**Internal distribution code:**

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

# Datasheet for the decision of 1 October 2014

**Case Number:** T 2317/11 - 3.5.05

**Application Number:** 98903798.1

**Publication Number:** 0965095

**IPC:** G06F19/00

**Language of the proceedings:** EN

**Title of invention:**
Method and system for interactive prescription and distribution of drugs in conducting medical studies

**Applicant:**
University of Florida

**Headword:**
Automation of a medical workflow/FLORIDA

**Relevant legal provisions:**
EPC Art. 56
EPC R. 103(1)(a)
RPBA Art. 15(3)

**Keyword:**
Oral proceedings - non-attendance of the party
Inventive step - main and auxiliary request (no)
Reimbursement of appeal fee - (no)

**Decisions cited:**

**Catchword:**

Europäisches Patentamt
European Patent Office
Office européen des brevets

**Beschwerdekammern**
**Boards of Appeal**
**Chambres de recours**

European Patent Office
D-80298 MUNICH
GERMANY
Tel. +49 (0) 89 2399-0
Fax +49 (0) 89 2399-4465

**Case Number: T 2317/11 - 3.5.05**

# D E C I S I O N
# of Technical Board of Appeal 3.5.05
# of 1 October 2014

| | |
|---|---|
| **Appellant:** (Applicant) | University of Florida<br>223 Grinter Hall<br>Gainesville, FL 32611-5500 (US) |
| **Representative:** | Patentanwälte<br>Ruff, Wilhelm, Beier, Dauster & Partner<br>Postfach 10 40 36<br>70035 Stuttgart (DE) |
| **Decision under appeal:** | **Decision of the Examining Division of the European Patent Office posted on 15 June 2011 refusing European patent application No. 98903798.1 pursuant to Article 97(2) EPC.** |

**Composition of the Board:**

| | |
|---|---|
| **Chair** | A. Ritzka |
| **Members:** | K. Bengi-Akyuerek |
| | F. Blumer |

## Summary of Facts and Submissions

I. The appeal is against the decision of the examining division, posted on 15 June 2011, to refuse European patent application No. 98903798.1 on the ground of lack of inventive step (Article 56 EPC), having regard to the disclosure of

D1: M.A. Kelly and J. Oldham: "The Internet and randomised controlled trials", International Journal of Medical Informatics, Elsevier Science, Vol. 47, pp. 91-99, November 1997.

Also, the following article was quoted in the impugned decision as evidence of the actual publication date and content of D1:

D2: T.N. Arvanitis: "Editorial - The Internet in Medicine", International Journal of Medical Informatics, Elsevier Science, Vol. 47, pp. 1-3, November 1997.

II. Notice of appeal was received on 25 August 2011. The appeal fee was paid on the same day. With the statement setting out the grounds of appeal, received on 24 October 2011, the appellant filed a new set of claims as an auxiliary request. It requested that the decision of the examining division be set aside and that a patent be granted on the basis of the claims filed in the first-instance proceedings on 15 April 2011 and underlying the appealed decision, as its main request, or on the basis of the auxiliary request. Furthermore, the appellant requested "to refund the official fee for the appeal" (without giving any reasons for such a refund) and that D1 not be admitted

as a prior-art document into the proceedings.

III. A summons to oral proceedings scheduled for 1 October 2014 was issued on 8 July 2014. In an annex to this summons, the board expressed its preliminary opinion on the appeal pursuant to Article 15(1) RPBA. In particular, it raised objections under Article 56 EPC, mainly having regard to D1, and introduced the following document under Article 114(1) EPC into the appeal proceedings due to its relevance for the assessment of novelty and inventive step:

D4: M.A. Kelly and J. Oldham: "The Internet and randomised controlled trials", Proceedings of the European Congress of the Internet in Medicine MEDNET 96, pp. 1-9, October 1996.

IV. By letter of reply dated 22 August 2014, the appellant informed the board that it would not be attending the scheduled oral proceedings and that it "looked forward to receiving a decision on the merits of this case". No comments were submitted on the substance of the board's communication under Article 15(1) RPBA.

V. Oral proceedings were held as scheduled on 1 October 2014 in the absence of the appellant. The board established from the file that the appellant's final request was that the decision under appeal be set aside and that a patent be granted on the basis of the main request as filed with letter dated 15 April 2011 in the examination proceedings, or, subsidiarily, on the basis of the auxiliary request as filed with the statement setting out the grounds of appeal dated 24 October 2011. Furthermore, it was requested that the "official fee for the appeal" be refunded.

After due deliberation on the basis of the pending requests and the written submissions, the decision of the board was announced at the end of the oral proceedings.

