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Datasheet for the decision of 7 November 2023

Case Number:	T 2171/21 - 3.3.04
Application Number:	16163440.7
Publication Number:	3111954
IPC:	A61K39/395, C07K16/24, A61K31/519, A61P37/06
Language of the proceedings:	EN

Title of invention:

Methods of treating ankylosing spondylitis using anti-IL-17 antibodies

Patent Proprietor:

Novartis AG

Opponents:

Dr. Reddy's Laboratories Limited
Strawman Limited
Boult Wade Tennant LLP

Headword:

Anti-IL-17 antibody for treating ankylosing spondylitis/ NOVARTIS

Relevant legal provisions:

EPC Art. 100(c), 76(1)

Keyword:
Amendments - extension beyond the content of the application as filed (yes)

Decisions cited:
G 0002/10, T 0783/09, T 2273/09, T 3035/19

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Case Number: T 2171/21 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 7 November 2023

Appellant: (Opponent 2)	Strawman Limited Orchard Lea Horns Lane Combe, Witney Oxfordshire OX29 8NH (GB)
Representative:	D Young & Co LLP 120 Holborn London EC1N 2DY (GB)
Respondent: (Patent Proprietor)	NOVARTIS AG Lichtstrasse 35 4056 Basel (CH)
Representative:	Carpmaels & Ransford LLP One Southampton Row London WC1B 5HA (GB)
Party as of right: (Opponent 1)	Dr. Reddy's Laboratories Limited 8-2-337, Road No. 3, Banjara Hills Telangana 500034 Hyderabad (IN)
Representative:	Maiwald GmbH Elisenhof Elisenstraße 3 80335 München (DE)
Party as of right: (Opponent 3)	Boult Wade Tennant LLP Salisbury Square House 8, Salisbury Square London EC4Y 8AP (GB)
Representative:	Boult Wade Tennant LLP Salisbury Square House

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Decision under appeal: **Decision of the Opposition Division of the European Patent Office posted on 14 October 2021 rejecting the oppositions filed against European patent No. 3111954 pursuant to Article 101(2) EPC**

Composition of the Board:

Chairwoman M. Pregetter
Members: B. Rutz
M. Blasi

Summary of Facts and Submissions

I. An appeal was lodged by opponent 2 (appellant) against the decision of the opposition division to reject the oppositions against European patent No. 3 111 954. The patent is entitled "*Methods of treating ankylosing spondylitis using anti-IL-17 antibodies*". The patent is based on European application No. 16 163 440.7, which is a divisional application of European application No. 11 778 903.2. The latter had been filed as an international application published as WO 2012/059598 (the earlier application as filed).

II. The patent was opposed on the grounds in Article 100(a) EPC, in relation to inventive step (Article 56 EPC), and in Article 100(b) and (c) EPC.

III. With its reply to the statement of grounds of appeal, the patent proprietor (respondent) relied on the patent as granted and the sets of claims of auxiliary requests 1 to 3 as filed during the opposition proceedings.

IV. Independent claim 1 of the main request reads:

"1. Secukinumab for use in treating ankylosing spondylitis (AS), characterized in that secukinumab is to be:
a) subcutaneously administered to a patient in need thereof as five doses of 150 mg, each of the five doses being delivered weekly;
wherein the first weekly dose is administered during week 0, and
the second weekly dose is administered during week 1, and

the third weekly dose is administered during week 2, and
the fourth weekly dose is administered during week 3, and
the fifth weekly dose is administered during week 4; and
b) thereafter, a maintenance regimen is administered to the patient as a first dose during week 8 and every month thereafter."

Auxiliary request 1 differs from the main request in that dependent claim 2 is deleted.

Auxiliary request 2 differs from auxiliary request 1 in that a maintenance regimen is administered "subcutaneously" to the patient.

Auxiliary request 3 differs from auxiliary request 1 in that a maintenance regimen is administered "subcutaneously" to the patient as a first dose "of 150 mg".

V. Opponents 1 and 3 did not appeal and did not file any submissions. They are parties as of right to the proceedings.

VI. The board summoned the parties to oral proceedings as requested and informed them of its preliminary opinion in a communication pursuant to Article 15(1) RPBA.

VII. Oral proceedings before the board took place on 7 November 2023 in the absence of opponents 1 and 3, which had indicated by letter that they would not attend the oral proceedings. The proceedings were continued in the absence of opponents 1 and 3 in accordance with Rule 115(2) EPC and Article 15(3) RPBA.

At the end of the oral proceedings, the Chairwoman announced the board's decision.

VIII. The appellant's arguments relevant to the decision may be summarised as follows.

Added subject-matter (Article 100(c) EPC)

Several selections were required to arrive at the subject-matter of claim 1. There was no pointer towards the resulting combination of these selections in the earlier application as filed or the application as filed. Therefore, the combination of features in claim 1 could only be arrived at by making multiple selections from lists, with the consequence that the claimed subject-matter extended beyond the content of the (earlier) application as filed.

