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**Datasheet for the decision
of 8 November 2006**

Case Number: T 0624/04 - 3.4.02

Application Number: 94306553.2

Publication Number: 0643301

IPC: G01N 29/02

Language of the proceedings: EN

Title of invention:

Method and apparatus for ultrasonic detection of air bubbles

Patentee:

Gambro, Inc.

Opponent:

Fresenius Medical Care Deutschland GmbH

Headword:

-

Relevant legal provisions:

RPBA Art. 10a, 10b

EPC Art. 56, 108

Keyword:

"Admissibility of the appeal (yes)"

"Admission of documents that became available late (yes)"

"Inventive step - main request (yes)"

Decisions cited:

T 0220/83, T 0328/87, T 0065/96, T 1197/03, T 0295/04

Headnote:

1. The duty to attach copies of papers referred to in the statement of grounds of appeal, as imposed by the original version of Article 10a(2), third sentence, RPBA, does not constitute a requirement for the admissibility of an appeal.
2. From the entry into force of the amended version of that provision, i.e. from 1 January 2005, copies of such papers are deemed to have been filed.



Case Number: T 0624/04 - 3.4.02

D E C I S I O N
of the Technical Board of Appeal 3.4.02
of 8 November 2006

Appellant: Fresenius Medical Care Deutschland GmbH
(Opponent) Else-Kröner-Straße 1
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Respondent: Gambro, Inc.
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Representative: Roberts, Mark Peter
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Decision under appeal: Decision of the Opposition Division of the
European Patent Office posted 29 March 2004
rejecting the opposition filed against European
patent No. 0643301 pursuant to Article 102(2)
EPC.

Composition of the Board:

Chairman: A. Klein
Members: M. Rayner
B. Müller

Summary of Facts and Submissions

I. The opponent lodged an appeal against the decision of the opposition division rejecting the opposition against European patent 643 301 (application number 94 306 553.2), which relates to ultrasonic detection of air bubbles. The opponent's appeal against the impugned decision posted on 29 March 2004 was received by the Office on 8 May 2004, and the statement of grounds of appeal was filed on 5 August 2004.

II. In the opposition and appeal proceedings, reference has been made, amongst others, to the following documents,

- D1 US-A-4 015 464
- D2 US-A-4 447 150
- D3 Krautkrämer: "Werkstoffprüfung mit Ultraschall", 1986, pp. 238-239
- D4 EP-A-0 239 467.

III. The wording of independent claims 1 and 24 as granted is as follows.

" 1. An inclusion detector (22) for detecting the presence of inclusions in a flow of a liquid (36) while compensating for slowly varying characteristics of the detection environment comprising:

a transmitting transducer (40) for transmitting a signal through a liquid flowing in a conduit (34) at a transmitted signal level;

a means (70,74) for driving the transmitting transducer a receiving transducer (44) for receiving the signal transformed by passage through the conduit (34);

interpreting means (76,B0,8492,94) for interpreting the

received signal, a sudden change in the received signal level being indicative of the presence of an inclusion in the liquid flow; and a signal adjusting means (88) to account for the slowly varying characteristics of the detection environment while allowing the detection of said sudden changes; characterized by the signal adjusting means (88) adjusting the average level of the signal that is transmitted by said transmitting transducer in reaction to the slowly varying characteristics of the detection environment so as to maintain an average value of said signal received by said receiving transducer at a constant value.

24. A method for detecting the presence of inclusions in a liquid (38) flowing in a conduit (34) while compensating for slowly varying characteristics of the detection environment comprising: driving a transmitting transducer (40) to transmit a signal through the liquid at a transmitted signal level; receiving the signal at a received signal level by means of a receiving transducer (44) the received signal being transformed by passage through the liquid; interpreting the received signal to detect the presence or absence of an inclusion, a sudden change in the received signal level being indicative of the presence of an inclusion; and adjusting a signal to account for the slowly varying characteristics of the detection environment while allowing the detection of said sudden changes; characterized by adjusting the average level of the signal transmitted by said transmitting transducer (40) in reaction to the slowly varying characteristics of the detection environment to maintain the average value of the signal

received by laid receiving transducer (44) at a constant level."

No wording is given for claims of the auxiliary requests as this is not necessary for the present decision (see Section 2.14 of the Reasons below).

- IV. In the decision under appeal, it is recorded that the parties agreed that document D1 constituted the closest prior art, compared with which the opposition division saw the problem to be solved as provision of alternative evaluation circuitry for ultrasonic transmission measurements. Starting from document D1, the skilled person would have had to embark on a plurality of non-obvious steps to reach the subject matter of claim 1. The skilled person would have had to realise that varying signal to noise ratio is a problem in document D1. As document D1 uses ultrasonic waves in the rf-range to detect micro emboli in blood while eliminating other slowly varying characteristics of the blood stream, it would not be obvious to consult document D2, which uses electromagnetic waves in the optical range to detect slowly varying characteristics like blood oxygen saturation level. Finally, even if the skilled person were to have combined the teachings of documents D1 and D2, it remained obscure how the circuit could have been modified in view of technical incompatibilities of the systems. The division therefore reached the conclusion that the subject matter of claim 1 can be considered to involve an inventive step.

