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Datasheet for the decision of 6 September 2022

Case Number: T 0467/20 - 3.2.02

Application Number: 12825326.7

Publication Number: 2744400

IPC: A61B5/0215, A61B5/00

Language of the proceedings: EN

Title of invention:
DEVICES, SYSTEMS, AND METHODS FOR VISUALLY DEPICTING A VESSEL AND EVALUATING TREATMENT OPTIONS

Patent Proprietor:
Philips Image Guided Therapy Corporation

Opponent:
Abbott Laboratories

Relevant legal provisions:
RPBA 2020 Art. 12(4), 13(2)
EPC Art. 56, 83, 123(2)

Keyword:

New evidence filed on appeal - admitted (yes)
Late-filed objection - admitted (no)
Added subject-matter - (no)
Sufficiency of disclosure - (yes)
Inventive step - (yes)

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Case Number: T 0467/20 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 6 September 2022

Appellant: (Opponent)	Abbott Laboratories 100 Abbott Park Rd. Abbott Park, IL 60064-6004 (US)
Representative:	Gill Jennings & Every LLP The Broadgate Tower 20 Primrose Street London EC2A 2ES (GB)
Respondent: (Patent Proprietor)	Philips Image Guided Therapy Corporation 3721 Valley Centre Drive, Suite 500 San Diego CA 92130 (US)
Representative:	Philips Intellectual Property & Standards High Tech Campus 52 5656 AG Eindhoven (NL)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 20 December 2019 rejecting the opposition filed against European patent No. 2744400 pursuant to Article 101(2) EPC.**

Composition of the Board:

Chairman	C. Schmidt
Members:	S. Dennler
	D. Ceccarelli

Summary of Facts and Submissions

I. The opponent filed the appeal against the Opposition Division's decision to reject the opposition to the contested patent.

II. In its decision, the Opposition Division held that the invention of the patent was sufficiently disclosed, that the patent did not contain added subject-matter and that the subject-matter of claim 1 as granted involved an inventive step in view of the documents

D1 WO 2006/041346 A1
D1' US 2002/0072880 A1
D2 WO 2011/038044 A2

III. Oral proceedings before the Board were held on 6 September 2022.

IV. The appellant (opponent) requested that the decision under appeal be set aside and that the patent be revoked.

V. The respondent (proprietor) requested as its main request that the appeal be dismissed. As auxiliary measures, the respondent requested that the patent be maintained in amended form based on one of auxiliary requests Ia, I, I1, I', I1', II, II1, II', II1', III, IV, V, IIIb, IVb, IV1b, Vb and V1b, ranked in that order and filed with the reply to the statement of grounds of appeal.

VI. Claim 1 of the main request, i.e. claim 1 of the patent as granted, reads as follows (feature numbering introduced by the Board):

1 *"A system for evaluating a vessel (100) of a patient comprising:*

2 *a first instrument (130) sized and shaped for introduction into the vessel of the patient;*

3 *a second instrument (132) sized and shaped for introduction into the vessel of the patient;*

4 *a computing device (172) in communication with the first and second instruments, the computing device configured to:*

4.1 *obtain pressure measurements from the first and second instruments while the second instrument is moved longitudinally through the vessel of the patient from a first position to a second position while the first instrument is maintained in a fixed longitudinal position with respect to the vessel;*

4.2 *visually depict the vessel on a display based on a pressure differential calculated as the ratio of the pressure measurements obtained from the first instrument and the pressure measurements obtained from the second instrument; and*

4.3 *modify the visual depiction of the vessel to simulate one or more treatment options based on expected results of the one or more treatment options on the pressure differential."*

VII. This decision also refers to the following documents:

D8 *"Fractional Flow Reserve versus Angiography for Guiding Percutaneous Coronary Intervention"*, Tonino *et al.*, The New England Journal of Medicine, vol. 360, No. 3, 15 January 2009, pages 213-24

D9 *"Measurement of Fractional Flow Reserve to Assess the Functional Severity of Coronary-Artery*

Stenoses", Pijls *et al*,, The New England Journal of Medicine, vol. 334, No. 26, 27 June 1996, pages 1703-8

