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Datasheet for the decision of 7 April 2021

Case Number: T 1297/18 - 3.3.01

Application Number: 11706838.7

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IPC: G01N33/569, G01N33/74

Language of the proceedings: EN

Title of invention:
PROCALCITONIN FOR THE DIAGNOSIS OF BACTERIAL INFECTIONS AND GUIDANCE OF ANTIBIOTIC TREATMENT IN PATIENTS WITH NON-SPECIFIC COMPLAINTS

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

Opponent:
Radiometer Medical ApS

Headword:
Patients with non-specific complaints/BRAHMS

Relevant legal provisions:
EPC Art. 84
RPBA Art. 12(4)

Keyword:

Admittance - main request, auxiliary request 1 (no)
Clarity - auxiliary requests 2-7 (no)

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Case Number: T 1297/18 - 3.3.01

D E C I S I O N
of Technical Board of Appeal 3.3.01
of 7 April 2021

Appellant: (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)
Respondent: (Opponent)	Radiometer Medical ApS Akandevej 21 2700 Bronshoj (DK)
Representative:	Huenges, Martin Maiwald Patentanwalts- und Rechtsanwaltsgesellschaft mbH Elisenhof Elisenstraße 3 80335 München (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 18 January 2018 revoking European patent No. 2545379 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman	A. Lindner
Members:	J. Molina de Alba
	R. Romandini

Summary of Facts and Submissions

I. The appeal by the patent proprietor (appellant) lies from the decision of the opposition division revoking European patent No. 2 545 379.

The patent had been granted with nine claims. Independent claim 1 as granted reads as follows:

"*1. A method for diagnosing a bacterial infection in a patient who presented to the emergency department with non-specific complaints (NSC), comprising the steps of:*

(i) determining the level of Procalcitonin (PCT) or a fragment thereof of at least 12 amino acids in length in a sample from a patient who presented with non-specific complaints; and

(ii) determining whether said patient has a bacterial infection or not by comparing said determined PCT level with a predetermined threshold level,

wherein the predetermined threshold level is between 0.02 ng/ml and 0.25 ng/ml and wherein the patient does not exhibit one of the following complaints: pain (chest, abdominal, head, leg, joint, back), dyspnea, cough, weakness (localized), stroke-like symptoms, swollen extremity (leg, arm), diarrhea, dysuria, GCS<14, confusion, intoxication, seizure, bleeding, syncope, anxiety, psychotic symptoms, suicidal ideation, skin lesion, allergic skin reaction, fever, vertigo, palpitations, nausea with vomiting, trauma."

II. The patent had been opposed under Article 100(a) for lack of novelty and inventive step, 100(b) and 100(c) EPC.

The appealed decision was based on the claims of the main request and the auxiliary request filed with the appellant's letter dated 6 November 2017. All previous claim requests had been withdrawn (see minutes of oral proceedings before the opposition division, page 1, lines 2-8).

In the appealed decision, the opposition division considered that claim 1 of the main request neither added subject-matter beyond the content of the application as filed nor extended the protection conferred by the patent as granted (Article 123(2) and (3) EPC). However, the claim contained several terms that rendered it unclear (Article 84 EPC). As those terms were also present in claim 1 of the auxiliary request, the latter was unclear too.

III. With the statement of grounds of appeal, the appellant filed the claims of a main request and auxiliary requests 1-7. The claims of the main request are identical to those of auxiliary request II filed with the letter dated 13 September 2017 and withdrawn at the oral proceedings before the opposition division. The claims of auxiliary requests 2 and 3 are identical to those of the main request and the auxiliary request on which the decision is based, respectively.

Claim 1 of the **main request** differs from claim 1 as granted in that the following clause has been added at the end of the claim:

"*and wherein said patient has a bacterial infection when said determined PCT level is higher than the predetermined threshold level*."

Claim 1 of **auxiliary request 1** differs from claim 1 of the main request in that the upper limit of the predetermined threshold level is 0.1 ng/mL.