V. Oral proceedings were requested on an auxiliary basis by both parties, which led to appointment thereof by the Board. In the annex to the summons to oral proceedings, the Board observed that lack of novelty had not been a ground for opposition. The Board also stated that it seemed likely that it would consider the appeal admissible.

VI. The case of the appellant can be summarised as follows.

The appellant requested that the decision under appeal be set aside and the patent revoked.

Admissibility of the Appeal

With respect to admissibility of the appeal, the appellant submitted that all the formal requirements had been met in a timely manner. Moreover the appeal was sufficiently substantiated. Attaching documents already present in the file and to which reference had been made in the proceedings before the first instance is just a formality. No sensible objection can be made to non-observance of this formality, the more so as these documents are in the file, were correctly referenced and must be known to the patent proprietor. Therefore, the conditions of admissibility of the appeal were complied with, it not being a condition of admissibility that copies of documents D1 to D4 be furnished in the appeal proceedings. In any case, would it have been necessary to do so, the Office would have had to issue a pertinent invitation.

Substantive Patentability

It is not disputed by the patent proprietor that the features of the pre-characterising part of the claim are known from document D1. The opposition division considered that the level of the signal transmitted by the transmitting transducer in the oscillating loop is constant even when the received signal is affected by slowly varying characteristics of the detection environment. This aspect gives rise to a new view on novelty. In particular, the oscillatory system according to document D1 is a feedback system, which means that the signal level on the input side of the transducer cannot be differentiated from that on the output side. Thus, if adjustment of the received signal makes it tend to be constant, then the transmitted signal must also be adjusted. Consequently, there is disclosure not only of the pre-characterising features of the claim, but also of adjusting the average level of the signal that is transmitted by said transmitting transducer in reaction to the slowly varying characteristics of the detection environment is adjusted. Therefore the features characterising the claim are not even new.

Assuming there is any difference in relation to the amplifier gain or exact position of the signal, any such difference is not clearly specified in the claim. Nevertheless, supposing the claimed subject matter were new, it would not involve an inventive step. An explanatory drawing sheet filed during the oral proceedings by the appellant illustrates a simple movement of amplifier 17 in the circuit diagram of figure 1 of document D1 from a position downstream to a

position upstream of the probe 3, which is well within the competence of a skilled person and renders any artificial difference in the claimed subject matter obvious over document D1.

Even if it is argued that the claim is limited to an open loop system rather than a closed loop system, it is obvious that the skilled person knew of two equivalent alternatives for generating an ultrasonic signal. One was the closed feedback system of document D1. The other possibility is that of document D2, also finding application in the medical area and involving a free oscillator. The basic principle of the patent in dispute is then simply not using a feedback loop but adapting the transmitter power responsive to the environment level. The skilled person knew that document D1 is only a specialised example. Generally, the choice of the two alternatives is obvious to the skilled person, for example from signal to noise considerations, as can be seen from document D3 or D4 and cannot therefore involve an inventive step. Equally, the claimed subject matter is also obvious starting from document D2; in this case it is just necessary to measure inclusions in a liquid. The subject matter of the independent claims cannot therefore be considered to involve an inventive step.

The patent should therefore be revoked.

VII. The case of the respondent (=patent proprietor) can be summarised as follows.

The respondent requested that the appeal be dismissed or, in the alternative, the patent be maintained on the

basis of the claims of one of auxiliary requests one to four, as filed with the letter of 4 October 2006.

Admissibility of the Appeal

In its reply to the statement of grounds submitted on 16 December 2004, the respondent requested that the appeal be deemed inadmissible for failure to comply with Article 10a(2) of the Rules of Procedure of the Boards of Appeal (RPBA) in the version in force at that time. Pursuant to the third sentence of that provision, copies of papers referred to in the statement of grounds of appeal shall be attached as annexes thereto, unless the Board authorises otherwise. The grounds of appeal mentioned four documents, D1 to D4, copies of which, however, were not attached. Therefore, in the respondent's view, the appellant did not comply with the RPBA. According to Article 10a(4) RPBA the Board shall take into account everything presented by the parties if and to the extent it relates to the case and meets the requirements in paragraph 2. As the mere mention of documents D1 to D4 does not meet those requirements, the Board will not take them into account. This means that there are no facts and evidence in the proceedings. An opposition with no facts and evidence is inadmissible under Rule 56(1) EPC.

In the alternative, the respondent contended that, even if the appeal were admissible, it had to be dismissed because the appellant had not filed documents D1 to D4 on which all the grounds of appeal are based. Therefore, the appellant's grounds are not substantiated. Accepting documents D1 to D4 by virtue of their mere citation in the grounds would circumvent the last

sentence of Article 10a(2) RPBA and render it ineffective in practice.

Nevertheless, the respondent, in reply to a question by the Board during the oral proceedings, acknowledged that it had not had any problem in understanding the appellant's reasoning in its statement of grounds. The Board also drew the respondent's attention to the fact that an amendment to Article 10a(2) RPBA was made in the meantime, which took effect on 1 January 2005. According to the amended version of that provision, it was no longer necessary to furnish documents that were already made available during opposition proceedings. Documents D1 to D4 had been introduced in those proceedings. In the respondent's view, however, the decisive moment was not the date of entry into force of the amendment of Article 10a(2) RPBA but, rather, the date of filing of the statement of grounds. At that time, under the former version of that provision, it had still been necessary to submit the documents in question and such submission needed to be made at the beginning of the appeals proceedings. Non-respect of Article 10a(2) RPBA in the former version relevant in the present case needed to entail some sort of sanction.

