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Datasheet for the decision of 2 June 2015

Case Number: T 2187/10 - 3.5.06

Application Number: 02801707.7

Publication Number: 1436699

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Language of the proceedings: EN

Title of invention:
DIGITAL MEDIUM ENHANCED IMAGE-GUIDED PROCEDURE SYSTEM AND METHOD

Applicant:
Z-Kat Inc.

Headword:
IMAGE-GUIDED PROCEDURE/Z-KAT

Relevant legal provisions:
EPC Art. 53(c)
EPC 1973 Art. 56

Keyword:
Exceptions to patentability - method for treatment by surgery
Inventive step - (no)

Decisions cited:
G 0001/07, G 0001/04, T 0641/00

Catchword:

Beschwerdekammern
Boards of Appeal
Chambres de recours

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Case Number: T 2187/10 - 3.5.06

D E C I S I O N
of Technical Board of Appeal 3.5.06
of 2 June 2015

Appellant: (Applicant)	Z-Kat Inc. 2903 Simms Street Hollywood, FL 33020 (US)
Representative:	Gasquet, Denis CABINET GASQUET Les Pléiades 24C Park-Nord Annecy 74370 Metz Tessy (FR)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 23 June 2010 refusing European patent application No. 02801707.7 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman	W. Sekretaruk
Members:	A. Teale
	M. Müller

Summary of Facts and Submissions

I. This is an appeal against the decision, dispatched with reasons on 23 June 2010, to refuse European patent application No. 02 801 707.7 *inter alia* on the basis that the subject-matter of claim 1 according to the main and first and second auxiliary requests did not involve an inventive step, Article 56 EPC, in view of D1 and that the independent method claim according to the main and first auxiliary requests was not allowable under Article 53(c) EPC, because it set out a method for treatment of the human or animal body by surgery. This document is as follows:

D1: EP 0 119 886 A1.

II. A notice of appeal was received on 19 August 2010, the appeal fee being paid on the same day.

III. In a statement of grounds of appeal, received on 23 October 2010, the appellant requested "to consider the request made in the time", "to reconsider the rejection for non inventive step" and "to declare that the invention as asserted is inventive, contrary to what was pronounced during the examination". The board considers that the appellant is implicitly requesting that the decision be set aside.

IV. In an annex to a summons to oral proceedings the board set out its preliminary view *inter alia* that the application seemed not to comply with Articles 53(c) (exceptions to patentability), 84 (clarity) and 56 EPC (inventive step). In considering inventive step, the board took into account not only D1 but also the prior

art acknowledged in the application and the combination of the two.

V. No amendments or substantive arguments were received in reply to the board's preliminary opinion. Instead the appellant stated, in a letter received on 31 May 2015, that it would not be attending the oral proceedings.

VI. Oral proceedings were held on 2 June 2015 in the absence of the appellant, at the end of which the board announced its decision.

VII. The application is being considered in the following form:

Description (all requests):
pages 1, 2 and 5 to 10, as originally filed,
pages 3, 3a and 4, received on 22 July 2008,
pages 4a and 4b, received on 4 May 2006.

Claims:
Main request: 1 to 20, received on 4 May 2010.
First auxiliary request: 1 to 20, received on 4 May 2010.
Second auxiliary request: 1 to 10, received on 10 June 2010.

Drawings (all requests):
Sheets 1/3 to 3/3, as originally filed.

VIII. The claims according to the main request comprise an independent apparatus claim 1 and an independent method claim 15, the latter reading as follows (emphasis by the board):

"A method of implementing a computer-implemented procedure, the method comprising: inserting with a media drive (52) of a computer (10) a one-time-use digital medium (50) containing high level graphics processing software (72) with algorithms for graphics processes that are specific to a selected surgical procedure {p. 8, l. 15-20} wherein the high level graphics processing software interacts with low level graphics processing software (60) to enable the computer (10) to perform image and graphics processing which it may be called on to perform during a surgical procedure {p. 8, l. 21-26}; **performing the surgical procedure**; after the procedure, erasing, encrypting or deforming the digital medium against reuse in the computer (10) {p. 3, l. 30-32; p. 9, l. 31-36}."

