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D E C I S I O N
of 28 September 2004

Case Number: T 0906/01 - 3.2.2

Application Number: 91111328.0

Publication Number: 0468264

IPC: A61B 17/58

Language of the proceedings: EN

Title of invention:
Spinal column retaining apparatus

Patentee:
DePuy Spine, Inc.

Opponent:
Sofamor Danek Group, Inc.

Headword:
-

Relevant legal provisions:
EPC Art. 54(2), 56
EPC R. 55(c)

Keyword:
"Alleged prior use not made available to the public"
"Prima facie assumption to confidentiality"

Decisions cited:
T 0328/87, T 0109/91, T 0818/93, T 0152/03

Catchword:
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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0906/01 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 28 September 2004

Appellant: (Opponent)
Sofamor, Danek Group, Inc.
1800 Pyramid Place
Memphis
Tennessee 38132 (US)

Representative:
Croston David
Withers & Rogers
Goldings House
2 Hays Lane
London SE1 2HW (GB)

Respondent: (Proprietor of the patent)
DePuy Spine, Inc.
325 Paramount Drive
Raynham
MA 02767-0350 (US)

Representative:
Mercer, Christopher Paul
Carpmaels & Ransford
43, Bloomsbury Square
London WC1A 2RA (GB)

Decision under appeal:
Decision of the Opposition Division of the European Patent Office posted 20 March 2001 rejecting the opposition filed against European patent No. 0468264 pursuant to Article 102(2) EPC.

Composition of the Board:

Chairman: T. K. H. Kriner
Members: M. G. Noël
E. J. Dufrasne

Summary of Facts and Submissions

I. Following an opposition filed by the appellant (opponent) against European patent No. 0 468 264, the opposition division decided on 20 March 2001 to reject the opposition and to maintain the patent as granted.

In the decision, the opposition division held that the grounds for opposition cited by the appellant (Article 100(a), (b) EPC) did not prejudice the maintenance of the patent as granted.

II. The appellant lodged an appeal, received at the EPO on 17 May 2001, against the first instance's decision. The appeal fee was paid simultaneously and the statement setting out the grounds of appeal was filed on 27 July 2001.

III. Oral proceedings were held on 28 September 2004, at the end of which the requests of the parties were as follows:

The appellant requested that the decision under appeal be set aside and that the European patent No. 0468264 be revoked.

The respondent requested that the appeal be dismissed and that the patent be maintained.

IV. Documents referred to in the present decision:

D2: "Introducing the Isola Spinal System", AcroMed Corporation brochure, Copyright 1990 (sheet LT403).

D7: Transcript of the videotape deposition of Dr Thomas Flatley, 23 August 1994.

D11: US-A-4854311

D13: Signed original declaration of William R. Christianson of 12 January 1999, with Exhibit A containing three investigator's agreements between AcroMed Corporation and the medical doctors Samuel Chewning, Thomas Flatley and Marc Asher, respectively.

D15: "The Process of FDA Approval of a Spinal Implant: Governmental Perspective" by Thomas J. Callahan, Journal of Spinal Disorders, Vol. 2, 1989, No. 4, pp 288-291.

D17: Declaration of Dr Thomas Flatley dated 5 June 1997.

D19: AcroMed Isola and Kaneda Spinal Implant System-Manual, dated 1/91.

D21: Guidance Document for the Preparation of IDEs for Spinal Systems, pages 1 to 30, issued on 13 January 2000.

V. The parties argued as follows:

(i) the appellant (opponent)

In the present case where practically all the evidence in support of the alleged prior use of the Isola Spinal

System during the surgery conducted by Dr Flatley on 10 July 1989 at the Sinai Samaritan Medical Centre in Milwaukee (US) laid within the power and knowledge of the patent proprietor and the opponent had no access to it, the opponent could not prove his case up to the hilt. Therefore, the burden of proof had to be transferred to the patent proprietor. Otherwise, the case should be dealt with on the balance of probabilities, taking with caution the assertions made by the proprietor.

Only the Investigator's Agreement (D13) between AcroMed Corporation and Dr T. Flatley imposed to both parties some kind of confidentiality with respect to the information concerning the Isola Spinal System. But all other persons involved in the surgery conducted by Dr Flatley were not hold to secrecy.

The facts were that a spinal fixation device was shipped by the proprietor (AcroMed) to the hospital (purchaser) which owed no duty of confidence to the proprietor. This device, which was readily ascertainable from a visual inspection, was then prepared for implantation by the hospital staff who, in its turn, had no duty of confidence to the proprietor. Thus, the assertions of the proprietor of implied obligation of confidence were unsubstantiated in the absence of any evidence in this respect.

In particular the patient was not placed under any obligation of confidence since the Food and Drug Administration (FDA) regulations in relation to investigational device exemptions (IDE) made it clear (D21) that the participation of the patient was

voluntary and that he could refuse to participate any longer at any time without penalty. Also the existence of an investigational status in relation to the device did not carry with it an implied obligation of confidence, the more since the device might comprise known components. Only express agreements as to confidentiality would have created such an obligation.