Claim 1 of **auxiliary request 2** reads as follows (the underlined passages indicate the amendments with regard to claim 1 as granted):

"*1. A method for diagnosing a bacterial infection in a patient who presented to the emergency department with non-specific complaints (NSC), comprising the steps of:*

(i) determining the level of Procalcitonin (PCT) or a fragment thereof of at least 12 amino acids in length in a sample from a patient who presented with non-specific complaints; and

(ii) determining whether said patient has a bacterial infection or not by comparing said determined PCT level with a predetermined threshold level,

wherein the predetermined threshold level is between 0.02 ng/ml and 0.25 ng/ml and wherein the patient is included as a patient with non-specific complaints (NSC), who does not exhibit one of the following chief complaints: pain (chest, abdominal, head, leg, joint, back), dyspnea, cough, weakness (localized), stroke-like symptoms, swollen extremity (leg, arm), diarrhea, dysuria, GCS<14, confusion, intoxication, seizure, bleeding, syncope, anxiety, psychotic symptoms, suicidal ideation, skin lesion, allergic skin reaction,

fever, vertigo, palpitations, nausea with vomiting, trauma,
who has no chief complaint after initial assessment leading to a standardized work-up or treatment,
who has no vital signs out of range and for whom after initial assessment, it cannot be provided a working diagnosis with sufficient certainty,
and wherein said patient has a bacterial infection when said determined PCT level is higher than the predetermined threshold level."

Claim 1 of **auxiliary request 3** differs from claim 1 of auxiliary request 2 in that the upper limit of the predetermined threshold level is 0.1 ng/mL.

Claim 1 of **auxiliary request 4** reads as follows (the marked passages indicate the amendments with regard to claim 1 as granted: insertions have been underlined and deletions struck through):

"*1. A method for diagnosing a bacterial infection in a patient who presented to the emergency department with non-specific complaints (NSC), comprising the steps of:*

(i) determining the level of Procalcitonin (PCT) or a fragment thereof of at least 12 amino acids in length in a sample from a patient who presented with non-specific complaints; and

(ii) determining whether said patient has a bacterial infection or not by comparing said determined PCT level with a predetermined threshold level,

wherein the predetermined threshold level is between 0.02 ng/ml and 0.25 ng/ml, ~~and~~ wherein the patient

- *who has no chief complaint ~~does not exhibit one of the following complaints,~~ selected from: pain (chest, abdominal, head, leg, joint, back), dyspnea, cough, weakness (localized), stroke-like symptoms, swollen extremity (leg, arm), diarrhea, dysuria, GCS<14, confusion, intoxication, seizure, bleeding, syncope, anxiety, psychotic symptoms, suicidal ideation, skin lesion, allergic skin reaction, fever, vertigo, palpitations, nausea with vomiting, trauma, after initial assessment including history, physical examination and ECG reading, thus not leading to a standardized work-up or treatment,*
- *who has no vital signs, including body temperature, pulse and heart rate, that are out of range, and*
- *for whom, after initial assessment, a working diagnosis cannot be provided,*

is included as a patient with non-specific complaints (NSC), and
wherein said patient has a bacterial infection when said determined PCT level is higher than the predetermined threshold level."

Claim 1 of **auxiliary request 5** differs from claim 1 of auxiliary request 4 in that the upper limit of the predetermined threshold level is 0.1 ng/mL.

Claim 1 of **auxiliary request 6** differs from claim 1 of auxiliary request 4 in that it further specifies that the patient is presenting with an ESI (emergency severity index) of 2-3.

Claim 1 of **auxiliary request 7** differs from claim 1 of auxiliary request 6 in that the upper limit of the predetermined threshold level is 0.1 ng/mL.

IV. In its reply to the statement of grounds of appeal, the opponent (respondent) requested that the appeal be dismissed and that the main request and auxiliary requests 1 and 4-7 not be admitted into the appeal proceedings.

