

Internal distribution code:

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

**Datasheet for the decision
of 9 July 2025**

Case Number: R 0015/24

Appeal Number: T 1159/22 - 3.2.02

Application Number: 16786952.8

Publication Number: 3288448

IPC: A61B5/024, A61B5/021,
A61B5/0456, A61B5/046,
A61B5/0464, A61B5/0468,
A61B5/0472, A61N1/40, A61N5/02

Language of the proceedings: EN

Title of invention:

HEMODYNAMIC PARAMETER (HDP) MONITORING SYSTEM FOR DIAGNOSIS OF
A HEALTH CONDITION OF A PATIENT

Applicant:

TheraBionic Inc.

Headword:

Petition for review

Relevant legal provisions:

EPC Art. 112a(2)(c), 112a(2)(d)
EPC R. 104(b)

Keyword:

Petition for review - no decision on a relevant request (no) -
fundamental violation of Article 113 EPC (no) - clearly
unallowable

Decisions cited:

R 0019/10



Große Beschwerdekammer
Enlarged Board of Appeal
Grande Chambre de recours

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

Case Number: R 0015/24

D E C I S I O N
of the Enlarged Board of Appeal
of 9 July 2025

Petitioner: TheraBionic Inc.
(Applicant) 4108 Ryan Way
Winston-Salem, NC 27106-3567 (US)

Representative: Schneiders & Behrendt München
Schneiders & Behrendt
PartmbB Patentanwälte München
Mühlthaler Straße 91c
81475 München (DE)

Decision under review: **Decision of the Technical Board of Appeal 3.2.02**
of the European Patent Office of 21 March 2024.

Composition of the Board:

Chairman I. Beckedorf
Members: T. Bokor
G. Pricolo

Summary of Facts and Submissions

- I. The applicant in case T 1159/22 has filed a petition for review under Article 112a EPC against the decision of Technical Board of Appeal 3.2.02 (hereinafter "Board") dated 21 March 2024, dismissing the appeal and thus confirming the refusal of European patent application No. 16786952.8. The decision of the Board reasoned the refusal on the ground that none of the main and first to third auxiliary requests met the requirements of Article 83 EPC. The petition is only directed at issues concerning the third auxiliary request.
- II. The petitioner contends that a fundamental violation of Article 113 EPC occurred in the appeal proceedings, furthermore the Board did not decide on a relevant request, so that the petition relies on both grounds under Article 112a(2)(c) and (d) EPC, the latter in conjunction with Rule 104(b) EPC.

Overview of the examination and appeal proceedings

- III. The invention is essentially about the use of a statistical method based on the so-called principle component analysis, shortly PCA, for diagnosing various forms for cancer, from analysis of measured heart functions. The Examining Division refused the application by deciding that the invention as claimed in the main request and in the first and second auxiliary requests was not disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art, contrary to the requirements of Article 83 EPC. The main and third auxiliary requests was refused for not meeting the

requirements of Article 123(2) EPC. The decision was silent whether the invention claimed in the third auxiliary request was sufficiently disclosed for the purposes of Article 83 EPC.

- IV. The applicant pursued the same requests on appeal. In the grounds of appeal they argued that the inventions claimed in the main request and the first and second auxiliary requests were sufficiently disclosed and that the third auxiliary request complied with the requirements of Article 123(2) EPC.
- V. The Board issued a communication pursuant to Article 15(1) RPBA containing a negative opinion on the question of sufficiency of disclosure under Article 83 EPC for all requests, and summoned the applicant to oral proceedings. The Board also opined that the third auxiliary request did not meet the requirements of Article 123(2) EPC.
- VI. In oral proceedings before the Board, the application was refused for not meeting the requirements of Article 83 EPC, for all requests. This was also reflected in the undisputed minutes. The Board also stated that the third auxiliary did not contain added subject-matter. The decision was issued in writing on 22 May 2024. It did not address the issue of added subject-matter, and only contained reasons on the requirements of Article 83 EPC, in respect of all decided requests.

Proceedings before the Enlarged Board of Appeal

- VII. The petitioner filed the reasoned petition and paid the prescribed fee was paid in due time.

