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D E C I S I O N
of 31 March 2004

Case Number: T 0306/01 - 3.2.2

Application Number: 95929314.3

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Language of the proceedings: EN

Title of invention:
A flexible expandable stent

Patentee:
MEDINOL LIMITED

Opponents:
1. Tomlinson, Edward James
2. Cordis B.V.
3. Boston Scientific Corporation
4. Janssen Pharmaceutica N.V.

Headword:

Relevant legal provisions:
EPC Art. 84

Keyword:
"Admissibility of interventions (yes)"
"Clarity (any request), after amendments (no)"

Decisions cited:
G 0001/94, T 0338/89

Catchword:
-



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D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 31 March 2004

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Decision under appeal: Interlocutory decision of the Opposition
Division of the European Patent Office posted
18 December 2000 concerning maintenance of
European patent No. 0762856 in amended form.

Composition of the Board:

Chairman: W. D. Weiß
Members: M. G. Noël
R. T. Menapace

Summary of Facts and Submissions

- I. Following an opposition initiated by opponent 01 against the grant of the European patent No. 0 762 856 and an intervention under Article 105(1) EPC by a third party (opponent 02) in the course of the opposition proceedings, the Opposition Division decided by interlocutory decision of 18 December 2000 to maintain the patent in a form amended during the oral proceedings.
- II. Opponent 02 (appellant) lodged an appeal on 1 March 2001 against the first instance's decision and filed a statement of grounds on 19 April 2001.

By notice received on 19 August 2003 and accompanied by facts and arguments BOSTON SCIENTIFIC CORPORATION (opponent 03) declared its intervention in the proceedings under Article 105 EPC and, on 2 October 2003, filed a copy of a motion for preliminary injunction ("Antrag auf Erlass einer einstweiligen Verfügung") which was directed against opponent (03) for alleged infringement of *inter alia* the patent underlying the present appeal and which had been filed by the respondent with the Landgericht (District Court of) Düsseldorf on 2 July 2003.

By notice received on 9 October 2003 Janssen Pharmaceutica N.V. (opponent 04) declared its wish to exercise its right to intervene in the proceedings under Article 105 EPC. The notice of intervention was accompanied by facts and arguments and a copy and translation of a writ of summons in summary proceedings served to opponent (04) on 15 July 2003. In those

proceedings before the Court of First Instance ("Rechtbank van Eerste Aanleg") in Brussels the proprietor (respondent) sought relief against an alleged infringement of the patent underlying the present appeal.

III. Oral proceedings were held on 31 March 2004 during which the interventions by the interveners (03) and (04) were first decided to be admissible. Then the discussion turned to the formal issues of the claims according to the various requests. Having regard to the first auxiliary request the chairman announced that the so-called "last (amended) first auxiliary request" was not admitted to the proceedings because filed late and not being clearly allowable.

At the end of the oral proceedings the final valid requests of the parties were as follows:

- the appellant (02), the opponent (01) and the interveners (03) and (04) all requested that the decision under appeal be set aside and that the European patent be revoked.

- the respondent (patentee) requested that the appeal be dismissed and that the patent be maintained in the version underlying the decision under appeal (main request), or in one of the versions according to auxiliary requests 2 to 5 filed at the oral proceedings.

IV. Arguments presented by the parties on substantive issues.

- (i) The appellant and the interveners objected against the clarity and support of the claims according to any request presented by the respondent. In particular, the configurations and directions of the meander patterns in the main request were so broadly defined that they gave rise to a plurality of interpretations going far beyond the objectives and embodiments as disclosed in the patent. Further, the claimed features did not actually provide all means of the solution for compensating foreshortening of the stent during expansion. Also the amendments successively introduced in the claims according to the various auxiliary requests were not sufficient to remove the clarity objections or were not adequately supported by the application as filed.

- (ii) The respondent maintained that the claim according to the main request fulfilled all the formal requirements of the EPC, in particular those relating to clarity and support, as was also admitted by the Opposition Division in the contested decision, including the amendments introduced during the oral proceedings before the first instance, (cf. minutes attached to the decision, section 4). In particular, it was not necessary to define the directions of the meander patterns more specifically as the patent description allowed for some flexibility in the definitions. The auxiliary requests added principally features relating to the directions of

said meander patterns, all derivable from the application as filed, including the drawings. The amendments, therefore, were clear and fairly supported.

