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Case Number: T 1920/21 - 3.3.08

Application Number: 15190192.3

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Title of invention:
A breath test for the diagnosis of Helicobacter pylori infection

Applicant:
Infai GmbH

Headword:
Breath test/INFAI

Relevant legal provisions:
EPC Art. 53(c)

Keyword:
Exceptions to patentability - diagnostic method (no)

Decisions cited:
G 0001/04, T 0125/02, T 1197/02, T 0143/04, T 1016/10

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Case Number: T 1920/21 - 3.3.08

D E C I S I O N
of Technical Board of Appeal 3.3.08
of 16 January 2024

Appellant: (Applicant)	Infai GmbH Gottfried-Hagen-Str. 60-62 51105 Köln (DE)
Representative:	dompatent von Kreisler Selting Werner - Partnerschaft von Patent- und Rechtsanwälten mbB Deichmannhaus am Dom Bahnhofsvorplatz 1 50667 Köln (DE)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 10 June 2021 refusing European patent application No. 15190192.3 pursuant to Article 97(2) EPC**

Composition of the Board:

Chairwoman	T. Sommerfeld
Members:	R. Morawetz
	D. Rogers

Summary of Facts and Submissions

I. The appeal filed by the applicant (appellant) is against the examining division's decision refusing European patent application No. 15 190 192.3, which has been published as EP 3 009 838 A1 ("the application"). The application is entitled "*A breath test for the diagnosis of Helicobacter pylori infection*".

II. By a communication under Rule 71(3) EPC the appellant had been informed that the examining division intended to grant a European patent on the basis of the set of claims filed on 14 August 2018, wherein claims 1 and 3 had been reworded by the examining division to avoid an objection under Article 53(c) EPC.

III. In reply, the appellant submitted that rewording of claim 1 of the set of claims filed on 14 August 2018 was unnecessary since the claimed method was not excluded from patentability under Article 53(c) EPC.

IV. The examining division maintained that the method of claim 1 of the set of claims filed on 14 August 2018 was a diagnostic method within the meaning of Article 53(c) EPC and summoned the appellant to oral proceedings to be held on 10 May 2021.

V. In response, the appellant submitted with a letter dated 9 April 2021 a set of claims of an auxiliary request I in which the wording of claim 1 had been amended. During oral proceedings, the appellant submitted the set of claims as annexed to the communication under Rule 71(3) EPC as auxiliary request II.

VI. The decision under appeal is based on the set of claims of a main request filed on 14 August 2018, auxiliary request I filed on 9 April 2021 and auxiliary request II filed during oral proceedings on 10 May 2021. The examining division held that claim 1 of all claim requests defined a diagnostic method practised on the human body in the sense of Article 53(c) EPC and was therefore excluded from patentability.

VII. With the statement of grounds of appeal (SGA), the appellant maintained the main request and auxiliary requests I and II underlying the decision under appeal.

VIII. The board scheduled oral proceedings and issued a communication under Article 15(1) RPBA informing the appellant of its preliminary opinion with respect to the allowability of the appeal. The board furthermore invited the appellant to clarify its procedural requests.

IX. In reply, the appellant stated its procedural requests (see section XII. below).

X. The oral proceedings were cancelled.

XI. Claim 1 of the main request reads:

"1. A method for diagnosing a Helicobacter pylori infection in a patient treated with proton-pump-inhibitors (PPIs) comprising the steps of administering to the patient a mixture of citric acid, malic acid, tartaric acid in amount of 5 to 7 g, collecting a first breath sample, administering to the patient ^{13}C-labeled urea, wherein the amount of ^{13}C-labelled urea corresponds to 10 to 100 mg 99% ^{13}C-urea waiting for a time of 10 to 60 minutes, thereafter collecting a

second breath sample from the patient, measuring the content of ^{13}C in the CO_2 of the first and second sample and determination of a $^{13}C/^{12}C$ ratio by spectroscopy in the respective samples characterized in that
a difference $\Delta\delta$ of the $^{13}C/^{12}C$ ratio of the first breath sample and $^{13}C/^{12}C$ ratio of the second breath sample is calculated and
the value of the difference in the range of 2 per mille to 2.9 per mille is used as a cut-off to indicate the presence of a H. pylori infection in the patient, wherein the method requires only a 1 day stop of PPI intake."

XII. The appellant requested that the decision under appeal be set aside and that a patent be granted upon the basis of the set of claims of the main request filed on 14 August 2018, or alternatively, of auxiliary request I filed on 9 April 2021 or of auxiliary request II filed during oral proceedings on 10 May 2021, or further alternatively, that the case be remitted to the examining division for further prosecution. Oral proceedings were requested in the event that the board contemplated a decision that did not meet any one of these requests.

Reasons for the Decision

Main request

Exceptions to patentability (Article 53(c) EPC)

1. The sole reason given by the examining division for refusing the main request was that claim 1 defined a diagnostic method practised on the human body within the meaning of Article 53(c) EPC and therefore excluded

from patentability.

