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Datasheet for the decision of 27 March 2012

Case Number: T 2093/09 - 3.2.08

Application Number: 03754476.4

Publication Number: 1539269

IPC: A61L 31/02, C61L 31/18

Language of the proceedings: EN

Title of invention:
Stents comprising a molybdenum/rhenium alloy

Patentee:
Boston Scientific Limited

Opponent:
ICON Interventional Systems, Inc.

Headword:
-

Relevant legal provisions:
EPC Art. 56

Keyword:
"Inventive step (no) - main and first auxiliary request"
"Inventive step (yes) - second auxiliary request"

Decisions cited:
-

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 2093/09 - 3.2.08

D E C I S I O N
of the Technical Board of Appeal 3.2.08
of 27 March 2012

Appellant: (Opponent)
ICON Interventional Systems, Inc.
387 Technology Circle NW, suite 500
Atlanta, GA 30313 (US)

Representative:
Goddar, Heinz J.
Forrester & Boehmert
Pettenkoferstrasse 20-22
D-80336 München (DE)

Respondent: (Patent Proprietor)
Boston Scientific Limited
The Corporate Centre
Bush Hill
Bay Street
St. Michael
Barbados, West Indies (BB)

Representative:
Peterreins, Frank
Fish & Richardson P.C.
Highlight Business Towers
Mies-van-der-Rohe-Strasse 8
D-80807 München (DE)

Decision under appeal:
Decision of the Opposition Division of the European Patent Office posted 18 August 2009 rejecting the opposition filed against European patent No. 1539269 pursuant to Article 101(2), 2nd sentence EPC.

Composition of the Board:

Chairman: T. Kriner
Members: R. Ries
A. Pignatelli

Summary of Facts and Submissions

I. By its decision posted on 18 August 2009 the opposition division rejected the opposition against European Patent No. 1 539 269.

II. The appellant (opponent) lodged an appeal against this decision on 20 October 2009, paying the appeal fee on the same day. The statement setting out the grounds of appeal was received on 18 December 2009.

III. In an official communication, the Board gave its provisional view on the case, in particular with respect to the documents

D7: US-A-5 843 172, and

D11: Metals Handbook, Desk Edition, edited by J.R. Davis, second edition, ASM International, Materials Park, OH 44073-0002, 1998, ISBN 0-87170-654-7, pages 629 to 631.

Moreover the parties essentially referred to documents

D1: WO-A-95/30384, and

D4: US-A-4 990 138.

IV. Oral proceedings took place before the Board on 27 March 2012. The following requests were made:

The appellant requested that the decision under appeal be set aside and that the patent be revoked.

The respondent (patent proprietor) requested that the appeal be dismissed (main request) or, alternatively, that the patent be maintained according to claims 1 to 11 filed as auxiliary request III on 29 May 2009, now the first auxiliary request, or to claims 1 to 8 according to the second auxiliary request filed during the oral proceedings.

Auxiliary requests I, II, IV and V filed on 29 May 2009 were withdrawn.

V. Claim 1 of the patent as granted reads as follows:

"A stent (10) comprising a tubular member comprising a molybdenum/rhenium alloy, wherein the molybdenum/rhenium alloy includes between 10 % and 70 % molybdenum by weight and between 35 % and 55 % rhenium by weight."

Claim 1 of the first auxiliary request reads (amendments over claim 1 as granted in bold):

"A stent (10) comprising a tubular member comprising a molybdenum/rhenium alloy, wherein the molybdenum/rhenium alloy includes between **50**% and **60**% molybdenum by weight and between **40**% and **50**% rhenium by weight."

Claim 1 of the second auxiliary reads (amendments over claim 1 of the patent as granted in bold):

"A stent (10) comprising a tubular member comprising a molybdenum/rhenium alloy, wherein the molybdenum/rhenium alloy includes between 10 % and 70%

molybdenum by weight and between 35 % and 55 % rhenium by weight**, and wherein the tubular member comprises a first portion (28) comprising the molybdenum/rhenium alloy and a second portion (30) comprising a material selected from the group of stainless steel and nickel titanium alloy.**"