V. The board scheduled oral proceedings in line with the parties' requests. In a communication annexed to the summons to oral proceedings, the board gave its preliminary opinion.

VI. The parties reacted to the board's preliminary opinion with letters dated 17 December 2020 (respondent) and 4 February 2021 (appellant).

VII. Oral proceedings before the board took place on 7 April 2021 by videoconference with the agreement of the parties.

VIII. The appellant's arguments, where relevant to the present decision, can be summarised as follows:

The main request had to be admitted into the appeal proceedings because it was a direct attempt to overcome the lack-of-clarity objections which had led to revocation of the patent. This was apparent from the fact that all the terms held unclear by the opposition division had been deleted. Moreover, the request had been filed with the statement of grounds of appeal, which had been the first possible occasion to do so. Indeed, the lack-of-clarity objections had been raised for the first time at the oral proceedings before the opposition division. The fact that the main request had the same claims as auxiliary request II, which had been filed and withdrawn during the opposition proceedings, should not preclude the admission of the main request.

Auxiliary request II had been withdrawn for procedural economy and before any lack-of-clarity objections had been raised: it had not been withdrawn to avoid a decision on it. The respondent's submission on clarity in its letter of 16 October 2017 (page 7), i.e. before withdrawal of auxiliary request II, was merely a comment on a potential issue: it was very brief and unsubstantiated and did not qualify as an objection.

Auxiliary request 1 should be admitted into the appeal proceedings for the same reasons as for the main request. Its amendment with regard to the main request might be relevant to the issues of novelty and inventive step.

The method in claim 1 of auxiliary request 2 was clear. It was directed to a group of patients for which a diagnosis could not be established and, therefore, doctors did not know how to proceed with them. The method was well-defined and objective with respect to the level of procalcitonin as an indicator of bacterial infection and with respect to the application of the method to patients who presented to the emergency department with NSC. The requirement that "a working diagnosis cannot be provided" was clear: the concept of "working diagnosis" was well-known and generally used in the field of medical emergencies. The decision of whether a patient had NSC was left to the physician, who decided on the basis of their assessment of the patient's symptoms and complaints. Although this decision involved a certain degree of subjectivity, it did not render the claimed method unclear: every diagnostic method inherently involved some subjectivity, but this was not in conflict with Article 84 EPC.

For the same reasons, the method of claim 1 of auxiliary request 3 was clear too.

The method in claim 1 of each of auxiliary requests 4-7 had been further characterised and overcame the outstanding lack-of-clarity objections.

IX. The respondent's arguments, where relevant to the present decision, can be summarised as follows:

The main request was inadmissible pursuant to Article 12(4) RPBA because it had been filed and withdrawn as auxiliary request II in the opposition proceedings. By withdrawing auxiliary request II, the appellant had avoided a decision on the request with regard to Article 123(2) EPC. Admitting the main request would bring the appeal proceedings back to the issue of Article 123(2) EPC and would go against the principle of procedural economy. Moreover, in its letter dated 16 October 2017 (page 7), i.e. before auxiliary request II had been withdrawn, the respondent had explicitly raised a lack-of-clarity objection against the requests underlying the decision. The appellant nevertheless had withdrawn auxiliary request II. Furthermore, at the end of the oral proceedings the opposition division had offered the appellant the opportunity to file an additional request to overcome the outstanding lack-of-clarity objections, but the appellant had decided not to use it.

For the same reasons, auxiliary request 1 should not be admitted either. It was based on the main request and the only amendment it contained did not address any of the issues raised in the appealed decision. The amendment was irrelevant to the case, and the request

could and should have been filed in opposition proceedings.

