Internal distribution code:

(A) [-] Publication in OJ
(B) [-] To Chairmen and Members
(C) [-] To Chairmen
(D) [X] No distribution

Datasheet for the decision of 2 January 2023

Case Number: T 1624/21 - 3.3.08

Application Number: 17159000.3

Publication Number: 3192807

IPC: C07K16/18, A61K39/395, A61P19/02, G01N33/53, C07K16/00, G01N33/543

Language of the proceedings: EN

Title of invention:
14-3-3 eta antibodies and uses thereof for the diagnosis and treatment of arthritis

Applicant:
The University of British Columbia

Headword:
14-3-3 eta antibodies/UNIVERSITY OF BRITISH COLUMBIA

Relevant legal provisions:
EPC Art. 54, 111(1)

Keyword:
Novelty - burden of proof, standard of proof
Remittal to the department of first instance (yes)

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

Boards of Appeal

Chambres de recours

Boards of Appeal of the
European Patent Office
Richard-Reitzner-Allee 8
85540 Haar
GERMANY
Tel. +49 (0)89 2399-0
Fax +49 (0)89 2399-4465

Case Number: T 1624/21 - 3.3.08

D E C I S I O N
of Technical Board of Appeal 3.3.08
of 2 January 2023

Appellant: (Applicant)	THE UNIVERSITY OF BRITISH COLUMBIA University-Industry Liaison Office 103-6190 Agronomy Road Vancouver, British Columbia V6T 1Z3 (CA)
Representative:	van Kooij, Adriaan Arnold & Siedsma Bezuidenhoutseweg 57 2594 AC The Hague (NL)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 21 May 2021 refusing European patent application No. 17159000.3 pursuant to Article 97(2) EPC**

Composition of the Board:

Chair	B. Claes
Members:	A. Schmitt
	R. Romandini

Summary of Facts and Submissions

I. The applicant's appeal lies from the decision of the examining division to refuse European patent application No. 17 159 000.3, which is a divisional application from European patent application No. 08 855 660.0. This earlier application was filed on 26 November 2008 as an international patent application and published as WO 2009/067811. The title of the application is "*14-3-3 eta antibodies and uses thereof for the diagnosis and treatment of arthritis*".

II. The examining division considered a main request and three auxiliary requests. It decided, *inter alia*, that the subject-matter of claim 1 of auxiliary request 1 was not novel (Article 54 EPC).

Claim 1 of auxiliary request 1 reads as follows:

"1. An anti-14-3-3 eta antibody, wherein said antibody is capable of specifically binding to an epitope located between positions 142 to 158 of the human 14-3-3 eta protein, the epitope is represented by the amino acid sequence KKNSVVEASEAAYKEAF (SEQ ID NO:24)."

III. With the statement of grounds of appeal, the appellant submitted sets of claims of a new main request and auxiliary requests 1 and 2 together with five documents. Claim 1 of the new main request was identical to claim 1 of auxiliary request 1 considered by the examining division (see section II.).

IV. The board summoned the appellant to oral proceedings as requested. Subsequently, the board issued a communication pursuant to Article 15(1) RPBA, in which

it provided, *inter alia*, its preliminary opinion that the examining division, in its assessment of novelty of the subject-matter of claim 1 of auxiliary request 1 underlying the decision (now the main request), had neither applied the correct standard of proof nor correctly identified the party bearing the burden of proof. The board therefore envisaged that the decision under appeal would be set aside and that the case would be remitted to the examining division for further prosecution.

V. In response to the board's communication, the appellant withdrew its request for oral proceedings and reformulated its requests.

VI. The board cancelled the oral proceedings.

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

D6 Y. S. Kim et al., "Role of 14-3-3 as a Positive Regulator of the Glucocorticoid Receptor Transcriptional Activation", Endocrinology 146(7), 2005, 3133-3140

D7 R&D Systems, "Affinity-Purified Goat Anti-human/ mouse/rat 14-3-3 eta Antibody", Catalog Number AF4420, September 2007

VIII. The appellant's arguments relevant to the decision are summarised as follows:

Main request

Novelty (Article 54 EPC) - claim 1

By requiring "absolute certainty" that the claimed antibody was not anticipated by the antibodies disclosed in documents D6 and D7, the examining division had applied the wrong standard of proof. It was established case law of the boards of appeal that decisions on issues arising before EPO departments did not need to be based on absolute conviction, but were to be arrived at on the basis of the overall balance of probabilities.