D13a affidavit signed by Dr. Pijls, dated 5 May 2020

D13b affidavit signed by Dr. West, dated 30 April 2020

D13c affidavit in the name of Dr. Fearon, not signed

VIII. The **appellant's arguments** that are relevant to this decision can be summarised as follows:

Admittance of the affidavits

Affidavits D13a to D13c had been filed as evidence of the common general knowledge of the person skilled in the art at the priority date of the contested patent, in direct response to the Opposition Division's reasoning presented in the decision under appeal. They supported the appellant's interpretation of D1 based on the conventional definition of the fractional flow reserve (FFR) technique, which had not been correctly taken into account in that reasoning. In this respect, reference was made to the content of the appellant's request for correction of the minutes of the first-instance oral proceedings, which the Opposition Division had refused.

Due to working restrictions imposed by the coronavirus situation, it had been difficult to submit signed versions of all the affidavits with the statement of grounds of appeal. The fact that an affidavit was signed showed that the signatory agreed with the content of the affidavit.

For these reasons, the affidavits should be admitted into the appeal proceedings.

Added subject-matter

(a) Claim 1

In contrast to the original claim 30 of the application as filed, which defined both a "control system" and a "processing unit", claim 1 as granted defined a "computing device". This presented the person skilled in the art with information not originally disclosed.

Though not raised in the statement of grounds of appeal, this objection was discussed in the decision under appeal (point 3.1.1.1) and was *prima facie* convincing. Moreover, it was always in the public interest not to maintain a manifestly invalid patent. This objection should therefore be admitted into the appeal proceedings.

(b) Paragraph [0034] of the description

During the examination phase, the clause "using one or more of the techniques described in (...) hyperemic agent to the patient" in the paragraph bridging pages 15 and 16 of the original description, which corresponded to paragraph [0034] in the patent as granted, had been deleted.

Whereas the unamended original paragraph indicated that the selection of a diagnostic window was not optional when a hyperemic agent was not used, the remaining part of the sentence which had not been deleted ("In that regard, in some embodiments a diagnostic window is selected") suggested on the contrary that the selection of a diagnostic window was optional. Hence the deletion had changed the meaning of that paragraph. It resulted

that paragraph [0034] of the patent as granted comprised added subject-matter.

Sufficiency of disclosure

The patent failed to provide all the information necessary for a person skilled in the art to reproduce the alleged invention, whether or not a hyperemic agent was used.

In particular, the patent did not explain how to obtain reliable pressure measurements and to calculate average pressure differentials from these measurements, be it across a whole heartbeat cycle or across a limited diagnostic window. Many questions were left open, for example how many pressure measurements and heartbeat cycles should be taken into account for calculating the average and what the correct timing for calculating a differential pressure value was. Figure 11 was obscure, showing only one single fluctuating pressure curve, and did not enable the person skilled in the art to understand the principles of the device.

Although the use of a diagnostic window was described as a means of avoiding the administration of hyperemic agents (paragraph [0034]), which was one of the alleged objects of the patent (paragraph [0005]), the patent did not explain how to identify this diagnostic window, which was of crucial importance. In this regard, paragraph [0034] merely listed various variables that could be used for this purpose, though without indicating how. It was not apparent how the selection of a diagnostic window avoided the need to reduce and stabilise microvascular resistance as done in the conventional method of determining FFR.

Inventive step

D1 disclosed a system for evaluating a blood vessel (page 1, lines 15-27) comprising a guiding catheter and a pressure sensor guidewire, anticipating features 1 to 4.2 of claim 1. In particular, D1 disclosed that FFR values could be calculated from the pressure measurements and displayed along the vessel (page 4, lines 5-6; claim 9 of D1). The resulting display was a visual depiction of the vessel based on a pressure differential as defined in feature 4.2.

The subject-matter of claim 1 differed from the system of D1 only on account of feature 4.3.

The objective technical problem to be solved could be formulated as facilitating selection of a treatment method.