Substantive Patentability

It is not correct that in the teaching of document D1, the output signal is fed back to the input because the receiver output is amplified to yield a signal having no slowly varying characteristics and it is this signal which is fed back to the transmitter. There is no disclosure in document D1 of adjusting the average level of the signal that is transmitted in reaction to

slowly varying characteristics so as to maintain an average value constant. Document D2 discloses a device only capable of measuring characteristics which are slowly varying. As a consequence, an application to the teaching of document D1 would result in the purpose of the device being changed, i.e. it would no longer be suitable. Document D3 is rather distant from document D1 and merely teaches increasing ultrasound amplitude to overcome noise, not keeping the received signal at a constant value, so that even an unlikely combination would not lead to the subject matter claimed. Document D4 concerns a mobile radio system, i.e. a technology far from that of the invention. The skilled person would not have turned to a document relating to a different problem in a different field when considering document D1. Document D2 does not have the same use or function or the most common features with the claimed invention because it relates to measuring slowly varying characteristics, so that there is no question of it being the closest prior art for a system the effect of such characteristics is countered. The subject matter of the invention can therefore be considered to involve an inventive step.

The appeal should therefore be dismissed.

VIII. The Board gave its decision at the end of the oral proceedings.

Reasons for the Decision

1. Admissibility of the appeal

In general

- 1.1 The respondent contends that the appeal is inadmissible as no copies of documents D1 to D4 referred to in the statement of grounds of appeal were attached thereto in contravention of Article 10a(2), third sentence, RPBA. Rule 65 EPC refers to a number of provisions of the Convention and the Implementing Regulations failure to comply with will lead to inadmissibility of the appeal. The only provision among them whose wording is pertinent for the issue in the case at hand is Article 108 EPC, which deals with the statement of grounds. According to the third sentence of that provision, "[w]ithin four months after the date of notification of the decision, a written statement setting out the grounds of appeal must be filed". Article 10a(2), third sentence, RPBA, on which the respondent relies to argue its case for inadmissibility, imposes the duty to file copies of papers referred to in the statement of grounds of appeal but, different from Article 108, it is not expressly identified as an admissibility provision. The analysis below will first examine whether the present appeal meets the conditions of Article 108, third sentence, EPC and subsequently assess the bearing of Article 10a(2), third sentence, RPBA, if any, on the admissibility of the appeal.

Article 108, third sentence, EPC

1.2 The issue to be addressed is whether copies of papers referred to in the statement of grounds, i.e. D1 to D4 in the present case, are an indispensable part of that statement so that omission to produce them within the time limit for filing the grounds will lead to inadmissibility of the appeal pursuant to Rule 65(1) in conjunction with Article 108, third sentence, EPC. According to long-standing case law of the boards of appeal, the grounds of appeal should specify the legal or factual reasons on which the case for setting aside the decision is based. The arguments must be clearly and concisely presented to enable the board and the other party or parties to understand immediately why the decision is alleged to be incorrect, and on what facts the appellant bases his arguments, without first having to make investigations of their own. (See Case Law of the Boards of Appeal of the European Patent Office, 4th edition 2001, at VII.D.7.5.1, and particularly T 220/83, OJ 1986, 249.) It has also been held that irrelevancy and lack of cogency of arguments may lead to an unsuccessful outcome of the appeal, but do not of themselves render it inadmissible (see T 65/96). The boards have thus required that the statement of grounds must contain relevant facts and arguments but they have not also imposed the obligation that evidence be furnished as a condition for admissibility. Such a duty would also run counter to the above holding that irrelevant or non-cogent arguments need not result in inadmissibility, as, obviously, the submission of evidence in support of such arguments would be of no avail. As a consequence, failure to submit copies of papers referred to in the

statement of grounds, i.e. D1 to D4 in the present case, does not lead to inadmissibility of the appeal due to non-compliance with Rule 65(1) in conjunction with Article 108, third sentence, EPC. This is true for the interpretation that the boards of appeal have given to Article 108, third sentence, independent of Article 10a(2), third sentence, RPBA. It will now be assessed whether that latter provision has any bearing on the admissibility of the appeal and could thus lead to a different conclusion.

Article 10a(2), third sentence, RPBA

1.3 Article 10a(2) RPBA in its original version reads as follows:

"The statement of grounds of appeal and the reply shall contain a party's complete case. They shall set out clearly and concisely the reasons why the decision under appeal is challenged or supported and should contain, expressly or by specific reference to material filed in the first instance proceedings, all the facts, arguments and evidence relied on and all requests made. Unless otherwise authorised by the Board, copies of papers referred to shall be attached as annexes."

1.4 Article 10a RPBA applies to proceedings in which the notice of appeal was received by the EPO after 1 May 2003 (see Articles 2 and 3 of the decision of the authority referred to in Rule 10(1) EPC (the "Presidium" of the Boards of Appeal) of 28 October 2002 (OJ 2003, 62) in conjunction with Article 2 of the decision of the Administrative Council of 12 December 2002 (OJ 2003, 61)).

