Datasheet for the decision of the Enlarged Board of Appeal of 10 June 2013

Case Number: R 0002/13
Appeal Number: T 1676/11 - 3.3.10
Application Number: 09159082.8
Publication Number: 2078532
IPC: A61L 24/10, A61L 24/04, B01F 13/00, B01F 15/02, B65D 25/08, A61K9/00, B01F 3/12, A61L 33/12
Language of the proceedings: EN
Title of invention: Medical device comprising a haemostatic agent and haemostatic kit comprising the medical device
Applicant: Ferrosan Medical Devices A/S
Headword: -

Relevant legal provisions:
EPC Art. 112a(2)(c), 113(1)
Keyword: "Clearly inadmissible (no)"
"Clearly unallowable (yes)"

Decisions cited:
G 0004/92; R 0018/09; R 0010/10; R 0019/10; R 0023/10; R 0006/11; R 0018/11; R 0021/11; R 0013/12; T 0682/89; T 0951/92; T 0778/98; T 0462/06; T 0343/08; T 1621/09

Catchword: -
Case Number: R 0002/13

DECISION
of the Enlarged Board of Appeal
of 10 June 2013

Appellant: Ferrosan Medical Devices A/S
(Applicant)
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Decision under review: Decision of the Technical Board of Appeal 3.3.10 of the European Patent Office of 26 June 2012.

Composition of the Board:

Chairman: W. van der Eijk
Members: M.-B. Tardo-Dino
G. Pricolo
Summary of Facts and Submissions

I. The petition for review concerns decision T 1676/11 of the Board of Appeal 3.3.10 of 26 June 2012 to dismiss the petitioner's appeal against the decision of the examining division to refuse European patent application No. 09 159 082.8. The decision was posted on 13 November 2012. The petitioner filed the petition on 23 January 2013 and paid the petition fee on the same date.

II. The petition is based, in accordance with Article 112a(2)(c) EPC, on the grounds that two fundamental violations of Article 113 EPC occurred.

III. The European patent application, which is a divisional of European patent application No. 02 790 278.2 concerns:
   - a medical device for preparing a haemostatic paste, consisting of a containment unit, a sterile haemostatic agent in powder form contained in the said containment unit and an outer packaging defining a sterile barrier (main and auxiliary requests 1-5),
   - a process for preparing a haemostatic paste including in its step A: removing the outer packaging of the claimed medical device (auxiliary requests 6 and 7).

IV. The previous proceedings, to the extent they are relevant for an understanding of the present petition proceedings, may be summarised as follows.
(a) The examining division refused the main and first to third auxiliary requests for lack of inventive step having regard to D3 and D5.

(b) As far as the subject-matter of the petition is concerned, the key point in the appeal proceedings was the inventive step of the medical device (auxiliary requests 2 to 5) and of the process (auxiliary request 6 and 7). D3 was selected as the closest prior art. This document disclosed two separate embodiments for making a haemostatic paste with different haemostatic agents: the Gelfoam jar (gelatine powder) (first embodiment) and the Avitene jar (micro-fibrillar collagen) (second embodiment). The petitioner contended that D3 would not have encouraged the skilled person to pursue the first embodiment due to problems teaching away from it, inter alia, the difficulty of removing the Gelfoam powder and the possibility of contamination. These difficulties had prompted the authors of D3 to change their material and process for making a paste and to switch to the second embodiment.

(c) The Board of Appeal did not accept this argumentation and stated (point 14 of the reasons of the decision) that the jar of the first embodiment described in D3 had the largest number of features in common with the claimed subject-matter, that D3 identified the same problem underlying the claimed invention, namely the possibility of contamination in connection with the first embodiment and thus was the most promising springboard. The Board did not accept
that the skilled person would have been dissuaded by D3 from modifying its teaching because the authors of D3 were not manufacturers and turned their attention to commercial material more suitable for their goals. By contrast the skilled person in the field of the claimed invention, namely the manufacturing of medical devices had a different approach and would be capable of modifying the device disclosed in D3. The Board concluded that the medical device of auxiliary request 2 was not inventive over D3 taken in combination with D1 and that the added features in auxiliary request 3 to 5 did not add any inventive step to the claimed subject-matter either. Claim 1 of the process for preparing a haemostatic paste using the medical device according to claim 1 of the second auxiliary request was also found not to be inventive because the process steps merely reflected the obvious steps for using the non-inventive device of the second auxiliary request.

