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**Datasheet for the decision  
of 14 April 2010**

**Case Number:** T 0708/07 - 3.2.02

**Application Number:** 99952949.8

**Publication Number:** 1049421

**IPC:** A61F 2/06

**Language of the proceedings:** EN

**Title of invention:**

Longitudinally flexible expandable stent

**Patentee:**

Boston Scientific Limited

**Opponent:**

MEDINOL LTD.

**Headword:**

-

**Relevant legal provisions:**

EPC Art. 123(2), 54(3)

**Relevant legal provisions (EPC 1973):**

EPC Art. 54(1)(2), 107

**Keyword:**

"Admissibility of appeal (yes)"

"Extended subject-matter (no)"

"Novelty (yes)"

**Decisions cited:**

G 0001/88, G 0004/95, T 0260/85, T 0331/87, T 0857/91

**Catchword:**

-



Case Number: T 0708/07 - 3.2.02

**D E C I S I O N**  
**of the Technical Board of Appeal 3.2.02**  
**of 14 April 2010**

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**Decision under appeal:** **Interlocutory decision of the Opposition  
Division of the European Patent Office posted  
5 March 2007 concerning maintenance of European  
patent No. 1049421 in amended form.**

**Composition of the Board:**

**Chairman:** M. Noël  
**Members:** C. Körber  
J. Geschwind

## Summary of Facts and Submissions

I. By interlocutory decision posted on 5 March 2007 the Opposition Division decided to maintain European patent No. 1049421 in amended form.

II. Appeals were lodged against this decision by both the patentee (appellant 1) and the opponent (appellant 2), by notices received on 27 April 2007 and 14 May 2007, respectively. The appeal fees were paid on the same respective days. The statements setting out the grounds of appeal were received on 16 July 2007 and 13 July 2007, respectively.

III. Oral proceedings were held on 14 April 2010, at the end of which appellant 1 requested that the decision under appeal be set aside and that the patent be maintained unamended or in the alternative in amended form according to auxiliary request 1 or 2 filed with letter of 13 December 2006. Appellant 2 requested that the decision be set aside and that the patent be revoked.

IV. The following documents are of importance for the present decision:

D5: US-A-4994071

D6: EP-A-0540290

D7: US-A-5158548

D9: WO-A-9915108.

V. Claim 1 of the patent as granted (main request) reads:

"A stent comprising a plurality of serpentine bands, adjacent serpentine bands being connected (192) one to

the other, characterized in that the serpentine bands include larger serpentine bands (132) and smaller serpentine bands (120), the larger serpentine bands of larger wavelength and amplitude than the smaller serpentine bands, the larger and smaller serpentine bands alternating with one another over the length of the stent."

VI. The arguments of appellant 1 can be summarized as follows:

As to be seen from the minutes of the oral proceedings held in opposition, appellant 2 did not argue with respect to auxiliary request 2 and thus fully prevailed in the first instance. He was thus not entitled to appeal the decision of the Opposition Division to maintain the patent in amended form according to this request.

The request submitted by appellant 2 to allow Mr. J. Richter to speak during the oral proceedings should be denied since it did not fulfil the criteria set forth in G 4/95. If Mr. J. Richter were nevertheless allowed to speak, it was requested that the first-named inventor of the patent in suit, Mr. B. Brown, also be allowed to speak.

The coloured illustrations based on a finite element analysis (FEA) submitted by appellant 2 with letter of 15 March 2010 should be excluded from the proceedings as they were not presented in good time before the oral proceedings to allow their verification.

The replacement of "interconnecting elements" in claims 1 and 25 as originally filed by the term "connected" according to claim 1 as granted did not violate Article 123(2) EPC. This amendment was generally supported by various passages of the "Summary of the Invention" and self-supporting passages specifically describing preferred embodiments. It corresponded to the first one of the alternatives described in the sentence bridging pages 2 and 3 to accomplish the goal of the invention. The use of the definite article "the" before "interconnecting elements" in line 1 of page 3 related to those interconnecting elements previously mentioned at page 2 in reference to the background of the invention, and not to the first alternative.

