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**Datasheet for the decision
of 10 January 2020**

Case Number: T 0304/17 - 3.3.04

Application Number: 04754234.5

Publication Number: 1641822

IPC: C07K14/54, C12N15/24,
C07K16/24, A61K38/20,
A61K39/395, G01N33/53

Language of the proceedings: EN

Title of invention:

IL-17 A/F heterologous polypeptides and therapeutic uses thereof

Patent Proprietor:

Genentech, Inc.

Opponents:

Ablynx N.V.

Merck Patent GmbH

Novartis AG

Janssen Biotech, Inc.

Adams, Harvey Vaughan John

Eli Lilly and Company (intervener I)

Eli Lilly Nederland B.V. (intervener II)

Headword:

Antibody that binds IL-17A/F and inhibits induction of IL-8 and IL-6/GENENTECH

Relevant legal provisions:

EPC Art. 105(1)(a), 105(1)(b), 105(2), 123(2)
EPC R. 89(1)

Keyword:

Intervention of the assumed infringer - admissible (yes)
Main request, auxiliary requests 1 to 3: amendments - allowable
(no)

Decisions cited:

G 0005/83, G 0002/10, T 0296/93, T 0188/97, T 0392/97,
T 0018/98, T 0228/03, T 1713/11

Catchword:



Beschwerdekammern

Boards of Appeal

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Case Number: T 0304/17 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 10 January 2020

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Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on
24 November 2016 revoking European patent No.
1641822 pursuant to Article 101(3)(b) EPC**

Composition of the Board:

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

Summary of Facts and Submissions

- I. The appeal of the patent proprietor (appellant) lies from the opposition division's decision revoking European patent No. 1 641 822. The patent, entitled "*IL-17 A/F heterologous polypeptides and therapeutic uses thereof*", derives from European patent application No. 04 754 234.5, which was filed as an international application under the PCT with the international application number PCT/US2004/017581 ("application as filed" or "application"), published as WO 2005/010044.
- II. Five oppositions to the patent were filed. These invoked Article 100(a), (b) and (c) EPC. The grounds for invoking Article 100(a) EPC were exception to patentability (Article 53(c) EPC), lack of novelty (Article 54 EPC) and lack of inventive step (Article 56 EPC). Opponents 01 to 05 are respondents I to V in these appeal proceedings.
- III. The opposition division held that claim 1 of the main request and claim 1 of each of auxiliary requests 1, 2 and 3 contained subject-matter extending beyond the content of the application as filed, contrary to Article 123(2) EPC.
- IV. With the statement of grounds of appeal, the appellant filed sets of claims of a main request and auxiliary requests 1 to 3, these requests being identical to the main request and auxiliary requests 1 to 3 underlying the appealed decision (all emphases below added by the board).

Claim 1 of the main request reads as follows:

"1. An isolated antibody which specifically binds to an isolated IL-17A/F heterodimeric complex and **which inhibits the activity of the IL-17A/F heterodimeric complex to induce production of IL-8 and IL-6**, wherein the isolated IL-17A/F heterodimeric complex comprises SEQ ID NO:3 and SEQ ID NO:4, without their associated signal peptides, and further comprises two interchain disulfide linkages between SEQ ID NO:3 and SEQ ID NO:4; and wherein the antibody is either human or humanized."

Claim 1 of auxiliary request 1 reads as follows:

"1. An isolated antibody which specifically binds to an isolated IL-17A/F heterodimeric complex and **which inhibits the activity of the IL-17A/F heterodimeric complex to induce production of IL-8 and IL-6**, wherein the isolated IL-17A/F heterodimeric complex comprises SEQ ID NO:3 and SEQ ID NO:4, without their associated signal peptides, and further comprises two interchain disulfide linkages between SEQ ID NO:3 and SEQ ID NO:4; and wherein the antibody is for use in a method of medical treatment."

Claim 1 of auxiliary request 2 reads as follows:

"1. An isolated antibody which specifically binds to an isolated IL-17A/F heterodimeric complex and **which inhibits the activity of the IL-17A/F heterodimeric complex to induce production of IL-8 and IL-6**, wherein the isolated IL-17A/F heterodimeric complex comprises SEQ ID NO:3 and SEQ ID NO:4, without their associated signal peptides, and further comprises two interchain disulfide linkages between SEQ ID NO:3 and SEQ ID NO:4; and wherein the antibody is either human or humanized."

Claim 1 of auxiliary request 3 reads as follows:

"1. An isolated antibody which specifically binds to an isolated IL-17A/F heterodimeric complex and **which inhibits the activity of the IL-17A/F heterodimeric complex to induce production of IL-8 and IL-6**, wherein the isolated IL-17A/F heterodimeric complex comprises SEQ ID NO:3 and SEQ ID NO:4, without their associated signal peptides, and further comprises two interchain disulfide linkages between SEQ ID NO:3 and SEQ ID NO:4; and wherein the antibody is for use in a method of medical treatment."