The person skilled in the art proceeding from D1 and faced with this problem would obviously have considered D2, which specifically addressed this problem and disclosed a similar system based, like the system of D1, on moving a sensor longitudinally within a vessel while acquiring data, for optimising stent sizing and positioning (paragraphs [0013] and [0064]).

On the basis of optical coherence tomography (OCT) data acquired on the vessel, the system of D2 computed a number of clinically significant parameters to characterise its flow properties, such as a vascular resistance ratio (VRR) (paragraph [0015]) or, equivalently, the FFR index (paragraphs [0107]-[0110]). Various user displays of interest were generated to simulate the placement of a stent and to determine the effect of the placement on these parameters. For

example, Figure 25 showed how two different stents affected VRR differently. In Figure 23, a calculated change in VRR resulting from a stent addition was also displayed, and the VRR display could be updated as the stent length and location were changed by the operator (paragraph [0121]). At the same time, the lower graph of Figure 23 visually demonstrated how the presence of the simulated stent modified the graph showing the total pressure along the vessel.

In view of D2, especially given that D2 taught that FFR could be computed instead of VRR, it would have been obvious to the person skilled in the art seeking a solution to the problem above to further configure the computing device of D1 (which was configured to calculate and display FFR values along a vessel) so that it also modified the visual depiction of the vessel based on the FFR values to simulate one or more treatment options (the use of stents of different lengths) based on expected results (the expected FFR values) of the one or more treatment options on the pressure differential, i.e. to implement feature 4.3.

The person skilled in the art would therefore have arrived at the subject-matter of claim 1 without exercising any inventive skill.

IX. The **respondent's arguments** that are relevant to this decision can be summarised as follows:

Admittance of the affidavits

The definition of FFR, to which the affidavits related, had already been extensively discussed before the Opposition Division. The appellant should thus have

filed the affidavits during the first-instance proceedings.

Furthermore, there were strong doubts as to their credibility, especially whether, being dated 2020, they could credibly give evidence of the person skilled in the art's understanding of how to measure FFR values at the priority date of the contested patent, i.e. about nine years before. Moreover, the main part describing the working principle of FFR in all the affidavits was identical word for word. This showed that the affidavits had been prepared purposefully by someone else and that they were not trustworthy statements phrased by their alleged authors.

For these reasons, the affidavits should not be admitted into the proceedings.

Added subject-matter

(a) Claim 1

It was irrelevant that the appellant's objection of added subject-matter relating to the "computing device" defined in claim 1 was discussed in the decision under appeal. This objection was not substantiated in the statement of grounds of appeal but was filed by the appellant on appeal for the first time at the oral proceedings before the Board, hence very late. There were no exceptional circumstances that could justify admitting this objection at such a late stage of the appeal proceedings. Consequently this objection should not be admitted.

(b) Paragraph [0034] of the description

The text remaining after the deletion was a mere repetition of what had already been stated in the preceding sentences. Hence no new information had been introduced by the deletion and the patent did not comprise added subject-matter.

Sufficiency of disclosure

It was not necessary for the patent to disclose precisely all the details of the various calculations for the invention to be considered sufficiently disclosed. Rather, the criterion was whether the person skilled in the art could carry out the invention without undue burden, which was the case for the contested patent. In particular, claim 1 defined how the pressure measurements were obtained by the first and second instruments of the device as a moving pressure and a fixed pressure respectively, and how the pressure differential was then calculated as the ratio of the moving pressure and the fixed pressure. Figure 11 further illustrated how the pressure differential could be calculated on the basis of average pressure values, resulting in an average pressure differential.

These calculations could be performed equally with or without the administration of a hyperemic agent, either over the whole heartbeat cycle or over only a limited portion of it by considering only some of the measurements. Whether or not to select a diagnostic window and whether or not to use a hyperemic agent actually depended on circumstances of the specific clinical situation.

Moreover, the person skilled in the art would have no difficulty in identifying a suitable diagnostic window.

Inventive step

D1 failed to disclose at least feature 4.3 of claim 1.

Feature 4.3 was neither disclosed in, nor suggested by, D2.

Indeed, unlike the system of D1, the system of D2 was not based on pressure measurements but relied entirely on OCT measurements, i.e. on an imaging technique which only provided an indication of the internal morphology of the vessel.