This amendment was also allowable because the criteria of the essentiality test in T 331/87 were met. The interconnecting elements were not consistently presented as essential to the invention (criterion (i)). They were not indispensable either for the function of the invention (criterion (ii)) since the problem of improving the flexibility of the stent (page 2, lines 20 to 32) was not limited to avoiding pinching or overlap between adjacent bands. Moreover, mitigation of this latter drawback, at least to a certain extent, was in fact achieved by the stent according to claim 1 as granted. Crimping the stent onto a balloon was not the subject of the patent in suit and the possible difficulties resulting therefrom raised by appellant 2 were therefore irrelevant. Reducing to zero the length of the oblique interconnecting elements shown in Figure 2 was at least theoretically possible and would not result in a

radically altered stent design, as argued by appellant 2. Consequently, the replacement of the "interconnecting elements" by their function also satisfied criterion (iii).

The expression "serpentine bands" was sufficiently supported by page 7, lines 28 to 29, and page 8, lines 1 to 3. The broader terms "having a generally serpentine configuration" and "band-like elements" also comprised the more specific terms "serpentine" and "band", which could thus be used in claim 1 without violating Article 123(2) EPC.

A basis for the feature of the larger and smaller serpentine bands "alternating with one another over the length of the stent" in claim 1 as granted could be found, for example, at page 3, lines 26 to 27, page 8, lines 13 to 14, and in Figures 2 and 3.

The longitudinal segments 14 of D9 consisted of a plurality of laterally interconnected closed cells 13 which lacked flexibility. This drawback was avoided in the patent in suit by the serpentine bands yielding an open structure. Moreover, determining from D9 the amplitude and wavelength relationships between the bands would require taking measurements from the entirely schematic drawings, which was not allowable. Finally, none of the three interpretations of the longitudinal segments 14 attempted by appellant 2 would result in serpentine bands "alternating with one another" as defined by granted claim 1.

D5 was not novelty-destroying since determining the amplitude and wavelength relationship would also

require taking measurements from the schematic drawings. Moreover, D5 failed to disclose bands "alternating with one another".

Document D6 only showed serpentine bands of identical wavelength and amplitude. The general statement that the wavelength or amplitude may be varied was not sufficient to anticipate the subject-matter of claim 1 in suit.

The stent 14 depicted in Figures 11 to 15 of D7 had an open reticulated structure including an array of diamond shaped apertures 32. It failed to disclose any kind of serpentine bands. The interpretation of Figure 11 of this document as submitted by appellant 2 with letter of 13 July 2007 (page 5) represented a misconstruction.

VII. The arguments of appellant 2 can be summarized as follows:

The fact that no arguments were presented with respect to auxiliary request 2 during the oral proceedings in opposition did not imply that the main request for revocation of the patent in its entirety was withdrawn.

Mr. J. Richter could shed important light on how changes in the structure of stents may affect their function in the vessel and he was offered as an expert. It was requested that he be allowed to speak at the oral proceedings, accordingly.

Claim 1 as granted violated Article 123(2) EPC due to the deletion of the feature "interconnecting elements"

from original independent claims 1 and 25. This feature was also present in all the original drawings and there was no statement in the description that it was only optional or preferred. The fact that some passages did not explicitly refer to the interconnecting elements did not imply that they were not needed. The use of the definite article "the" before "interconnecting members" in line 1 of page 3 of the application as filed was a clear indication of the essential character of this feature and the absolute necessity of its presence in claim 1. This became clear from page 3, lines 5 et seq. and 15 et seq. as well.