- 1.5 An amendment of Article 10a(2) RPBA was made taking effect from 1 January 2005 (see OJ 2004, 541). For documents already on file, the third sentence as amended turns the rule according to which documents referred to in the statement of grounds had to be enclosed, unless otherwise authorised, into its opposite, so that they need no longer be attached unless otherwise requested. The third sentence, which has been in force ever since, now is as follows:
- "All documents referred to shall be
- (a) attached as annexes insofar as they have not already been filed in the course of the grant, opposition or appeal proceedings or produced by the Office in said proceedings;
- (b) filed in any event to the extent that the Board so directs in a particular case."
- 1.6 The present appeal was received on 8 May 2004, viz. after the entry into force of Article 10a(2) RPBA in its original version that remained valid until the end of year 2004. Therefore, that version applies to the case at hand, at least until the end of 2004. Pursuant to that version, the appellant was required to attach copies of documents D1 to D 4 to which it had referred in its statement of grounds, as annexes thereto, since the Board had not dispensed the appellant from complying with this duty. The question is whether the original version of Article 10a(2), third sentence, RPBA must be interpreted as making respect of this duty a prerequisite for admissibility of the appeal.
- 1.7 The interpretation must be made in the light of those legal provisions in whose context Article 10a(2), third sentence, has to be seen. These provisions are

Article 10a (as a whole) and Article 10b whose heading "Amendment to a party's case" already suggests that it complements Article 10a. Corresponding to the heading of Article 10a RPBA, i.e. "Basis of Proceedings", this provision deals with the kind of documents on the basis of which appeal proceedings are to be conducted (paragraphs (1), (2) and (4)) and the necessary contents of the statement of grounds, as well as the reply, where *inter partes* cases are concerned (paragraph 2). It also addresses the point in time when the case may be decided (paragraph (3)) and the conditions under which time limits may be extended (paragraph (5)). Article 10b RPBA, entitled "Amendment to a party's case", complements Article 10a by specifying the conditions under which the board may (paragraph 1), has to (paragraph 2) or may not (paragraph 3) consider amendments to the documents on the basis of which appeal proceedings are to be conducted. Article 10b RPBA also applies to proceedings in which the notice of appeal was received by the EPO after 1 May 2003 (see the provisions cited in relation to Article 10a above, at 1.4, which are equally pertinent for Article 10b).

- 1.8 To determine whether observance of the original version of Article 10a(2), third sentence, RPBA constitutes a prerequisite for the admissibility of the appeal, recourse shall be had to the legislative intent behind Articles 10a and 10b. This intent was laid down in the Presidium's explanatory notes to the set of amendments of the RPBA in the course of which both Articles 10a and 10b, together with other amendments, were introduced into the RPBA.

The legislative intent behind Articles 10a and 10b RPBA

1.9 The explanations that the Presidium gave for the amendments of the RPBA (see document CA/133/02 dated 12 November 2002), in pertinent part, are as follows: "The measures [that] aim at achieving the goal of **more efficient and shorter appeal proceedings** include a more defined and controlled initial phase of proceedings ... [See point A.3. of the Explanatory Memorandum.] The intended overall effect of the amendments in Articles 10a and 10b is to prevent 'ping pong' submissions and 'salami' tactics in written proceedings and to provide the Board (and the rapporteur in particular) with an appeal file containing one comprehensive submission from each party. [See point B.2. of the memorandum.]" (Emphasis added.)

1.10 More specifically, the commentary to Article 10a reads in relevant part: "This article requires appeal proceedings to be based on the notice of and statement of grounds of appeal, in inter partes cases additionally on the reply of other parties, and any communication from the Board and any duly filed answer thereto. **This provision, together with Article 10b(1), also provides a cut-off point after which any further material submitted is ipso facto late**, codifies the Board's existing power to ignore material unrelated to a case, and makes extensions of time not only discretionary (as at present) but also exceptional and, perhaps more importantly, dependent on reasons being supplied.

Furthermore, the **requirement to attach copies of papers referred to** (which must of course be interpreted in a

common sense manner) **underlines the separate identity of the appeal proceedings** and moreover will probably reduce the number of appeals filed without mature consideration of their likely success."

(Emphases added.)

- 1.11 It should be added that the second sentence of Article 10a(2) RPBA explaining the necessary contents of the statement of grounds amounts to a condensed summary of the case law set out above, under point 1.2, which was handed down in the context of the admissibility provision of Article 108, third sentence, EPC. This means that Article 10a(2), second sentence, affirms the basic principles established by the case law on the interpretation of that provision, which it codifies. (Cf. T 295/04, where it was held that Article 10a RPBA set out more specifically what the requirement to file the statement of grounds under Article 108 meant and where solely Article 10a RPBA was relied on to assess that requirement. On the other hand, T 1197/03 interprets Article 108, third sentence, mainly on the basis of the corresponding case law.)

