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Datasheet for the decision of 13 October 2022

Case Number: T 0649/20 - 3.3.01

Application Number: 07762319.7

Publication Number: 2035837

IPC: G01N33/86

Language of the proceedings: EN

Title of invention:
PROTOCOL FOR MONITORING DIRECT THROMBIN INHIBITION

Patent Proprietor:
Haemonetics Corporation

Opponent:
Ponti & Partners, S.L.P.

Headword:
Monitoring thrombin inhibition/HAEMONETICS

Relevant legal provisions:
EPC Art. 54(2), 56
RPBA 2020 Art. 12(4), 12(6)

Keyword:
Amendment to case - amendment admitted (no: auxiliary request 3)
Novelty - availability to the public
Inventive step - (no: auxiliary requests 1 and 2)

Decisions cited:
T 0834/09

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Case Number: T 0649/20 - 3.3.01

D E C I S I O N
of Technical Board of Appeal 3.3.01
of 13 October 2022

Appellant: (Patent Proprietor)	Haemonetics Corporation 400 Wood Road Braintree, MA 02184 (US)
Representative:	Strych, Sebastian Mitscherlich PartmbB Patent- und Rechtsanwälte Sonnenstraße 33 80331 München (DE)
Respondent: (Opponent)	Ponti & Partners, S.L.P. C. Consell de Cent, 322 08007 Barcelona (ES)
Representative:	Ponti & Partners, S.L.P C. de Consell de Cent 322 08007 Barcelona (ES)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 3 January 2020 revoking European patent No. 2035837 pursuant to Article 101(3)(b) EPC**

Composition of the Board:

Chairman	J. Molina de Alba
Members:	T. Sommerfeld
	L. Bühler

Summary of Facts and Submissions

I. European patent 2035837 is based on application 07762319.7, which was filed as an international application and published as WO 2007/140250. The patent is entitled "Protocol for monitoring direct thrombin inhibition" and was granted with six claims.

Independent claim 1 as granted reads as follows:

"1. A method of evaluating patient anti-coagulation hemostasis therapy, the method comprising:
testing a first blood sample obtained from a subject to determine a first clot strength related quantitative indication of a first blood sample hemostasis characteristic, the first clot strength related quantitative indication including at least a time to initial clot formation indication, the first blood sample being obtained from the subject prior to in vivo administration of the anti-coagulation hemostasis therapy;
testing a second blood sample obtained from the subject to determine a second clot strength related quantitative indication of a second blood sample haemostasis characteristic, the second clot strength related quantitative indication including at least a time to initial clot formation indication, the second blood sample being obtained from the subject following in vivo administration to the subject of the anti-coagulation hemostasis therapy; and
determining a parameter indicative of the efficacy of the anti-coagulation hemostasis therapy based upon the first and the second quantitative indications, the second quantitative indication demonstrating a

contribution to clot formation delay in comparison to the first quantitative indication,
wherein
the anti-coagulation hemostasis therapy comprises a direct thrombin inhibition therapy and each of the first blood sample and the second blood sample is prepared including in vitro administration of a prothrombin activator, which comprises ecarin."

II. An opposition was filed against the granted patent, the opponent requesting that the patent be revoked in its entirety on the grounds of lack of novelty and inventive step (Articles 54(2) and 56 EPC and Article 100(a) EPC), lack of sufficiency of disclosure (Article 100(b) EPC) and added subject-matter (Article 100(c) EPC). The opposition division first issued a decision in which the opposition was rejected; however, this decision was set aside on appeal by decision T 1333/16 and the case was remitted to the opposition division pursuant to Articles 111(1) and 113(1) EPC.

III. The decision being presently appealed in this case is the opposition division's decision to revoke the patent pursuant to Article 101(3)(b) EPC.

The opposition division decided that the set of claims according to the main request (claims as granted) complied with Article 123(2) EPC but its subject-matter lacked novelty over document D1, which was considered prior art, that the claims of the first auxiliary request complied with Articles 123(2), 83 and 54 EPC but their subject-matter lacked inventive step, and that the claims of the second auxiliary request complied with Article 123(2) EPC but their subject-matter lacked inventive step.