2. Under Article 53(c) EPC diagnostic methods practised on the human or animal body are excluded from patentability. In opinion G 1/04 (OJ EPO 2006, 334) the Enlarged Board of Appeal interpreted the scope of the exclusion from patentability under Article 52(4) EPC 1973 in respect of diagnostic methods practised on the human or animal body. It noted that this interpretation would remain valid under the EPC 2000, i.e. Article 53(c) EPC (which corresponds to Article 52(4) EPC 1973).

3. The Enlarged Board of Appeal stated in G 1/04 (Conclusion 1) that to be excluded from patentability the claim is to include the features relating to:

(i) the diagnosis for curative purposes *stricto sensu* representing the deductive medical or veterinary decision phase as a purely intellectual exercise,

(ii) the preceding steps which are constitutive for making that diagnosis, and

(iii) the specific interactions with the human or animal body which occur when carrying those out among these preceding steps which are of a technical nature.

4. In addition, the method steps of a technical nature belonging to the preceding steps which are constitutive for making the diagnosis for curative purposes *stricto sensu* must satisfy the criterion "practised on the human or animal body" (G 1/04, Conclusion 3).

5. A preceding step of a technical nature satisfies the criterion "practised on the human or animal body" if

its performance implies any interaction with the human or animal body, necessitating the presence of the latter (G 1/04, Conclusion 4).

6. The preceding method steps which are constitutive for making the diagnosis for curative purposes include:

(i) the examination phase involving the collection of data,
(ii) the comparison of these data with standard values,
(iii) the finding of any significant deviation, i.e. a symptom, during the comparison (G 1/04, Reasons 5, 6.2, 6.4.1).

Diagnostic method

7. Claim 1 at issue relates to a method for diagnosing a *Helicobacter pylori* (*H. pylori*) infection in a patient treated with proton-pump-inhibitors.

8. To determine whether claim 1 is directed to a diagnostic method within the meaning of Article 53(c) EPC and thus excluded from patentability, it must first be established whether all of the necessary method steps (see point 3. above) are included in the claim.

9. The examining division held that this was the case.

10. The appellant's argument to the contrary which is based on the assertion that "collecting a breath sample does not qualify as phase (i)" is not found persuasive.

11. The board agrees with the examining division that phase (i) consists not only of "collecting a breath sample" but comprises the following steps in claim 1:

-administering to the patient a mixture of citric acid, malic acid, tartaric acid in amount of 5 to 7 g,
-collecting a first breath sample,
-administering to the patient ^{13}C-labeled urea, wherein the amount of ^{13}C-labelled urea corresponds to 10 to 100 mg 99% ^{13}C-urea,
-waiting for a time of 10 to 60 minutes, thereafter collecting a second breath sample from the patient,
-measuring the content of ^{13}C in the CO_2 of the first and second sample and determination of a $^{13}C/^{12}C$ ratio by spectroscopy in the respective samples.

12. Contrary to the appellant's understanding, the "data" of phase (i) which are compared with standard values in step (ii) of the method are not the breath samples as such.

13. The board furthermore agrees with the examining division that the method of claim 1 also includes features relating to phases (ii) to (iv). This was not disputed by the appellant.

14. The method of claim 1 therefore satisfies the first requirement for a method to constitute a diagnostic method.

The criterion "practised on the human or animal body"

15. A diagnostic method is only excluded from patentability if all the method steps of a technical nature belonging to the preceding steps which are constitutive for making the diagnosis for curative purposes *stricto sensu* satisfy the criterion "practised on the human or animal body" (G 1/04, Conclusion 3, Reasons 6.4.2 and

6.4.4; 4. and 5. above).

16. As regards these preceding method steps, the Enlarged Board held that activities falling within steps (ii) and (iii) are predominantly of a non-technical nature, and in any event, are not normally practised on the human body (G 1/04, Reasons 6.4.1). Therefore, in most cases only the first phase which relates to the examination phase and the collection of data can be of a technical nature and, therefore, concerned with the criterion "practised on the human or animal body".

17. The examining division held that all method steps of a technical nature belonging to phase (i) met the criterion "practised on the human or animal body". It considered that "for the measurement of the ^{13}C isotopes in the sample, the step of the physical detection of the isotopes cannot be isolated from the step of collecting the sample from the patient. This is even more interrelated in the present examination phase, since the patient is first administered with an acid mixture, then a first breath sample taken, then the patient is administered with ^{13}C-labeled urea, and a second breath sample is taken from that very same patient, i.e. the measurements of the two samples are tied to the steps involving the presence of the patient" (decision under appeal, Reasons 1.3).

18. The appellant submitted that the method of claim 1 is not a diagnostic method practised on the human body because the steps of collecting a breath sample were not invasive and because measuring the content of ^{13}C in the CO_2 of the first and second sample was isolated from taking the breath samples.

19. To satisfy the criterion "practised on the human or animal body" it is however not required that a preceding step of a technical nature be invasive. It suffices that its performance implies any interaction with the human or animal body, necessitating the presence of the latter (G 1/04, Conclusion 4). Collecting a breath sample necessarily requires the presence of the patient from which the breath sample is collected. The two technical steps of claim 1 relating to the collection of breath samples (see point 11. above) therefore satisfy the criterion "practised on the human or animal body".