The visual depictions of the vessel disclosed in Figure 25 and in the upper part of Figure 23 were all based on this kind of morphological measurement and simply illustrated how the vessel diameter varied along the vessel. In the lower part of Figure 25, the visual depictions were modified to simulate the implantation of a stent: however, this modification was not based on the expected results or effects the stent had on a pressure differential, but rather on the effects it had on the morphology of the vessel determined previously by the OCT measurements.

The updated VRR calculations that the appellant asserted as modifications of the visual depiction of the vessel were also based on the OCT measurements and not on pressure measurements. The FFR calculations disclosed in D2 were also derived from the OCT measurements and differed from a pressure differential calculated according to feature 4.2 from pressure measurements.

The lower graph in Figure 23 illustrated the total pressure along the vessel, with and without a stent. This graph could not be regarded as a visual depiction of the vessel based on a pressure differential, let alone a pressure differential calculated according to feature 4.2, either. Moreover, this total pressure graph, both for the unstented and stented vessels, was simulated on the basis of the OCT measurements, and not measured.

In suggesting a modification of the visual depiction of the vessel based on OCT imaging instead of pressure measurements, D2 actually taught away from feature 4.3.

For these reasons, combining D1 with D2 would not therefore have led to the subject-matter of claim 1 in an obvious manner. The subject-matter of claim 1 therefore involved an inventive step starting from D1.

Reasons for the Decision

1. Subject-matter of the contested patent

The contested patent relates to a system for assessing the severity of a stenosis in a blood vessel.

As illustrated in Figure 3 of the patent, reproduced below, a stenosis (108) is a blockage or narrowing of a blood vessel (100), caused for example by accumulation of plaque, which decreases the space available for blood to flow and results in a drop in blood pressure across the stenosis.

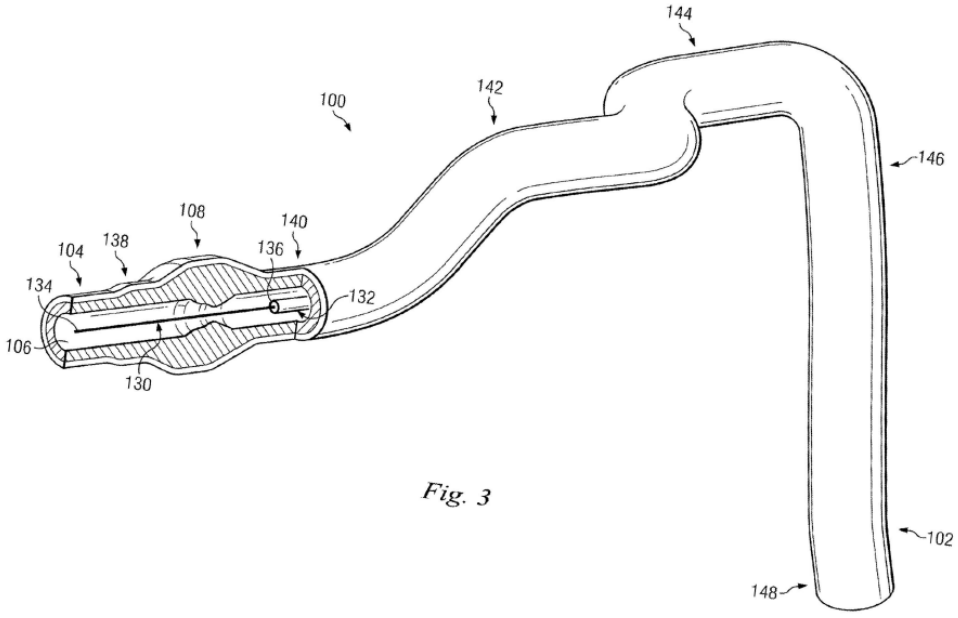

Fig. 3

The claimed system comprises a first and a second instrument, both sized and shaped for introduction into the vessel, such as a guidewire (130) and a catheter (132) in the example illustrated in Figure 3.