The only example relating to ankylosing spondylitis (AS) was Example 5, which disclosed a different dosage regimen to claim 1.

IX. The respondent's arguments relevant to the decision may be summarised as follows.

Added subject-matter (Article 100(c) EPC)

Table 5 on pages 66 and 67 of the earlier application as filed disclosed nine "*preferred treatment regimens*" for a variety of inflammatory arthritides, including AS. Each of these "*preferred*" regimens was therefore disclosed in combination with each of these inflammatory arthritides, including the claimed regimen in the final row of the table (see also the disclosure of the diseases on page 14, third paragraph). Claiming only one of these was in line with decision T 783/09

(see point 6.1 f. of the Reasons, also cited in Case Law of the Boards of Appeal, II.E.1.6.3, 10th edition 2022). The disclosure in the paragraph below Table 5, bridging pages 67 to 68, provided a basis for the preference of 150 mg as the induction dose.

The situation was different than for lists of substituents in Markush formulae.

Furthermore, no unwarranted advantage which could be damaging to the legal security of third parties relying on the content of the (earlier) application as filed was given to the respondent by the subject-matter of the claim (see decision G 1/93, point 9 of the Reasons).

X. The appellant requested that the decision under appeal be set aside and that the patent be revoked.

The respondent requested that the appeal be dismissed, i.e. that the patent be maintained as granted, or, alternatively, that the patent be maintained in amended form based on the set of claims of one of auxiliary requests 1 to 3 as filed during opposition proceedings.

Reasons for the Decision

Main request
Extension of subject-matter (Article 100(c) EPC)

1. The appellant considers the subject-matter of claim 1 to require combining multiple selections from

embodiments disclosed in the (earlier) application as filed, namely:
1. selection of ankylosing spondylitis (AS) from a list of at least four inflammatory diseases (feature (i))
2. selection of the claimed regimen from a list of at least nine regimens (feature (ii))
3. selection of 150 mg from a list of two induction dosages (feature (iii))

2. The appellant further argues that neither in the examples nor in the rest of the (earlier) application as filed there was a pointer to the combination of features of claim 1.

3. The respondent counter-argues that because the disclosed dosage regimens were preferred "*for treating RA* [Rheumatoid arthritis] *patients (e.g. high risk RA patients) and patients having other inflammatory arthritis, e.g. spondyloarthropathy, ankylosing spondylitis (AS), and psoriatic arthritis (PsA)*" (see sentence preceding Table 5 on page 66 and similar disclosure on page 14, paragraph 3), each of them was also disclosed in combination with each of the four diseases. The way Table 5 and the introduction to it were drafted represented only shorthand for stating all the disclosed combinations individually. The disclosure, however, was the same. An applicant could not be forced to claim all these disclosed combinations, hence it was legitimate to claim only one of the conceptually individualised combinations.

4. The board does not agree with the line of argument presented by the respondent because a difference exists between the conceptual disclosure of a number of possible combinations and the individualised disclosure of specific combinations. While the former might be a

more economical way of drafting a patent application, it does not necessarily allow the skilled person to derive each and every individual combination directly and unambiguously.

5. In the current case, claim 1 is directed to a specific dosage regimen (see section IV.: steps (a) and (b) of the claim) including a specific induction dose (150 mg) for a specific disease (AS). The disease AS is disclosed in the earlier application as filed in a list comprising RA and a generic reference to other forms of inflammatory arthritis, which are exemplified by three concrete disease (see sentence preceding Table 5 on page 66). The dosage regimen is disclosed in the last of nine rows in Table 5 on pages 66 to 67, and the induction dose is disclosed as one of two options in the last row of Table 5. To arrive at the claimed subject-matter, the skilled person has to select one element from each of the three lists and combine the three, or they have to "compute" all possible combinations (48 in this case) and discard 47 of them. Neither approach can be considered to lead to subject-matter disclosed directly and unambiguously in the earlier application as filed. The former manner, i.e. the selection from three lists, cannot be seen, due to the repeated necessity for making selections, as resulting in subject-matter derivable from what is directly at the disposal of the skilled person. The latter, due to the step of computing, is not direct.

6. The respondent further argues that the situation was fundamentally different from the selection of groups for substitution in a Markush formula. The board does not agree with this argument. In the same way that Markush formulae can represent conceptual combinations of lists of different chemical groups (e.g. R1 and R2)

with different core structures, the disclosure in the earlier application as filed represents conceptual combinations of different dosage regimen and induction dosages with different diseases. Just as different chemical groups cannot coexist at the same position on a given chemical core structure (i.e. one substituent cannot be two different chemical groups at the same time), the same patient with a disease cannot be treated at the same time with different dosage regimens or different induction dosages. The reference to Markush formulae does thus not change the board's view that several selections have been effected.