The prior use of the Isola Spinal System during the surgery on 10 July 1989, therefore, made the system available to the public.

Since the Isola Spinal System comprised all features of the granted claim 1, the subject-matter of the patent in suit lacked novelty.

(ii) the respondent (patent proprietor)

In the present case like in T 152/03 there was a *prima facie* assumption that any person involved in a medical process was obliged to confidentiality, given the need for patient confidentiality and the need to protect the development and testing of prototype devices. Therefore, any evidence proving the contrary was important and had to be produced as soon as possible. In the absence of such evidence, the *prima facie* assumption was not controverted.

Moreover, the patent proprietor should be given the benefit of the doubt, if the parties made contrary assertions which could not be substantiated by any of them. Since the proprietor already filed all evidence in its possession and knowledge, the availability to

the public of the alleged prior use had to be established on the balance of probabilities.

In the process of approval of the spinal implant device by the FDA (D15) it was the responsibility of the investigator (AcroMed) to follow the IDE regulations and to keep the device under control. But since Dr Flatley entered a confidentiality agreement with AcroMed (D13) and was in charge of the operation on 10 July 1989, his obligation of confidentiality was implicitly and necessarily transmitted to the hospital team and the equipment involved in the clinical tests. The proprietor was not aware of the measures taken by the hospital to preserve secrecy. As to the patient, he was bound to confidentiality through his relationship with Dr Flatley. Furthermore, the device was implanted under the skin and, therefore, not accessible for visual inspection. Although the patient had the possibility to refuse to continue with the experience at any time, this eventuality was hardly credible.

Therefore, the use of the Isola Spinal System during the surgery of Dr Flatley could not be regarded as a public prior use.

Reasons for the Decision

1. The appeal is admissible.

2. *Documents*

D2: The mention "copyright 1990" on the last sheet (LT 403) is not sufficient alone to establish with

certainty that this document was published before the priority date (24 July 1990) of the contested patent. This document, therefore, is not considered as prior art by the Board.

D19: This manual is dated 1/91, i.e. published after the priority date of the present patent. Moreover, though reference is made in section IX-1 (Outcome) to an IDE clinical trial that began 26 April 1989, it cannot be established that the operation conducted by Dr Flatley on 10 July 1989 was performed using components identical to the components described in this post-dated manual. Therefore, this document is also not considered by the Board.

D21: This document was issued on 13 January 2000, i.e. also after the priority date of the present patent. The mention on the first page that this document supersedes a previous version dated 1998 does not render the present version relevant. An older version should have been provided, instead. Therefore, the Board does not consider this document, either.

3. *Availability of the alleged prior use*

3.1 As stated for example in decision T 328/87, OJ 1992, 701, Headnote I and section 3.3, where there are allegations of public prior use, the requirements of Rule 55(c) EPC are satisfied if the following items can be determined:

(i) the date on which the alleged use occurred

(ii) what has been used (the object of the prior use)

(iii) all the circumstances relating to the use, by which it was made available to the public, as for example the place and the form of use.

3.2 With respect the first two items, the alleged public prior use in the present case refers to a surgery conducted by Dr Flatley on 10 July 1989 at the Sinai Samaritan Medical Centre in Milwaukee, Visconsin (US), and concerns the implantation of a correction device (Isola Spinal System) into a patient. The Isola Spinal System is a temporary internal fixation device comprising slotted connectors, pedicle screws and spinal rods. The use of slotted connectors enables lateral adjustability to attach the rods to the screws. Pedicle screws are, according to Dr Flatley, screws of the type having something like a wood screw on one side, a machine screw on the other side and an integral nut in between (cf. D7, from page 27, line 25 to page 28, line 9).

However, there remains some doubt as to the system which was really implanted since, further according to Dr Flatley (D7, page 34, lines 7 to 20) slotted connectors were not used with pedicle screws in this surgery but with iliac screws.

3.3 As to the circumstances (third item) it results from the different allegations and depositions presently on file that the surgery by Dr Flatley was part of an investigation conducted by AcroMed Corporation. To this end (see D17), Dr Flatley entered into an

investigator's agreement produced as Exhibit A with the declaration of W.R. Christianson (Vice President of Clinical and Regulatory Affairs for AcroMed Corp.) dated 12 January 1999 (D13). The understanding of Dr Flatley was that the Isola System was investigational (D7, pages 30, 33, 36) and part of a research project at the time as he used it in that surgery. The patient was also advised of these facts and the surgery was not open to the public. The communications between the patient and Dr Flatley as well as the records regarding the surgery were confidential.