VI. The appellant's arguments can be summarized as follows:

A stent manufactured from a Mo-Re alloy was already known from document D7, which represented the closest prior art. Since good radiopacity, superior strength and a high elastic modulus etc. were inherent properties of Mo-Re alloy stents, these objects addressed in the patent in issue were already achieved by the known stent. Mo and Re were known in the medical industry as being radiopaque substances, as shown in document D4, claims 15 and 26. However, document D7 was silent on a specific composition. The objective technical problem when putting into practice the teaching of D7 thus merely resided in selecting a suitable binary Mo-Re alloy for the stent disclosed in this document. Since this problem was concerned with the selection of an appropriate metal material, the person to solve it was skilled in the field of materials science and in particular of metal alloys. The person skilled in metal materials would take into account document D11, which in Table 1 disclosed the most common molybdenum-rhenium alloys Mo-5Re, Mo-41Re and Mo-47.5Re. At least the latter two compositions fell within the ranges claimed for the Mo-Re alloy featuring in all requests. Given that both alloys showed favourable mechanical properties and good working properties at high and low temperatures, the

teaching of D11 would have prompted the skilled person to select e.g. Mo-47.5Re or Mo-41Re as an appropriate material for the Mo-Re stent disclosed in D7. The subject matter of claim 1 of the patent as granted and of the first auxiliary request was therefore obvious from the technical teaching of D7 in combination with the skilled person's basic technical knowledge, as given in document D11.

Claim 1 of the second auxiliary request related to a stent comprising a first portion composed of the claimed Mo-Re alloy and second portion composed of stainless steel or nickel-titanium alloy. As set out in the list of suitable metals in document D7, column 4, lines 32 to 37, the metal stent material member could be made of, inter alia, stainless steel, nickel-titanium alloy, platinum-iridium alloy, molybdenum-rhenium alloy, gold, magnesium, and also combinations thereof. According to the embodiment of D7, given in column 2, lines 47 and 48, the known stent received a coating on its surface. Stents composed of first and second portions were therefore known from D7. Selecting a stent comprising a first portion composed of Mo-Re alloy and second portion composed of stainless steel or nickel-titanium alloy, respectively, did not involve an inventive step since stents composed of different materials were already described in D7, and since the selection of an alloy according to claim 1 of the second auxiliary request was suggested by document D11.

VII. The respondent's arguments are summarized as follows:

Contrary to the appellant's position, document D7 did not qualify as the closest prior art since it did not

address the same problem as that underlying the patent in suit, i.e. the provision of a stent having a substantially enhanced radiopacity without adversely affecting the favourable mechanical properties. This problem was amply dealt with in document D1, page 2, lines 21 to 23 and, in one embodiment, solved by a W-Re alloy. Therefore, document D1 represented the closest prior art.

By contrast, document D7 was concerned with a stent coated with a drug-eluting coating for delivering a therapeutic agent. In the list of various other metals and alloys in column 4, lines 32 to 37, document D7 mentioned inter alia a Mo-Re alloy without however giving a specific Mo-Re alloy composition. Furthermore, D7 did not describe any properties of the Mo-Re alloy, let alone the topic of radiopacity, the improvement of which was one of the main problems to be solved by the patent (the patent specification column 1, lines 51 to 54). Given that the object of D7 differed fundamentally from that addressed in the patent, the skilled person would not have chosen D7 as a starting point, and even if he had, no reason or hint was given in this document prompting him to turn to the Mo-Re alloy featuring in the list with many other different materials given in D7, column 4, lines 32 to 38. Only by an inadmissible *ex-post facto* consideration could one argue that the skilled person would have picked the Mo-Re alloys out of the list of metal materials mentioned in D7.

Even when starting from document D1 or D7, the skilled person would not take into consideration document D11, since this document was concerned with refractory metals, which were used in a totally different

technical field. Due to their exceptional high-temperature properties including an extremely high melting point and very low vapour pressures, refractory metals and their alloys found application in the aerospace, electronics, nuclear and high-energy physics and chemical-process industries. D11 did not contain any hint that the Mo-Re alloys listed in Table 1 on page 630 could be used for any medical application, let alone as a base material for medical stents. Finally, even when combining D1 or D7 and D11, the skilled person had no reason just to pick a Mo-Re alloy having a rhenium content of 41 wt% or 47.5 wt%, opposed to a Mo-Re alloy comprising only 5% Re also mentioned in the list. Only by an *ex-post facto* analysis could it be argued that the skilled person would select a Mo-50%Re alloy for producing medical stents. The subject matter of claim 1 of the patent as granted and of the first auxiliary request thus involved an inventive step.

This was all the more true for claim 1 of the second auxiliary request, which was concerned with a two-part stent, a first portion being composed of the claimed Mo-Re alloy and a second portion consisting of stainless steel or nickel-titanium alloy, respectively. Even if D7 listed, amongst others, these metal materials individually and also possible combinations thereof, a multiple selection was necessary to arrive at the claimed stent design. The stent featuring in claim 1 of the second auxiliary request therefore also involved an inventive step.