IX. The claims according to the first auxiliary request comprise an independent apparatus claim 1 and an independent method claim 16, the latter reading as follows (emphasis by the board):

"A method of implementing an image guided surgery procedure {p. 1, l. 2-3; p. 2, l. 21-23}, the method comprising: providing a one-time-use digital medium (50) containing high level graphics processing software (72) which interacts with low level graphics processing software to enable the computer to perform image and graphics processing during the surgical procedure {p. 8, l. 22-26}; inserting the digital medium (50) into a media drive (52) of a computer (10){p.7, l. 24-25}; **performing the surgical procedure**; after the surgical procedure, erasing, encrypting, or deforming the digital medium against reuse {p. 9, l. 31-36}."

X. The claims according to the second auxiliary request comprise a single independent claim 1 which reads as follows:

"An apparatus having a human-viewable display (14), and a computer (10) for displaying and manipulating images on the display, characterized by: a one-time-use digital medium (50) containing high level graphics processing software (72) with algorithms for graphics processes that are specific to a selected surgical procedure {p. 8, l. 15-20} wherein the high level graphics processing software interacts with low level graphics processing software (60) to enable the computer (10) to perform image and graphics processing which it may be called on to perform during a surgical procedure {p. 8, l. 21-26}; and, a means (80) to insure one-time-use of the digital medium (50), wherein the means (80) erases or encrypts all or part of the digital medium, or physically deforms the physical medium to prevent reuse {p. 4, l. 1-2; p. 9, l. 29-35} at the end of the surgical procedure

- a software-integrated disposable kit (20) including:
- the digital medium (50) {p. 7, l. 22-23}; and,
- tools (30, 34) corresponding to the surgical procedure, the tools being instrumented (32) to be tracked {p. 6, l. 6-7, 10-11}.
- the computer having an interface (70) which interfaces with cameras (16) of a tracking system (p. 8, l. 9-13}. the computer (10) including: a drive (52) which receives the digital medium (50) {p. 5, l. 32-33; p. 7, l. 24-25}."

Reasons for the Decision

1. The admissibility of the appeal

1.1 The notice of appeal did not give the address of the appellant, contrary to Rule 99(1)(a) in conjunction with Rule 41(2)(c) EPC. In a communication dated 10 March 2011 the registry invited the appellant to remedy this deficiency within two months of notification. On 14 March 2011, within the time limit, the appellant provided its address, overcoming the deficiency.

1.2 Hence the board finds that the appeal complies with the admissibility criteria under the EPC, in particular Rule 99(1)(a) EPC, and is thus admissible.

2. Technical summary of the invention

2.1 The application relates to an apparatus (all three requests) and a method (main and first auxiliary requests) for carrying out an "image guided" surgical procedure, for instance neurosurgical or orthopedic procedures, on humans and animals; see page 1, lines 2 to 10. The images result from processing imaging data of a patient using MRI (Magnetic Resonance Imaging) or CT (Computer Tomography) together with anatomical reference markers to yield three-dimensional guidance within the imaged region, for instance orthogonal views and slices; see page 1, lines 11 to 21. Surgical tools are also provided with markers so that, during the surgical procedure, a tracking system (acoustic, infrared or video camera) can determine their location. This allows the position of a tool or probe relative to obscured portions of the patient's anatomy to be determined.

2.2 According to figures 1 and 3, the system includes a computer 10 which can be upgraded with a single-use digital medium 50 containing software which allows the system to carry out a preselected surgical procedure only once. As set out in the claims, the software is disabled from being used to upgrade the computer software after the preselected procedure by erasing or encrypting all or part of the medium or by physically deforming the medium itself; see page 9, line 29, to page 10, line 4. The medium may be provided as part of a kit also containing *inter alia* sterile surgical tools; see figure 2. This approach is said to offer the advantages *inter alia* of reducing the initial cost of the equipment, because a new single-use kit must be bought for each subsequent surgical procedure (see page 10, lines 5 to 13).