- V. Respondents II and III submitted replies to the statement of grounds of appeal.
- VI. On 4 April 2018, notice of intervention under Article 105 EPC was received from Eli Lilly and Company (intervener I) and the opposition fee was paid. A copy of Genentech's counterclaim of infringement in proceedings before the Patents Court, High Court of England and Wales, case reference HP-2017-000041, was filed in support of the intervention. The counterclaim is dated 5 January 2018 and document D97 in these proceedings.
- VII. In reply, the appellant submitted arguments and supporting evidence, including as to why intervener I's intervention was inadmissible.
- VIII. Intervener I submitted further arguments as regards the admissibility of the intervention, together with *inter alia* an Extract of the Travaux Préparatoires as recorded in the Minutes of the 14th Meeting of the Committee on Patent Law (CA/PL PV 14, pages 11 to 12;

document D117 in these proceedings), and requested accelerated processing of the appeal.

- IX. The board summoned the parties to oral proceedings, as they had requested, and issued a communication pursuant to Article 15(1) RPBA, in which it indicated *inter alia* that, in line with the parties' requests, it did not intend to deal with the grounds for opposition under Article 100(a) and (b) EPC.
- X. In a further communication pursuant to Article 15(1) RPBA, the board provided a preliminary opinion on the admissibility of intervener I's intervention and the compliance with the requirements of Article 123(2) EPC of the feature "*which inhibits the activity of the IL-17A/F heterodimeric complex to induce production of IL-8 and IL-6*", which appeared in claim 1 of all the pending requests.
- XI. By letter dated 21 November 2019, notice of intervention under Article 105 EPC was filed, together with supporting evidence, by Eli Lilly Nederland B.V. (intervener II). The opposition fee was paid on the same date.
- XII. In response, with a letter dated 10 December 2019 the appellant filed sets of claims of a new main request and of auxiliary requests 1 to 6.
- XIII. At the oral proceedings before the board, which took place in the absence of duly summoned respondents IV and V pursuant to Rule 115(2) EPC and Article 15(3) RPBA, the appellant withdrew the sets of claims filed with their letter dated 10 December 2019, and reverted to the claim requests filed with the statement of grounds of appeal (see section IV).

XIV. At the end of the oral proceedings the Chair announced the board's decision.

XV. The appellant's arguments, submitted in writing and during the oral proceedings, are summarised as follows:

Admissibility of the interventions

Intervener I's intervention was inadmissible since notice of intervention had been filed after the three-month time limit under Rule 89(1) EPC.

Eli Lilly and Company had initiated national proceedings before the Patents Court, High Court of England and Wales, requesting *inter alia* revocation of the GB designation of the patent in suit. These earlier national proceedings had also included institution of proceedings for a declaration of non-infringement issued by the court on 3 July 2017 and received by the appellant on 6 July 2017. Thus, the three-month time limit for filing notice of intervention had started running on 6 December 2017, when the appellant had given a binding undertaking to the UK court that it would counterclaim for infringement of the patent in suit and that it would seek appropriate injunctive relief. For the three-month time limit to be triggered, it was necessary but also sufficient for the two criteria mentioned in Article 105(1)(b) EPC to be fulfilled, regardless of the order in which they occurred. This was consistent with case law, in particular decisions T 1713/11 and T 392/97, and passages in the Travaux Préparatoires to the EPC 1973; see MPR/I 421. Accordingly, Eli Lilly and Company had had standing to intervene in the proceedings at an earlier point in time than 5 January 2018, the date of the appellant's counterclaim for infringement. As a

consequence, the three months had already expired by 4 April 2018, when notice of intervention had been filed.

Furthermore, the requirements of Article 105(1)(a) EPC were not fulfilled, namely that the proprietor of the patent had taken the first step by instituting proceedings relating to infringement of the patent. This interpretation was supported by decision T 1713/11. In a situation such as the present, where an action had been brought by the infringer requesting a declaration of non-infringement and a subsequent counterclaim for infringement had been made by the patent proprietor, the patent proprietor had not taken the first step. Moreover, in accordance with the rationale of decision T 188/97, the appellant's counterclaim for infringement was a continuation of the proceedings for a declaration of non-infringement and therefore not the start of new and separate court proceedings for infringement capable of triggering a time limit for intervention under Article 105(1)(a) EPC.

There were no objections in relation to intervener II's intervention.

Main request

Amendments (Article 123(2) EPC) - claim 1

Main line of argument

The application related to the identification of a covalent heterodimer of IL-17 and IL-17F, designated IL-17A/F; see page 5, lines 5 to 6.

The application disclosed antibodies which either mimicked (agonist antibodies) or inhibited (antagonist antibodies) the immunological activities of IL-17A/F; see page 5, lines 18 to 19 and page 6, lines 2 to 3.

The application clearly indicated that antagonists, and in particular antagonist antibodies, were preferred over agonists; see page 69, line 11 to page 71, line 36.

Importantly, in the only section where antibody assays were explicitly discussed, it was expressly indicated that the test format was the use of antibodies that inhibited the indicative activities of the IL-17A/F heterodimer; see page 72, lines 33 to 35 of the application. Accordingly, the preference for antagonist antibodies had been directly and unambiguously expressed.