The subject-matter of claim 1 of auxiliary request 2 was unclear. The use of procalcitonin for the diagnosis of bacterial infection was known. Allegedly, the claimed method differed from the prior art in the specific patient group which was diagnosed. Hence it was paramount to define the patient group clearly. However, the definition of the patient group in claim 1 included subjective elements which did not allow the skilled person to distinguish whether a patient presenting to an emergency department did indeed have NSC. One of the conditions in claim 1 for a patient to be classified as having NSC was that a working diagnosis could not be provided with sufficient certainty. This requirement depended not only on standards that might change from one country to another and even from one hospital to another, but also on the physician's experience, skills and ability to establish a diagnostic. Thus, depending on the specific physician at the emergency department, a patient could be classified as having NSC or not, i.e. as being in accordance with claim 1 or not. This rendered the subject-matter of claim 1 unclear.

For the same reasons, the methods claimed in each of auxiliary requests 3-7 lacked clarity.

X. The parties' final requests, as far as relevant to the present decision, were as follows:

The appellant requested:

- that the appealed decision be set aside and the case be remitted to the opposition division for

further prosecution on the basis of the main request or any of auxiliary requests 1-7, all filed with the statement of grounds of appeal;

- alternatively, that the patent be maintained in amended form on the basis of the main request or any of auxiliary requests 1-7, all filed with the statement of grounds of appeal; and
- that the main request and auxiliary request 1, both filed with the statement of grounds of appeal, be admitted into the appeal proceedings.

The respondent requested:

- that the appeal be dismissed;
- that the main request and auxiliary requests 1 and 4-7, all filed with the statement of grounds of appeal, not be admitted into the appeal proceedings; and
- that the case not be remitted to the opposition division for further prosecution.

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

Reasons for the Decision

1. The appeal is admissible. It meets the requirements of Articles 106 to 108 and Rule 99(2) EPC.

2. *Admittance of the main request (Article 12(4) RPBA 2007)*

2.1 The claims of the main request are identical to those of auxiliary request II filed during the opposition proceedings with the letter dated 13 September 2017. This letter introduced three new claim sets, namely auxiliary requests I, II and III, and was filed in response to the opposition division's preliminary opinion sent in preparation for oral proceedings.

By a letter dated 16 October 2017 (see page 7, paragraphs 4-6) the respondent raised a lack-of-clarity objection against the claims of auxiliary requests I and III, based on the terms "initial assessment", "sufficient certainty" and "standardized work-up". Auxiliary request II did not contain any of these terms.

Subsequently, with a letter dated 6 November 2017, the appellant filed a new main request and a new auxiliary request, and stated (see point 1): "*for the sake of concise and conclusive proceedings we currently do not pursue all of our previous positions and file a new set of requests (new main request and new auxiliary request)*". These new main and auxiliary requests are those on which the appealed decision is based. Both

contain the terms "initial assessment", "sufficient certainty" and "standardized work-up".

At the beginning of the oral proceedings before the opposition division (see minutes of oral proceedings, page 1, line 6) the appellant confirmed that it had withdrawn all requests filed on 13 September 2017, i.e. auxiliary requests I to III. Thus, even though the respondent had objected to the clarity of the terms "initial assessment", "sufficient certainty" and "standardized work-up", the appellant decided to continue the proceedings with two claim requests containing those terms and to drop auxiliary request II, which did not contain any of them.

During the oral proceedings (see minutes of oral proceedings, page 1, headings "MR; Art 84 EPC" and "Further requests"), the opposition division considered that the two requests on file lacked clarity and asked the appellant whether it had a further request. After a break for consultation with its client, the appellant's representative stated that it had no further requests. As a consequence, the opposition division revoked the patent for lack of clarity of, *inter alia*, the terms "initial assessment", "sufficient certainty" and "standardized work-up" (see decision, points 15.2 and 17).

It is apparent from the sequence of events described above that the appellant could and should have maintained, or at least re-filed, auxiliary request II in opposition proceedings. Even if the appellant had underestimated the clarity issues raised by the respondent in the letter of 16 October 2017 and had withdrawn auxiliary request II, it had still had the opportunity to re-file the request when the opposition

division considered that the requests on file lacked clarity and gave the appellant the chance to file a further request. The appellant nevertheless decided not to use this opportunity. Therefore, the main request (auxiliary request II in opposition proceedings) is inadmissible pursuant to Article 12(4) RPBA 2007.