Document D6 did not characterise the disclosed 14-3-3 eta antibody, but merely stated that a "*monoclonal anti-14-3-3 antibody purchased from Santa Cruz Biotechnology, Inc. (Santa Cruz, CA)*" was used (see the first paragraph of the "Materials and Methods" section on page 3134). This did not constitute evidence that the 14-3-3 eta antibody used in document D6 was antibody sc-293464 (6A12) from Santa Cruz Biotechnology as alleged by the examining division. In fact, the latter antibody was not known to the skilled person.

Document D7 taught a polyclonal goat IgG antibody raised against a full-length (Met1-Asn246) *E. coli*-derived recombinant human 14-3-3 eta antigen, which had been affinity-purified against this same antigen. The examining division had not shown by evidence or argument that this polyclonal antibody bound the same epitope as the claimed antibodies.

The claimed subject-matter of the main request was therefore novel over the antibodies disclosed in documents D6 and D7.

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

Reasons for the Decision

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

Main request

Novelty (Article 54 EPC) - claim 1

2. In the decision under appeal, the examining division considered that the claimed antibody was not novel over those disclosed in documents D6 and D7. In its view, the appellant's arguments in support of novelty of the claimed subject-matter did "*not help the instant authority to ascertain with the absolute certainty required for novelty criteria assessment under Article 52(1) and 54 EPC whether the anti-14-3-3 eta isoform protein antibodies disclosed in the prior art documents at hand, i.e. D6 and D7 are binding the epitope contained in the claim*". Since the antibody of the claim was only defined by a linear epitope to which it bound, the examining division considered that "*the applicants did not discharged* [sic] *themselves from the burden to provide the necessary evidences* [sic] *that mAb 6A12 and the antibody disclosed in D7 do not bind to the claimed epitope or at least to part of it, ...*".

3. The board does not agree with the examining division's conclusion and reasoning for the following reasons:

4. It is a question of fact whether or not an antibody which is disclosed in a cited document binds to a particular antigen or epitope. According to established case law of the boards of appeal, the applicable standard of proof to assess whether a specific statement of fact is true or not is the balance of probabilities. According to this standard, the EPO shall base its decision on facts that are more likely to be true than not true (see also the decisions summarised in Case Law of the Boards of Appeal of the European Patent Office, 10th edition, 2022 ["Case Law"], III.G.4.3 and III.G.4.3.1). This standard of proof also applies to facts relevant to the assessment of novelty. Absolute certainty, as stipulated by the examining division, is not required.

5. For the case in hand, this means that the examining division should have assessed whether it was more likely or not that the 14-3-3 antibody disclosed in document D6 and the 14-3-3 eta antibody disclosed in document D7 bind to an epitope located between amino acids 142 to 158 of the human 14-3-3 eta protein. The examining division did not conduct such an assessment in the decision under appeal. Thus, for this reason alone, the decision under appeal must be set aside.

Remittal (Article 111(1) EPC)

6. Pursuant to Article 111(1) EPC, the board may either exercise any power within the competence of the department which was responsible for the decision appealed or remit the case to that department for further prosecution.

7. It is the primary function of appeal proceedings to give a judicial decision on the correctness of the decision under appeal (see Case Law, section V.A.1.1, second paragraph, the decisions referred to therein and Article 12(2) RPBA 2020).

8. The examining division decided that the subject-matter of claim 1 of the main request submitted with the statement of grounds of appeal was not novel. The board has now reviewed this decision and held that it had not been based on the correct assessment of facts (see points 2. to 5. above).

9. Consequently, not remitting the case to the examining division would require the board to carry out an examination of the application rather than review the contested decision in a judicial manner (see point 7. above). In view of these considerations, special reasons within the meaning of Article 11 RPBA present themselves for remitting the case to the department whose decision was appealed.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the examining division for further prosecution.

The Registrar: The Chair:

L. Malécot-Grob B. Claes

Decision electronically authenticated