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Datasheet for the decision of 28 November 2019

Case Number: T 2063/14 - 3.3.01

Application Number: 10188289.2

Publication Number: 2293076

IPC: G01N33/68, G01N33/74

Language of the proceedings: EN

Title of invention:
Use of procalcitonin (PCT) in risk stratification and prognosis of patients with a primary, non-infectious disease

Patent Proprietor:
B.R.A.H.M.S GmbH

Opponent:
Söylemez, Mehmet Ali

Headword:
Procalcitonin in diabetes/BRAHMS

Relevant legal provisions:
EPC Art. 108, 114(2), 54(2), 113(1)
EPC R. 99
RPBA Art. 12(4)

Keyword:
Admissibility of appeal - notice of appeal - request defining subject of appeal
Late-filed evidence - admitted (no)
Novelty - (yes)
Right to be heard - opportunity to comment (yes)

Decisions cited:
G 0009/91

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

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Case Number: T 2063/14 - 3.3.01

D E C I S I O N
of Technical Board of Appeal 3.3.01
of 28 November 2019

Appellant: (Opponent)	Söylemez, Mehmet Ali Neyzenbasi Halil Can Sk. Sadibey apt. No:48/8 Salacak-Üsküdar 34668 Istanbul (TR)
Respondent: (Patent Proprietor)	B.R.A.H.M.S GmbH Neuendorfstrasse 25 16761 Hennigsdorf (DE)
Representative:	Hertin und Partner Rechts- und Patentanwälte PartG mbB Kurfürstendamm 54/55 10707 Berlin (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 26 August 2014 rejecting the opposition filed against European patent No. 2293076 pursuant to Article 101(2) EPC**

Composition of the Board:

Chairman	A. Lindner
Members:	T. Sommerfeld
	L. Bühler

Summary of Facts and Submissions

I. European patent 2293076 is based on application 10188289.2, which was filed as a divisional application of European patent application 08786791.7. The patent was granted with 7 claims, of which claim 1 read as follows:

"1. Use of an ultrasensitive procalcitonin assay having a lower limit of detection of below about 0.05 ng/mL for determining in a patient having a primary disease not being an infection the risk of the patient to contract a further disease or medical condition which has not yet been manifested and/or is not yet symptomatic wherein the level of procalcitonin or fragments thereof of at least 12 amino acids in length is determined in a sample selected from the group comprising a blood sample, a serum sample and a plasma sample or an extract of any aforementioned sample obtained from said patient and wherein said level of procalcitonin or fragments thereof is correlated to a risk of the patient to contract a further disease or medical condition which has not yet been manifested and/or is not yet symptomatic, wherein said correlating step of the *in vitro* method comprises comparing said level of procalcitonin or fragments thereof to a threshold level, whereby, when said level of procalcitonin or fragments thereof exceeds said threshold level, said patient is predisposed to said risk and wherein said threshold level is between 0.02 and 0.25 ng/ml."

II. Opposition was filed against the granted patent, the opponent invoking lack of novelty (Article 100(a) EPC) against granted claim 1.

III. The documents cited during the proceedings before the opposition division and the board of appeal include the following:

D1 Söylemez et al. 2005, Mol. Ther., 11, p. S346

D2 Söylemez et al. 2006, Mol. Ther., 13, p. S86

IV. In a decision taken without oral proceedings, the opposition division rejected the opposition under Article 101(2) EPC.

V. The opponent (appellant) lodged an appeal against that decision. With the notice and statement of grounds of appeal, the appellant submitted new documentary evidence, designated "My thesis documents".

VI. In its letter of reply, the patent proprietor (respondent) requested that the appeal be rejected as inadmissible, or, in the case that the appeal be deemed admissible, that the late-filed documents, submitted with the notice of appeal, not be admitted into the proceedings and that the appeal be dismissed for not being allowable.