- VIII. The petition is essentially based on two distinct factual grounds. The first ground is that the Board did not decide on the question of added subject-matter under Article 123(2) EPC for the third auxiliary request, an issue which the petitioner discussed in its grounds of appeal. Instead, the Board did not allow this request under Article 83 EPC. This was argued to be equivalent to not taking a decision on a relevant request within the meaning of Rule 104(b) EPC (petition chapter B.I).
- IX. The second ground is that the Board, when deciding on the sufficiency of disclosure for the third auxiliary request, in point 2.5 of the Reasons, presented surprising arguments by referring to Examples 2 and 3 as being the only support for carrying out the invention, without mentioning Example 1. Had the applicant known this argument of the Board, it could have pointed to Example 1 which also formed an embodiment of the invention falling under the third auxiliary request. This was argued to be a violation of the right to be heard (petition chapter B.II.).
- X. The Enlarged Board of Appeal (in its present composition hereinafter also referred to as the 'EBA') summoned the petitioner to oral proceedings and issued a communication pursuant to Articles 13 and 14(2) RPEBA. The communication set out that the petition appeared to be clearly unallowable for both petition grounds. With regard to the argued not treated issue of Article 123(2) EPC for the third auxiliary request, the EBA preliminarily considered that this was not an undecided request within the meaning of Rule 104(b) EPC, while the allegedly surprising and new reasoning was apparently not decisive for the Board's decision on the third auxiliary request so that no

fundamental violation of the petitioner's right to be heard was apparent. These observations of the EBA are discussed in more detail below.

XI. In their response to said communication, the petitioner argued that the petition was allowable and provided further arguments on the second petition ground. These were further expounded during the oral proceedings before the EBA, held on 9 July 2025. These new arguments of the petitioner are set out in more detail below. The arguments from the earlier written submissions were also maintained.

XII. The petitioner requested that

- the decision under review be set aside; and
- the proceedings before the Technical Board of Appeal be re-opened.

Reasons for the Decision

Admissibility of the petition (Rule 106 EPC)

1. The EBA is satisfied that the petition is not clearly inadmissible under Rules 106, 107(1), (2) and 109(2) (a) EPC.

Allowability of the petition

First petition ground, not decided relevant request

2. The first ground is clearly unfounded.

3. On the merits of the first petition ground the EBA stated the following (see points 6 and 7 of the preliminary opinion):

"6. The petitioner refers to Rule 104(b) EPC, i.e. a relevant but undecided request. The EBA cannot identify any undecided request falling under Rule 104(b) EPC. It is at least questionable whether the applicant's submissions addressing the distinct patentability requirements of the EPC which are implied by Articles 97(1) or 97(2) EPC indeed constitute a "request" for the purposes of this rule.

7. It is not overlooked that the appellant's case in respect of the third auxiliary request inevitably had to be directed at this issue, given that this had been the formal basis of the refusal of the third auxiliary request before the Examining Division. The not treated patentability condition, even if discussed and argued by the appellant applicant in support of a certain request (here the request to grant a patent on the basis of the third auxiliary request) is not a request (Antrag, requête) in the sense of Rule 104(b) EPC. Such requests seek to achieve a direct substantive or procedural legal effect, such as a claim request upon which a patent can be granted or maintained, or a request for the admittance of a document or the like (see also R 19/10, Reasons 5.1, cited in CLBA V.B. 4.4.2). Such requests normally require an express and separate decision of the Board, directly deciding on the request, typically refusing or allowing the sought substantive or procedural legal effect. The appellant's request for the Board's to re-examine the issue of added-subject matter for the third auxiliary request is not a request in this sense. The relevant request was rather the third auxiliary request, seeking to grant a patent on that basis as the legal effect. The third auxiliary request has been duly decided on."