3. *Admittance of auxiliary request 1*
(Article 12(4) RPBA 2007)

Claim 1 of auxiliary request 1 is claim 1 of the main request amended to set the upper limit of the predetermined threshold level at 0.1 ng/mL. This amendment does not address the issue of lack of clarity which led to revocation of the patent. Therefore, the amendment is not a direct response to the appealed decision. The board agrees with the respondent that the reasons for not admitting the main request apply equally to auxiliary request 1, i.e. the request could and should have been filed in the opposition proceedings. Hence, auxiliary request 1 is also inadmissible (Article 12(4) RPBA 2007).

4. Clarity of claim 1 of auxiliary request 2
(Article 84 EPC)

Claim 1 is directed to the diagnosis of a bacterial infection using procalcitonin or a fragment thereof as a marker. This technique was already known in the art, as acknowledged in the patent (see paragraph [0003]). It was common ground that the gist of the invention resides in the specific patient group to which the known diagnostic method is applied, namely the patients presenting to an emergency department with NSC. The matter of dispute between the parties was the clarity of the definition of this patient group in claim 1.

The patent (see page 5, lines 49-54) recognised the difficulty of defining such a patient group in positive terms. Ultimately, as submitted by the appellant, patients with NSC are those for whom a working diagnosis cannot be established (see patent, page 6, line 7-8), and therefore the physician at the emergency department does not know how to proceed further with them. This is reflected in claim 1 by the requirement that, after initial assessment, a working diagnosis cannot be provided with sufficient certainty.

In this respect, the patent states in paragraph [0026] that (emphasis added by the board):

"T*he classification of "non-specific" complaints implies the* ***subjective judgement*** *of the ED physician. Such* ***judgement depends on physician-related factors such as clinical experience and skills,*** *and on weighting the different complaints which may guide further assessment.*"

Thus whether a working diagnosis can be provided depends on the clinical experience and skills of the physician who receives the patient at the emergency department. A patient could be classified as having NSC by less-experienced or less-skilled physicians who are unable to establish a diagnosis, while more-experienced or skilled physicians might be able to provide a working diagnosis. Under such circumstances, it is apparent that the skilled person cannot distinguish whether or not a patient falls within the group defined in claim 1. Indeed, this depends on the specific physician who is on duty at the time the patient arrives at the emergency department. Therefore, the

method of claim 1 lacks clarity and the claim does not meet the requirements of Article 84 EPC.

5. *Clarity of claim 1 of auxiliary request 3 (Article 84 EPC)*

Like claim 1 of auxiliary request 2, claim 1 of auxiliary request 3 contains the requirement that, after initial assessment, a working diagnosis cannot be provided with sufficient certainty. Hence, for the reasons given in relation to claim 1 of auxiliary request 2, claim 1 of auxiliary request 3 does not meet the requirements of Article 84 EPC either.

6. *Admittance of auxiliary requests 4-7 (Article 12(4) RPBA 2007)*

In the board's view, by filing auxiliary requests 4-7 the patentee was reacting to the decision under appeal, and did so at the first possible occasion in the appeal proceedings. Taking into account the assessment of clarity in relation to these requests (see point 7), the board does not need to substantiate further its decision to admit the requests into the appeal proceedings under Article 12(4) RPBA 2007.

7. *Clarity of claim 1 of each of auxiliary requests 4-7 (Article 84 EPC)*

Claim 1 of each of auxiliary requests 4-7 still contains the feature that, after initial assessment, a working diagnosis cannot be provided. Thus, for the reasons given in relation to claim 1 of auxiliary request 2, claim 1 of each of auxiliary requests 4-7 does not meet the requirements of Article 84 EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

M. Schalow A. Lindner

Decision electronically authenticated