Because the skilled person was informed that antagonist antibodies were preferred, it was also unambiguous that the test for determining antagonist activity against the IL-17A/F heterodimer was whether the antibody blocked its activity in the only characterising assay provided for this new cytokine. The characterising assay system for IL-17 activity, and indeed the sole assay system in the application for this purpose, monitored the induction of IL-8 and IL-6. Thus, the indicative activity of the antagonistic anti-IL-17A/F antibody was the inhibition, i.e. antagonism, of the induction of IL-8 and IL-6 production.

The application provided the skilled person with a working example demonstrating what the inventors considered the most characteristic and indicative activity of the IL-17A/F molecule, i.e. the ability to

induce IL-8 and IL-6 production (Example 1B). Thus, the skilled person immediately understood that the relevant and practical assay characterising this new molecule was the induction of IL-8 and IL-6.

When the skilled person asked what activity should be used to assess whether an anti-IL-17A/F antibody was an inhibitory antibody, they would derive from the fact that this was the only activity for which an example was given in the application as filed that it was suitable for this purpose.

The assay in Example 1B was not used to compare the IL-17A/F heterodimer with the IL-17 homodimers; see page 115, line 10.

Further lines of argument

Induction of IL-6 and IL-8 was highlighted in the longer list of activities on page 33 of the application precisely by virtue of it being the sole activity for which an example was given, and hence had not been selected arbitrarily.

The general disclosure on page 75, lines 9 to 11, mentioned blocking antibodies and inhibiting lymphokine secretion.

The passage on page 115, lines 10 to 11, when read in combination with the preceding passage, lines 7 to 9, clearly linked antibodies to the cell-based assay of Example 1B.

The passage from page 116, line 28, to page 117, line 5, discussed the results of Examples 1 and 2 and concluded that "*these studies provide and identify a*

novel immune stimulant (i.e. IL-17A/F) that can boost the immune response to respond to a particular antigen". After this section, on page 117, lines 20 to 22, antibodies that inhibited the immunological activities of IL-17A/F were mentioned. These lines were linked to the preceding paragraph. The immunological activity referred to on page 117, line 21, was the immunological activity referred to in the preceding paragraph, not that on page 33, lines 29 to 30. The studies mentioned at the beginning of the preceding paragraph were the studies in Examples 1 and 2. Example 1 was the link to IL-8 and IL-6; it was the only assay provided. In particular, it followed from the preceding paragraph that the immunological activity was the assay disclosed in Example 1B. The concluding section on page 117 thus provided the link between antagonist antibodies and IL-8 and IL-6 inhibition.

Auxiliary requests 1 to 3

Amendments (Article 123(2) EPC) - claim 1

The subject-matter of claim 1 of auxiliary requests 1 to 3 complied with the requirements of Article 123(2) EPC for the same reasons as those given for claim 1 of the main request.

XVI. The arguments of respondent VI regarding the admissibility of its intervention are summarised as follows:

When filing notice of intervention on 4 April 2018, it had met the three-month time limit under Rule 89(1) EPC. Proceedings for alleged infringement of the patent in suit had been instituted by the appellant against it in the form of the appellant's counterclaim of infringement dated 5 January 2018 in proceedings

before the Patents Court, High Court of England and Wales, case reference HP-2017-000041.

The appellant's interpretation of Article 105(1)(b) EPC was not in line with the wording of the provision. Moreover, the addition of "following" had been discussed during the EPC 2000 revision - see CA/PL PV 14, points 67 to 70 (document D117) - and was understood and intended to indicate a certain chronology of events. Thus, the conditions of Article 105(1)(b) EPC had not been satisfied by the commencement of the proceedings for a declaration of non-infringement followed by the appellant's undertaking to the UK court of 6 December 2017.

Furthermore, it could not be derived from Article 105(1)(a) EPC that the patent proprietor had to take the first step. This was confirmed by decision T 228/03, for example. Under UK law, a counterclaim was to be treated in the same way as a free-standing claim. Thus, for example, if the claim for a declaration of non-infringement was discontinued, the counterclaim for infringement could continue. Decision T 1713/11 considered a different scenario.

As followed from decisions T 18/98 and T 296/93, the two alternatives in Article 105(1) EPC both required a clear demarcation line for calculation of the time limit for intervention. The appellant's counterclaim for infringement of 5 January 2018 was such a clear demarcation line. Relying on other dates would lead to uncertainty as to the start of the time limit. Accordingly, the requirements under Article 105(1)(a) EPC had been met.

XVII. The arguments of respondents I, II and III and the further arguments of respondents VI and VII, submitted in writing and during the oral proceedings, are summarised as follows:

Main request

Amendments (Article 123(2) EPC) - claim 1

Main line of argument

Nowhere in the application was inhibition of IL-8 and IL-6 production disclosed as a relevant property of any antibody; see page 5, lines 18 to 19, page 25, lines 19 to 24, and pages 69 to 71.

Contrary to the appellant's statements, induction of IL-8 and IL-6 production was not "the characterising and indicative property" of the IL-17A/F heterodimer; on the contrary, this activity was shared with the IL-17 and IL-17F homodimers; see example on page 113 and also the legend of Figure 5 on page 17, line 16. The example did not define a standard for the activity of the IL-17A/F heterodimer. Still less did it define an activity that was to be inhibited by an antibody.