V. The Enlarged Board sent a communication to the petitioner by letter of 18 April 2013 to inform him of its provisional view before the oral proceedings that the petition seemed to be, at least, clearly unallowable.

VI. The petitioner replied by letter dated 10 May 2013 expressing his disagreement with the analysis of the Enlarged Board and maintained his first contentions about the violation of his right to be heard.

VII. The oral proceedings took place on 10 June 2013 at the end of which the Enlarged Board announced its decision.
VIII. The petitioner's submissions as set out in the petition and subsequent letter and as expanded orally during the oral proceedings may be summarised as follows. He contends that his right to be heard was violated in two ways by the reasoning in the decision:

- the decision is based on an assessment or a reasoning relating to grounds or evidence he was not aware of and had had no opportunity to comment upon (point 14 of reasons for the decision)(i). In the petition there are two points to this first ground.

- the decision is not reasoned and the petitioner's arguments were not heard (point 27 of the reasons of the decision) (ii).

i) The petitioner argues with respect to the first fundamental violation that the Board did not consider his arguments that it was not only a question of exchanging one material for another.

Not only did the Board overlook this argumentation, it also introduced in its written decision a completely new line of reasoning on which the petitioner had no opportunity to comment. The Board of Appeal referred to a concept of the two different skilled persons the petitioner had never read before in the case law. In this case, the petitioner claims, the EPO changed its mind: The Board of Appeal did not have the same approach to the problem to be solved as the examining division. The latter applied a partial problems approach and refused the application for lack of inventive step on the basis of D3 as closest prior art,
combined with D5, or in a second line of reasoning over D5 as closest prior art. The Board, by contrast, based its decisive reasoning on the distinction between two different readers of D3: the authors of D3 and the person skilled in the art for the present application. The rebuttal of the "teaching away" argument which the Board recognised was only possible, the petitioner argued, because the Board relied on a specific notion of the skilled person as someone different from the authors of D3, but this particular argument, set out in point 14 of the decision, had not been submitted to the petitioner, and so came as a surprise, all the more so because, the petitioner said, he was not aware of any case law where a technical board had decided that a pointer in the closest prior art could be ignored because it was not directed to the skilled person relevant for inventive step.

The petitioner contended that the situation before the Board of Appeal in the present case was comparable to the situation in case T 778/98, where the Board of Appeal stated that the examining division had committed a violation of Article 113 EPC because it had not given the applicant the opportunity to comment on the crucial argument in its reasoning of obviousness before refusing the application. The standard of the right to be heard should be the same for the Boards of Appeal as for the department of first instance and the principles applied in the cited case law should apply analogously to ex parte appeal proceedings, in which the Board of Appeal has to perform the role of the opposing party in inter partes cases. Put in other words, when there was an amendment to a case, which in the present case had been caused by a new argument, the Board should abide by the Rules of Procedure of the Boards of Appeal and,
like a party, make the appellant aware of its reasons and arguments, particularly any new key argument in its chain of reasoning. This applies particularly in cases where this key argument could not be anticipated in the light of the case law of the Boards of Appeal.

ii) The decision was not reasoned with respect to the process claims. The petitioner maintained that he had presented three different process alternatives which showed that the process claimed was not obvious and the Board did not refute all of them, which proved that it had not checked them.

**Reasons for the Decision**

1. Admissibility of the petition for review

   1.1 The petition was filed and the corresponding fee paid within the time limit in compliance with Article 112a(4) EPC. The other formal requirements of Rule 107 were also met.