Moreover, the removal of this feature from claim 1 was not allowable according to the essentiality test developed in T 331/87. It was explicitly stated in the description (e.g. on page 8, lines 19 to 20, and page 17, lines 17 to 19) that one or more interconnecting elements were required, these being thus described as essential to the invention (criterion (i)). Moreover, they were indispensable to the function of the invention (criterion (ii)) since the object of avoiding pinching and overlapping between adjacent bands could not be achieved without them as no other mechanism was taught in order to solve this problem. Particularly when a stent as claimed was crimped onto a balloon, as was necessary for all balloon expandable stents, such pinching and overlapping would lead to balloon burst during expansion, and thus to potentially fatal consequences for the patient, who would then require emergency open heart surgery. Finally, the removal of the interconnecting elements resulted in a completely different stent design, which would contravene both the drawings and description of the



patent in suit. Reducing the length of the interconnecting members in Figure 2 to zero, as suggested by appellant 1, would change the phase relationship between adjacent bands such that they would be aligned, with an exact alignment between the larger and smaller serpentine bands repeating along the stent and with the larger serpentine bands all being in phase. This would result in a radically altered stent such that criterion (iii) was not fulfilled either. The limitation of the original disclosure to stents having interconnecting elements was also derivable from the arguments of appellant 1 presented in parallel opposition proceedings with regard to EP 01975572.3.

The replacement of the term "undulating band-like elements" by "serpentine bands" in granted claim 1 was not supported as such by the application as originally filed, which thus also violated Article 123(2) EPC. Undulations had a distinct wavelength while serpentines were made up by windings having different widths. Moreover, both terms "serpentine" and "bands" used in claim 1 as granted were more specific than the broader terms "having a generally serpentine configuration" and "band-like elements" used in the application as originally filed.

The term "alternating with one another" introduced in claim 1 as granted was more specific than the term "alternate" used in the description. Moreover, this feature could not be extracted in isolation from the embodiment shown in Figures 2 and 3, which also comprised interconnecting elements in combination. This constituted an unallowable generalisation contrary to Article 123(2) EPC.

Document D9 was novelty-destroying for claim 1 as granted. The stent shown in Figures 38, 42 and 43 comprised a plurality of interconnected serpentine bands 21 of smaller wavelength and amplitude and serpentine bands 14 of larger wavelength and amplitudes. With respect to the larger serpentine bands, three different interpretations of this feature according to the drawings were possible, either regarding the whole segment 14 or one or both of the serpentine bands comprised therein as corresponding to the "larger serpentine bands" defined in claim 1.

Figure 1 of D5 showed a bifurcating stent wherein the serpentine bands 12 in the right portion thereof to be inserted into a large vessel had a larger wavelength and amplitude than the bands 12' and 12" in the left portions to be inserted into the smaller vessel branches, thus anticipating claim 1 as granted.

In view of the statement in the third paragraph of column 6 of D6 that the amplitudes and wavelengths of the undulating pattern could be chosen to fill particular requirements, the stent shown in Figures 4, 5 and 11 was also novelty-destroying.

Based on the interpretation of Figure 11 of D7 shown on page 5 of the statement of the grounds of appeal dated 13 July 2007, the stent 14 disclosed in D7 was prejudicial to the novelty of claim 1 as granted.

## Reasons for the Decision

### 1. Admissibility of the appeals

The appeals are admissible. The fact that appellant 2 refrained from arguing on auxiliary request 2, as indicated under point 6.2 of the minutes of the oral proceedings held before the Opposition Division, does not imply that he withdrew his request for revocation of the patent in its entirety. Otherwise, this would have been tantamount to surrender of his right to appeal, which cannot be simply presumed but requires an express statement (cf. G 1/88, point 2 of the reasons). From the appealed decision (point I.8) as well as from the minutes (point 2) it is indisputably clear that appellant 2 maintained his request to revoke the patent in its entirety. Accordingly, to the extent that the Opposition Division has decided to maintain the patent in amended form, appellant 2 did not fully prevail in the first instance proceedings. He was therefore adversely affected by the decision and thus entitled to appeal under Article 107 EPC 1973.

### 2. Procedural aspects

#### 2.1 Technical experts

According to G 4/95 (point 2.(a) of the headnote), oral submissions by accompanying persons can only be made with the permission of and under the discretion of the EPO. In the Board's view, hearing the technical experts offered by both parties was not necessary in the present case, which does not exhibit any particular technical complexity. Moreover, in view of the ample

information already provided in writing by both parties, the Board has a sufficient basis to reach a decision on the contested issues of added subject-matter and novelty. Accordingly, any interventions by the technical experts would have been restricted to specific technical points to be identified at the Board's discretion, depending on a need for clarification, which turned out not to be the case.