Reasons for the Decision

1. The appeal is admissible.

2. The closest prior art

The determination of the disclosure which is nearest to the claimed invention and which therefore presents the most promising springboard for its development is essential to the assessment of inventive step.

According to the established jurisprudence of the Boards of Appeal, that disclosure qualifies as the closest prior art which relates to the same purpose as the claimed invention and has the most relevant technical features in common with it. In practice, the closest prior art is generally that which corresponds to a similar use and requires the minimum structural and functional modifications to arrive at the claimed invention.

Contrary to the respondent's position, these criteria apply to document D7 which discloses, as one embodiment, a medical stent which consists of molybdenum-rhenium alloys as a metal suitable for that purpose and which furthermore corresponds to the Mo-Re metal alloy stent claimed in the patent (D7, column 4, lines 32 to 37). The only feature missing in D7 is a specific composition of the Mo-Re alloy.

By contrast, one embodiment of the stents disclosed in D1 describes a stent core consisting of a tungsten-rhenium alloy including 5 to 40% Re rather than a Mo-Re alloy (D1, page 16, lines 13 to 15, claim 9). Although

a range for rhenium is given, the stent in D1 is manufactured from a different basic metal material and exhibits a rhenium content lower than that claimed in the patent.

The respondent argued that, like the patent at issue, D1 addressed the problem of enhancing the stent's visibility by increasing its radiopacity. Contrary thereto, document D7 was totally silent on the problem of radiopacity but was concerned rather with providing a drug-eluting stent having porous cavities on its surface so that drugs could be loaded directly into the pores. Hence, D7 could not serve as the starting point for a person skilled in the art faced with the problem of enhancing the stent's radiopacity.

The Board does not agree. It is undisputed that medical stents consisting of Mo-Re alloys are known in the art, e.g. from D7. Consequently, document D7 does not require a structural modification by selection of a different metal alloy in order for the subject-matter of claim 1 to be arrived at. To the skilled person, Mo-Re alloys are known per se to exhibit a combination of inherent physical and chemical properties such as a high density, melting point, tensile strength, modulus of elasticity, and also a specific linear attenuation coefficient which is the parameter to describe the alloy's inherent physical property of radiopacity. The problem of providing a stent with a good radiopacity, addressed in paragraph [0007] of the patent, is therefore already solved by the stent of D7 in that it consists of a Mo-Re alloy. In that respect, the problem underlying the patent at issue is of minor importance, contrary to the respondent's position.

Starting from D1, at least two structural modifications are required in order to arrive at the claimed stent, namely the W-Re alloy must replaced by another metal material and, in addition thereto, a suitable composition must be selected. Despite the fact that D1 actually mentions the problem of improving the stent's radiopacity, the teaching of this document requires more structural modifications compared to that given in document D7 for the claimed subject matter to be arrived at. Consequently D1 is rated as being more remote than D7 and, therefore, document D7 is regarded as representing the closest prior art.

3. The problem to be solved; main and first auxiliary requests

3.1 The subject-matter of claim 1 of the main request differs from D7 in that the claimed Mo-Re alloy comprises 35 to 55% Re. Starting from the teaching of document D7, the objective problem underlying the patent at issue therefore resides in selecting for the Mo-Re alloy a percentage of rhenium that suits the claimed purpose. As already mentioned in D7, column 4, lines 29 to 31, the selection of an appropriate metal composition should be carried out by the person skilled in the technical field of metal materials and metals fabrication.

3.2 Inventive step

Given this situation, the skilled person, taking into account his general technical knowledge as represented by the Metals Handbook D11, would at least in a first

step consider the most common Mo-Re alloys containing 5% Re, 41% Re and 50% Re (nominal composition 47.5% Re) disclosed in D11, Table 1. In a second step, the skilled person would carry out some routine experiments in order to test which of the known materials suits the required needs. It is true, as pointed out by the respondent, that the Mo-Re alloys given in D11 are generally used in high-temperature oxidising aerospace structural parts or have found application in electronics, nuclear and high-energy physics, and chemical-process industries and are therefore entitled "refractory metals". Contrary to the respondent's view, however, the different technical field in which the refractory alloys and specifically the Mo-Re alloys are used, would not deter the skilled person from turning to the most common Mo-Re alloys listed in Table 1 of D11 since he is already aware from the teaching in document D7 that Mo-Re alloys are suitable for the claimed purpose of producing medical stents.

