any of these ELISA tests was used for isolating the antibody. As for document D43, it discloses another anti-p19 antibody, which was selected by passing sera from immunised goats over a human IL-23 affinity column and then passing the bound fraction over a human IL-12/23 p40 column to remove p40 specific IgG. However, neither document D13 nor document D43 discloses an ELISA that can be used to screen a pool of anti-hIL-23 antibodies to identify antibodies that bind to p19. *A fortiori*, these documents are unsuitable to provide evidence that the skilled person could have used a routine ELISA to identify and isolate antibodies that bind a conformational epitope on the p19 subunit of hIL-23.

47. The appellant's further argument that alternatively, or in addition, a routine ELISA could have been used to screen for antibodies that bind to the hIL-23 heterodimer but do not bind to the related hIL-12 heterodimer (which lacks the p19 subunit) or to p40 alone and a conventional bioassay to screen the antibodies for inhibition of IL-23 activity but not IL-12 activity is not found persuasive either.

48. There is no teaching or guidance in the patent that would suggest the use of any of these ELISA assays, nor has the appellant referred to any evidence that they were common general knowledge at the priority date. *A fortiori*, there is no guidance or information with respect to how these assays would need to be performed and whether they would at all be suitable to reliably identify antibodies that bind a conformational epitope on the p19 subunit of hIL-23.

49. Screening for antibodies inhibiting the biological activity of hIL-23, as also suggested by the appellant, cannot differentiate between antibodies binding to the p19 and the p40 subunit of hIL-23. Therefore, this method is not suitable to specifically select antibodies that bind a conformational epitope on the p19 subunit of hIL-23.

Optional additional pre-screening to narrow down the pool of anti-hIL-23p19 antibodies

50. The appellant's argument that the skilled person could narrow down an initial pool of anti-hIL-23p19 antibodies to a smaller group of candidates by a conventional cross-blocking assay to eliminate antibodies that are unlikely to bind at the claimed conformational epitope is not found persuasive either. In fact, the patent proposes to use such an assay for exactly the opposite purpose, namely "*to screen for antibodies that bind to the epitope on human IL-23 (i.e. the p19 subunit) bound by an antibody of interest*" (see paragraph [0110]), not to eliminate antibodies that are unlikely to bind.

51. Moreover, the appellant's reasoning for using a cross-blocking assay to eliminate antibodies that are

unlikely to bind at the claimed conformational epitope is based on its knowledge of antibody 7G10's footprint on hIL-23. However, this footprint is only disclosed in post-published document D18 (see page 948). Based on the teaching in the patent, the skilled person had no reason to expect that a cross-blocking assay would significantly reduce the number of candidate antibodies in a preselected pool of anti-p19 antibodies.

52. Finally, even if the skilled person were to use a cross-blocking assay to eliminate antibodies unlikely to bind at the claimed conformational epitope, they would be aware that the remaining antibodies will not necessarily bind at the claimed epitope. Indeed the patent confirms that not all cross-blocking antibodies necessarily bind at precisely the same epitope, since cross-blocking may result from steric hindrance (see paragraphs [0110] of the patent).

53. As regards the further strategy proposed by the appellant to reduce a pool of anti-p19 antibodies, the board notes that the patent does not teach that grouping of antibodies based on CDR sequences should be included in the process for identifying antibodies that bind at the epitope defined in the claim. No evidence was presented by the appellant that such an assay represented common general knowledge or was routine for the skilled person. Furthermore, the board has seen no evidence to support the thesis that the probability of finding an antibody with the desired binding properties increases by grouping the candidate antibodies into such sub-classes (see also documents D80, points 20 and 21 and document D81, point 58).

Undue burden

54. It is apparent from the above considerations (see points 41. to 49.) that the evidence on file does not support the appellant's assertion that suitable methods for screening a pool of anti-hIL-23 antibodies for p19-specificity were part of the skilled person's common general knowledge at the priority date. Since the patent provides no guidance in this respect either, the skilled person wanting to perform the claimed invention would have to develop a screening process for identifying antibodies that bind an epitope on the p19 subunit of hIL-23 and without risking to miss antibodies that bind the claimed conformational epitope, an undertaking that cannot be regarded as routine.

55. The appellant's argument that it was a matter of routine for the skilled person to perform further screening and narrow down a pool of p19-specific antibodies to arrive at a subset of antibodies that is "*most likely to bind the claimed epitope*", is not supported by the evidence on file either. Indeed, none of the screening assays proposed by the appellant selects specifically for antibodies that have the same specificity as the exemplified antibody 7G10 (see points 50. to 53. above).