## 2.2 FEA illustrations

Like any other drawings or illustrations already filed with the written submissions of both parties, the coloured illustrations based on a finite element analysis (FEA) submitted by appellant 2 with letter of 15 March 2010 only reinforce his previous line of argument and their filing does not constitute an abuse of procedure. These illustrations are therefore admitted as part of the argumentation of appellant 2, and, as such, cannot be considered late-filed.

## 3. Amendments

### 3.1 Interconnecting elements

The feature "a plurality of interconnecting elements", which was present in both original independent claims 1 and 25, was replaced in claim 1 as granted by the functional requirement of the bands being "connected". A basis for this amendment can be found in the first paragraph of the "Summary of the Invention" bridging pages 2 and 3 of the original description as published, which explicitly refers to "interconnected bands", which equates in claim 1 as granted to "bands being

connected one to the other". In the sentence bridging these two pages, "and/or" implies three optional alternatives for accomplishing the goal of the invention, the first one being simply bands of different wavelengths over the length of the stent, without any mention of interconnecting elements or members. As a consequence, the other alternatives introduced by "and/or", and in particular "the interconnecting members" referred to in line 1 of page 3, are irrelevant and can be left aside since the claimed invention may be given the broadest definition supported by the application. The fact that the definite article "the" is used does not imply that interconnecting members must also be present in the first alternative. The reading of this passage within the context of what was described further above at page 2 reveals that the definite article refers to the previously discussed flexible joints (line 22-23) or elements (lines 9 to 10), corresponding to the interconnecting members.

It is true that interconnecting elements are present in both of the drawings relating to the invention, namely Figures 2 and 3. There are, however, self-supporting passages (penultimate paragraph on page 3 and paragraph bridging pages 3 and 4) which describe general embodiments without interconnecting elements. In the detailed description, the "inventive stents" are also first introduced without any reference to interconnecting elements (third paragraph of page 7). These passages provide a clear basis for stents without interconnecting elements as defined in granted claim 1. The argument that the mere fact that interconnecting elements are not mentioned in these passages does not

teach that no such elements are needed is not acceptable. This would be tantamount to requiring that a feature can only be omitted if explicitly described as optional.

Furthermore, interconnecting elements are not essential to the invention from an application of the essentiality test developed in T 331/87. It is first to be noted that the description nowhere states expressis verbis that interconnecting elements are essential to the invention. The passage on page 8, lines 19 to 20, indicating that "a minimum of one connecting element is required", only deals with the **number** of connecting elements in a specific case where such connecting elements are present. The same applies to the statement at page 17, lines 3 to 19 dealing with the **shape** and **position** of the interconnecting elements, provided that they are present. The strict necessity of the **presence** of interconnecting elements is never emphasised. As mentioned above, there are self-supporting paragraphs and embodiments without interconnecting elements. Accordingly, this feature is not **consistently** presented as essential (T 260/85, point 2 of the headnote, and T 331/87, point 4 of the reasons). Consequently, criterion (i) of the above-mentioned essentiality test is fulfilled.

With respect to criterion (ii), the technical problem underlying the invention has to be considered, viz. mainly improving the radial and longitudinal flexibility of the stent (see page 2, lines 20 to 23). Further partial problems concern allowing side branch access and avoiding pinching or overlap between adjacent bands (page 2, lines 28 to 30). From the

sentence bridging pages 2 and 3 it is clear that these problems can be solved either by providing bands of different wavelengths as defined in granted claim 1, resulting in the peaks and troughs of adjacent bands being circumferentially displaced relative to each other (thus mitigating the problem of pinching or overlapping), **or** by disposing interconnecting members in such a way that the phase relationship between adjacent bands is altered, **or** by combining both solutions (cf. granted claim 3). From the statement at page 2, lines 20 to 23 it appears that the open configuration of the stent and the segments or bands themselves are primarily concerned with flexibility, rather than the joints or interconnecting elements between these segments. It is further to be noted that an inventive solution does not have to be perfect. With respect to pinching and overlapping, it is sufficient that this problem is mitigated at least to some extent, which is clearly the case when the wavelengths of the bands are different as defined in claim 1. This is underlined at page 3, lines 19 to 22, where it is stated that it is desirable that upon expansion "at least some" of the peaks and troughs are displaced relative to each other about the periphery of the stent to accommodate longitudinal flexing of the stent without interference between adjacent band-like elements. Therefore, the arguments raised by appellant 2 with respect to pinching and resulting balloon burst during expansion are not convincing. Those situations where the stent is crimped onto the balloon and then subjected to bending simulated in a FEA are not a subject of the patent in suit. It follows that criterion (ii) is also fulfilled, i.e. the presence of