4. In its submissions of 3 July 2025 and during the oral proceedings the petitioner did not provide any counter-arguments against this assessment, but referred to its written submissions.
5. Having reviewed these reasons, the EBA confirms them as set out in its communication, and concludes that the appellant's request for the Board's to re-examine the issue of added-subject matter for the third auxiliary request is not a request within the meaning of Rule 104(b) EPC. Thus no fundamental procedural defect within the meaning of Article 112a(2) (d) EPC can be identified in the appeal proceedings. Apart from this finding, merely for the sake of completeness, the EBA observes that the question of the compliance of the third auxiliary request with Article 123(2) EPC was also not relevant to the decision. Thus the Board did not have to address it, and there was no fundamental violation of Article 113 EPC either. This means that the objection would be unfounded even if it had been submitted as a petition ground under Article 112a(2) (c) EPC.
6. From this it follows that the first petition ground is clearly unfounded and as such clearly unallowable within the meaning of Rule 109(2) (a) EPC.

Second petition ground under Article 112a(2) (c) EPC, unexpected argument from the Board, violation of the right to be heard

7. The EBA holds that the petition is clearly unfounded also in respect of the second petition ground.
8. The petitioner's original argument in support of this petition ground, as put forward in the petition, was stated as follows:

"There was a violation of Article 113 EPC because the following argument ("**the Example 2 and 3 argument**") was presented for the first time in **the Decision**: ... as mentioned in point 2.2 above, the disclosure ... is limited to Examples 2 and 3, ... [verbatim citation of point 2.5 of the Reasons]). **The Example 2 and 3 argument** is the only argument **the Decision** is based on with regard to objecting **the third auxiliary request**. **[The petitioner]** never had been given the opportunity to comment on **the Example 2 and 3 argument**." (petition point B.II.3.a, maintaining the emphasis in bold added by the petitioner, emphasis by underlining added by the EBA).

The petitioner argued that Examples 1 and 2 had to be seen as input and output, together forming an embodiment example of implementing PCA. However, the Board's decision was wholly silent about Example 1 (petition point B.II.3.b).

It is the EBA's understanding that the core of the "Example 2 and 3 argument" is the Board's finding that **only** examples 2 and 3 (i.e. Tables 2 and 3) contain some limited information how the PCA method may be applied to analyse the measured heart parameters, and the remaining general information in the application is not sufficient for the skilled person to carry out the PCA method for the claimed purpose.

9. This argument of the petitioner was further supported by explanations why the "Example 2 and 3 argument" was causal to the outcome of the decision (see petition point B.II.3.b for more details).

10. On the merits of the second petition ground the EBA stated the following (see points 9 to 15 of the preliminary opinion):

"9. The petitioner does not argue, and it is not apparent from other circumstances, that the petitioner was unaware of the question of insufficiency under Article 83 EPC and its significance for the Board's decision on the third auxiliary request. Against this background, the EBA concludes that the petitioner had the opportunity to comment on those reasons of the Board that were also known to it, namely the question whether the application gives sufficient information to the skilled person to carry out the invention.

10. The EBA points to the settled case law, according to which the right to be heard does not go so far as to impose a legal obligation on a board to disclose in advance to the parties, how and why, on the basis of the decisive issues under discussion - or at least those foreseeable as the core of the discussion - it will come to its conclusion. This is part of the reasoning given in the written decision. Reference is made to CLBA 10th Edition 2022, Chapter V.B.4.3.5, and the decisions cited.

11. In the EBA's reading, the Board set out already in its communication in sufficient detail that it sees too little information in the description for carrying out the PCA method, because the skilled person would not know how to derive meaningful representative Hdp values, see point 1.1.2 of the communication under Article 15(1) RPBA dated 22.12.2023. In the same communication the Board also made it clear that this finding was applicable also without the "three group limitation", see last sentence of point 2.1 of the

communication. Accordingly, the appellant was well aware that the Board was looking for the proper teaching in the application and the appellant was free to point to all those parts of the application that it considered important, including the allegedly overlooked Example 1. The applicant does not argue and the EBA does not see that any of its core arguments that it actually presented were ignored or misunderstood by the Board. In the EBA's view, this alone is sufficient to establish that Article 113(1) EPC has been respected.