7. The respondent, furthermore, considers decision T 783/09 to exemplify a computational approach leading to acknowledging a number of individualised combinations derived from two lists from which several combinations could be deleted. In its view, such an approach would also be applicable in the current case.

8. The board agrees with the respondent that considerations on a selection from several lists is not meant to take the place of the gold standard, i.e. the consideration 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. The Enlarged Board of Appeal in decision G 2/10 recalled this common and well-established principle of disclosure (see point 4.3 of the Reasons). An aspect that the Enlarged Board of Appeal, in point 4.5.4 of the Reasons, also addressed was the issue of "singling out" by holding that "*there would be added matter*" where the amendment, in the case of G 2/10 the insertion of a disclaimer into a claim, *"would result in singling out any hitherto not specifically mentioned*

or at least implicitly disclosed individual compound or group of compounds ...".

9. The "singling out" of a combination of features is precisely what happened in the drafting of current claim 1. A single disease is selected for which a single dosage regimen and a single induction dosage is chosen from a considerable number of conceptual but not specifically mentioned or at least implicitly disclosed individual combinations (see point 5. above).

10. This is in accordance with decision T 2273/09 (Reasons, point 2.1.12, which applied decision G 2/10 when dealing with the selection of a combination from several lists instead of relying on the finding in decision T 783/09 (which was issued before the handing down of decision G 2/10).

11. The board furthermore agrees with decision T 3035/19 (see points 1.4 and 1.5 of the Reasons), cited by the appellant, that considerations on selections from two or more lists of some length provide valuable guidance. The board, however, also recognises that the combination of features resulting from selections from two or more lists only adds subject-matter in the absence of a pointer to that particular combination. In other words, the concept of selection from lists has to be applied with due regard to the whole content of the earlier application as filed.

12. However, in the circumstances of the current case, a preference for or pointer to any of the combined features, i.e. (i) ankylosing spondylitis, (ii) subcutaneous administration of weekly doses over five weeks (induction phase) followed by monthly administration (maintenance phase), and (iii) fixed

dose of 150 mg for the induction phase, cannot be found in the earlier application as filed.

13. For features (i) and (ii), there is no preference or pointer, and the respondent has also not argued that this was the case. Rather, rheumatoid arthritis is the preferred disease in the earlier application as filed, as is evident from its prominent place in the description (see e.g. page 1, "*TECHNICAL FIELD The disclosure relates to novel methods for treating rheumatoid arthritis, which employ a therapeutically effective amount of an IL-17 binding molecule...*"; page 2, "*SUMMARY OF THE DISCLOSURE Secukinumab, a new biological in clinical development for RA*") and most of the examples (see Examples 1 to 4). Ankylosing spondylitis, in contrast, is mentioned for the first time only on page 9 in a list of further diseases and is only covered by one example (Example 5). The same holds true for the dosage regimen in claim 1. Table 5 does not indicate any preference for the dosage regimen in the last row. The respondent has also not referred to any other passage in the earlier application as filed which would indicate a preference for this regimen, which is also not used in any example.

14. As pointed out by the appellant, the only example which relates to the treatment of AS (Example 5) discloses a different dosage, which includes 10 mg/kg (resulting in 750 mg for an average patient of 75 kg) intravenous administration given three weeks apart and does therefore not point to the claimed regimen.

15. With regard to the dosage of 150 mg in claim 1 (feature (iii)), the respondent argued that the passage bridging pages 67 and 68 provided an "*implicit preference*" for 150 mg because it represented the only dose suitable

for all body weights. The board does not agree because the claim does not indicate that the dosage should be suitable for all body weights, so no "implicit" preference can be recognised. Also, in no other passage of the earlier application as filed is a dosage of 150 mg indicated as preferred. It is also not preferentially used in the examples.

16. The earlier application as filed therefore does not contain a pointer to the chosen combination of features. The claimed subject-matter thus represents a single individualised combination in the absence of a preference for this combination or, at least, a preference for one of the combined features having been disclosed in the earlier application as filed. The claimed subject-matter thus extends beyond 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 earlier application as filed.

17. The ground for opposition in Article 100(c) EPC prejudices the maintenance of the European patent.

Auxiliary requests 1 to 3
Extension of subject-matter (Article 76(1) EPC)

18. The same reasoning as for the main request applies to the auxiliary requests because each of their sole claims contains the same combination of features as claim 1 of the main request.

19. The subject-matter of claim 1 of auxiliary requests 1 to 3 extends beyond the subject-matter of the earlier application as filed.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

The Registrar: The Chairwoman:

I. Aperribay M. Pregetter

Decision electronically authenticated