   1.2 As to Rule 106 EPC the subject-matter of the alleged fundamental violation of the right to be heard relates to the written reasoning for the decision, so that the Enlarged Board accepts that no objection could be raised during the appeal proceedings.
2. Allowability of the petition for review

2.1 The first fundamental violation of Article 113 EPC

The two aspects of this ground revolved, as became apparent during the oral proceedings before the Enlarged Board, around the alleged new line of argumentation introduced by the Board of Appeal in its decision. The petitioner's complaint in this respect is based on the premise that in ex parte cases the Board of Appeal is under an obligation to make the appellant aware of the Board's reasons and arguments (emphasis added by the Enlarged Board) and thereby perform the role usually incumbent upon the opposing party in inter partes cases.

For the reasons below the Enlarged Board does not agree with the petitioner.

2.1.1 First of all the Enlarged Board cannot find in the file any factual support for the assertion that the petitioner had always argued in line with the same understanding of the skilled person as the examining division and that, by distinguishing between the skilled person defined as the manufacturer of medical devices, and the authors of D3 who were surgeons, the Board, all of a sudden, brought an unpredictable change of the case. Even though the Board did not take the same approach as the department of first instance, as may happen in any appeal proceedings, nothing in the decision of the examining division or in the petitioner's submissions points to an implicit consensus about the skilled person being the authors of D3. On the contrary, the examining division's
combination of D3 and D5, which belongs to a different classification (containers), when considering the Group c) features of the claimed invention, which precisely address the problem of contamination, rather points to a broader notion of the skilled person than the surgeon (point 2.3 of the decision of the examining division).

As to the petitioner, he never made clear when mentioning the authors of D3 that they were to be considered the skilled person; he referred to the skilled person in general as well and did not specify that the authors of D3 were to be regarded as the skilled person with a view to disqualifying D5 as the closest prior art (page 6 (2.1.2.3) and 11 (2.3.2 (3)) of the statement of grounds).

2.1.2 Against this background of the undefined skilled person the Board of Appeal had to consider the assertion that, because D3 itself solved the problem of contamination raised by its first embodiment, it would preclude any further consideration of this first embodiment by the skilled person. To that end, the Board, in point 14 of the decision evaluated the teaching of D3 against its general background, namely its origin and its purpose, and, in order to assess inventive step, through the eyes of the relevant skilled person; this being the case the Enlarged Board does not accept the alleged contradiction with the established case law, regarding the pointer in the closest prior art (see supra VIII(i) facts and submissions).

In fact in the current case, where neither the examining division nor the petitioner had specifically identified the skilled person, the Board did so, this definition being the missing intellectual link required
to properly deal with the contention that D3 would deter the relevant skilled person from taking D3 into account. In this respect the petitioner acknowledged during the hearing before the Enlarged Board that it was not the definition of the skilled person (the manufacturer of medical devices in the field of manufacturing the medical devices) which was odd, but the teaching drawn by the Board from D3.

Thus, by defining the skilled person the Board merely dealt with the argumentation that D3 taught away from the first embodiment the petitioner had put forward without however giving any further explanation as to who the skilled person was and why he/she was taught away.

Under such circumstances, defining who was, and who was not the skilled person was merely an intellectual sequence in the articulation of the reasoning only based on an interpretation of D3 at variance with the petitioner's own interpretation, which was discussed at length, and on the notion of the skilled person inherent in the debate of inventive step. The petitioner who had not elaborated on this point, cannot now claim that it was unpredictable that the Board took the further step of identifying the skilled person when assessing inventive step.

It follows from the above that it is the petitioner's personal and subjective view that the Board put forward an unpredictable line of argumentation or entered "uncharted territory" or that, by merely defining the skilled person the Board suddenly deviated from the facts, grounds or evidence discussed as part of the
debate or that this definition was so creative that it would objectively amount to bringing in a new fact. To require that the Board should have made the petitioner aware of the particular steps in its reasoning goes too far, as has been reiterated many times in the case law (see, for examples R 18/09 of 27 September 2010, points 14, 15 and 18; R 10/10 of 17 December 2010, point 2.4).