Conclusion re Article 10a(2), third sentence, RPBA

- 1.12 Different from the second sentence of Article 10a(2), there is nothing in its *third* sentence that suggests a connection with the admissibility of the appeal. Therefore, what has been said in the context of Article 108, third sentence, above, under point 1.2, applies. This means that, for admissibility purposes, it is not necessary to furnish papers or documents referred to in the statement of grounds.

- 1.13 In the light of the foregoing, the appellant's failure to submit documents D1 to D4 within the four-month period allowed for filing the statement of grounds has no impact on the admissibility of its appeal. As the respondent has not cast any other doubt on the admissibility of the appeal and the Board likewise has no such doubt, the appeal is admissible.
- 1.14 The respondent's contention that there must be some sort of sanction for the failure to respect Article 10a(2), third sentence, RPBA in its original version may still be correct. The sanction, however, will not be inadmissibility as it alleged. Rather, part 2 below will discuss whether documents D1 to D4 that were not re-filed in the appeal proceedings must be excluded from those proceedings.
- 1.15 This legal situation corresponds, in principle, to that in opposition proceedings. Different from what the respondent believes, an opposition with no facts and evidence placed on file is *not*, for that reason alone, inadmissible under Rule 56(1) EPC. Following Rule 55(c) EPC the notice of opposition shall contain "an indication of the facts, evidence and arguments" presented in support of the grounds on which the opposition is based. While such *indication* constitutes an admissibility requirement (see Rule 56(1) EPC), it has been held that it is not necessary for purposes of admissibility that the said facts, evidence and arguments are placed on file during the opposition period. (Cf. T 328/87, OJ 1992, 701, point 3.3.2 and head note 1.) In any case, evidence can be filed later in the course of the proceedings.

2. Admission of documents D1 to D4 to the appeal proceedings

2.1 It must now be analysed whether documents D1 to D4 that were introduced and considered in the opposition proceedings but not attached to the statement of grounds of the appeal, nor filed again subsequently in the appeal proceedings, must be excluded from those proceedings or whether the Board may admit them to and consider them in the appeal proceedings. This depends on whether those documents must be *deemed* to have been filed in the appeal proceedings and, if so, whether the conditions imposed by the RPBA for their admission have been fulfilled.

Whether D1 to D4 must be deemed to have been filed on appeal

2.2 On 1 January 2005 the amended (and current) version of Article 10a(2) RPBA entered into force. As stated above, for documents, which were already made available in opposition proceedings, such as D1 to D4 in the present case, sentence three of the amended version turned the rule according to which documents referred to in the statement of grounds had to be enclosed, unless otherwise authorised, into its opposite, so that they need no longer be attached (see sub-paragraph (a)) unless otherwise requested (see sub-paragraph (b)). The question is whether, by virtue of the current version of Article 10a(2), third sentence, the appellant must be treated as if its case had been amended on 1 January 2005 because, on that day, documents D1 to D4 had to be considered as submitted automatically. That would require, as a precondition, that the amended version of

Article 10a(2), third sentence, were applicable to the present case and not the original version, as the respondent contends.

2.3 Article 10a(2) RPBA as amended gives no indication of those appeal cases to which it applies, i.e. whether the relevant date is the filing of the appeal, as in the decision of the Presidium relating to the previous amendments of the RPBA (see above, at point 1.4), or whether it is the filing of the statement of grounds, or any other date. In the absence of any restriction, as from the date mentioned as entry into force, i.e. 1 January 2005, amended Article 10a(2) RPBA must be considered to pertain to all appeals being filed from that date but also to all appeals then pending. Amended Article 10a(2) RPBA, from 1 January 2005, thus applies in the case at hand, and, following sentence 3, subparagraph (a), it covers documents D1 to D4, which the appellant had already filed in the course of the opposition proceedings.

2.4 To assess the impact of this fact on the present case, it is useful to explore the background of the amendment of Article 10a(2). The Explanatory Memorandum drawn up by the Presidium of the Boards of Appeal (see document CA/123/04 dated 22 September 2004), in pertinent part, reads as follows:

"Article 10a(2) RPBA - "Basis of proceedings" - details the requirements to be met by the statement of grounds and the reply, and defines the extent to which copies of documents referred to therein should also be filed. The introduction of electronic files for all proceedings before the Office (see Rule 95a EPC) has set new parameters for these requirements. **The**

availability of electronic files for all proceedings before the boards of appeal has not only led to changes in file maintenance (as carried out by the registries of the boards of appeal), but **has also provided the parties to the proceedings and the general public with direct and considerably improved access to the content of the file. There is therefore both reason and opportunity to clarify and simplify the provisions relating to the filing of documents in appeal proceedings.**

According to these provisions, documents already incorporated in an electronic file (pertaining to the European patent application or European patent on which the appeal is based) **do not have to be re-submitted; they are deemed to be originals (Rule 95a(3) EPC) and are available to anyone at any time,** both electronically and in the form of printed paper copies." (Emphasis added.)

- 2.5 In accordance with the explanatory memorandum above, under Rule 95a EPC, documents D1 to D4 filed in the course of the opposition proceedings have been deemed to be originals from 1 January 2005 and have since been available to anyone at any time. From that date, therefore, they did not have to be re-submitted any more. As a consequence, the appellant must be treated as if it had filed those copies on 1 January 2005. In other words, these copies must be deemed to have been submitted automatically on that date. The Board had seen no reason to direct the appellant to file those generally available documents again under Article 10a(2), third sentence, sub-paragraph (b).