2.3 Figure 1 shows a computer mounted in a mobile cart 12 having a display 14 and being linked to two tracking system cameras 16. The software-integrated disposable kit shown in figure 2 comprises the presterilized and individually wrapped tools instrumented with markers 32 (see drill guides 26, 28 and probes 30) necessary for performing a specific surgical procedure. The kit also includes a digital medium 50, such as a diskette, CD-ROM or DVD, for insertion into the drive 52 of the computer; see figures 1 and 3. As shown in figure 3, the software on the medium 50 comprises software which, in conjunction with software already present in the computer, is necessary for the surgical procedure. In particular, the medium contains high level graphics processing software 72 with algorithms for graphics processes specific to the surgical procedure and which interacts with low level graphics processing software already in the computer; see page 8, lines 17 to 26.

3. The main and first auxiliary requests, Article 53 EPC

3.1 According to the reasons for the appealed decision, the independent method claims according to the main and first auxiliary requests were not allowable under Article 53(c) EPC which states that methods for treatment of the human or animal body by surgery were not patentable.

3.2 This has not been disputed by the appellant in the grounds of appeal. For this reason, the board considers that it is not obliged to consider, of its own motion, the substantive merits of the appeal as regards the main request and the auxiliary request on this point. However, it chooses to give its view on the issue nonetheless.

3.3 Under Article 53(c) EPC, European patents shall not be granted in respect of "methods for treatment of the human or animal body by surgery ..., this provision shall not apply to products ... for use in any of these methods". In decision G1/07 (OJ EPO 2011, 134) the Enlarged Board of Appeal upheld the principle confirmed in opinion G1/04 (OJ EPO 2006, 334) that a method claim falls under the prohibition in Article 53(c) EPC *inter alia* if it comprises at least one feature defining a physical activity or action that constitutes a method step for treatment of a human or animal body by surgery; see Case Law of the BOA of the EPO, 7th edition, I.B.4.3.1.

3.4 In the present case, independent method claims 15 and 16 according to the main and first auxiliary request, respectively, set out the step of "performing the

surgical procedure" which, understood in the light of page 1, lines 3 to 5, of the description, which mentions "neurosurgical and orthopedic procedures", is a method step for treatment of a human or animal body by surgery. Hence the board agrees with the finding in the decision that the subject-matter of these claims is unpatentable, Article 53(c) EPC.

4. The second auxiliary request

4.1 Clarity, Article 84 EPC 1973

4.1.1 In the annex to the summons to oral proceedings the board expressed doubts regarding the clarity of claim 1. Firstly, the meaning of the term in the claim "integrated" in the expression "software-integrated ... kit" seemed unclear. In view of figure 2 and page 7, lines 22 to 24, it seemed that the kit 20 contained a digital medium 50 comprising the software, no further "integration" of the software and the kit being disclosed. Hence the board understood the expression "software-integrated ... kit" to mean a kit comprising software. Secondly, the expression in the claim "algorithms for graphics processes that are specific to a selected surgical procedure" seemed unclear, since the algorithms in the apparatus were being defined by a non-specified surgical procedure.

4.1.2 The appellant has not commented on these issues. The board takes the view that claim 1 is nevertheless sufficiently clear, understood in the context of the application, for the purposes of assessing inventive step.

4.2 Document D1

4.2.1 D1 relates to preventing software from being loaded onto more than one computer; see figure 1, page 2, lines 10 to 34, and page 8, line 34, to page 10, line 29. According to page 3, lines 15 to 18, the software can be the indispensable software required to use the computer (logiciel de base). Software stored on a "mother diskette" (disquette mère) is not assigned to a specific machine and is in a non-standard format which cannot be copied by standard methods. The software is then transferred using special software (see page 6, lines 1 to 10) from the mother diskette to a "daughter diskette" (disquette fille) of a computer, which may be a hard drive (see page 5, lines 36 to 38), in a form which is assigned to a specific computer, meaning that it can only be executed on that computer; see page 7, lines 16 to 19. After the transfer, the mother diskette is reset (remise à zero) so that it cannot be used to create another daughter diskette for another computer; see page 6, lines 22 to 24. D1 mentions displaying information when it is turned on, implying a display and graphics processing software; see page 7, lines 5 to 9.