The appellant's approach focused unduly on a single experiment while ignoring the rest of the application. The skilled person could not ignore the application's overall disclosure, and would not focus only on the passages which the appellant had highlighted.

The application clearly and unambiguously related to different activities to be inhibited by antibodies; see claim 53 in combination with claim 34.

The application contained two sections on antibodies and their properties; see section M, on pages 80 to 92, and section P, on pages 94 to 95. Section P was entitled "*Screening for Anti-IL-17A/F Antibodies, IL-17A/F Binding Oligopeptides and IL-17A/F Binding Organic Molecules with the Desired Properties*". On page 94, lines 28 ff it was stated that "[t]he growth inhibitory effects of an anti-IL-17A/F antibody, oligopeptide or other organic molecule of the invention may be assessed by methods known in the art." Page 95, line 3 referred to the inhibition of cell proliferation, while line 11 referred to the induction of cell death. The application thus disclosed functional properties in the context of antibodies, none of which was the inhibition of IL-8 and IL-6 production.

Concerning the appellant's further lines of argument

The induction of IL-8 and IL-6 was originally linked to another activity on page 33, lines 21-22, presumably NFκB. There was no basis for isolating IL-8 and IL-6 from the other activity, whatever that activity was. Moreover, page 33, lines 15-30 as a whole referred to several activities for the IL-17A/F heterodimer, without giving any special prominence to the production of IL-8 and IL-6. The appellant could not arbitrarily select this single activity from the list. This list in the application as filed did not expressly state that any of these effects in particular should be inhibited by an antibody.

The passage on page 75, lines 8 to 10, of the application provided no basis for the subject-matter of claim 1. It mentioned antibodies and lymphokine

secretion generally, but not IL-8 and IL-6 specifically.

Page 115, first paragraph, of the application disclosed modulation of activity, not inhibition, and there was no link between the antibodies mentioned in the first paragraph of page 115 and the assay mentioned in the second paragraph.

Page 117, lines 17 to 19, of the application referred to molecules which inhibited IL-17A/F activity but not to antibodies as defined in claim 1. On page 117, lines 20 to 21, the application defined the activities that should be inhibited by an antagonist antibody as the "*immunological activities*". Immunological activities were defined on page 33, lines 29 to 30, of the application. The preceding paragraph on page 117 mentioned the "*proliferation of T cells*" as in claim 53 as filed and boosting the immune system, but not the induction of IL-8 and IL-6.

Auxiliary requests 1 to 3

Amendments (Article 123(2) EPC) - claim 1

The objections under Article 123(2) EPC raised against the subject-matter of claim 1 of the main request applied also to the subject-matter of claim 1 of auxiliary requests 1 to 3.

XVIII. Respondents IV and V did not submit any arguments or requests during the appeal proceedings.

XIX. The appellant requested that the decision under appeal be set aside and that the case be remitted to the opposition division for further prosecution on the

basis of the claims of the main request, or alternatively of one of auxiliary requests 1 to 3. All these requests had been filed with the statement of grounds of appeal.

- XX. Respondents I, II, III, VI and VII requested that the appeal be dismissed.

Reasons for the Decision

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

Interventions (Article 105 EPC)

Intervention of Eli Lilly and Company

2. Notice of intervention was filed on behalf of Eli Lilly and Company on 4 April 2018 in a written reasoned statement in accordance with Rule 89(2) EPC and Rule 76 EPC. The opposition fee was paid on the same date.
3. Pursuant to Rule 89(1) EPC, notice of intervention is to be filed within three months of the date on which proceedings referred to in Article 105 EPC are instituted, i.e. either when proceedings for infringement of the same patent have been instituted against the assumed infringer (Article 105(1) (a) EPC), or when, following a request of the patent proprietor to cease alleged infringement, the assumed infringer has instituted proceedings for a ruling that he is not infringing the patent (Article 105(1) (b) EPC).

4. There was no dispute that the appellant's counterclaim for infringement was made on 5 January 2018 (see also document D97) and that the three-month time limit under Rule 89(1) EPC was met when calculated on this basis (see also Rule 131(1) and (4) EPC).
5. However, the appellant argued that Eli Lilly and Company had had standing to intervene at an earlier point in time, such that the three-month time limit had already expired by 4 April 2018. This point is of relevance because it is established case law that the two alternative means for intervention under Article 105(1) EPC are mutually exclusive in the sense that once an opportunity has existed for the third party to intervene under one alternative, subsequent fulfilment of the requirements under the second alternative does not provide any further opportunity to intervene (see also decision T 296/93, OJ EPO 1995, 627, point 2.6 of the Reasons, and decision T 18/98, point 2.2 of the Reasons).
6. The appellant's objection was based on the argument that Article 105(1)(b) EPC did not specify a particular chronology of events and that, accordingly, the three-month time limit was triggered once the two conditions - the patent proprietor's request to cease infringement and the institution of proceedings by the assumed infringer for a ruling of non-infringement - were fulfilled.
7. However, the board does not agree with this understanding of Article 105(1)(b) EPC. The principles set out in Articles 31 and 32 of the Vienna Convention on the Law of Treaties (VC) are taken into account when interpreting EPC provisions (see also decision G 5/83, OJ EPO 1985, 64, points 1 to 6 of the Reasons).