The system further comprises a computing device in communication with both instruments and configured to perform the following steps:

(a) *obtain pressure measurements from the first and second instruments while the second instrument is moved longitudinally through the vessel of the patient from a first position to a second position while the first instrument is maintained in a fixed longitudinal position with respect to the vessel.*

In the example illustrated in Figure 3, the catheter (132) remains at a fixed location outside the stenosis while the guidewire (130) is moved through the stenosis. Hence pressure can be measured simultaneously both at a fixed reference

location outside the stenosis and at various locations across the stenosis.

(b) *visually depict the vessel on a display based on a pressure differential calculated as the ratio of the pressure measurements obtained from the first instrument and the pressure measurements obtained from the second instrument.*

Examples of such a visual depiction of the vessel based on the calculated pressure differential are shown, for example, in Figure 7 and Figure 9 (dashed curve) reproduced below. By analysing the shape of plots 212 and 236, this visual depiction can be used to both identify the location of a stenosis and assess its severity (paragraphs [0041] and [0046]).

(c) *modify the visual depiction of the vessel to simulate one or more treatment options based on expected results of the one or more treatment options on the pressure differential.*

An example of a visual depiction of the vessel modified in accordance with step (c) is the solid curve shown in Figure 9, reproduced below, in which a treatment option across the region 244 previously identified as a stenosis has been simulated on plot 238. By simulating and evaluating a plurality of treatment options, the most promising treatment approach for the patient can be selected (paragraphs [0047]-[0048]).

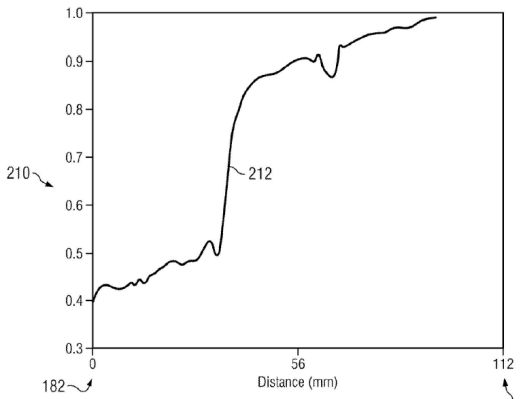

FIG. 7

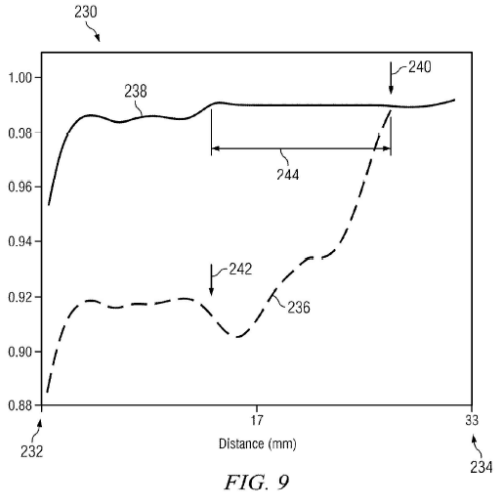

FIG. 9

2. Admittance of the affidavits

2.1 The appellant justified the submission of the affidavits on appeal as a direct response to the reasoning presented in the impugned decision, to provide evidence of the common general knowledge of the person skilled in the art at the priority date of the contested patent. The affidavits are intended to support the appellant's interpretation of D1 according to which, in view of the conventional definition of the fractional flow reserve (FFR) technique, a person skilled in the art would have understood that the system of D1 in fact included two instruments for simultaneously measuring pressure both proximally and distally to the stenosis, and not only one as considered by the Opposition Division in the decision under appeal.

2.2 This line of argument was indeed already raised by the appellant during the first-instance proceedings (see point 3.3.3 of the decision). The appellant argued that it had not been correctly taken into account by the Opposition Division, and referred in this respect to

its request for correction of the minutes of the oral proceedings, which the Opposition Division had refused.

While the affidavits could arguably have been filed during the first-instance proceedings, the Opposition Division's preliminary opinion communicated to the parties in advance of the oral proceedings concurred with the appellant's view that claim 1 did not involve an inventive step (point 7.3 of the communication annexed to the summons). Accordingly, the appellant may not have considered it necessary to file further evidence in support of its view until the oral proceedings before the Opposition Division.