VII. The board issued a communication pursuant to Rule 100(2) EPC, providing its preliminary opinion regarding admissibility of the appeal, admission of late-filed documents, and novelty and concluding that the board was inclined to dismiss the appeal. It also drew the appellant's attention to the fact that, in the absence of a request by the appellant for oral proceedings, the board could issue a decision without summoning to oral proceedings.

VIII. The appellant did not submit any reply to the communication of the board, while the respondent, by letter dated 10 June 2019, repeated its request that the appeal be dismissed.

IX. The appellant's submissions, in so far as they are relevant to the present decision, may be summarised as follows:

The use of procalcitonin in risk stratification and the prognosis of patients with diabetes mellitus as well as the use of the lower and upper limit threshold levels were prior art, taught by D1 and D2, which were part of the appellant's "physiology thesis". The features that the opposition division found to be missing from the disclosures of D1 and D2, such as the threshold levels, were in fact part of said "thesis". As to the argument that D1 pertained to the use of procalcitonin as a diagnostic marker for a type II diabetic patient but not for determining the risk of a patient with diabetes contracting a further disease or medical condition which had not yet manifested itself and/ or was not yet symptomatic, it was known that the developmental stages of diabetes mellitus also included non-symptomatic and non-manifested stages. A further argument of the opposition division that D2's disclosure of procalcitonin as a marker for diabetic foot did not fall within the ambit of the claim, which required that the condition had not yet manifested itself or was not yet symptomatic, was also not valid, because it should be understood that diabetic foot was a pre-complication stage of diabetes mellitus.

X. The respondent's arguments, in so far as they are relevant to the present decision, may be summarised as follows:

The appeal should be rejected as inadmissible because the notice of appeal did not fulfil the formal requirements of Rule 99(1)(c) EPC, in particular it did not contain a request defining the subject of the appeal. Moreover, the appellant did not present its complete case since it relied on documents that were either not provided or were inaccessible.

The new documents filed with the grounds of appeal should not be admitted as they were late-filed, incomplete and not translated into an official language.

As to novelty, the disclosure of D1 merely confirmed that procalcitonin could be used as a diagnostic marker for diabetes type II but not as a marker for determining the risk that a patient with diabetes may contract a further disease or medical condition which was not yet symptomatic or had not yet manifested itself. D2 on the other hand disclosed that procalcitonin was a marker for diabetic foot, but did not disclose the use of procalcitonin to predict the risk of developing diabetic foot or any other disease that was not yet symptomatic or had not yet manifested itself.

XI. Although not explicitly formulated by the appellant, the board interprets the appellant's submissions in the statement of grounds of appeal as comprising a request that the decision under appeal be set aside and the patent be revoked.

The respondent requested that the appeal be dismissed.

Reasons for the Decision

1. Admissibility of the appeal

1.1 According to Rule 101(1) EPC, if the appeal does not comply with Articles 106 to 108, Rule 97 or Rule 99, paragraph 1(b) or (c) or paragraph 2 EPC, the board shall reject it as inadmissible, unless any deficiency has been remedied before the relevant period under Article 108 has expired.

According to Rule 99(1)(c) EPC, the notice of appeal shall contain a request defining the subject of the appeal. Rule 99(2) EPC states that in the statement of grounds of appeal the appellant shall indicate the reasons for setting aside the decision impugned, or the extent to which it is to be amended, and the facts and evidence on which the appeal is based.

1.2 As argued by the respondent, the notice of appeal does not contain an explicit request defining the subject of the appeal, as is required by Rule 99(1)(c) EPC. Instead, the appellant merely stated that the notice of appeal is filed against certain passages and embodiments of patent application no. 10188289.2.

1.3 While in principle such a statement would not be sufficient to define the subject of the appeal, the board notes that the present opposition was only directed against the same passages and embodiments of the patent, and that the appealed decision (which has been clearly identified on page 1 of the notice of appeal, as required by Rule 99(1)(b) EPC, only dealt with the same issues. Hence, even if not explicitly stated, the subject of the appeal is considered to be

implicit in the notice of appeal since the appeal was directed against a clearly identified adverse decision and could be understood as aiming to reverse the opposition division's findings. Furthermore, the notice of appeal is at the same time the statement of grounds of appeal and it is immediately apparent from the grounds of appeal what the subject of the appeal is.