Pursuant to Article 31(1) VC, a treaty is to be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose.

8. It follows from the clear wording of Article 105(1)(b) EPC that the provision is based on a specific sequence of events ("**following** a request of the proprietor of the patent ..., the third party has instituted proceedings ..."; emphasis added by the board).
9. The Travaux Préparatoires confirm that this sequence of events had intentionally been chosen by the legislator (see document D117; for the legislative history of Article 105 EPC 1973 see [http://webserv.epo.org/projects/babylon/tpepc73.nsf/0/A58D54B45320BD46C125742700477DCC/\\$File/Art105eTPEPC1973.pdf](http://webserv.epo.org/projects/babylon/tpepc73.nsf/0/A58D54B45320BD46C125742700477DCC/$File/Art105eTPEPC1973.pdf); in this context, see in particular BR/144/71, point 78; M/PR/I, points 417 to 419; M/19, point 14; and M/21, point 8; for the role of the Travaux Préparatoires in the context of interpreting EPC provisions, see Article 32 VC).
10. The result of a literal interpretation is also in line with a systematic interpretation, because in both alternative scenarios - Article 105(1)(a) and (b) EPC - it is the formal institution of proceedings (at a court or another competent national authority) which triggers the time limit. These are events which can be unambiguously established with legal certainty, since they are official dates (see also decision T 296/93 above, point 2.5 of the Reasons) and thus set "a clear demarcation line" (see also decision T 18/98, point 2.2 of the Reasons). It is important that the start of the

time limit can be established with legal certainty, because this triggers a time limit, the purpose of which is to enable a third party to acquire the status of an opponent after expiry of the opposition period. Accordingly, the date should be unambiguously identifiable for the parties involved and for the EPO.

11. The decisions relied upon by the appellant in this context do not support its case since none of the underlying situations was comparable to the present one; rather, they were concerned with different issues. Decision T 392/97 addressed the question of whether certain letters qualified as a request to cease infringement within the meaning of Article 105(1)(b) EPC, and decision T 1713/11 addressed the question of whether the institution of a specific criminal action under Austrian law constituted the institution of proceedings under Article 105(1)(a) EPC.
12. In the absence of an earlier standing to intervene, in the present case the event triggering the three-month time limit under Rule 89(1) EPC was the filing of the appellant's counterclaim for infringement of the patent in suit. Given the uncontested date of 5 January 2018 for the counterclaim, the intervention of 4 April 2018 occurred in due time and the requirements under Article 105(1)(a) EPC were thus met.
13. In its second line of argument, the appellant had argued that its counterclaim for infringement of the patent in suit did not qualify as an event triggering the three-month time limit.
14. In contrast to the appellant's opinion, however, the board does not consider it relevant that the counterclaim for infringement did not initiate new

proceedings and was to be dealt with in existing proceedings. Whether or not separate proceedings take place is a consequence of the relevant national law. It was not contested that the appellant was not obliged to launch a counterclaim for infringement and whether a counterclaim was made had therefore been up to the appellant. Nor was it in dispute that in the UK a counterclaim is treated in the same way as a free-standing claim and that, if proceedings for a declaration of non-infringement are discontinued, the counterclaim for infringement can continue.

15. Irrespective of the fact that the underlying situation of decision T 1713/11 is not comparable to the present one (see point 11), the board sees no conflict with the section referred to by the appellant. In point 2.3 of the Reasons of decision T 1713/11, the board in that case described the two alternative scenarios pursuant to Article 105(1) EPC and noted that, under Article 105(1)(a) EPC, the patent proprietor had to take the first step. The "step" referred to was the institution of proceedings for infringement which, as further noted in that decision, did not require court proceedings but it did "*require the patentee to take the first step*".

16. It is of no relevance that, at the moment of the appellant's (counter)claim for infringement, proceedings for a declaration of non-infringement were already pending, because those could not have triggered the time limit for filing notice of intervention in the absence of a preceding request by the appellant to cease alleged infringement (see also decision T 228/03, point 2.3 of the Reasons).

17. Lastly, decision T 188/97, referred to by the appellant, relates to a situation in which seizure proceedings containing an injunctive order were brought by the patent proprietor, followed by court proceedings brought by the patent proprietor for infringement. This is not comparable to the present situation, where proceedings for a declaration of non-infringement brought by the assumed infringer were followed by a counterclaim for infringement brought by the patent proprietor.

Intervention of Eli Lilly Nederland B.V.