56. Moreover, as set out above (see points 38. and 39.), there is no guarantee that even a single antibody having the same specificity as the exemplified antibody 7G10 is generated when using hIL-23 heterodimer for immunisation. Therefore, removing antibodies that are unlikely to bind at the claimed epitope, does not guarantee that any of the remaining antibodies is more likely to have the required specificity. Indeed, there

is no guarantee that even a single antibody that is taken forward to determine its epitope, by X-RC or otherwise, has the same specificity as the exemplified antibody 7G10.

57. The patent does not provide any information regarding the epitopes recognised by the antibodies raised against hIL-23 heterodimer. In particular, the patent provides no evidence that antibodies having the required properties would be generated frequently enough to be identified reliably. Whilst the appellant submitted that the pool of antibodies raised against hIL-23 heterodimer would be expected to include many p19-specific antibodies that are highly unlikely to bind to hIL-23p19 at either of the epitope regions recited in claim 1, it provided no argument let alone evidence on how likely it was that such a pool of antibodies would include ones that do have the required specificity.

58. In summary, given the lack of relevant guidance in the patent or in the common general knowledge, the skilled person attempting to carry out the claimed invention is confronted with having to develop an elaborate screening strategy, without a reasonable expectation of success. Indeed such a screening strategy relies on chance, without the skilled person having any knowledge of the likelihood of success.

59. Finally, if after such a screening process, the antibody taken forward for epitope determination does not have the required specificity, i.e. in case of failure, neither the patent nor the common general knowledge provides adequate information regarding what should be changed or how to guarantee success.

Conclusion on disclosure of the invention (Article 100(b) EPC)

60. An invention may be regarded as sufficiently disclosed even if it requires a certain amount of experimentation by the skilled person to carry it out, as long as this experimentation is not an undue burden on the skilled person. Such a situation may exist where the skilled person has sufficient information to lead them directly towards success through the evaluation of initial failures. Based on the evidence on file, the board considers that in the present case, critical information on the antigen suitable for raising antibodies with the desired properties and screening assays for reliably identifying them is lacking. Moreover, the board has seen no evidence that antibodies binding at the claimed epitope can be generated frequently enough and can be identified reliably enough to guarantee success (see points 34. to 59. above). Therefore, the functional definition of the claimed antibody amounts to an invitation to perform a research program without any guarantee of success. Such a situation is considered to amount to an undue burden for the skilled person (see also CLBA, section II.C.6.7 and II.C.7.4).

61. Contrary to the appellant's submissions, the fact pattern of the case under consideration (see points 34. to 53. above) is comparable to the facts underlying the case considered in decision T 1466/05. Thus, also in decision T 1466/05, the claimed antibodies were defined functionally (by their binding activity) and while the application provided one exemplary antibody having this function, it failed to provide (i) the antigen required to raise further antibodies as claimed and (ii) a screening process for the specific selection of the

same (see Reasons, points 9 and 25).

62. Disclosure of the specific regions within the p19 subunit of hIL-23 that are comprised in the epitope of the claimed antibodies does not distinguish the case at hand from the case underlying T 1466/05 because it does not equate with disclosure of a suitable antigen that can be used for raising and screening antibodies binding at the claimed epitope by applying routine methodology (see also point 30. above).

63. In the circumstances of the case at hand, serious doubts arise from the verifiable fact that there is no relevant guidance in the patent and in the common general knowledge with respect to (i) an antigen suitable for raising antibodies with the desired properties and (ii) screening assays for reliably identifying them. Contrary to the appellant's assertion, the respondents were therefore under no obligation to provide experimental evidence to support the insufficiency objection.

64. The claimed invention is not sufficiently disclosed in the patent and therefore the ground for opposition under Article 100(b) EPC prejudices the maintenance of the patent as granted.

Auxiliary requests 1 to 49

Disclosure of the invention (Article 83 EPC)

65. Claim 1 of these claim requests is directed to antibodies defined solely by the functional feature of binding the conformational epitope defined therein (see section VI. above). The provision of these antibodies involves an undue burden for the reasons set out in

points 23. to 64. above. The invention defined in auxiliary requests 1 to 49 is thus not sufficiently disclosed within the meaning of Article 83 EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chair:

C. Rodríguez Rodríguez A. Chakravarty

Decision electronically authenticated