4.2.2 The appellant has argued that D1, instead of disclosing the means for insuring one-time-use set out in the claims, discloses means for preventing the same software copy from being loaded onto several computers and executed simultaneously. In the application "single use" meant "single surgery", after which the software was made unusable by erasing or encrypting the software or by deforming the medium. In D1 however unlimited use could be made of the software on the computer on which it was loaded. The board accepts the appellant's point

that in D1 the software installed in the computer can be used an unlimited number of times, however, contrary to the appellant's argument, the resetting of the mother diskette after the software has been installed on the daughter diskette does, as far as the mother diskette is concerned, fall under the expression in claim 1 "means to ensure one-time-use of the digital medium, wherein the means erases ... all ... of the digital medium ... to prevent reuse".

4.2.3 It is true that, as the appellant has argued, D1 does not disclose the software being used for a single surgical procedure which includes a surgical kit including the tools, hardware and software needed to perform the surgical procedure only once with surgical tools for the surgical procedure. This is common ground between the decision, the appellant and the board.

4.2.4 In terms of claim 1, D1 discloses an apparatus having a human-viewable display (see page 7, lines 7 to 9) and a computer (figure 1; M1), for displaying and manipulating images on the display, the computer including a drive which receives a one-time-use digital medium (diskette mère DM) and the computer comprising means to insure one-time-use of the digital medium by erasing all of the digital medium.

4.3 The prior art acknowledged in the application

4.3.1 According to page 1, line 11, to page 3, line 20, it was known in the prior art to use MRI and CT systems to make images of a region of a patient in which surgery was planned and to use software to manipulate these images to yield orthogonal views, slices and perspective renderings which were displayed to provide three-dimensional guidance within the imaged region.

The board takes the view that the mention of the use of software implies a computer. The region of the patient was imaged together with anatomical reference markers. At the surgical site, video cameras were used to track the location of surgical tools instrumented with similar markers to determine their location relative to obscured portions of the patient's anatomy. In the board's view, this implies a human-viewable display. As different surgical tools were required for operations on different portions of the human anatomy, the tools were calibrated to the system to establish their dimensions. The surgical tools were reusable. Universal image guided surgery systems were known which were applicable to any portion of the human anatomy and included software for imaging and alignment in virtually any region of the human anatomy. Such systems were prohibitively expensive for most customers.

4.3.2 In terms of claim 1, the acknowledged prior art discloses an apparatus having a human-viewable display and a computer for displaying and manipulating images on the display using high level graphics processing software which interacts with low level graphics processing software to enable the computer to perform image and graphics processing which it may be called on to perform during a surgical procedure, the high level graphics processing software being stored on a digital medium and the computer having an interface which interfaces with cameras of a tracking system.

4.4 Inventive step, Article 56 EPC 1973

4.4.1 According to the appealed decision, the apparatus according to claim 1 lacked inventive step in view of the method for protecting software distributed by a supplier known from D1. D1 was seen as implicitly

disclosing a computer with a human-viewable display for displaying and manipulating images, a media drive and high- and low-level graphics processing software. The "mother diskette" (disquette mère) disclosed in D1 (page 2, lines 20 to 29) was seen as falling under the claimed "one-time-use digital medium". The reference in D1 to resetting the mother diskette was seen as falling under the claimed erasure of all or part of the digital medium. According to the decision, claim 1 differed from the disclosure of D1 in that the high level graphics software in the apparatus had algorithms for graphics processing "specific to a selected surgical procedure" which it could be "called on to perform during a surgical procedure" and the means to ensure a one-time-use of the digital medium erased/decrypted/ deformed "at the end of the surgical procedure", a "software-integrated disposable kit" comprising "tools corresponding to the surgical procedure", the tools being "instrumented to be tracked", the "computer having an interface which interfaces with cameras of a tracking system". The problem to be solved was seen as protecting software stored on a medium that is to be sold to doctors performing surgical procedures, while providing them with the necessary surgical tools, said tools being tracked by a camera. The subject-matter of claim 1 did not involve an inventive step because "the use of image-guided system in the field of surgery having such 'high level graphics software', even if said software is incorporated in such a kit, belongs to the common general knowledge in said technical field". Moreover the difference features over D1 were an aggregation of features lacking a synergistic effect and erasing, encrypting or deforming the digital medium at the end of the surgical procedure did not solve a technical problem, the skilled person knowing how to implement this feature at any other point in time.