18. The intervention of Eli Lilly Nederland B.V. complies with the requirements pursuant to Article 105(1)(a) EPC and Rule 89 EPC. This was also not contested by the appellant. Notice of intervention was filed on 21 November 2019 in a written reasoned statement in accordance with Rule 89(2) EPC and Rule 76 EPC. The opposition fee was also duly paid. The three-month time limit pursuant to Rule 89(1) EPC was met in view of the infringement proceedings which were instituted by the appellant against Eli Lilly Nederland B.V. on 11 September 2019 before the Regional Court of Düsseldorf.
19. The interventions by intervener I and intervener II were therefore admissible. Thus, the interveners had the status of opponents, in accordance with Article 105(2) EPC, and were designated opponent 06 (intervener Eli Lilly and Company) and opponent 07 (intervener Eli Lilly Nederland B.V.), or respondent VI and VII, respectively.

Main request

Amendments (Article 123(2) EPC) - claim 1

20. In the decision under appeal, the opposition division held that the subject-matter of the claim failed to meet the requirements of Article 123(2) EPC, *inter alia* because there was no clear and unambiguous disclosure that the way to test the antagonistic activity of an antibody binding IL-17A/F was to measure the inhibition of the activity of the IL-17A/F heterodimeric complex to induce production of IL-8 and IL-6 (see point 3.7.2 of the decision under appeal).

21. It is not disputed by the appellant that the application does not contain an explicit disclosure of the feature "*which inhibits the activity of the IL-17A/F heterodimeric complex to induce production of IL-8 and IL-6*" in the context of an antibody which specifically binds to an isolated IL-17A/F heterodimeric complex. Instead, the appellant developed several lines of argument in support of a direct and unambiguous disclosure in the application as a whole.

22. According to the established case law of the boards of appeal, amendments are only permitted within the limits of what a skilled person would derive directly and unambiguously, using common general knowledge, and seen objectively and relative to the date of filing, from the whole of the application as filed. It is not permitted for the skilled person to be presented with new technical information after the amendment (see decision G 2/10, OJ EPO 2012, 376, points 4.3 and 4.5.1 of the Reasons; see also Case Law of the Boards of

Appeal of the European Patent Office, 2019,
9th edition, II.E.1.1 and II.E.1.3.1).

23. It was common ground that for the purpose of this case the person skilled in the art is a scientist or team of scientists specialised in the fields of microbiology, immunology and treatment of immune-related and/or inflammatory diseases, aware of the IL-17 family of cytokines and experienced in testing their functions. The board has no reason to see this differently.
24. In its main line of argument, the appellant relied on page 5, lines 18 to 19; page 6, lines 2 to 3; page 69, line 12 to page 71, line 36; page 72, lines 33 to 35; and Example 1B of the application. The appellant's argument is based on the contention that the passage on page 72, lines 33 to 35, is the only one in the application where antibody assays are explicitly discussed, and that induction of IL-8 and IL-6 production in Example 1B is the only activity given as an example and hence the characteristic and "indicative" activity of the IL-17A/F heterodimer. From this they concluded that the "indicative" activity of the antagonistic anti-IL-17A/F antibody is the inhibition of the induction of IL-8 and IL-6 production (see section XV).
25. The board is not persuaded by the appellant's main line of argument for the following reasons.
- 25.1 In Example 1B on page 113, lines 14 to 18, under the heading "*Cell-based Assays - IL-17A/F Induces the production of IL-8 and IL-6*", the application discloses that fractions of purified recombinantly produced IL-17A/F were incubated with TK-10 cells and conditioned media collected and analysed by ELISA for

the production of IL-8 and IL-6. Furthermore, "[d]ose response curves comparing IL-8 and IL-6 induction by IL-17A/F, IL-17 and IL-17F" (emphasis added by the board) were determined (see page 113, lines 29 to 30 and Figure 5). However, while Example 1B discloses the induction of IL-8 and IL-6, this activity is not explicitly disclosed on page 113 as the "indicative" activity of the IL-17A/F heterodimer, nor as an activity that should be inhibited, let alone by an antibody.

- 25.2 Moreover, in the board's judgement, the skilled person reading Example 1B would not understand that induction of IL-8 and IL-6 is the "indicative" activity of the IL-17A/F heterodimer. On the contrary, it is apparent from the example, in particular from Figure 5 and its legend on page 17 and from the discussion of the example on page 115, lines 10 to 20, that the IL-17A/F heterodimer's ability to induce IL-8 and IL-6 production was compared with that of the IL-17 homodimers, IL-17 and IL-17F, which were well known to possess that ability (see page 3, lines 14 to 15; page 4, lines 36 to 37; page 115, line 11). Thus, the ability to induce IL-8 and IL-6 production does not distinguish the IL-17A/F heterodimer from the IL-17 homodimers. At best, the heterodimer is more potent than the homodimers as regards the induction of IL-8 but not that of IL-6.
- 25.3 Secondly, contrary to the appellant's contention, the passage on page 72 of the application is not the sole section in the application where antibody assays are explicitly discussed. The skilled person reading the application as a whole would have noted that the application explicitly emphasises other activities to be inhibited by antibodies binding to IL-17A/F and also

that it provides the appropriate assays for screening for such antibodies.