12. The petitioner appears to argue that the Board's only reasons on the third auxiliary request are in point 2.5 of the Reasons. There the Board seems to make a logical connection to the three-group limitation and the corresponding (still insufficient) disclosure for this element in the Examples 2 and 3. This assumption of the petitioner appears wrong in fact. Already in the Reasons 2.2 and 2.3 the Board gives sufficient reasons for the lacking teaching, for all requests and in particular, also for the third auxiliary request, see last paragraph of Reasons 2.3. The starting phrase of Reasons 2.4 make it clear that the lacking information for carrying out the three-group limitation is only an additional line of argument for the main and first to second auxiliary requests. Similar additional arguments are provided in point 2.5 for the third auxiliary request.

13. Accordingly, the Board's arguments in Reasons 2.5 are not decisive for the final outcome. Even if erroneous or possibly being surprising for the petitioner, they do not constitute a fundamental violation of Article 113 EPC (Article 112(2)(c) EPC) for lack of causality.

14. As to the substance of the Reasons 2.2. and 2.3, the petitioner does not argue that it has been surprised by those reasons or had not been heard on it. Indeed, these reasons appear to correspond to those that were indicated by the Board in its preliminary opinion, in the point 1.1.2 mentioned above.

Further remarks on the hypothetical argument of Example 1

15. In the present case, the EBA fails to understand the significance of the Example 1 for the petitioner's case, because it is not apparent what additional information the skilled person could have derived from the data of Example 1. This example simply seem to show that the nine claimed Hdp values actually do exist, but nothing more. This fact was not disputed in the impugned decision, not even implicitly. The EBA does not see how the suggested hypothetical arguments based on Example 1 may have been of help to counter the Board's finding of insufficiency of disclosure."

11. In the submissions of 3 July 2025 and also in the oral proceedings before the EBA, the petitioner emphasised that the Board's Example 2 and 3 argument was surprising, and the petitioner would have pointed to Example 1. The petitioner confirmed the observation of the EBA that Reasons 2.2 and 2.3 of the Board's decision contained the decisive points of the Board's reasoning also in respect of the third auxiliary request, and argued in detail why the Board's reasons presented there were surprising. They also argued that the relevant parts in the Board's communication under Article 15(1) RPBA also did not hint at the Board's "Example 2 and 3 argument".

12. In particular, the Board's disregarding of Example 1 meant that the petitioner could not properly counter the Board's argument in point 2.3 of the Reasons, namely that there would be a problem of scaling due to the different units of the input parameters (Hdp values) when applying the PCA method (Reasons 2.3, last sentence). The petitioner could have pointed to Example 1, which contained Hdp values without units, and could have countered the Board's objection.
13. That Example 1 showed no units was a central argument repeatedly emphasised by the petitioner in their submissions of 3 July 2025. They strongly emphasised that Example 1 directly contradicted the Board's argument about 'different scales and units' raised in Reasons 2.3 of the contested decision.
14. The EBA is not convinced by these arguments.
15. As a preliminary remark, the EBA observes that the petitioner does not seek to refute, nor seems to comment on point 14 of the EBA communication, where it was observed that the petition did not appear to contain any objections in respect of the Reasons 2.2 and 2.3. The petitioner's arguments against reasons 2.2 and 2.3 as submitted on 3 July 2025 constitute a new case. The argument that Example 1 could have countered the problems of scaling and different units (as set out in Reasons 2.3) is nowhere hinted at in the petition. The petition only addressed the Board's reasons given against the third auxiliary request in Reasons 2.5, but not those given for the main request. The petitioner's main objection was apparently the Board's reliance **only** on examples 2 and 3 to demonstrate the lack of disclosure, but this objection was stated only in

respect of the third auxiliary request. Thus the question may arise whether the new submissions of the petitioner can be considered under Article 12(1) RPEBA. For the benefit of the petitioner, the EBA accepts that the explanations on the potential teaching of Example 1 can be seen as the petitioner's reaction to the EBA's observations in point 15 of the preliminary opinion, cited in point 10. above.