V. The main claims according to the various requests read as follows:

- main request (version held allowable by the opposition division):

"A stent formed of a flat metal tube having, in a non-expanded form and in an expanded form, a patterned shape, comprising

- (a) even first meander patterns (11e), having axes (9) extending in a first direction;
- (b) odd first meander patterns (11o), also having axes (9) extending in said first direction, wherein said odd first meander patterns (11o) are 180° out of phase with said even first meander patterns (11e) and occur between every two even first meander patterns (11e),
- (c) second meander patterns (12) having axes (13) extending in a second direction different from said first direction, wherein said second meander patterns (12) are intertwined with said even and odd first meander patterns (11e, 11o) to form a generally uniform distributed structure;
- (d) wherein said first and said second meander patterns (11, 12) comprise loops (14, 16; 18, 20);

- (e) wherein said even and odd first meander patterns (11e, 11o) are connected to said second meander patterns (12) so as to leave a loop (18, 20) of said second meander patterns (12) between each odd and even first meander pattern (11o, 11e); and
- (f) wherein said second meander patterns (12) are connected to said even and odd first meander patterns (11e, 11o) so as to leave loops of said first meander patterns (11) between each pair of second meander patterns (12).

- First auxiliary request (last amended version):

"A stent formed of a tube having in a non-expanded form and in an expanded form a patterned shape, comprising

- a) even first meander patterns (11e), having axes (9) extending in a first, circumferential direction in the plane orthogonal to the longitudinal axis of the stent;
- b) odd first meander patterns (11o), also having axes (9) extending in said first direction, wherein said odd first meander patterns (11o) are 180° out of phase with said even first meander patterns (11e) and occur between every two even first meander patterns (11e);
- c) second meander patterns (12) having axes (13) extending in the longitudinal direction wherein said second meander patterns (12) are intertwined with said even and odd first meander patterns

(11e, 11o) to form a generally uniform distributed structure;

- d) wherein said first and said second meander patterns (11, 12) comprise loops (14, 16; 18, 20);
- e) wherein said even and odd first meander patterns (11e, 11o) are connected to said second meander patterns (12) so as to leave one loop (18, 20) of said second meander patterns (12) between each odd and even first meander patterns (11o, 11e); and wherein said loops of said second meander patterns are expandable in the longitudinal direction of the stent;
- f) wherein said second meander patterns (12) are connected to said even and odd first meander patterns (11e, 11o) so as to leave loops of said first meander patterns (11) between each pair of second meander patterns (12)."

- second auxiliary request:

as the main request, but adding to the end of feature (a): "orthogonal to the stent axis",

replacing in feature (e) "a loop (18, 20)" by "one loop (18, 20)" and "first meander pattern (11o, 11e)" by "first meander patterns (11o, 11e)", and

adding to the end of feature (e): "wherein said loops of said second meander patterns are expandable in the longitudinal direction of the stent;"

- Third auxiliary request:

as the second auxiliary request, but deleting at the end of feature (e) the feature previously added ("wherein ... stent"), and

adding a new feature: "(g) wherein the growth of the loops of the second meander pattern (12) in the longitudinal direction compensates for the longitudinal shrinkage of the first meander pattern (11) upon expansion."

- Fourth auxiliary request:

as the second auxiliary request, but replacing in feature (a) "in a first direction orthogonal to the stent axis" by "in a first circumferential direction", and

deleting at the end of feature (e) the feature previously added ("wherein ... stent").

- Fifth auxiliary request:

as the fourth auxiliary request, but adding a new feature: "(g) wherein, during bending, the loops (14-20) change shape in order to compensate for the differences in length between the inside and outside curves."

Reasons for the Decision

1. The appeal is admissible.
2. *Admissibility of the interventions*
 - 2.1 The respondent (proprietor) contested the admissibility of the intervention by opponent (03) on the ground that it constituted *venire contra factum proprium* and was contrary to the principle of good faith; in particular, it was in conflict with the principle behind Article 105 EPC that the intervener has to use the first opportunity that presents itself to intervene in the proceedings. Although opponent (03) invoked the injunction issued against it by the District Court of Düsseldorf, this was the first opportunity to declare its intervention (which counts for the time limit pursuant to Article 105 EPC) since opponent (03) could have already caused its German subsidiary to declare its intervention in the ongoing opposition proceedings against the patent in suit when it was sued by the proprietor (respondent) under that patent in April 2002. The same applies to BSC International B.V. which had been sued in the Netherlands and the other European subsidiaries of opponent (03) which were involved in those proceedings. None of them declared an intervention, even though opponent (03) could have instructed them to do so. Opponent (03) having actively participated in all of the patent infringement proceedings against its subsidiaries, could not then retreat to its formal legal position, without it being taken into account that its dependent subsidiaries failed to intervene in the present proceedings. Furthermore, opponent (03) had forfeited its right to

intervention because it had initiated different nullity proceedings in several Contracting States of the EPC with the consequence that it did not benefit anymore from the bundling effect contemplated by the EPC.