20. For the following reasons, the board is however satisfied that the further method step of a technical nature of phase (i), i.e. "measuring the content of ^{13}C in the CO_2 of the first and second sample and determination of a $^{13}C/^{12}C$ ratio by spectroscopy in the respective samples" does not meet the criterion "practised on the human or animal body".

21. Pursuant to the wording of claim 1, two breath samples are collected from the patient and then the content of ^{13}C in the CO_2 of the samples is determined. The board cannot derive from the wording of claim 1 any requirement that the measurement of these two samples also requires the presence of the patient. The board therefore disagrees with the examining division's interpretation of claim 1 (see point 17. above).

22. In the board's opinion, the skilled person familiar with ^{13}C-urea breath tests is furthermore aware from their common general knowledge of the devices used for "measuring the content of ^{13}C in the CO_2 of the first and second sample and determination of a $^{13}C/^{12}C$ ratio by spectroscopy in the respective samples" in breath

samples. These include devices for gas isotope ratio mass spectroscopy or infrared spectrometer (see also paragraph [0013] of the application) and are in any case devices which analyse the collected breath samples without any interaction with the patient or necessitating its presence.

23. The present case can therefore be distinguished from the case underlying T 125/02 relating to a method for ascertaining the lung function of a human subject in which the presence of the human subject and its connection to the device measuring the endogenous nitrogen monoxide was necessary as the measuring occurred "during one or more exhalation phases" (Reasons 2.2). The present case can also be distinguished from the diagnostic methods considered in T 1197/02 (Reasons 2.3), T 143/04 (Reasons 3.2) and T 1016/10 (Reasons 2.7.1) in which all steps of a technical nature of phase (i) necessitated the presence of the human body and implied an interaction therewith.

24. As regards the examining division's further consideration that "the outcome of the analysis whether an exemption under Article 53(c) EPC is present cannot be dependent on whether in the examination phase of the diagnostic method, the practitioner uses a diagnostic tool which measures a sample directly on (or in) a patient, or whether he uses a diagnostic tool which takes a sample from that patient which is subsequently analyzed in a detector remote from the patient" (decision under appeal, Reasons 1.4), the board agrees with the appellant that G 1/04 does distinguish these two situations.

25. Indeed, the Enlarged Board held in G 1/04 that since a narrow interpretation of the scope of the exclusion

from patentability under Article 52(4) EPC 1973 in respect of diagnostic methods was equitable, it was justified to require that the performance of each and every one of the method steps of a technical nature of a diagnostic method should satisfy the criterion "practised on the human or animal body" (Reasons 6.4.4).

26. Conversely, the Enlarged Board held that a claim is not excluded from patentability under Article 52(4) EPC 1973 if at least one of the preceding steps which are constitutive for making a diagnosis for curative purposes comprises a method step of a technical nature which does not satisfy the criterion "practised on the human or animal body", e.g. a method step carried out by a device without implying any interaction with the human or animal body or a method step carried out *in vitro* in a laboratory (G 1/04, Reasons 6.4.3 and 6.4.4).

27. The board concludes from the above considerations that not all steps of a technical nature belonging to phase (i) in claim 1 of the main request satisfy the criterion "practised on the human or animal body". The method of claim 1 therefore does not satisfy the second requirement for a method to constitute a diagnostic method within the meaning of Article 53(c) EPC (see point 15. above). Accordingly the board concurs with the appellant that the subject-matter of claim 1 of the main request is not excluded from patentability under Article 53(c) EPC.

28. The appeal is thus allowable.

Remittal (Article 111 EPC)

29. 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.

30. It is the primary object of appeal proceedings to review the decision under appeal in a judicial manner (see Article 12(2) RPBA).

31. As explained in point 1. above, the sole reason for refusing the present application was that the subject-matter of claim 1 of the main request was excluded from patentability pursuant to Article 53(c) EPC, a decision which the board reviewed (see points 2. to 27. above).

32. With respect to the appellant's argument that the examining division had already issued a communication under Rule 71(3) EPC (see also section II. above), the board notes that a communication under Rule 71(3) EPC informing the applicant of the examining division's intention to grant a patent is not binding on the examining division. Indeed, Rule 71a(2) EPC makes it clear that, until the decision to grant the European patent is issued, the examining division may resume the examination proceedings at any time.

33. The board's conclusion in point 27. applies to the main request. Accordingly, auxiliary requests I and II are of no relevance. As the examining division has not taken an appealable decision on any other requirement for patentability, the board does not accede to the appellant's request to order that a patent be granted. However, the present circumstances represent special

reasons as stipulated in Article 11 RPBA that warrant remittal of the case.

34. In view of the above considerations, the board decides to remit the case to the examining division for further prosecution.

35. The decision is thus in line with one of the appellant's requests and could be taken without holding oral proceedings.

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 Chairwoman:

L. Malécot-Grob T. Sommerfeld

Decision electronically authenticated