VI. Claim 1 of the **main request** reads as follows:

"A computer system for conducting a clinical study concerning subjects at a plurality of participating sites, said participating sites being remote from a study management site for managing the clinical study, the computer system comprising: a host computer (11) disposed at the study management site and an Internet network server computer (13) disposed at the study management site, and computers (17, 18, 19) disposed at the participating sites, wherein each participating site has a computer (17, 18, 19) for inputting, transmitting and receiving data over the Internet (15), wherein

the host computer (11) includes means for receiving identification, demographic and medical data about the subjects from the Internet network server computer (13), means for randomization of the subjects to respective treatment strategies and means for responding to such randomization with transmission of a proposed drug prescription to the Internet network server computer (13);

the Internet network server computer (13) includes means connected for receiving said identification, demographic and medical data about the subjects from computers (17, 18, 19) at the participating sites over the Internet (15) and means connected for transferring said identification, demographic and medical data about the subjects to said host computer (11), said Internet network server computer (13) thereafter having means for receiving said proposed drug prescription from said

host computer (11) and means for communicating said proposed drug prescription to a respective one of the computers (17, 18, 19) at the participating sites; and

the computers (17, 18, 19) at the participating sites are configured for running a participating site communication program for inputting and encrypting identification, demographic and medical data about the subjects and transmitting said encrypted identification, demographic and medical data about the subjects over the internet (15) to the Internet server computer (13) at the study management site and for receiving from the Internet server computer (13) at the study management site, and displaying, data comprising said proposed drug prescription."

Claim 1 of the **auxiliary request** reads as follows (amendments compared to the main request have been underlined by the board):

"A computer system for conducting a clinical study concerning subjects at a plurality of participating sites, said participating sites being remote from a study management site for managing the clinical study, the computer system comprising: a host computer (11) disposed at the study management site and an Internet network server computer (13) disposed at the study management site, and computers (17, 18, 19) disposed at the participating sites, wherein each participating site has a computer (17, 18, 19) for inputting, transmitting and receiving data over the Internet (15), wherein

the host computer (11) includes means for receiving identification, demographic and medical data about the subjects from the Internet network server computer (13), means for automated randomization of the subjects to respective treatment strategies using a random

number generator and validated random assignment algorithms, and means for responding to such randomization with transmission of a proposed drug prescription to the Internet network server computer (13);

the Internet network server computer (13) includes means connected for receiving said identification, demographic and medical data about the subjects from computers (17, 18, 19) at the participating sites over the Internet (15) and means connected for transferring said identification, demographic and medical data about the subjects to said host computer (11), said Internet network server computer (13) thereafter having means for receiving said proposed drug prescription from said host computer (11) and means for communicating said proposed drug prescription to a respective one of the computers (17, 18, 19) at the participating sites; and

the computers (17, 18, 19) at the participating sites are configured for running a participating site communication program for inputting and encrypting identification, demographic and medical data about the subjects and transmitting said encrypted identification, demographic and medical data about the subjects over the internet (15) to the Internet server computer (13) at the study management site and for receiving from the Internet server computer (13) at the study management site, and displaying, data comprising said proposed drug prescription."

## Reasons for the Decision

1. The appeal is admissible.

2. *Non-attendance of the appellant at oral proceedings*

2.1 The appellant decided not to attend the scheduled oral proceedings before the board (cf. point IV above). Pursuant to 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 who may then be treated as relying only on its written case."

2.2 In the present case, the appellant did not submit any comments in response to the objections raised in the board's communication under Article 15(1) RPBA. The board reconsidered and maintained those objections to the pending requests, and was in a position to take a decision, in the exercise of its discretion according to Article 15(3) RPBA, at the end of the oral proceedings held in the absence of the appellant.

3. MAIN REQUEST

The claims of this request are identical to those underlying the appealed decision.

3.1 Article 52(1) EPC: Novelty and inventive step

In the board's judgment, claim 1 of this request does not meet the requirements of Article 52(1) EPC in conjunction with Article 56 EPC, for the following reasons:

3.1.1 The examining division held that claim 1 did not involve an inventive step having regard to D1 (cf. appealed decision, section 4). As to document D1, the impugned decision stated that D1, even though it had

been published after the priority date of the present application, formed part of the prior art under Article 54(2) EPC. This was demonstrated beyond any reasonable doubt in particular by editorial D2, published by a reliable source of science journals and books, namely Elsevier Science. D2 stated that the content of D1 - apart from possible minor changes due to checks for consistency and presentation style - had been presented by the same authors at the European Congress of the Internet in Medicine (MEDNET 96) which had taken place in October 1996, i.e. before the application's priority date (cf. appealed decision, section 3).

The appellant contended that D1 did not give a true account of the actual content presented at the above congress, essentially since it was not possible to gather more information about the MEDNET 96 congress than that given in the corresponding congress programme (cf. statement setting out the grounds of appeal, section 1).

However, the board retrieved the actual article presented at MEDNET 96 and introduced it into the appeal proceedings as document D4 (cf. point III above). It is immediately apparent from D4 that it was published before the priority date of the present application, i.e. that it constitutes prior art under Article 54(2) EPC, and that its content corresponds exactly to that of D1.