IV. The patent proprietor (appellant) lodged an appeal against that decision. With the statement of grounds of appeal, the appellant requested that the patent be maintained as granted (main request) or, alternatively, according to auxiliary request 1 of 14 February 2017, auxiliary request 2 of 19 September 2019 or auxiliary request 3 filed with the statement of grounds of appeal.

The claims of the **main request** are the claims as granted.

Claim 1 of **auxiliary request 1** differs from claim 1 of the main request by the feature "the method further comprising comparing the first and the second quantitative indications to correlation data and determining a dosing parameter of the anti-coagulation hemostasis therapy in view of the correlation data" having been added.

Claim 1 of **auxiliary request 2** differs from claim 1 of auxiliary request 1 by the features "using a hemostasis analyzer" and "wherein the correlation data is contained in a database included or linked to the hemostasis analyzer" having been added.

Claim 1 of **auxiliary request 3** differs from claim 1 of auxiliary request 2 by the feature "and the rate of clot lysis (LY30)" having been added, as shown:

"1. A method of evaluating patient anti-coagulation hemostasis therapy using a hemostasis analyzer, the method comprising:
testing a first blood sample obtained from a subject to determine a first clot strength related quantitative indication of a first blood sample hemostasis

characteristic, the first clot strength related quantitative indication including at least a time to initial clot formation indication and the rate of clot lysis (LY30), the first blood sample being obtained from the subject prior to in vivo administration of the anti-coagulation hemostasis therapy;
testing a second blood sample obtained from the subject to determine a second clot strength related quantitative indication of a second blood sample haemostasis characteristic, the second clot strength related quantitative indication including at least a time to initial clot formation indication and the rate of clot lysis (LY30), the second blood sample being obtained from the subject following in vivo administration to the subject of the anti-coagulation hemostasis therapy; and ..."

V. In its reply to the statement of grounds of appeal, the opponent (respondent) requested that the appeal be dismissed and that auxiliary request 3 not be admitted. It also submitted a new document, D17.

VI. In a further letter, the appellant requested that document D17 not be admitted.

VII. By letter dated 30 November 2021, the respondent withdrew its request for oral proceedings and announced that it would not be represented at oral proceedings.

VIII. Summons to oral proceedings before the board were issued, followed by a communication pursuant to Article 15(1) RPBA in which the board provided a preliminary opinion concerning issues to be discussed at the oral proceedings.

IX. Oral proceedings before the board took place as scheduled, in the absence of the respondent. At the end of the oral proceedings, the chairman announced the board's decision.

X. The documents cited during the proceedings before the opposition division and the board of appeal include the following:

D1 Carroll R et al. 2006, Anesth. Analg. 102:1316-9
D1a Extract from the homepage of the publication "Anesthesia & Analgesia"
D14 Extract from the medical library database of Leibniz-Informationszentrum Lebenswissenschaften
D15 Email statement by the senior managing editor of the journal Anesthesia & Analgesia
D16 Email statement by the senior publisher at Wolters Kluwer
D17 Printout of the website "journals.lww.com/anesthesia-analgesia/toc/2006/05000"

XI. The appellant's submissions may be summarised as follows:

Main request, novelty

D1 itself only indicated the year of publication, 2006, but otherwise did not indicate a month. Each of the respondent's cited documents provided different alleged publication dates, so this evidence was contradictory and it was not clear when D1 was indeed published. D14 indicated a date on which the journal issue might have been received at the library, but this did not prove that it was also available to the public from that date. D15 and D16 did not help any further because they did not refer specifically to D1, but to the issue of

the journal; moreover, Ms Lynly (D15) and Mr Bowling (D16) had no legal obligation to give a correct, definite answer, and their statements might not have been independent, since it was Ms Lynly who provided Mr Bowling's contact details. While there was no evidence on file that the document was published after the priority date of the patent, the evidence submitted by the respondent did not make it possible to conclude that the document was published before said date, either. It was up to the respondent to provide convincing evidence.