2.3 On appeal, the affidavits were filed on the same date on which the appellant filed its statement of grounds of appeal, or shortly afterwards, i.e. at an early stage of the appeal proceedings.

The affidavits are intended to prove the conventional definition of FFR as understood by experts in the field, which was not disputed by the respondent.

The fact that the affidavits have a very similar or even identical text in some sections is not, in the present case, detrimental to their credibility as long as they are signed by their author, which means that the latter agrees with the content of the affidavit. This applies regardless of the probative value of the opinions expressed in the affidavits regarding the present appeal proceedings, which value would then - for those affidavits admitted into the proceedings - in any event have to be assessed by the Board.

2.4 Under these circumstances, the Board, exercising its discretion under Article 12(4) RPBA 2020, decided to

admit the signed affidavits D13a and D13b into the appeal proceedings, and not to admit the unsigned one D13c.

3. Added subject-matter

3.1 Claim 1

During the oral proceedings before the Board, the appellant, for the first time on appeal, raised an added-matter objection relating to the "computing device" defined in claim 1 as granted.

This objection, which was not substantiated in the statement of grounds of appeal, is an amendment of the appellant's appeal case, which was made after notification of the summons to attend oral proceedings before the Board. Accordingly, its admittance into the appeal proceedings is subject to Article 13(2) RPBA 2020, according to which any amendment to a party's appeal case made at this stage of the proceedings must, in principle, not be taken into account unless there are exceptional circumstances, which have been justified with cogent reasons by the party concerned.

The appellant did not provide any reason why this objection had not been raised on appeal earlier. Contrary to the appellant's view, the fact that this objection had been discussed in the decision under appeal (see point 3.1.1.1) does not constitute exceptional circumstances that would justify its admission at such a late stage of the appeal proceedings. Had the appellant wished the decision under appeal to be reviewed in this regard, it could and should have addressed the Opposition Division's

reasons for dismissing the objection at the beginning of the appeal proceedings.

The Board therefore decided not to admit this objection into the appeal proceedings.

3.2 Paragraph [0034] of the description

The appellant's other added-matter objection concerns the deletion prior to grant of a clause in the passage of the description as filed which bridges pages 15 and 16 and now forms paragraph [0034] of the description of the patent as granted. This objection does not convince the Board.

As argued by the respondent and also accepted by the Opposition Division (point 3.1.3.3 of the decision under appeal), the sentence "In that regard, in some embodiments a diagnostic window is selected" which remains in paragraph [0034] after the deletion is a mere repetition of what is already disclosed in the unamended part of the passage in question, see especially the sentence "In other embodiments, only a portion of the heartbeat cycle is utilized to calculate the pressure differential". The "diagnostic window" is indeed nothing other than the portion of the heartbeat cycle across which the pressure differential is calculated when the heartbeat cycle is not used in its entirety. Moreover, the deleted clause merely indicated several possible techniques for selecting such a diagnostic window. These techniques could be used "in some embodiments" of the claimed invention and were thus purely exemplary, i.e. optional.

Hence, contrary to the appellant's view, this deletion does not present the person skilled in the art with new

information extending beyond the content of the application as filed.

3.3 It follows that the patent as granted meets the requirements of Article 123(2) EPC.

4. Sufficiency of disclosure

4.1 The appellant raised several objections according to which the invention of the contested patent was not sufficiently disclosed. These objections do not convince the Board.

4.2 Contrary to the appellant's view, the person skilled in the art would have no difficulty in obtaining pressure measurements and calculating a pressure differential as the ratio of these measurements as defined in claim 1, including calculating this pressure differential from averages of the pressure measurements, either across a whole heartbeat cycle or a limited diagnostic window.

Indeed, aspects related to the number of pressure measurements or the number of heartbeat cycles to be taken into account in order to achieve relevant averaging are indeed a mere matter of technical implementation and are well-known to the person skilled in the art. This is, for example, reflected in D9, cited by the appellant itself as evidence of what was well-known in the art at the priority date, which also discloses calculating a ratio of mean pressures (page 1704, first paragraph of section "Pressure Measurements and Calculation of FFR", last sentence). Moreover, in accordance with established case law, the person skilled in the art may use their common general knowledge to supplement the information contained in the patent.