1.4 Accordingly, the board comes to the conclusion that the present appeal complies with the requirements of Article 108 EPC and Rule 99 EPC and is therefore admissible.

2. Admission of late-filed documents

2.1 According to the established case law of the boards of appeal, the function of appeal proceedings is to give a judicial decision on the correctness of a separate earlier decision taken by a department of first instance. It derives directly from its review character and judicial nature that an appeal proceedings can in principle only be based on the reasons already submitted before the department of first instance. Moreover, in the particular case of *inter partes* proceedings, the power of an opposition division or a board of appeal to examine and decide on the maintenance of a European patent under Article 101 EPC depends upon the extent to which the patent is opposed in the notice of opposition pursuant to Rule 76(c) EPC (G 9/91, OJ 1993, 408), and the appeal proceedings are thus largely determined by the factual and legal scope of the preceding opposition proceedings. It is thus at the board's discretion, pursuant to Article 114(2) EPC and Article 12(4) RPBA, to admit or disregard new facts and arguments filed with the statement of grounds of appeal.

2.2 With the notice and statement of grounds of appeal, the appellant has submitted new documentary evidence, designated "My thesis documents" and consisting of a "Thesis title document", a "Thesis Summary" and the "thesis original pages 9, 10, 33, 34, 35 and 43". While arguing against the conclusions of the opposition division, the opponent stated that prior art documents D1 and D2 "are only a part of my physiology thesis" (page 4, section 5, of the grounds of appeal) and relied on the newly filed evidence (in particular on the thesis excerpt) to conclude that the claimed features that the opposition division considered to be distinguishing from the prior art D1 and D2 are in fact disclosed in the thesis.

2.3 The board notes that the new documents have not been filed in an attempt to prove that the opposition division's conclusions were wrong as regards novelty over D1 and D2. Rather the now filed "thesis" has been submitted as the novelty-destroying document. This not only goes against the nature of appeal proceedings, which is to review the decision of the department of first instance rather than to continue examination by other means, but it also raises a fresh case, tantamount to a new opposition. The board also notes that the newly filed evidence is incomplete (consisting only of a number of pages of the allegedly novelty-destroying "thesis") and is mostly in an non-EPO-official language with only some passages translated into English (in a non-official translation provided by the appellant).

2.4 The board thus makes use of its discretionary power under Article 114(2) EPC and Article 12(4) RPBA not to admit the newly filed documents into the proceedings.

3. Novelty (Article 54(2) EPC)

3.1 In the appealed decision, the opposition division concluded that documents D1 and D2 were not novelty destroying for the subject-matter of granted claim 1 because there were at least two distinguishing features, namely: neither D1 nor D2 disclosed the correlating step of comparing the measured level of procalcitonin with a threshold level between 0.002 and 0.25 ng/ml; and neither D1 nor D2 disclosed its use for determining the risk of a patient with diabetes contracting a further disease or medical condition which has not yet manifested itself and/or is not yet symptomatic.

3.2 The appellant has not argued that D1 or D2 disclose the above-mentioned distinguishing features of claim 1 and the board cannot identify said features in D1 or D2 either. Rather, the appellant attempted to support the argument for lack of novelty by referring to further documents (such as the newly filed document, the "thesis"). There is however no teaching or direct reference in D1 or D2 that incorporates or renders implicit the disclosure of said further document. Hence, based on the evidence on file, the board concludes that granted claim 1 is novel over documents D1 and D2.

4. Right to be heard (Article 113(1) EPC)

4.1 The present decision is based on facts and evidence put forward during the written proceedings and which both parties have had an opportunity to comment on.

4.2 In the absence of a request by the appellant for oral proceedings, the board could issue the present decision without summoning to oral proceedings.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

M. Schalow A. Lindner

Decision electronically authenticated