D1 was not novelty-destroying because it did not disclose the feature "determining a parameter indicative of the efficacy of the anti-coagulation hemostasis therapy based upon the first and the second quantitative indications, the second quantitative indication demonstrating a contribution to clot formation delay in comparison to the first quantitative indication". The claim required a parameter to be determined that was derived from the first and second quantitative indications; however, such a parameter was not directly and unambiguously disclosed in D1. Even if Figures 1 and 2 of D1 showed that there was a difference between the clotting time before and after treatment, a parameter based upon the two quantitative indications was still not explicitly or implicitly disclosed in D1.

Auxiliary request 1, inventive step

D1 did not disclose a comparison of the parameter with any correlation data. The information in Figure 2 could not be combined with that in Figure 4; Figure 4 only showed data obtained after treatment, so it only related to the second quantitative indication. D1 at

most suggested using correlation data with regard to the second quantitative indication, but not to the first quantitative indication. Figure 1 also only related to data obtained after treatment. The technical problem was to provide an improved method and the solution was inventive because there was no pointer in D1 towards that solution and no indication of how the dosing parameter should be determined, either.

Auxiliary request 2, inventive step

Again, there was no pointer in D1 towards the added feature and the respondent had not indicated why this feature should be obvious. The added technical feature had an effect in that the method became more efficient; it was not enough that the feature was known for other methods or that it could be introduced even if there was no motivation. The respondent had not proved its allegation, contested by the appellant, that the feature was common general knowledge.

Auxiliary request 3, admission

This request had been filed with the statement of grounds of appeal, and so the respondent had had ample opportunity to comment. It did not unduly complicate the appeal case, as the subject-matter was straightforward. It was a fair attempt to overcome all the objections raised. Since in D1 the focus was on the R value and not on the rate of clot lysis, the claims of this request *prima facie* overcame the objections based on D1. It could not have been filed earlier because it was filed as a response to the opposition division's decision and could only have been formulated once the reasons for the decision were available.

XII. The respondent's arguments may be summarised as follows:

Main request, novelty

There was sufficient evidence on file to prove the publication date of D1, considering the relevant standard of proof, which was the balance of probabilities. From D1a it was apparent that D1 was published in the May 2006 issue of the journal; D14 was evidence that this issue was received twice at a public library on 19 May 2006, and D15 and D16 were statements from the journal's senior editor and publisher, respectively, indicating that the publication date of the relevant issue was 21 April 2006. It could thus be concluded that document D1 was publicly available before the priority date of the patent.

It was undisputed that D1 disclosed all the features of claim 1 with the exception of the feature "determining a parameter indicative of the efficacy of the anti-coagulation hemostasis therapy based upon the first and the second quantitative indications, the second quantitative indication demonstrating a contribution to clot formation delay in comparison to the first quantitative indication". Figure 1 of D1 showed the influence of anti-coagulation therapy on the time to initial clot formation R, and hence a parameter indicative of the efficacy of the anti-coagulation hemostasis therapy based upon the first and second quantitative indications (value R). Furthermore, D1 directly and unambiguously disclosed the use of the R value as the first and second clot strength related quantitative indication. With regard to said feature, Figure 1 of D1 and the disclosure on page 1318, right-hand column, first paragraph, second sentence

corresponded to the disclosure in the patent in suit in paragraph [0064] and Figures 14a and 14b.

Auxiliary request 1, inventive step

If novel at all, the only difference between the claimed subject-matter and D1 was the further method step "comparing the first and the second quantitative indications to correlation data and determining a dosing parameter of the anti-coagulation hemostasis therapy in view of the correlation data". The technical effect would be that the claimed method made it possible to determine a desired dose of an anti-coagulation therapeutic and the objective technical problem could be considered that of providing a method for determining a desired dose of an anti-coagulation therapeutic in view of correlation data. As discussed in D1 itself, individualised dosing could be determined based on a TEG® ECT test (page 1319, left-hand column, lines 4 to 7). In addition, anti-coagulation therapy correlation data were provided in the form of a graph of the linear correlation of TEG clotting time versus plasma bivalirudin levels (Figure 4 of D1). It would thus be obvious to the skilled person that, in order to determine the individualised dosing as disclosed in D1, the first and second quantitative indications (as measured in Figure 2 of D1) would be compared with the correlation data set out in Figure 4, and the dose of bivalirudin would then be adjusted according to the desired clotting time.