- 2.2 By intervention as provided in Article 105 EPC a third party may, under certain conditions and if it so wishes, acquire the procedural status of a party to pending opposition proceedings (including appeal proceedings – decision of the Enlarged Board of Appeal G 1/94) even after the opposition period has expired. The direct purpose of intervention is to allow the assumed infringer to defend itself against the patentee's action by making use of all available means of attacking the patent, which he is accused of infringing (decision G 1/04, point 8 of the reasons). In the interest of legal security and of orderly proceedings the concept of a party to proceedings is a strict and formal one. Only persons or legal entities, which have formally acquired that status for specific proceedings, are entitled to act in those proceedings. All others constitute "third parties" and have no right to act, irrespective of their relationship to a party to the proceedings and notwithstanding any interest they may have in the outcome of the proceedings in question, even if it is substantial. In particular corporations, even if fully owned by a parent company and thus acting under its full control, are legal entities on their own, separate from their parent company or any other group member. This holds true not only for the proceedings before the Office but also for national proceedings including those which have to be initiated either against or by the potential intervener as a precondition for the right to intervene under

Article 105 EPC. As a consequence, the preconditions set out in that provision, including the observation of the prescribed time limit, have to be fulfilled by or in respect of the person or legal entity that gives the notice of intervention (see decision T 338/89, point 4.1 of the reasons), all other circumstances and acts or omissions by legally distinct entities or other persons being excluded from consideration for the purposes of Article 105(1) EPC.

- 2.3 Hence, as long the patent proprietor (respondent) had initiated infringement proceedings only against the subsidiaries of opponent (03), the latter had no right to intervene itself nor was its own right to intervene, should the proprietor later initiate infringement proceedings also against opponent (03), in any way prejudiced. For these reasons the fact that the subsidiaries of opponent (03) had not, for whatever reason, exercised their right to intervene, was not contrary to any fundamental principle in respect of the exercising of that right, in particular by opponent (03), the parent company. The same is true for the infringement proceedings opponent (03) had initiated against the proprietor (respondent) because such unilateral legal actions - so called "torpedoes" - do not qualify as a second alternative under Article 105(1) EPC, regardless of the reason why they were not preceded by a warning by the proprietor. Only the existence of a legal action which meets (all) the conditions of Article 105 EPC is decisive for determining whether or not an intervention is admissible (decision T 338/89, point 4.1.4 of the reasons)

2.4 The admissibility of the intervention by opponent (04) was also objected to by the respondent, in essence with similar arguments on the ground that opponent (04) (as well as opponent (02)) belongs to a group of companies which had, in order to circumvent negative judgments against opponent (02), shifted manufacture and distribution of the stents in dispute to opponent (04). The latter, in February 2003, had brought an action for nullity and declaration of non-infringement against the proprietor (respondent), who was not aware of the activities of opponent (04) and, thus, had not given a warning to him. Furthermore, other companies of the group had lodged several national actions for nullity against the patent in suit.

2.5 It is evident from what has been set out under points 2.2 to 2.4, above, that these circumstances are equally irrelevant for the right of opponent (04) to file a valid notice of intervention on 9 October 2003, which is within three months from the infringement action brought against it by the proprietor (respondent) on 15 July 2003.

2.6 As a result, the respondent's objections against the admissibility of the intervention by opponent (03) and (04) are unfounded. No other deficiency having been found, both interventions are admissible.

3. *Clarity of the amended claims*

Since the claims have been amended during the opposition proceedings and subsequently during the appeal proceedings, they have to be examined for all

the requirements of the EPC, in particular also with respect to clarity.

3.1 Main request

Claim 1 according to the main request corresponds to the version as maintained by the Opposition Division in the decision under appeal. With respect to the version as granted, the claim was amended during the oral proceedings before the first instance by introducing in the preamble of the claim the expression "in a non-expanded form and in an expanded form", and by deleting in feature (e) the "s" from the last word "patterns" so as to read "first meander pattern (11o, 11e)". Having regard to the first amendment, it was introduced by the respondent on its own motion (cf. minutes of the oral proceedings of 10 November 2000, section 4) in order to more clearly define the claimed subject-matter and to give a clear limitation of the extent of the protection.