As regards the Mo-Re alloy's chemistry, according to the patent application as originally filed, page 3, lines 16 to 23 and claim 1, every Mo-Re alloy, irrespective of its composition satisfies the required needs and is, therefore, suitable for producing the claimed stent. Moreover, the original application mentions on page 3, lines 18 to 23 that the Mo-Re alloy tubing, sheet, foil and wire are commercially available from a supplier. It is noted in this context that the composition of the preferred Mo-Re alloy of Mo-47.5% Re mentioned in this passage exactly corresponds to one of the three most common materials listed in D11. This fact supports the Board's assessment given in the previous paragraph that, for putting into practice the

teaching of D7, one of the most common commercially available Mo-Re alloys has been selected in the patent at issue. Doing this does not involve an inventive step. The respondent's argument the combination of the technical teaching of D7 with the skilled person's basic knowledge as represented by D11 was based on hindsight is therefore not justified.

The stent set out in claim 1 of the patent as granted and of the first auxiliary request comprises 35 to 55% Re, but the patent specification neither shows a particular reason as to why the limits for the rhenium range are critical with respect to radiopacity and are therefore preferred, nor attributes to that range a technical advantage or effect to be achieved by strictly adhering to the claimed ranges. This all goes to show that the ranges for the Mo-Re alloys featuring in claim 1 of the main request and the first auxiliary are not associated with a specific technical effect, but have been selected arbitrarily rather than on purpose.

The subject matter of claim 1 of the main request and of the first auxiliary request therefore does not involve an inventive step.

4. Second auxiliary request

4.1 Amendments, Article 123(2) EPC

Claim 1 of the second auxiliary request results from a combination of claims 4, 5, 8 and 9 as originally filed. Dependent claims 2 to 8 correspond to originally filed claims 6, 12 to 17, respectively. The description has

been suitably adapted to the wording of the revised claims. Hence, there are no formal objections under Article 123(2) EPC. The amendments were not objected to by the appellant at the oral proceedings.

4.2 Novelty

Claim 1 of the second auxiliary request is directed to a tubular member which is composed of one portion comprising a Mo-Re alloy and a second portion selected from stainless steel or a nickel-titanium alloy, respectively. None of the cited documents discloses such a composite medical stent. The subject matter of claim 1 is therefore novel. Besides, novelty was not disputed by the appellant at the oral proceedings.

4.3 Inventive step

As to inventive step, the appellant's main argument was based on D7, column 4, lines 32 to 38 which also disclosed combinations of suitable metal materials such as steel, tantalum, nickel-titanium alloy, platinum-iridium alloy, molybdenum-rhenium alloy, gold and magnesium. In the appellant's view, it was therefore obvious for a skilled person to combine the individual materials listed in D7 to design the composite medical stent set out in claim 1 of the second auxiliary request. The appellant further pointed to D7, column 2, lines 32 to 36 disclosing an embodiment of the known stent made up of a solid structure-reinforcing core and a porous outer section sintered to the surface of the non-porous metal wire core and suitable for absorbing drugs for delivery. From this point of view, a composite stent comprising different portions to

provide different properties was close at hand for a person skilled in the art

The Board cannot agree with the appellant's position. It is not disputed that D7 discloses a composite stent comprising two portions, one made of a non-porous wire material and the second porous outer section serving to absorb a therapeutic agent. However, D7 does not provide the skilled reader with further information about the specific metal materials that the first and second portions are made of. Although the list given in D7, column 4, lines 32 to 37 includes Mo-Re alloys, stainless steel and nickel-titanium alloys of the claimed stent as individual materials, no pointer exists anywhere in this document that would prompt the skilled person to select the claimed composite stent including a Mo-Re first portion and a second portion composed of stainless steel or nickel-titanium alloy, let alone for the purpose described in the patent in suit. As set out on page 5, first paragraph of the application as filed, the two sections cooperate to provide the claimed stent with a good combination of properties because it includes portions which exhibit an enhanced radiopacity and are balloon-expandable and other portions which are self-expanding. Therefore, only on the basis of hindsight could such a combination of metal materials be selected to form a composite stent.

4.4 Given this situation, the subject matter of claim 1 of the second auxiliary involves an inventive step.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the department of first instance department with the order to maintain the patent on the basis of the following documents:

Description: columns 1 to 4 filed at the oral proceedings before the Board;

Claims: 1 to 8 according auxiliary request II filed at the oral proceedings before the Board;

Figures: 1 to 5 as granted.

The Registrar: The Chairman:

V. Commare T. Kriner