Auxiliary request 2, inventive step

The technical effect of the distinguishing feature was that the method according to claim 1 could be automated. Hence, the objective technical problem could

be considered that of providing an automated analysing system for providing a patient-specific anti-coagulation therapy using correlation data. The use of a hemostasis analyzer was already disclosed in D1 (page 1316, left-hand column, paragraph 2, line 1; page 1318, left-hand column, paragraph 1, last sentence) and D1 itself disclosed that individualised dosing could be determined based on a TEG® ECT test (page 1319, left-hand column, lines 4 to 7) and provided correlation data in Figure 4. It would be common general knowledge for the skilled person to store the correlation data from Figure 4 in the form of a database in the hemostasis analyzer system and to use this database for the purpose of the comparison.

Auxiliary request 3, admission

The appellant had introduced a new feature from the description, namely the "rate of clot lysis (LY30)". It was not immediately apparent that said amendment had a basis in the application as filed, in combination with the other features of the claim, or that it did not raise other issues, e.g. issues of clarity. Furthermore, when filing said request, the appellant had not provided any arguments as to why the amendment overcame all the objections raised, instead stating only that the claims of auxiliary request 3 involved an inventive step for the same reasons as for the main request and auxiliary requests 1 and 2. Finally, the appellant had not provided any justification for filing said request at this late stage of the proceedings.

XIII. The appellant requested that the opposition division's decision be set aside and that the patent be maintained as granted (main request) or, alternatively, according to auxiliary request 1 of 14 February 2017, auxiliary

request 2 of 19 September 2019 or auxiliary request 3 filed with the statement of grounds of appeal. It also requested that document D17, filed by the respondent with the reply to the grounds of appeal, not be admitted.

The respondent requested in writing that the appeal be dismissed and that auxiliary request 3 not be admitted.

Reasons for the Decision

1. The appeal is admissible.

2. The oral proceedings before the board took place in the absence of the opponent (respondent), who was duly summoned but decided not to attend.

According to Rule 115(2) EPC, if a party duly summoned to oral proceedings does not appear as summoned, the proceedings may continue without that party. As stipulated by Article 15(3) RPBA, the board is not obliged to delay any step in the proceedings, including its decision, by reason only of the absence at the oral proceedings of any party duly summoned; that party may then be treated as relying on its written case.

3. Admission of document D17

3.1 According to Article 12(2) RPBA, a party's appeal case shall be directed to the requests, facts, objections, arguments and evidence on which the decision under appeal was based. Article 12(4) RPBA gives the board the discretion not to admit an amendment to the party's

case, i.e. any part of a party's appeal case which does not meet the requirements in paragraph 2, unless the party demonstrates that this part was admissibly raised and maintained in the proceedings leading to the decision under appeal. With regard to the admission of requests, facts, objections or evidence which should have been submitted, or which were no longer maintained in the proceedings leading to the decision under appeal, Article 12(6) RPBA stipulates that these should not be admitted unless the circumstances of the appeal case justify their admission.

3.2 Document D17 was filed for the first time by the respondent with the reply to the statement of grounds of appeal. Its admission is thus at the board's discretion, pursuant to Article 12(4) and (6) RPBA.

3.3 In the board's communication pursuant to Article 15(1) RPBA, the board indicated that it was inclined not to admit document D17 into the proceedings and provided reasons for this. The respondent has not made any further submissions as regards the admission of D17. The board thus had no reason to change its preliminary opinion and accordingly decided not to admit D17 into the appeal proceedings; however, in view of the outcome of the appeal, the board sees no need to further substantiate this part of the decision.

4. Status of D1 as prior art

4.1 The patent in suit claims priority from a US patent application filed on 25 May 2006. Document D1 is a scientific article which was published in 2006 in volume 102 of the journal Anesthesia & Analgesia. The exact publication date of D1 is not available in the document itself. As evidence for its publication date

being before the priority date of the patent, the respondent provided the following documents during the opposition proceedings: D1a, D14, D15 and D16.