For the sake of simplicity and consistency with the references made in both the impugned decision and the statement setting out the grounds of appeal, the board refers below to D1 rather than to D4 when assessing

novelty and inventive step.

3.1.2 As to the distinguishing features of claim 1 with regard to D1, the appellant argued that D1 failed to disclose any randomisation of the subjects to the respective treatment strategies and means for transmitting identification, demographic and medical data about the subjects over the Internet, since the patient data was not sent via the Internet but in a separate step by secure measures according to the abstract and section 6.1 of D1 (cf. statement setting out the grounds of appeal, section 2.2).

However, the board notes that D1 shows a trial data window comprising trial data fields for identification and medical data (see page 97, e.g. the fields "Surname" and "Obstetric History"), and also teaches that trial data may be obtained via the Internet (see e.g. page 96, left-hand column, penultimate paragraph: "... all trial data whether obtained via the WWW or entered locally resides in the same database"; page 98, left-hand column, last paragraph: "... all trial data will be intercepted by a sniffer ... that monitors or sniffs network traffic ..."). Furthermore, D1 covers two implementation variants, i.e. (i) sending all the required trial data over the Internet in an encrypted form or (ii) sending only the internal hospital unit number over the Internet and sending other identifying patient information later by more secure means (see page 98, left-hand column, last paragraph to page 98, right-hand column, first paragraph), while variant (ii) is the preferred one according to D1. From this the board concludes that D1 anticipates sending identification and medical data about the subjects (i.e. "patients") over the Internet. In addition, the board finds that D1 also anticipates randomisation of

the subjects to the corresponding treatment strategies as claimed (see e.g. page 96, left-hand column, last paragraph: "True Grit ... records trial entry and outcome data as well as providing randomisation ...").

3.1.3 In view of the above, the board agrees with the finding of the decision under appeal that the sole difference between the subject-matter of claim 1 and the disclosure of D1 consists in that, besides identification and medical data, also demographic data about the subjects is sent over the Internet. Hence, the subject-matter of claim 1 of the main request is held to be novel (Article 54 EPC).

3.1.4 The board considers, however, that the above distinguishing feature represents merely the use of additional cognitive data (rather than functional data), which cannot contribute to an inventive step, and that moreover D1 provides clear hints towards using demographic data of the patients (see e.g. page 93, right-hand column, section 3, first paragraph: "... The entry criteria are flexible since the degree of abnormality that would make obstetricians consider delivery will vary with gestational age ..."). In summary, the subject-matter of claim 1 constitutes an obvious Internet-based automation of a clinical study defined by the following workflow:

1) collecting relevant patient data;
2) randomly assigning the respective patients to different treatment types;
3) proposing a drug prescription for the patients based on the corresponding treatment type.

Therefore, and additionally taking into account that the appellant has provided no further arguments or

evidence in reply to the board's negative opinion expressed in its communication under Article 15(1) RPBA (cf. point IV above), the board has no reason to challenge the examining division's assessment of novelty and inventive step with regard to claim 1.

3.1.5 As a consequence, the subject-matter of claim 1 of this request lacks an inventive step.

3.2 In conclusion, the main request is not allowable under Article 56 EPC.

4. AUXILIARY REQUEST

Claim 1 of this request differs from claim 1 of the main request basically in that it further specifies that

A) an automated randomisation using a random number generator and validated random assignment algorithms is performed (emphasis added).

Feature A) is supported e.g. by page 8, last paragraph of the application as filed.

4.1 Article 52(1) EPC: Novelty and inventive step

4.1.1 The observations made in points 3.1.2 to 3.1.4 above with regard to claim 1 of the main request apply *mutatis mutandis* to claim 1 of the auxiliary request.

4.1.2 Moreover, the board holds that D1 (at least) implicitly discloses added feature A), since a randomisation via Randomised Controlled Trials (RCT) according to D1 (see e.g. D1, section 1) inevitably requires a random number generator and some pre-defined patient/treatment

assignment algorithms as claimed. For these reasons, the subject-matter of claim 1 of this auxiliary request also lacks an inventive step.

4.2 In conclusion, the auxiliary request is likewise not allowable under Article 56 EPC.

5. *Request for reimbursement of the appeal fee*

The board understands the appellant's request "to refund the official fee for the appeal" (cf. point II above) to be a request for reimbursement of the appeal fee pursuant to Rule 103 EPC. Since, however, the appeal is not considered allowable for the grounds given above, reimbursement of the appeal fee must be refused under Rule 103(1)(a) EPC for that reason alone.

Furthermore, the corresponding request has not been substantiated in the statement setting out the grounds of appeal. Nor is it apparent to the board that any procedural violation, let alone a *substantial* one, occurred in the first-instance proceedings.

**Order**

**For these reasons it is decided that:**

1. The appeal is dismissed.

2. The request for reimbursement of the appeal fee is refused.

The Registrar: The Chair:

B. ter Heijden A. Ritzka

Decision electronically authenticated