16. However, the admittance of the new arguments under Article 12(1) RPEBA need not be decided. The new submissions of the petitioner demonstrate to the EBA with even greater force that the petitioner's right to be heard has not been violated. As set out below, the EBA considers that the Board gave the applicant ample guidance why the invention was seen as insufficiently disclosed. The petitioner had the opportunity to comment on the Board's decisive findings, and to put forward Example 1 if they considered that example as suitable for countering the Board's Article 83 EPC objections.

17. It was undisputed that Reasons 2.2 and 2.3 contained arguments that were applicable for all requests, including the third auxiliary request. These set out the Board's general argument that the description contained very little information how a PCA analysis were to be carried out. It is true that Examples 2 and 3 were mentioned already in reasons 2.2, but only to observe that these were the only two examples that mentioned PCA, but still did not explain how the PCA was implemented (apart from mentioning the three-group detail). The statement was not that the skilled person could only learn how to apply the PCA method from Examples 2 and 3, but rather that the skilled person could not learn how to do so from anywhere in the

description. The same applied a *fortiori* to Examples 2 and 3, where some further details may possibly have been mentioned. Clearly, for the Board, the lack of teaching about the 'three-group limitation' led only to the conclusion that these examples were also useless to the skilled person. ("... the lack of any information in the application concerning a particular implementation of PCA renders the division of the PC values into the three groups completely obscure", see Reasons 2.4, last sentence of the third paragraph).

18. In reasons 2.3 the Board explained that the skilled person could not carry out the PCA method without further guidance, for example because of the different scaling and different units. Reasons 2.4 merely pointed to an additional problem under Article 83 EPC: the three group limitation, which was also insufficiently disclosed, although seemingly indispensable, as being the only concrete example of a PCA method. However, it was clear from the overall reasons that the Board considered the disclosure to be insufficient with or without the three-group limitation. This was already explicitly stated in the Board's communication: "The objection in point 1.1.2 applies irrespective of whether the representative Hdp values obtained by PCA are subsequently divided into three groups", see last sentence of point 2.1.

19. The scaling and unit problem as a general problem of sufficiency for carrying out the PCA method was clearly and explicitly addressed in point 1.1.2 of the Board's communication: "Indeed, the application does not provide any technical details on the practical implementation of PCA, which the Board considers to be not straightforward, **in particular because** the data set to be analysed **comprises data with different units,**

thus different scales.” (EBA’s emphasis). It was also clear that this problem applied to all requests, as point 2.1 clearly addressed the first to third auxiliary requests and explicitly referred back to the objections for the main request, and in particular referred to point 1.1.2, see again last sentence of point 2.1.

20. If the petitioner believed that Example 1 could solve this problem, they were free to put it forward. In cases before a Board of Appeal where the Examining Division found the disclosure to be insufficient and the Board shares this view, the Board is not obliged to analyse every piece of information in the description to determine whether it might assist the skilled person. Instead, it is the applicant's responsibility to identify all relevant parts of the description.
21. In this case, the petitioner had been made aware of the scaling and unit problem that was affecting all requests. Nothing prevented them from responding to it. Given their assertion that Example 1 in particular would have been eminently suitable for addressing the Board's scaling and unit problem, it would have been all the more reasonable for them to draw the Board's attention to it – or even to all three Examples 1 to 3 – to prove that such a problem would not have been apparent to the skilled person.
22. Thus the EBA concludes that the petitioner did not succeed to refute the conclusions of the EBA as stated in points 9 to 11 of its communication. The EBA confirms these findings and concludes that the petitioner could comment on the reasons that led to the rejection of the third auxiliary request (and the other requests), including the Board’s alleged assumption

that Example 1 did not offer any useful information for implementing the PCA method. The EBA finds no valid petition ground under Article 112a(2) (c) EPC with regard to any of the arguments set out by the Board in Reasons 2.2 to 2.5.

23. In summary, also the second petition ground is clearly unfounded. Accordingly, the petition as a whole is clearly unallowable and is to be rejected as such under Rule 109(2) (a) EPC.

Order

For these reasons it is decided that:

The petition for review is unanimously rejected as being clearly unallowable.

The Registrar:

The Chairman:



N. Michaleczek

I. Beckedorf

Decision electronically authenticated