Whether the conditions for admission of D1 to D4 are fulfilled

2.6 The issue to be addressed next is whether documents D1 to D4 can be admitted to and considered in the present appeal proceedings. In this context, Articles 10a(4) and 10b RPBA are relevant.

2.7 Article 10a(4) RPBA reads:

"Without prejudice to the power of the Board to hold inadmissible facts, evidence or requests which could have been presented or were not admitted in the first instance proceedings, everything presented by the parties under (1) shall be taken into account by the Board if and to the extent it relates to the case under appeal and meets the requirements in (2)."

2.8 Article 10b, in relevant part, is as follows:

"(1) Any amendment to a party's case after it has filed its grounds of appeal or reply may be admitted and considered at the Board's discretion. The discretion shall be exercised in view of inter alia the complexity of the new subject matter submitted, the current state of the proceedings and the need for procedural economy."

2.9 According to the commentary of the Presidium to Article 10a, that article, "together with Article 10b(1), ... provides a cut-off point after which any further material submitted is ipso facto late" (see above, at point 1.2.13). Pursuant to the commentary to Article 10b(1), this provision "makes the admissibility of any amendment to a party's case ... after the cut-off point defined by Articles 10a(1) and 10b(1) a matter for the Board's discretion ...".

Article 10a(1)(a) mandates that appeal proceedings shall be based on "the notice of appeal and statement of grounds of appeal filed pursuant to Article 108 EPC". Article 10b(1) refers, in particular, to amendments after a party has filed its grounds of appeal. This means that, in respect of the statement of grounds of appeal, the cut-off point is defined by the time limit set in Article 108 EPC.

- 2.10 In the Board's view, the above two provisions of the RPBA apply as follows:
- (i) Submissions that were not made at the cut-off point, i.e. within the time limits set under Article 10a(1) RPBA, such as Article 108 EPC, are considered *ipso facto* late. The board has discretion under Article 10b RPBA to admit them or not.
 - (ii) In addition, under Article 10a(4), the board may refuse to admit facts, evidence and requests (not arguments), which were furnished within the time limits of Article 10a(1), if this material could already have been supplied at first instance but was not, or was filed then but not admitted.
- 2.11 In the case at hand, documents D1 to D4 are deemed to have been submitted on 1 January 2005, i.e. roughly five months after the time limit for filing the statement of grounds of 8 August 2004 had expired. Under the original version of Article 10a(2), third sentence, RPBA, which was in force until end of year 2004, D1 to D4 would however have had to be attached to the statement of grounds, i.e. filed (or deemed to have been filed) on or before 8 August 2004. Therefore, Article 10a(4) RPBA on which the respondent relies is not pertinent.

- 2.12 Rather, Article 10b(1) applies. It presupposes an amendment to the appellant's case after the cut-off point, i.e. after expiry of the time limit to furnish the statement of grounds of appeal. It is true that no actual amendment was made because the appellant did not again supply copies of documents D1 to D4 in the appeals proceedings, which it had submitted in the opposition proceedings. However, as found above, the copies of documents D1 to D4 must be deemed to have been filed on 1 January 2005. Therefore, an amendment of the case must also be deemed to have been made. As set forth, that amendment took place after expiry of the period to file the grounds of appeal.
- 2.13 This means that the Board is called upon to exercise its discretion under Article 10b RPBA. That is the sanction for non-respect of Article 10a(2), third sentence, that the respondent considered indispensable.
- 2.14 The Board admits documents D1 to D4 to the appeal proceedings and considers them. The reason is that they had already been discussed in the opposition proceedings and thus have not brought anything new to the appeal stage, which could have led to a delay. Correspondingly, the respondent confirmed that it had no problems in understanding the appellant's reasoning in its statement of grounds, which dealt with these documents. The Board is not prevented by paragraph 3 of Article 10b from exercising its discretion under paragraph 1. Under paragraph 3, "[a]mendments sought to be made after oral proceedings have been arranged shall not be admitted if they raise issues which the Board or the other party or parties cannot reasonably be

expected to deal with without adjournment of the oral proceedings." These conditions are not met. D1 to D4 are deemed to be filed on 1 January 2005, which is long before oral proceedings were arranged on 2 August 2006. As a consequence, the respondent's claim that the appellant's grounds are not substantiated because the appellant had not again filed documents D1 to D4 must be dismissed.

3. *Substantive Patentability*

In procedures involving ultrasonic air bubble detectors, as described in the patent in dispute, a problem is that characteristics of the detection environment change over time during a procedure and vary from one procedure to another.

- 3.1 With respect to the prior art, the focus has been on document D1 as the document representing the closest prior art, dealing amongst other things with eliminating a slowly varying portion in an envelope of an rf electric wave due to hydraulic noise in the fluid flow system, such as that caused by pump motor operations. The disclosure of document D1, in relation especially to feedback loops, is pivotal to the present case and therefore, it is necessary to look closely at what is really disclosed.