interconnecting elements is not indispensable to the function of the invention.

The removal of the structural feature "interconnecting elements" and its replacement by the functional feature "connected one to the other" does not require any further modification of the remaining features of the invention (criterion (iii)). It is clear that shortening the oblique interconnecting elements 144 shown in Figures 2 and 3 while keeping their direction will change the phase relationship between adjacent bands (120 and 132). When the length of the interconnecting elements is effectively reduced to zero, so as to form a direct point contact, the troughs 140 of band 132 will be "aligned" with the corresponding peaks 124 of band 120. But the result is not a radically altered and "completely different stent design", as argued by appellant 2. It is to be noted in this respect that the embodiment with oblique interconnecting elements 144 shown in Figure 2 necessarily comprises peaks of one band which are also "aligned" with troughs of the adjacent band since adjacent bands have different wavelengths. Therefore, alignment always occurs somewhere, whatever the length of the connecting elements may be. The modification of the length of the interconnecting elements is explicitly suggested in the description, e.g. at page 13, lines 19 to 21.

Since all three criteria (i) to (iii) of the essentiality test are fulfilled, the replacement of the structural feature "interconnecting elements" by the broader but admissible functional requirement of the bands being "connected one to the other" does not



contravene Article 123(2) EPC. The arguments provided by appellant 1 in the parallel opposition proceedings with regard to EP 01975572.3 are irrelevant for the present case and not considered by the Board.

### 3.2 Serpentine bands

The term "serpentine bands" in claim 1 as granted as a replacement for the term "undulating band-like elements" used in original claim 1 is supported by page 7, lines 28 to 29, and page 8, lines 1 to 3, where band-like elements having a generally serpentine configuration are explicitly mentioned. The terms "band-like elements" and "bands" are used interchangeably throughout the description. It is also clear that the terms "undulating" and "serpentine" are in fact synonyms and have an identical meaning in the art. The argument of appellant 2 that undulations have a distinct wavelength which might not necessarily be the case for serpentines is moot as claim 1 as granted explicitly defines the wavelength relationship. Moreover, it is indicated at page 3, lines 10 to 12, that the undulations may have multiple wavelengths as well. The broader term "having a generally serpentine configuration" literally comprises the more specific term "serpentine" used in claim 1 as granted. Accordingly, this reworded formulation does not violate Article 123(2) EPC.

### 3.3 Alternating with one another

A basis for the feature "alternating with one another over the length of the stent" can be found at page 3, lines 26 to 27, and page 8, lines 13 to 14, where the

term "alternate" is used, and in Figures 2 and 3. Appellant 2 has argued that the term "alternating with one another" is more specific than the term "alternate" and may not be extracted in isolation from the embodiment shown in Figures 2 and 3, which discloses interconnecting elements in combination. However, reading the text passage together with the drawings leaves no doubt that bands "alternating with one another" are meant. Moreover, this feature has no functional or structural relationship with the interconnecting elements and is thus not inextricably linked thereto. Consequently, this amendment is also allowable under Article 123(2) EPC.

#### 4. Novelty

##### 4.1 Document D9

This document is prior art with respect to Article 54(3) EPC only. Figure 38 depicts a stent which is shown in the expanded state in Figures 42 and 43. It comprises a plurality of interconnection segments 21 formed by serpentine bands. These alternate with longitudinal segments 14 having a plurality of laterally interconnected closed cells 13 (see page 13, lines 20 to 22). Such a closed cell configuration lacks flexibility, a drawback which is to be avoided according to the patent in suit (see paragraphs [0008] and [0010]), and can thus not be equated to the open structure provided by a serpentine band, as convincingly argued by appellant 1.