In the Board's judgement, the added expression mentioned above introduces into the claim a fundamental lack of clarity. By this expression, the subsequent features (a) to (f) which determine the patterned shape of the stent refer simultaneously to the stent in two opposite configurations, namely in a non-expanded form and in an expanded form. However, only a stent having a stable and well established configuration, as it is obtained immediately after its manufacture but before its delivery and expansion within a human vessel, is clearly defined by structural features. During the expansion of the stent, depending on the degree of expansion and the envisaged application, the directions

of the respective meander patterns are deformed and so do the spaces defined by the intertwined meander patterns as shown in Figure 4. Thus, the directions of the meander patterns, essentially variable upon expansion, cannot be retained to unambiguously define the patterned shape in all the configurations of the stent. In the present wording of the claim it is left open which configuration of the stent the following features (a) to (f) refer to. This situation gives rise to a number of misleading and unacceptable interpretations which jeopardize any comparison with the state of the art.

Moreover according to features (a) and (b), the first meander patterns extend in a first direction whereas according to feature (c) the second meander patterns extend in a second direction different from the first direction. This broad definition comprises actually all relative directions between the meander patterns, a level of generalisation which is not justified nor supported by the context of the application as filed. Although a strict orthogonality between the directions of the first and second meander patterns is not required in the description (cf. page 7, lines 31 to 34), the advantageous effect of a stent which minimally shrinks in the longitudinal direction upon expansion (cf. page 2, lines 13 to 15) can only be achieved if said relative directions are arranged orthogonally, as specified on page 6, lines 23 to 25.

However, orthogonality alone is still not sufficient for the stated problem to be satisfactorily solved. As also explained in the application as filed (cf. page 6, line 23 to page 7, line 12) in relation to Figures 5A,

5B, the compensation for shrinkage of the stent in the longitudinal direction, during expansion, is caused principally by the opening of the loops 18, 20 of the second (horizontal) meander patterns. Therefore, a compensation for the shortening of the stent can only be achieved if the horizontal direction of the second meander patterns before expansion approximates the longitudinal axis of the stent. In the absence of more specific features in the claim at issue, not any orientation of the relative directions between the first and the second meander patterns would allow for the compensating mechanism to work correctly in accordance with the principle illustrated by Figures 5A and 5B.

It results therefrom that the definition of the stent recited in the claim according to the main request is unclear, contrary to the requirements of Article 84 EPC.

3.2 First auxiliary request

At the oral proceedings the first auxiliary request (last version) was not admitted to the proceedings because it's final amendment was made at a very late stage (close to the end of the oral proceedings) and it still was not clearly allowable (after a number of successively filed unsuccessful amendments).

Besides the fact that this request suffers from the same fundamental lack of clarity as the main request (cf. point 3.1 above), the features added for specifying the directions of the first and second meander patterns were not sufficient to confer clarity

to the claimed subject-matter, in particular because the "longitudinal direction" of extension of the second meander patterns (feature (c)) has no antecedent in the previous features and is no further defined in the description.

3.3 Second to fifth auxiliary requests

The auxiliary requests two to five suffer principally from the same clarity deficiencies as the previous requests, since the expression "in a non-expanded form and in an expanded form" still is present in the preamble of the respective claims. Therefore, the same conclusion applies.

For the sake of completeness, however, the Board observes the following additional objections of clarity:

- second and third auxiliary requests

feature (a): "first meander patterns ... extending in a first direction orthogonal to the stent axis". This definition is unclear since there is an indefinite number of directions orthogonal to an axis, all contained in a same plane. A notion of circumference is, therefore, missing.

feature (c): "second meander patterns ... extending in a second direction different from said first direction". This definition is vague and indefinite since it allows for all directions other than the first direction according to feature (a). It is, therefore, not excluded that

said second direction extends in the same plane as the plane containing the first direction, which would represent a configuration far away from the described gist of the patent at issue.

- fourth and fifth auxiliary requests

feature (a): "first meander patterns ... extending in a first circumferential direction". This definition is not clear since a circumferential direction may be generated obliquely around the tube, i.e. around a cross-section non-orthogonal with respect to the axis of the tube, which is not covered by the disclosed embodiments.

feature (c): "second meander patterns ... extending in a second longitudinal direction different from said first direction". This definition lacks clarity in the absence of any relation to the longitudinal axis of the stent.

3.4 It results from the foregoing that none of the claims according to the requests submitted in the appeal stage fulfils the requirements of Article 84 EPC.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The patent is revoked.

The Registrar:

The Chairman:

V. Commare

W. D. Weiß