Included in the teaching of Document D1 with reference to Figure 1 thereof is the following:-

(a) Ultrasonic probe 3

A probe 3 has inlet and outlet ports, 7 and 9 respectively, for a cavity 11 to permit the flow of a fluid medium therethrough. A pair of matched piezoelectric crystal transducers 13 and 15 is positioned on opposite sides of cavity 11 parallel to and in registry with each other. Crystal 13, when excited by an electric field, continuously propagates across cavity 11 an ultrasonic compression wave which is received by crystal 15 and converted to an rf electric wave of the same frequency. The rf electric wave is amplified by an rf amplifier 17 and fed back through circuit path 19 to provide the excitation field for crystal 13. Impedance matching networks 18 and 20 match the amplifier 17 input and output impedances with those of crystal transducers 15 and 13.

(b) First Feedback Loop 19

The combination of the crystal transducers 13 and 15, the rf amplifier 17, and feedback path 19 establishes an oscillatory circuit whose operation is made marginally oscillatory by a variable attenuator 21 located in feedback path 19. The amplitude of the rf electric wave produced by the crystal transducer in response to received ultrasonic compression waves has an envelope with a slowly varying portion due to hydraulic noise and, if a particle is present, also a perturbation

caused thereby. The marginally oscillatory circuit is sensitive to variations in the input to amplifier 17. Gain is normally defined as the ratio of amplifier output voltage to input voltage. For small values of amplifier input voltage, a plot of amplifier gain versus input voltage is nearly linear, but as amplifier input voltage increases gain decreases because the amplifier begins to saturate. The oscillatory circuit is operated in the nearly linear gain versus input voltage region of the amplifier. Therefore, small variations in the rf wave amplitude caused by the particles 65 passing through cavity 11, produce relatively larger changes in the output rf wave amplitude. The increased sensitivity to particles 65 occurs because the small input voltage changes to amplifier 17 require rather large changes in output level to provide the necessary increase in gain to keep the circuit oscillatory, whereas if the oscillator were operated in a more stable condition, small amplifier input voltage changes would require only small output level changes to provide the necessary gain changes to maintain the circuit in oscillation.

(c) Second Feedback Loop 25

Since response should only be to the presence of particles 65, the slowly varying rf electric wave envelope amplitude due to the system operating environment is eliminated by a filter gain control circuit 73 positioned in a feedback loop 25 of rf amplifier 17 to provide the negative feedback necessary to cancel out these slow variations. The

filter portion of circuit 73 is a low-pass filter which senses the slow amplitude variations while being insensitive to the variations 71 caused by particles, and changes the amplifier 17 gain accordingly. The output of amplifier 17 besides being fed back to crystal transducer 13 is also detected.

3.2 There was no dispute between the parties that the pre-characterising features of claim 1 of the patent in dispute are known from document D1, i.e. basically the inclusion detector with the probe and the transducers, with, in general, circuitry for dealing with sudden changes in level of the received signal and slowly varying characteristics in the detection environment. However, there is no disclosure in document D1 that the second feedback loop adjusts the average level of the signal which is transmitted by the transmitting transducer to maintain an average value of the received signal constant. As can be seen from section 3.1(c) above, this is because the second feedback loop adjusts the gain of the amplifier 17 receiving the signal from the receiving crystal to tend to keep the slowly varying output envelope constant, this then being fed back to maintain the driving signal constant.

3.3 In the patent in dispute, the signal received by the receiving transducer 44 passes to an amplifier 76 and via a demodulator/filter 80,84 is transformed to a DC signal. The DC signal is compared to a defined value (at 214 in Figure 8) in an automatic level control 88, which then adjusts via an amplifier 74 the signal driving the transmitting transducer 40 to maintain the DC signal at the value. The effect of this is to

maintain the average level of the signal received constant at the defined value. There is no question of the gain of the amplifier 76, which receives the signal from the receiving transducer being adjusted by the DC signal so that the amplifier output level is constant.

3.4 In the appeal proceedings, a question arose concerning the novelty of the characterising feature of claim 1 in the general context of feedback oscillator systems, from a viewpoint that the signal levels on the input and output sides of the amplifier 17 in the first feedback loop 19 including the probe cannot be differentiated. In this context, if adjustment takes place both on the transmitter and receiver side, it was argued by the appellant that the transmitter is adjusted responsive to slowly varying characteristics. In the Board's view, this is a dangerous line to take because it runs counter to what is shown in the figure of document D1, where there is no doubt that the envelope amplitude of the waveform is shown as different on the amplifier 17 input side (roughly sinusoidal upper and lower boundaries representing pump noise) and output side (generally straight). It is more sensible to accept the disclosure in the figure about the envelope and consider the rf wave in connection with the oscillator. The argument of the appellant therefore raises no serious question in relation to novelty and did not convince the Board.

3.5 In addition, lack of novelty was not a ground for opposition and the respondent did not agree to introduction of novelty as a ground for opposition at the appeal stage. Quite apart from the question dealt with in point 3.4, the Board thus sees itself,

consistent with established case law, as excluded from introducing novelty as a ground for opposition into the appeal proceedings anyway. With respect to the novel features, the Board agrees with the opposition division that the problem solved is to provide alternative evaluation circuitry for ultrasonic transmission measurements.