25.4 Thus, claim 53 as filed in combination with claim 34 as filed discloses "*the proliferation of T-lymphocytes in a mammal*" and "*decreasing infiltration of inflammatory cells into a tissue of a mammal*" as functions to be inhibited by an antibody, while inhibition of the induction of IL-8 and IL-6 production is not recited in any of the claims as filed.

25.5 Furthermore, on page 94, lines 28 to 35, under the heading "*Screening for Anti-IL-17A/F Antibodies [...] With the Desired Properties*", the application teaches that "*[t]he growth inhibitory effects of an anti-IL-17A/F antibody [...] of the invention may be assessed by methods known in the art, e.g., using cells which express an IL-17A/F polypeptide either endogenously or following transfection with the IL-17A/F gene. For example, appropriate tumor cell lines and IL-17A/F-transfected cells may treated with an anti-IL-17A/F monoclonal antibody [...] of the invention at various concentrations for a few days (e.g., 2-7) days and stained with crystal violet or MTT or analyzed by some other colorimetric assay. Another method of measuring proliferation would be by comparing ³H-thymidine uptake by the cells treated in the presence or absence an [sic] anti-IL-17A/F antibody [...]*". On the next page, the application teaches that "*[p]referably, the anti-IL-17A/F antibody [...] will inhibit cell proliferation of an IL-17A/F-expressing tumour cell in vitro or in vivo*" and that "*[t]o select for an anti-IL-17A/F antibody [...] which induces cell death, loss of membrane integrity as indicated by,*

e.g., propidium iodide (PI), trypan blue or 7AAD uptake may be assessed relative to control".

- 25.6 The application as filed thus informs the skilled person which functions are inhibited by antagonistic antibodies and which assays can be used to screen for such antibodies. These assays are familiar to the skilled person (see preceding point), and none of them involves testing the inhibition of IL-8 and IL-6 production.
- 25.7 The appellant has not advanced any argument why the skilled person would ignore this explicit teaching in the application as filed. In the board's judgement, the skilled person reading the application as a whole, when faced with the question of what activity should be used to assess whether an anti-IL-17A/F antibody is an inhibitory antibody, would turn to pages 94 and 95 of the application and not to Example 1B, as argued by the appellant.
26. In additional lines of argument, the appellant relied on a passage on page 33; on a passage on page 75; and on passages on pages 115 and 117 as proving a link between an inhibitory antibody and blocking the production of IL-8 and IL-6. None of the appellant's further lines of argument was found persuasive by the board, for the reasons set out below.
27. Page 33, lines 21 to 28, of the application lists several biological activities of IL-17A/F as follows: "*[o]ne preferred biological activity includes inducing activation of [hardly legible, presumably NFκB] and stimulation of the production of the proinflammatory chemokines IL-8 and IL-6. Another preferred biological activity includes stimulation of peripheral blood*

mononuclear cells or CD4⁺ cells. Another preferred biological activity includes stimulation of the proliferation of T-lymphocytes. Another preferred biological activity includes, for example, the release of TNF- α from THP1 cells. Another activity includes an enhancement of matrix synthesis in articular cartilage. Alternatively, another activity includes promoting breakdown of articular cartilage matrix as well as inhibiting matrix synthesis. Another preferred biological activity includes modulating the level of the interleukin-17 signalling pathway during mild to severe stages of inflammatory bowel disease or during stroke."

28. It is apparent from the preceding point that page 33, lines 21 to 28, refers to several activities for the IL-17A/F heterodimer, including the induction of IL-8 and IL-6, which however is not highlighted as particularly preferred. Moreover, on page 33, this activity is disclosed in combination with another activity, presumably NF κ B. Even if it is accepted that the example provides a pointer to the induction of IL-8 and IL-6, there is no basis for isolating the induction of IL-8 and IL-6 from this other activity. Moreover, the application as filed does not expressly state that any of these activities in particular should be inhibited by an antibody. There is thus no basis for selecting the induction of IL-6 and IL-8 as the particular function to which an IL-17A/F inhibitory antibody should be directed. Accordingly, the appellant's argument based on page 33 fails.
29. The passage on page 75, lines 8 to 10, reads as follows: "*[a]lternatively, compounds, e.g., antibodies, which bind to stimulating IL-17A/F polypeptides and block the stimulating effect of these molecules produce*

a net inhibitory effect and can be used to suppress the T cell mediated immune response by inhibiting T cell proliferation/activation and/or lymphokine secretion."

30. While the passage mentions blocking antibodies, it relates to the inhibition of lymphokine secretion generally and not to IL-8 and IL-6 specifically and hence does not disclose an antibody which inhibits the activity of the IL-17A/F heterodimeric complex to induce production of IL-8 and IL-6.
31. The passage on page 115, lines 7 to 9, reads: "*Thus, specific antibodies which bind selectively to the novel heterodimeric complex of IL-17A/F have been identified which may serve to modulate the activity of this novel cytokine*".
32. The passage which follows it, on page 115, lines 10 to 20, reads: "*IL-17A/F was analyzed for ability to stimulate a proinflammatory response using the TK-10 human kidney cell line (Figure 5). This cell line responds to both IL-17 and IL-17F by production of IL-8. IL-17A/F also robustly induced IL-8 production in this cell line (Figure 5A). Interestingly, IL-17A/F was observed to have a unique potency that differs from that of either IL-17 or IL-17F. The difference in activity differs from IL-17 and IL-17F by roughly an order of magnitude in each case. The substantially greater activity of IL-17A/F than IL-17F in this assay suggests that IL-17A/F may comprise a critical component of the cytokine activity resulting from the IL-17F gene product. This unique potency may enable the molecule to possess distinct range of actions in vivo. IL-17A/F also induced production of IL-6 from this cell line (Figure 5B). Additionally, it is likely that IL-17A/F may possess additional characteristics not*