4.2 D1a is a printout of an online entry entitled "Archive of 2006 Online Issues". The web address is "http://www.anesthesia-analgesia.org/content/by/year/2006". The document lists all 12 monthly issues of the journal. It is apparent that volume 102 includes the May issue, for which the following information is given: "May 1; 102(5): 1304-1600". The May issue was actually the last one of the issues belonging to volume 102 and in view of the page numbers covered by this issue, it clearly included the article corresponding to D1 (pages 1316-1319).

4.3 In addition, D14 is an extract from the public database from the Central Library for Medicine of the Leibniz Life Sciences Information Center (Zentralbibliothek für Medizin des Leibniz-Informationszentrum Lebenswissenschaften), wherein the dates of receipt of subscribed journal issues are listed, i.e. the journal Anesthesia & Analgesia in the present case. On page 4 of the extract, it can be seen that the May 2006 issue of volume 102 of the journal (labelled in D14 as "102.2006,5") was received twice ("2x") by the library on 19 May 2006.

4.4 Finally, documents D15 and D16 are two printouts of email exchanges between the respondent's professional representative Mr Stephan Tatzel and Ms Nancy Lynly (D15) and Mr Kivmars Bowling (D16). The email exchanges consist of enquiries by the above-mentioned professional representative on the publication date of the May 2006, volume 102 issue of the Anesthesia & Analgesia journal and the respective replies by Ms

Lynly, Senior Managing Editor at "Anesthesia & Analgesia", and Mr Bowling, Senior Publisher in the department of Health Learning, Research & Practice at Wolters Kluwer (publisher of the Anesthesia & Analgesia journal). Both Ms Lynly and Mr Bowling indicate the same date, 21 April 2006, as the "official date for public availability of the May 2006 issue" (Ms Lynly) and as the date when the "article went live" (Mr Bowling).

4.5 Accordingly, the board concludes that, although D1 does not feature any publication date other than the year of 2006, there is evidence on file indicating that the issue to which D1 belongs has the date of 1 May 2006 (D1a) and that it had been published on 21 April 2006 (D15 and D16). Moreover, there is evidence that the printed edition of the journal issue was publicly available on 19 May 2022, as this was the date of receipt at one public library (D14). There is no evidence on file contradicting this evidence.

4.6 The board is not persuaded by the appellant's arguments that the evidence on file is contradictory and does not make it possible to clearly establish when D1 was published. The fact that both a senior managing editor and a senior publisher of the journal independently indicate the same date as the date of publication for the issue in question makes it possible to conclude with a high degree of certainty that this is the correct publication date. The board fails to see any good reason to doubt the credibility of Ms Lynly and Mr Bowling, and the appellant has not provided any evidence to support such allegations. Moreover, it is sufficient to establish that the document was available to the public before the priority date in order to conclude that it is prior art. D14 is already

considered to provide sufficient evidence that D1 was in fact publicly available before the priority date. Contrary to the appellant's arguments, it is not relevant whether or not a member of the public indeed had access to it; the librarian that received the issue and registered it in the database from which D14 has been obtained is a member of the public in any case for the purposes of Article 54(2) EPC (see e.g. T 834/09, points 5.1 to 6.3 of the Reasons).

4.7 Document D1 is thus prior art pursuant to Article 54(2) EPC for the claimed subject-matter.

5. Main request, novelty

5.1 Document D1 discloses the measurement of patients' bivalirudin levels by a thrombelastograph ecarin clotting time assay (TEG® ECT); see e.g. the title. It is not disputed that such an assay is used to determine a "clot strength related quantitative indication of a (...) blood sample hemostasis characteristic" as defined in the claim; this is also the assay that is used in the patent (e.g. paragraphs [0027] and [0029]). D1 explicitly states that "The reaction time until detectable clot formation (R) was chosen as the comparative parameter" (page 1318, left-hand column, lines 4 to 6), which is also a feature of the claim. Moreover, D1 discloses measurements of said hemostasis parameters both before and after anti-coagulation hemostasis therapy (see Figures 1 and 2 of D1), as also required in the claim. Finally, D1 discusses Figure 2 as follows (page 1318, right-hand column, lines 1 to 5): "A typical set of patient TEG® tracings before and after bivalirudin treatment is shown in Figure 2. The R value shows the greatest change in response to bivalirudin with smaller reductions in time after the R