2.1.3 Coming now to the alleged obligation of the Boards to make the parties aware of the "reasons and arguments" crucial for the decision, the Enlarged Board considers that in fact the present petitioner's complaints lie on a confusion in the terminology (between the meaning of "arguments" or "reasons", "grounds, facts and evidence"), and on a debatable conception of the role of the Boards of Appeals in ex parte cases proceedings, which is anyway of no assistance regarding the definition of the respect of the right to be heard (see infra).

Reasons and Arguments

(a) Even though the term "arguments" is not the appropriate terminology when talking about the reasons for decisions, and even though the principles set out in G 4/92 (OJ94, 149) as to the distinction between "arguments" "grounds" and "reasons" are rather concerned with the parties' obligations, these principles nevertheless apply mutatis mutandis in the present case. In point 10 of G 4/92, the Enlarged Board stated: "As regards new arguments, the requirements of Article 113(1) EPC have been satisfied even if a party who has
chosen not to appear consequently did not have the opportunity to comment on them during oral proceedings, insofar as such new arguments do not change the grounds on which the decision is based. In principle, new arguments do not constitute new grounds or evidence, but are reasons based on the facts and evidence which have already been put forward.

(i) Without endorsing the petitioner's stance upon the role of the Boards of Appeal (see infra), the Enlarged Board observes that an analogy can be made between the definition given in G 4/92 of the arguments brought forward by a party and reasoning in the decisions of the Boards of Appeal, which, like arguments, consist of logical steps such as analysis, comparison and deduction based on the legal grounds and factual evidence such as discussed.

(ii) In the case at hand the Board of Appeal dealt with the petitioner's submissions regarding the issue of the skilled person and dismissed his interpretation of D3 in a way which did not introduce any change in the factual and legal framework of the debate, in the same way as "arguments" can be put forward by a party in the absence of the other party, as stated in G 4/92.

(iii) Furthermore this analysis is in line with the analysis made in T 1621/09 cited by the petitioner, despite the fact that the Board
of Appeal there came to different findings due to the circumstances of that case: the introduction of a new "argument" by the party was in fact based on a different part of a document (slides six and thirteen referred to for the first time during the oral proceedings) and thus amounted to putting forward an "alternative case" in the absence of the other party.

Role of the Boards in Appeal proceedings

(b) As to the Boards of Appeals' role, the analogy the petitioner seeks to draw between a board in ex parte cases and the opposing party in adversarial inter partes cases has no legal basis or legitimacy if only because the boards are the deciding body and it is a well established principle that one cannot be judge and party.

(c) Anyway, this assertion and the parallel with the application of Article 13 RPBA in the event of an amendment of the case lead to a moot point because the Enlarged Board agrees with the petitioner on the principle that the parties have a right to comment upon the points which will be decisive for the decision. However, the view that this right also extends to all the sequences of reasoning (the "arguments" in the sense of G 4/92 see supra) is based on a misunderstanding of the terminology used (see 2.1.3 a) supra).
Analysis of the case law cited

2.1.4 The petitioner contends that, in the present case, the Board of Appeal deviated from the standard of the right to be heard as applied in the case law of the boards of appeal and cited in this respect several decisions.

(a) The Enlarged Board firstly notices that the cases cited by the petitioner underscore the fact that the departments of first instance are subject to specific obligations, under Article 94(3) and Rule 71(2) EPC for the examining division, and Article 101(1) and Rule 81(3) EPC for the opposition division, which result in the corresponding power of the boards to check whether these obligations were correctly performed.

(i) This is precisely what happened in T 951/92 cited by the petitioner: the Board found that the examining division had not acted in compliance with Articles 96 and 97, Rule 51(3) EPC 1973 (Article 94(3); Rule 71(2) EPC 2000), which require that any communication under Article 94(3) EPC shall contain a reasoned statement covering, where appropriate, all the grounds against the grant of the European patent. The legal basis was the same in T 778/98, which was alleged to be similar to the case at hand, even though the Board there did not expressly quote the relevant provisions of the EPC mentioned above.
(ii) Of course, the fact that in the appeal procedure there is not the same obligation to send preliminary communications which gives the right to be heard at first instance a specific procedural framework, does not mean that less weight is attached to the right to be heard on appeal. The fact is that the decisions the petitioner cited do not give a comprehensive account of the whole case law about how the right to be heard is commonly applied and do not reflect the overall picture.