3.6 In both document D1 and in the patent in dispute, slow moving changes and fast moving changes are distinguished, but in the former case the slow moving envelope changes caused by the pump are simply ironed out to tend to maintain the same average transmitted signal value, whereas in the latter, the average value of the transmitted signal is adjusted to make the received signal constant despite environmental change. There is no reason at all in the teaching of document D1 to adjust the average level of the signal that is transmitted. On the face of document D1 alone, the characterising features of claim 1 are not therefore obvious.

3.7 In view of the possibility of destabilising the circuitry and making it inoperative, the Board does not consider it obvious that the skilled person would have transposed the amplifier 17 to a position on the transmitter side between the impedance matching networks 18 and 20 as proposed in the drawing submitted during the oral proceedings. That the skilled person could make the transposition is not obvious without any reason for so doing and is even contrary to the teaching of document D1 because it opens the possibility of pump noise reaching the detector 22. Even supposing the alteration were done and did not

disrupt operation, which was not demonstrated by the appellant, the Board concluded that the transmitter is still adjusted to a constant value by the amplifier 17 and there is no reason to think the average value of the signal received by the receiving transducer would not have an envelope modulated by the hydraulic pump noise, which would then go on to the detector. Thus, even had the transposition have been practicable and obvious, the subject matter of the claim in dispute would not have been reached.

- 3.8 The argument that it is an obvious step, when considering signal to noise ratio in the context of electrical or thermal noise, to increase amplitude of an ultrasound signal, as say document D3, finds some sympathy with the Board, but not starting from document D1. The argument does not fit very well with document D1 because there is no indication that the problem occurs there. On the contrary, the idea is to hold the transmitted signal constant in an environment with a marginally oscillatory circuit. The importance of the marginally oscillatory circuit is stressed at many points in document D1, see for example the discussion in point 3.1(c) above. This is a central plank of the argument of the respondent and is correct. The skilled person, who is starting from document D1 would not therefore have interfered with the first feedback loop needed for the marginally oscillatory circuit. Therefore, the Board does not see that taking this step can be considered obvious in this context, even having regard to document D3. Document D4 is in a field further removed from the patent in dispute than document D3 and is therefore even less relevant.

3.9 Although document D2 relates to measurements in blood using waves transmitted along a measurement path, the consideration discussed in point 3.8 also applies in respect of document D2, as adoption of its teaching would require the closed loop to be removed. Nevertheless, the appellant is asking the Board to decide that it is obvious that the first closed loop of document D1 can indeed be dispensed with as a simple matter of choice. The reality is, however, that there are significant differences between the teachings of documents D1 and D2, which preclude them from being fitted together in an obvious way to reach the teaching of the independent claims in dispute. The open loop disclosed in document D2 has the purpose of changing the transmitted optical signal to ensure that penetration into the blood remains constant with respect to a reference (V_{ref} 122 in Figure 2) even when blood density changes. However, inclusions are not involved in this process. In fact, the teaching of document D2 is that microemboli are avoided (column 2, line 19), contrary to document D1 where they are detected. Moreover, the teaching of document D2 uses electromagnetic radiation at two wavelengths (red and infrared) rather than exciting an ultrasonic transducer with rf frequency as in document D1. Therefore, the Board considers that only with the benefit of hindsight would a fitting of the teachings be considered.

3.10 Thus, when within the boundaries set by starting from document D1, the Board considers a recurring argument in the case of the respondent, that the skilled person would not manipulate the marginally oscillatory circuit in view of its importance to the teaching of the document, to be persuasive. Accordingly, all the

arguments submitted on inventive step and starting from document D1 failed to convince the Board as to lack of inventive step.

- 3.11 The Board does not consider document D2 to represent the closest prior art because it is concerned with measuring blood oxygen saturation avoiding microemboli interference and not measuring inclusions as in the claims of the patent in dispute. If document D2 were to be taken as the closest prior art document, significant changes are required to the extent of changing the purpose and structure of the disclosure as can be seen from the differences set out in point 3.9 above. Even the maintenance of a constant level of reflected transmitted light, as stressed by the appellant and mentioned in column 5, line 5 of document D2, is tied by the preceding sentence to the dual wavelength techniques taught in document D2. Without hindsight, it is not therefore obvious that the skilled person would have taken document D2 and set the problem of detecting inclusions, moving on to solve the problem by selecting features from document D1, ignoring, in particular, the closed loop taught in that document. The argument of the appellant that the skilled person knew document D1 to teach a special apparatus does not persuade the Board that a "generalisation" was obvious, on the contrary it is more likely that the teaching would have been respected. Only with hindsight could the approach advocated by the appellant appear plausible. The Board was not therefore persuaded by the approach of the appellant starting from document D2 as closest prior art document.

- 3.12 The Board is therefore satisfied that the subject matter of claim 1 can be considered to involve an inventive step having regard to the cases presented during the appeal proceedings.
- 3.13 The same novel features are contained in independent claim 24, so that the conclusion reached in point 3.12 also applies to this claim. As the remaining claims depend from the independent claims, the same conclusion also applies to them by virtue of their dependence.
- 3.14 Since the case of the appellant against the main request of the respondent failed to convince the Board, there is no need to deal with the claims according to the auxiliary requests of the respondent in the present decision.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:

M. Kiehl

A. G. Klein