point ...". The board thus agrees with the opposition division's conclusions and the respondent's arguments that D1 does disclose the method step of determining a parameter indicative of the efficacy of the anti-coagulation therapy based upon the first and the second quantitative indication.

5.2 For the above reasons, the board disagrees with the appellant's arguments that the feature "determining a parameter indicative of the efficacy of the anti-coagulation hemostasis therapy based upon the first and the second quantitative indications, the second quantitative indication demonstrating a contribution to clot formation delay in comparison to the first quantitative indication" is not directly and unambiguously disclosed in D1, because such a parameter was not implicitly, let alone explicitly, disclosed in D1. As explained above, said parameter is indeed at least implicitly disclosed in D1, even if it is not defined in the same way as in the claim. As argued by the respondent, the passages in D1 disclosing said feature (Figure 1 and page 1318, right-hand column, first paragraph) correspond to the disclosure in the patent in paragraph [0064] and Figures 14a and 14b, which are the passages on which the appellant relies in the context of sufficiency of disclosure (appellant's letter of 7 December 2020, page 3, first paragraph of section 4.2).

5.3 Claim 1 of the main request thus lacks novelty over D1 (Article 54(2) EPC).

6. Auxiliary request 1, novelty and inventive step

6.1 The board agrees with the appellant and the opposition division that the added feature that the method further

comprises "comparing the first and the second quantitative indications to correlation data and determining a dosing parameter of the anti-coagulation hemostasis therapy in view of the correlation data" is not disclosed in document D1. The subject-matter of claim 1 of auxiliary request 1 is thus considered novel over D1 (Article 54(2) EPC).

6.2 According to the opposition division and the respondent, the technical effect linked to said distinguishing feature was that the method made it possible to determine a desired dose of an anti-coagulation therapeutic and the objective technical problem could thus be formulated as that of providing a method for determining a desired dose of an anti-coagulation therapeutic in view of correlation data. The appellant formulated the problem differently, namely as the provision of an improved thromboelastographic method for monitoring anti-coagulation therapy and in particular for determining on a patient specific basis the attainment of therapeutic levels of a direct thrombin inhibitor in whole blood, thereby determining a desired dose of a direct thrombin inhibitor (appellant's letter of 7 December 2020, page 13, fourth paragraph).

6.3 The board fails to see any evidence on file for an improvement to the thromboelastographic method over the method in D1, being that the thromboelastographic method is the same in D1 and in the patent. As argued by the respondent, the added step of comparing the quantitative indications with correlation data makes it possible to determine a dosing parameter, and hence the problem is to be formulated as proposed by the opposition division and the respondent. Although D1 does not specifically teach using correlation data in

order to determine an individual anti-coagulation therapy dosing, it does teach that such individualised dosing could be determined based on the TEG® ECT test (page 1319, left-hand column, lines 4 to 7). This is in fact the aim of D1. Moreover, in Figure 4 of D1 correlation data is provided between plasma bivalirudin levels on the x axis and clotting time (as measured by the TEG® ECT test) on the y axis. Hence, the skilled person would just have to follow the suggestion of D1 and use the correlation data provided in this document in order to arrive at the claimed subject-matter.

6.4 The appellant's argument for non-obviousness was essentially that, at most, document D1 suggested using correlation data as regards the second quantitative indication but not the first quantitative indication, because both Figures 1 and 4 of D1 only related to data obtained after treatment. The board disagrees and notes that Figure 1 in fact relates to clotting time before and after bivalirudin treatment (see legend of the figure). Moreover, it would be obvious to the skilled person that, in order to determine a therapy dosing, the effect of the therapy first has to be established in relation to the absence of therapy. This is also clearly stated in D1 (e.g. page 1318, right-hand column, first paragraph).