The Board acknowledges that Figure 11 does not enable the two graphs 292 and 296 to be distinguished clearly, as the appellant objected. These graphs are deemed to represent the two pulsed pressure measurements acquired simultaneously by the two instruments while the second instrument is being pulled back from a position distal to the stenosis 268, through both stenoses 268 and 258, to a position proximal to the stenosis 258 at which the first instrument remains stationary (paragraph [0053] of the description).

However, despite its schematic nature, Figure 11 clearly illustrates how, as described in the patent specification, mean pressures are determined from the raw pressure measurements and then used to calculate an average pressure differential (as the ratio of these mean pressures) and display its variation along the vessel as shown in Figure 12. In particular, Figure 11 illustrates how the two mean pressures become closer to each other as the second instrument is pulled back through the stenoses and approaches the proximal location, in agreement with Figure 12, which shows their ratio converging to one.

4.3 Paragraph [0034] of the description explains that the pressure measurements can also be determined and their ratio calculated without administration of a hyperemic agent. The appellant doubted that the person skilled in the art would be able to carry out the invention in this case, especially in the absence of a detailed description of how to select an appropriate diagnostic window. The Board makes the following comments in this regard:

First, as explained by the respondent, whether or not to use a hyperemic agent depends on the circumstances of the specific clinical situation. This question relates only to the conditions in which the claimed invention, which is a system and not a method and which is defined independently of the administration of any hyperemic agent, is used. This question therefore has no bearing on the conclusion above that the invention is sufficiently disclosed.

Furthermore, paragraph [0034] of the description lists several criteria which could be considered by the person skilled in the art in order to select an appropriate diagnostic window to calculate a relevant ratio when no hyperemic agent is used. The Board agrees with the respondent's view, also adopted by the Opposition Division, that the person skilled in the art would have no difficulty or undue burden in making this selection.

4.4 Hence the Board concurs with the respondent's view that the person skilled in the art finds in the patent specification all the relevant information required to carry out the invention as defined in the claims. It follows that, contrary to the appellant's argument, the contested patent discloses the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

5. Inventive step

5.1 It is common ground that D1 discloses a system for evaluating a vessel of a patient, especially for identifying and assessing a stenosis (page 1, lines 15-27). Like the system of claim 1, this system comprises (Figure 1) a guiding catheter and a pressure

sensor guidewire 5, i.e. a first instrument and a second instrument both sized and shaped for introduction into the vessel. D1 therefore discloses features 1 to 3 of claim 1.

5.2 In use, after the guiding catheter has been positioned proximally to the area to be examined, for example a suspected stenosis, the guidewire is moved past this region of interest. The guiding catheter is then locked in position, and the guidewire is pulled back along the vessel while acquiring pressure data across the stenosis (page 8, lines 7-30). The pressure data is received at a computing unit in communication with the guidewire (processing means 1), processed and combined with image data representative of the vessel (for example an angiogram image) to generate an "integrated graphical image output", i.e. a visual depiction of the target vessel in which the pressure data is mapped onto a corresponding position on an image of the vessel (page 3, lines 20-25; page 2, lines 29-30).

While the processed data displayed in the "integrated graphical image output" may be a "numerical relation" between the pressure data acquired by the guidewire and a static reference pressure obtained initially proximally to the stenosis (page 3, lines 29-30; page 5, lines 11-13), D1 further discloses on page 4, lines 5-6 and claim 9 that "Fractional Flow Reserve (FFR) values may also be calculated and displayed along the vessel". The appellant argued that the resulting "integrated graphical image output" displaying the FFR values along the vessel constituted a visual depiction of the vessel based on a pressure differential (calculated according to feature 4.2), which the respondent contested.