Even if the longitudinal segments 14 are regarded as a serpentine band or serpentine bands, this construction

does not take away the novelty of the subject-matter of claim 1 as granted for the following reasons. Appellant 2 argued that the longitudinal segments 14 could be seen as consisting of two individual "serpentine bands". Further it could be deduced from the drawings that their wavelength was larger than that of the serpentine bands 21. The amplitudes depicted in Figure 43, however, appear to be roughly the same. With respect to the precise amplitude relationship, it is the Board's view that an exact comparison would require taking measurements from the drawings, which is not allowable since these are merely diagrammatic representations (see T 857/91). Moreover, there are also drawings such as Figure 5, where the amplitudes of these individual "serpentine bands" appear to be smaller than those of the serpentine bands 21, such that the representations are not consistent in this respect throughout the document. This indicates that the amplitude relationship is not reliable and plays no decisive role in D9. Finally, based on this interpretation, D9 only appears to disclose a sequence of the kind AABAAB..., but not bands alternating with one another, i.e. of the kind ABABAB..., as required by the last feature of claim 1 in suit. The argument that the bands according to the claim "include" serpentine bands and would therefore also cover sequences of either the kind AABAAB... or the kind AOBAOB..., i.e. in the latter case taking into account only one of the two individual "serpentine bands", results in a misconstruction of the term "alternating with one another". Appellant 2 has finally argued that in D9 each segment 14 as a whole could be regarded as a "serpentine band", and that its amplitude, corresponding to the distance between two peaks

connected by a strut 15, would be clearly larger than that of the serpentine band 21. Such an unusual and artificial definition of the term "amplitude" is, however, not in line with the description of the patent in suit (see paragraphs [0024] and [0025]), which indicates to the skilled person that the term "amplitude" must refer to the peak-to-trough distance of the wave, as in the usual sense. Consequently, even if the closed cell configuration 14 is regarded as including a "serpentine band", the remaining features of granted claim 1, which relate to wavelengths, amplitudes and sequence, are not anticipated by D9. Therefore this document does not take away the novelty of claim 1 under Article 54(3) EPC.

#### 4.2 Document D5

Figure 1 shows a bifurcating stent wherein the serpentine bands 12 represented in the right portion thereof, which are to be inserted into a large vessel, might appear to have a larger wavelength and amplitude than the bands 12' and 12" in the left portions to be inserted into smaller vessel branches. However, there is no explicit disclosure in the description in this respect. Determining the amplitude and wavelength relationship would again necessitate a comparison, requiring to take measurements from the (diagrammatic) drawings, which is not allowable. Moreover, the last feature of claim 1 in suit ("alternating with one another") is clearly missing in this document.

4.3 Document D6

The serpentine bands shown in the drawings (Figures 4, 5 and 11) are obviously of the same wavelength and amplitude. The general statements in the third paragraph of column 6 that the properties of the stent "may also be varied by alteration of the undulating pattern" and that the wavelength and amplitude of the undulations "are chosen to fill particular mechanical requirements for the stent", do not anticipate the specific features relating to the wavelengths, amplitudes and sequence of the bands as defined in the characterizing portion of claim 1.

4.4 Document D7

The stent 14 depicted in Figures 11 to 15 has an open reticulated structure, including an array of diamond shaped apertures 32. D7 fails to disclose any kind of serpentine bands. The interpretation of Figure 11 of this document shown on page 5 of the statement of the grounds of appeal dated 13 July 2007 represents a misconstruction.

4.5 Consequently, documents D5, D6 and D7 are not prejudicial to the novelty within the meaning of Article 54(1) and (2) EPC 1973 of the subject-matter of claim 1 as granted.

**Order**

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

1. The appeal of appellant 2 is dismissed.
2. The decision under appeal is set aside.
3. The patent is maintained as granted.

The Registrar:

The Chairman:

A. Vottner

M. Noël