4.4.2 In view of the analysis of D1 set out above, the board finds that the disclosure of D1 is less relevant to the subject-matter of claim 1 than was argued in the decision. The subject-matter of claim 1 differs from the disclosure of D1 in that the digital medium contains high level graphics processing software with algorithms for graphics processes that are specific to a selected surgical procedure, wherein the high level graphics processing software interacts with low level graphics processing software to enable the computer to perform image and graphics processing which it may be called on to perform during a surgical procedure, erasure of the medium occurring at the end of the surgical procedure, the apparatus also comprising a software-integrated disposable kit including the digital medium and tools corresponding to the surgical procedure, the tools being instrumented to be tracked, the computer having an interface which interfaces with cameras of a tracking system.

4.4.3 Hence the board disagrees with the finding in the decision that the one-time-use digital medium known from D1 contains high level graphics processing software. Already for this reason the board disagrees with the reasons given in the appealed decision for the finding that the subject-matter of claim 1 does not involve an inventive step in view of D1.

4.4.4 The board also does not accept the assertion in the decision, unsupported by any evidence, that "the use of image-guided system in the field of surgery having such 'high level graphics software', even if said software is incorporated in such a kit, belongs to the common general knowledge in said technical field". Although it seems that the acknowledged prior art discloses the use

of image-guided systems in the field of surgery having high level graphics software, this does not necessarily mean that this subject-matter was common general knowledge.

4.4.5 In view of these differences, the board considers it more appropriate to start the assessment of inventive step not from D1 but from the prior art acknowledged in the application.

4.4.6 The subject-matter of claim 1 differs from the acknowledged prior art in:

i. the computer including a drive which receives the digital medium;

ii. the high level graphics processing software having algorithms for graphics processes that are specific to a selected surgical procedure;

iii. a means to insure one-time-use of the digital medium, by erasing or encrypting all or part of the digital medium or physically deforming the physical medium, at the end of the surgical procedure;

iv. a disposable kit including the digital medium and

v. the kit also containing tools corresponding to the surgical procedure, the tools being instrumented to be tracked.

4.4.7 The difference features address different problems and their contributions to inventive step will be considered separately. Regarding difference feature "i", the skilled person would add a drive to a computer

as a matter of usual design. In this case, difference features "i" and "iii" limit the graphics processes of the apparatus to one use only. This is an obvious technical solution to a business problem, namely that derivable from page 4, lines 3 to 4, to reduce the capital cost of the apparatus by also charging the user a fee per surgical procedure carried out using the apparatus. This, following the approach in T 641/00 ("COMVIK", OJ EPO 2003, 352), is the aim to be achieved in a non-technical field. The claimed solution to this problem according to difference feature "iii" is known from D1, which discloses the "erasing" approach to ensuring one-time-use of a digital medium. The skilled person, given the above aim to be achieved, would apply the teaching of D1 as a matter of design.

4.4.8 Difference feature "ii" restricts the graphics processes of the apparatus to those which are specific to a selected surgical procedure. This does not solve a technical problem and thus cannot contribute to inventive step.

4.4.9 Difference feature "iv" addresses the packaging of the digital medium, a usual design consideration.

4.4.10 Difference feature "v" is not limited to providing new surgical tools or to the tools being sterilized and thus cannot solve the problems of avoiding the use of blunted tools or assuring the sterility of surgical tools. Moreover the application acknowledges surgical tools which are instrumented to be tracked as *per se* belonging to the prior art. The bundling of such tools with the software as a kit is seen as solving the business problem of increasing the value of the kit that has to be bought for each surgical procedure, this being an aim to be achieved in a non-technical field

(see T 641/00, cited above). As no technical problem is solved by this feature, it cannot contribute to inventive step.

4.4.11 Hence the board finds that the subject-matter of claim 1 does not involve an inventive step, Article 56 EPC 1973, in view of the prior art acknowledged in the application combined with the disclosure of D1.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

B. Atienza Vivancos W. Sekretaruk

Decision electronically authenticated