present in either IL-17 or IL-17F as a result of its novel heterodimeric composition that may alter the kinetics and utilization of receptor subunits in vivo, resulting in unique biological consequences".

33. These two passages relate to different experiments, and there is no link between the antibodies mentioned in the first paragraph and the assay mentioned in the second paragraph. Thus, the first passage on page 115 (see point 31) discusses antibodies which were identified by screening a phage library of synthetic Fab antibodies and which may serve to "modulate" the activity of the IL-17A/F heterodimer. The next passage, on page 115, lines 10 to 20 (see point 32), discusses the results of a different example, the cell-based assay, and while the potency of the IL-17A/F heterodimer to induce IL-8 and IL-6 is compared with that of the homodimers, the passage is silent on a possible inhibition of that activity, let alone by antibodies. Accordingly, these passages on page 115 fail to disclose an antibody which inhibits the activity of the IL-17A/F heterodimeric complex to induce production of IL-8 and IL-6.
34. On page 117, lines 4 to 6, Examples 1 and 2 are summarised as follows: "*Thus, these studies provide and identify a novel immune stimulant (i.e. IL-17A/F) that can boost the immune system to respond to a particular antigen that may not have been immunologically active previously. As such, the newly identified immune stimulant has important clinical applications. Other known immune stimulants such as IL-12 have been identified.*" The application then summarises the data of a recent cancer vaccine trial in which patients were treated "*with different doses of IL-12, an immune*

stimulant capable of inducing the proliferation of T cells".

35. The paragraph concludes with the statement on page 117, lines 16 to 19, that "*[l]ikewise, this novel IL-17A/F cytokine or agonists thereof, would therefore find practical utility as an immune stimulant. Whereas molecules which inhibit IL-17A/F activity (antagonists) would be expected to find practical utility when an inhibition of the immune response is desired, such as in autoimmune diseases.*"
36. In the next paragraph on page 117, lines 20 to 22, the application states that "*[t]hus, antibodies to this new cytokine which either mimic (agonist antibodies) or inhibit (antagonist antibodies) the immunological activities of IL-17A/F would possess therapeutic qualities. Small molecules which act to inhibit the activity of this novel cytokine would also have potential therapeutic uses.*"
37. It is apparent from point 35 above that on page 117, lines 16 to 19, the application refers to molecules which inhibit activities of IL-17A/F, but not to antibodies as defined in claim 1. On page 117, lines 20 to 22, the application then defines the activities that should be inhibited by an antagonist antibody as the "*immunological activities of IL-17A/F*".
38. "*Immunological activities*" are defined on page 33, lines 29 to 30, of the application as follows: "*An 'immunological' activity refers only to the ability to induce the production of an antibody against an antigenic epitope possessed by a native or naturally-occurring IL-17A/F polypeptide.*" While the definition

is confusing, it is clear that induction of IL-8 and IL-6 does not fall within it.

39. Even if it is accepted that the immunological activity is not as defined on page 33 of the application but that referred to in the preceding paragraph on page 117, IL-8 and IL-6 induction are still not mentioned on page 117. Indeed, page 117 mentions "*proliferation of T cells*", as in claim 53 as filed, and "*immune stimulant*", which is a different function from the induction of IL-8 and IL-6.
40. Therefore, in the board's view, the passage on page 117, lines 20 to 22, even when read in combination with the passage that precedes it, does not disclose an antibody which inhibits the activity of the IL-17A/F heterodimeric complex to induce production of IL-8 and IL-6.
41. From the above, the board concludes that the skilled person cannot derive from the application as filed as a whole, directly and unambiguously, using common general knowledge, and seen objectively and relative to the date of filing, that the activity of the IL-17A/F heterodimeric complex to induce production of IL-8 and IL-6 is an activity to be inhibited by an antibody. Therefore, the use of this activity to define a class of inhibitory antibodies does indeed provide the skilled person with new technical information that was not originally disclosed.
42. For this reason alone, claim 1 of the main request does not meet the requirements of Article 123(2) EPC.

Auxiliary requests 1 to 3

Amendments (Article 123(2) EPC) - claim 1

43. Claim 1 of each of the auxiliary requests specifies that the antibody "*inhibits the activity of the IL-17A/F heterodimeric complex to induce production of IL-8 and IL-6*" (see section IV). Therefore, claim 1 of these requests does not meet the requirements of Article 123(2) EPC for the same reasons as those given above for claim 1 of the main request.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chair:



I. Aperribay

M. Blasi

Decision electronically authenticated