6.5 Claim 1 of auxiliary request 1 is thus considered to lack an inventive step (Article 56 EPC).

7. Auxiliary request 2, inventive step

7.1 Two features were added to claim 1 of auxiliary request 2, namely the use of hemostasis analyzer and "wherein the correlation data is contained in a database included or linked to the hemostasis analyzer". The

appellant argued that the claimed subject-matter was inventive because there was no pointer in D1 or in the remaining prior art for the second feature, and the respondent had not provided evidence for its assertion that it was common general knowledge, either.

7.2 As argued by the respondent, the use of a hemostasis analyzer is already disclosed in D1 (page 1316, left-hand column, paragraph 2, line 1, and page 1318, left-hand column, paragraph 1, last sentence). The difference between the claimed subject-matter and the disclosure of D1 is that the correlation data is contained in a database included or linked to the hemostasis analyzer. The technical effect linked to said distinguishing feature is that the method can be automated, and the technical problem is to provide an automated analysing system for providing a patient-specific anti-coagulation therapy using correlation data.

7.3 In view of the information already provided by D1, the skilled person, motivated to automate the method in D1, would just need to use common general knowledge to store the correlation data from Figure 4 in the form of a database in the hemostasis analyzer system and use this database for comparison purposes in the process of determining the anti-coagulation therapy dose.

7.4 With regard to the appellant's argument that there was no pointer to such a feature in D1, and such a feature was not known in connection with a method as claimed, either, the board notes that, as argued by the respondent, such a feature belonged to the common general knowledge and was thus a trivial modification that the skilled person would envisage. The board is not convinced by the appellant's argument, raised for

the first time at oral proceedings, that such a measure would not be part of the common general knowledge, and the board does not agree that evidence is required to demonstrate that it is indeed common general knowledge since the use of a database is notorious knowledge when automating the use of (correlation) data.

7.5 Claim 1 of auxiliary request 2 is considered to lack an inventive step (Article 56 EPC).

8. Auxiliary request 3, admission

8.1 Auxiliary request 3 was filed with the statement of grounds of appeal and thus its admission is at the discretion of the board, pursuant to Article 12(4) and (6) RPBA (see also section 3.1).

8.2 When filing auxiliary request 3 with the statement of grounds of appeal, the appellant did not submit any arguments as to why this request should be admitted. In a subsequent letter, filed in response to the respondent's objection against the admission of auxiliary request 3, the appellant argued that the request could not have been filed earlier because it was filed in direct response to the reasoning of the opposition division's decision. The same argument was also submitted at oral proceedings. At the oral proceedings, the appellant also argued that no complexity had been added to the case and that the claims were filed as a fair attempt to overcome the objections on file.

8.3 As argued by the respondent, auxiliary request 3 contains amendments originating from the description and on which the appellant relies for inventive step. The board fails to see how these amendments constitute

a response to the reasoning of the opposition division's decision; the decision was based on the arguments already on file before the oral proceedings, and there was no unexpected turn of events at the oral proceedings that would justify these amendments being filed in appeal proceedings. Moreover, the appellant failed to indicate which part of the reasoning in the decision caused it to submit this request. Instead, these amendments appear to be another attempt to further distinguish the claimed subject-matter from the prior art by inserting additional features. By choosing not to file such a request at an earlier stage, i.e. during opposition proceedings, the appellant in fact prevented the opposition division from deciding upon such subject-matter. The appellant then filing the request at appeal proceedings is contrary to the purpose of appeal proceedings, which is to review the decision of the department of first instance. Moreover, since the added features come from the description and were not part of the claims as granted, it cannot even be assumed that the opponent or the opposition division has performed any search whatsoever in respect of said features.

8.4 The board thus considers that auxiliary request 3 could and should have been filed earlier, during opposition proceedings, and decides to exercise its discretion under Article 12(6) RPBA not to admit it into appeal proceedings.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

L. Malécot-Grob J. Molina de Alba

Decision electronically authenticated