5.3 Regardless of this point of dispute, it is common ground that D1 does not disclose feature 4.3 of claim 1, whereby the computing unit is further configured to "*modify the visual depiction of the vessel to simulate one or more treatment options based on expected results of the one or more treatment options on the pressure differential*". The Board disagrees that the person skilled in the art starting from D1 would implement feature 4.3 and thus arrive at the subject-matter of claim 1 in an obvious manner, even considering D2.

5.3.1 The appellant formulated the objective technical problem to be solved starting from D1 as being to facilitate the selection of a treatment method.

5.3.2 The Board first notes that D1 itself does not suggest that the "integrated graphical image output" may be used to simulate various treatment options. Without hindsight, the person skilled in the art proceeding from D1 alone would not implement feature 4.3 without an inventive step.

5.3.3 Concerning D2, it is true that this document discloses a system for evaluating a vessel that specifically addresses the technical problem above (paragraph [0013]). To this end, the system of E2 generates various displays to enable a user to simulate the placement of a stent in the vessel and to investigate the resulting effects on the vessel flow properties. On that basis, various treatment options can be simulated to determine the most appropriate one.

5.3.4 However, as submitted by the respondent, the system of D2 is entirely based on OCT measurements, i.e. on an imaging technique on the basis of which not only the

morphology of the vessel but also its flow properties are determined and simulated by running a computational fluid dynamics program (paragraphs [0015] and [0121]). Without hindsight, the person skilled in the art would find no incentive in D2 to implement feature 4.3 in the system of D1, in which the vessel flow properties are determined based on pressure measurements and then overlaid on a morphological view of the vessel.

5.3.5 The lumen profiles presented in Figure 25, to which the appellant referred, illustrate the morphology of a vessel, both in an unstented configuration and with various simulated stents implanted. A similar lumen profile for another vessel is shown in the upper part of Figure 23. As such, these profiles obtained from OCT measurements (paragraph [0125]) represent visual depictions of the vessel: however, they are merely based on imaging the vessel and not on its flow properties. Moreover, to simulate the presence of a stent the profiles are only modified based on the stent geometry, namely to reflect how the stent would modify the vessel lumen, and not based on the effects that the stent would have on the vessel flow properties.

Therefore this teaching would not motivate the person skilled in the art starting from D1 to modify the "integrated graphical image output" of D1 to simulate one or more treatment options "based on expected results of the one or more treatment options on the pressure differential", i.e. to implement feature 4.3.

The indication of a VRR value on these profiles, or equivalently the indication of an FFR value as disclosed in paragraphs [0107]-[0110], does not contradict this conclusion. Both parameters VRR and FFR are also calculated from the OCT measurements and

characterise the flow properties of the vessel as a whole. Even bearing such an indication, the lumen profiles of Figures 23 and 25 are thus not a visual depiction of the vessels based on these flow parameters. The teaching in D2 that these values are updated as the stent characteristics are changed by a user (paragraph [0121]) therefore does not point the person skilled in the art towards feature 4.3 either.

5.3.6 The appellant also referred to the lower graph of Figure 23. This graph does show two curves representing the total pressure along the vessel as a function of the distance, for the vessel either unstented or stented.

Even if these curves are regarded as visual depictions of the vessel as argued by the appellant, they are also derived from the OCT measurements and are actually a sub-product of the calculation of VRR (paragraph [0121]); moreover, they show the total pressure and not a pressure differential calculated according to feature 4.2. Thus they cannot point the person skilled in the art towards implementing feature 4.3 in the system of D1 either.

5.3.7 Rather, if the person skilled in the art were to combine D2 with D1 to solve the technical problem above, they would simply adopt the optimisation technique disclosed in D2 as a whole. As this technique is based solely on OCT imaging without necessitating pressure measurements, there would in this case be no reason to implement feature 4.3 in the resulting system. The person skilled in the art would therefore not arrive at the subject-matter of claim 1.

5.4 At least for these reasons, the Board concludes that the subject-matter of claim 1 involves an inventive step starting from D1. Due to this conclusion, there is no need to determine whether D1 discloses features 4 to 4.2.

6. It follows from the above considerations that none of the appellant's objections admitted into the appeal proceedings prejudices maintenance of the patent as granted.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

A. Chavinier-Tomsic C. Schmidt

Decision electronically authenticated