3.4 These statements are confirmed by the declaration of W.R. Christianson (D13) stating that on 27 June 1988 AcroMed submitted to the FDA an application for conducting Investigational Device Exemption (IDE) studies of its Isola Spinal System, labelled for pedicle fixation, in order to obtain approval to conduct clinical trials as to the desired stability and alignment of the system. On 24 March 1989 the FDA notified AcroMed that the application was provisionally approved and that an investigation could be conducted at certain approved investigating sites, of which the Sinai Samarital Hospital in Milwaukee. Dr Flatley was selected to participate in the IDE clinical study of the Isola System according to the Investigator's Agreement with AcroMed (D13).

In this Agreement Dr Flatley agreed, *inter alia*:

(I) to conduct the clinical investigation of the Isola Spine System sponsored by AcroMed Corporation;

(X) to inform the patient that the System was being used for clinical investigations; and

(XII) to consider as confidential any knowledge of product development and marketing information and not to disclose any information known to him by virtue of his participation in this study, provided identification by AcroMed, in writing, of that information which was considered proprietary and confidential.

Christianson added that finally AcroMed did not obtain approval from the FDA to commercially distribute the device and, therefore, did not commercialize the investigational components of the Isola System.

3.5 In the present case the Board considers that a device having an investigational status, being implanted and tested within the restricted area of an hospital, under the responsibility of a surgeon operating within the frame of an investigator's agreement provided with a clause of confidentiality, must be regarded as a prototype device. Usually the development and testing phases of such products or devices are necessarily surrounded by secrecy as long as said products or devices have not been approved and commercialized (see a nearly similar situation in T 818/93, point 4.1, unpublished). Therefore, even without the production of more specific evidence on behalf of the respondent, the Board is of the opinion that the clinical tests performed on the Isola Spinal System under the conduct and responsibility of Dr Flatley conferred to the overall operation an implicit obligation of confidentiality which had to be extended to the whole

team involved in said operation. Therefore neither the fact that the Isola Spinal System was received and prepared by hospital staff, not the fact that it was visible for the hospital staff during the operation, is suitable to prove that the Isola Spinal System was accessible to the public. Furthermore, it has to be assumed that the operating room was not accessible for other person than the operation team, and that the device was implanted at least partly under the patient's skin and, therefore, not immediately visible from the outside.

Neither did the appellant provide in this respect any evidence of the contrary, e.g. that some components of the spinal system had been disclosed by the hospital staff or by any person approaching the patient by way of a testimony or any other way.

The Board, therefore, follows the same reasoning as in case T 152/03, point 3,4, not published, that in this field there is a *prima facie* assumption that any person involved in a medical process is obliged to confidentiality, given the need for patient confidentiality and the need to protect the development and testing of prototype devices, and that any evidence proving the contrary is important and must be produced as soon as possible.

3.6 The Board is also aware (e.g. T 109/91, point 2.10, unpublished or T 818/93 supra), that the burden of proof is originally on the opponent to show that the implant system used during the operation was made available to the public and that the burden of proof

may be shifted constantly as a function of the weight of evidence.

In the present case the arguments and evidence provided by the proprietor did convince the Board that the implant was actually not made available by any of the events surrounding the investigation process.

More specifically, Dr Flatley had access to the Isola implants only by virtue of his being a member of the Isola investigational team. This membership placed him under an implicit obligation of confidentiality. Dr Flatley's participation was therefore confined to a clinical trial of the implant for the purpose of testing the equipment and reporting the results to AcroMed, in a collaborative research and development process. All these activities are by nature confidential and do not make the technical information concerned available to the public. The implant was purchased at a discount price by the hospital clearly for evaluation and testing purposes, which placed also the personal involved in the investigational team under an implied obligation of confidentiality by way of a binding effect. It is very likely that Dr Flatley informed the hospital staff as well as the patient of the confidential nature of the investigations being undertaken, so that all these persons cannot be regarded as members of the public. On the patient's side, the device was implanted and hidden under its skin and so remained confidential until it was explanted and analysed. However, there is no evidence that such analysis occurred in situ or otherwise.

The Board having been convinced, as demonstrated above, that in the present case an implicit obligation of confidentiality resulted from the circumstances, the onus for proving the contrary was shifted again on the opponent's side and, therefore, laid with the appellant. However the appellant failed to file any further evidence or convincing counter-argument that the Isola Spinal System was made available to a person other than the persons involved in the investigational process.

3.7 Therefore, in the Board's judgement, the alleged prior use of the Isola Spinal System during the surgery of Dr Flatley was not made available to the public and is not state of the art within the meaning of Article 54(2) EPC.

4. *Inventive step*

At the oral proceedings the appellant stated that he had no further submissions or comments to present with respect to the issue of inventive step. As a consequence he continued to adhere to his written submissions, in which the inventive step was always contested on the basis of the alleged prior use in combination with document D11. The allegations presented by the appellant are, therefore, aimless. Since the Board does not see from its own any lack of inventive step vis-à-vis the remaining prior art documents, it must be concluded that the claimed subject-matter involves an inventive step within the meaning of Article 56 EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

V. Commare T. Kriner