(iii) It would, therefore, serve no purpose to thoroughly analyse all the decisions cited. It is sufficient to note that the boards of appeal, when checking whether the right to be heard has been infringed, do not restrict themselves to the application of the legal provisions mentioned above, but take an overview of the case. Decisions referring to Rule 116 EPC (former Rule 71a) take a less formal approach to the right to be heard than those cited by the petitioner: for instance in T 462/06 (not published in the EPO OJ) point 4.3 and 4.5 last paragraph, the Board made clear that there was a point in time where the applicant no longer had a right to feedback before the oral proceedings and that what was presented as new arguments was in fact the assessment by the examining division of an example discussed during the oral proceedings (similarly T 343/08 not published, point 4
and 5). In T 682/89 (not published) which concerned opposition appeal proceedings, the Board came to the conclusion that the requirement of Rule 116 EPC (former Rule 71a) does not mean that all lines of arguments or a detailed reasoning for the decision should already be set out in the communication. These decisions are in the same line as the decision under the present petition.

(b) The Enlarged Board will turn now to the differences in nature between an appeal procedure and a petition for review procedure.

The petition for review was established as a remedy for a fundamental violation of Article 113 EPC or fundamental procedural defects in decisions that had become res judicata, which is applicable only as defined in Article 112a and Rule 104 EPC (see, for instance R 18/11 of 22 November 2012, point 2), unlike the appeal procedure, which empowers the boards of appeal to review the merits of the decision under appeal.

Generally speaking, a simple flaw in the reasoning in a decision does not necessarily correspond to a violation of the right to be heard which can be challenged by a petition, while a board of appeal has full competence to review such a flaw. There are cases where the borderline between a purely substantive mistake in the reasoning and a violation of the right to be heard is difficult to define and the diversity of the factual
circumstances of all the various cases dooms any attempt at general delimitation to failure.

Having said that, the right to petition on the ground of a fundamental procedural violation under Article 112a (c) EPC does not cover cases where examining the alleged violation would amount to a review of the substantive merit of the reasoning: this is in fact what is left to the Enlarged Board in the present case now as it has confirmed that the reasoning was based only on facts which were part of the debate.

The cases where the petition for review was allowed

2.1.5 The petitioner also made an analogy with the circumstances in cases R 23/10 and R 21/11, these being cases where the petition was allowed.

2.1.6 This argument fails for the reasons given above and it is not necessary to repeat them here: The Board of Appeal did consider the petitioner's arguments and did not use in its decision anything other than the facts and evidence the petitioner had an opportunity to discuss.

2.2 The absence of reasons with respect to the process claim

The petitioner submitted that he had argued that there were other conceivable ways of preparing the haemostatic paste, the argument that D3 "taught away" also being valid with respect to the claimed process. Instead of taking account of all these arguments the
Board, in point 27 of the decision, stated that the process steps of claim 1 merely reflect the obvious steps for using the non-inventive device of the second auxiliary request.

The Enlarged Board, however, can only confirm that the Board of Appeal gave a reason why the process claim was not inventive over the prior art. That this reason is not sufficient is the petitioner's subjective opinion. Apart from the fact that the sufficiency of reasoning is not on the list of fundamental defects (Article 112a and Rule 104 EPC), it is established case law that, provided that the reasons given enable the parties concerned to understand whether the decision was justified (or not), the deciding body is under no obligation to address each and every argument presented by the party concerned (R 19/10 of 16 March 2011 points 6.2 and 6.3; R 13/12 of 14 November 2012 point 2.2; R 06/11 of 4 November 2011 points 11.3;11.4-). If the Board has found one line of reasoning that rendered the process obvious it no longer had to address all the other alternative lines of reasoning which might have supported inventive step.

3. The upshot of the above is that the petition for review has to be rejected as clearly unallowable.
Order

For these reasons it is unanimously decided that:

The petition for review is rejected as clearly unallowable.

The Registrar: The Chairman:

P. Martorana W. van der Eijk