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Datasheet for the decision of 25 September 2008

Case Number: T 0276/06 - 3.3.10

Application Number: 94302807.6

Publication Number: 0623354

IPC: A61L 31/00

Language of the proceedings: EN

Title of invention:
Intravascular stents

Patentee:
MEDTRONIC, INC.

Opponent:
Advanced Cardiovascular Systems, Inc.

Headword:
Intravascular stents/MEDTRONIC

Relevant legal provisions:
EPC Art. 56

Keyword:
"Inventive step (yes) - improvement - no bonus effect - not obvious"

Decisions cited:
G 0001/93, T 0020/81, T 0184/82, T 0197/86, T 0564/89, T 0270/90, T 0939/92, T 0039/93, T 0355/97, T 0284/98, T 0836/02, T 0176/04

Catchword:
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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0276/06 - 3.3.10

D E C I S I O N
of the Technical Board of Appeal 3.3.10
of 25 September 2008

Appellant: (Opponent)
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Decision under appeal:
Interlocutory decision of the Opposition Division of the European Patent Office posted 27 December 2005 concerning maintenance of European patent No. 0623354 in amended form.

Composition of the Board:

Chairman: R. Freimuth
Members: J.-C. Schmid
D. S. Rogers

Summary of Facts and Submissions

I. The Appellant (Opponent) lodged an appeal on 28 February 2006 against the interlocutory decision of the Opposition Division, posted on 27 December 2005, that the European patent No. 623 354 in the form as amended during opposition proceedings according to the then pending main request met the requirements of the EPC.

II. Notice of opposition was filed against the granted patent by the Appellant requesting revocation of the patent in suit in its entirety on the grounds of lack of novelty and inventive step (Article 100(a) EPC).

Inter alia the following documents were submitted in opposition proceedings:

(1) US-A-5019096
(9) WO-A-91 12779 and
(32) US-A-4800882.

III. The Opposition Division held that the subject-matter of the amended claims neither extended beyond the content of the application as filed nor that the amended claims extended the protection conferred by the granted patent and that the documents cited neither anticipated nor rendered obvious the claimed subject-matter.

The Opposition Division found that the amended claims were admissible with respect to Article 123(2) and (3) EPC, the features "balloon expandable", "spraying" and "metal surface" having a support in the application as filed. The subject-matter of claim 1 was novel, since

no document disclosed the features of claim 1 in combination. Furthermore document (1) did not disclose balloon-expandable arterial grafts. For the assessment of inventive step, document (9) was considered to be the closest prior art. The technical problem was to provide a coating which remained attached to the stent when the stent expanded. Document (1) treated a method of coating by spraying as being equivalent to that of dipping. The skilled person would not combine document (9) and document (1) since spraying was only one alternative from the different methods of coating and since document (1) did not refer to a stent. The effect obtained by the distinguishing feature of "multiple coating by spraying" was the prevention of detachment of the coating and was shown by the comparison of example 5 with examples 3 or 4 of the patent in suit.

IV. During the oral proceedings held on 25 September 2008 before the Board, the Respondent (Proprietor of the patent) withdrew all its former objections with respect to the admissibility of the Appellant's late filed documents and evidences. Furthermore, it defended the maintenance of the patent in suit solely on the basis of claims 1 to 11 of the main request filed on 24 November 2006, on which the decision of the Opposition Division was based, i.e. claim 12 of this set of claims being removed and auxiliary requests 1 to 6 filed on 24 November 2006 all being withdrawn.

Claim 1 of the main request read as follows:

"1. A method of making an intravascular stent comprising the steps of:

(a) providing a generally cylindrical, balloon-expandable stent body having a metal surface;
(b) spraying onto the stent body in a plurality of application and drying steps a solution which comprises a solvent, a polymer dissolved in the solvent and a therapeutic substance dispersed in the solvent; and
(c) evaporating said solvent."

V. The Appellant raised no objections under Article 123(2) EPC with respect to the amendments made in the claims. However, it submitted that Article 123(2) EPC was infringed with respect to the formulation of the technical problem submitting that any amendment of the technical problem had to be in line with that Article relying *inter alia* on point 16 of the reasons of the decision of the Enlarged Board of Appeal G 1/93 (OJ EPO 1994, 541).

The patent was amended during the opposition proceedings in such a way as to add new subject-matter, contrary to the requirements of Article 123(2) EPC, by virtue of the fresh effect which suggested that coating the intravascular stent by spraying *per se* provided advantages which were not obtainable by other coating methods. There was no disclosure in the application as filed of a causal link between the spraying and the attachment of the coating onto the stent. The application as filed disclosed that all coating methods were equivalent so that there was no right for the Respondent to base an inventive step on the selection of a specific coating method.

Document (9) was the closest prior art document, which disclosed all the features of the stent obtained by the method of claim 1 of the patent in suit, save its method of preparation.

The technical problem, put forward by the Respondent in view of document (9), of providing a simplified process of making a coated balloon expandable intravascular stent having an improved attachment of the coating during its expansion and an improved control rate of drug delivery was not solved by the claimed subject-matter.

The test report of 24 November 2006 filed by the Respondent did not represent a fair comparison. The coating solution was not optimized for a method of coating by dipping due to an unsuitable viscosity value, so that the amount of coating onto the stents was much higher for the dipped coated stent than for the sprayed coated stent. The detachment observed during expansion for the dipped coated stent was due to these specific unsuitable conditions used in the method of preparation which led to pulling due to the much higher coating weight. On the contrary, the Appellant's comparative tests filed on 22 August 2008 showed that there was no difference of detachment of the coating after expansion between a spray-coated stent and a dip-coated stent having the same coating weight.

Furthermore, it was not clear what was meant by the expression "stents were dipped rapidly" used in the Respondent's test report. Since the amount of the coating could vary according to the dipping time, it

was not possible accurately to reproduce the experiment.

Even if an improvement in relation to the coating adhesion was accepted, it was not credible that it would apply across the whole scope of the claims. The comparative test of the Respondent was carried out with fine spraying, with only one specific drug, ratio drug/polymer or type of balloon-expandable stent, and with only two polymers, solvents and concentrations. Hence, there was no proof that the alleged improvement was achieved with any spraying, drug, solvent, polymer, ratio drug/polymer, concentration or type of balloon-expandable stent. The passage on page 3, lines 6 to 9 of the patent in suit indicated a relationship between the adhesion of the coating and the nature of the polymer in the coating solution. A solvent evaporating too quickly or too slowly might not be appropriate. Since the detachment of the coating was due to the pooling and that the pooling was due to a particular form of the stent, e.g. presence of struts or sharp curves, it was to be expected that certain stents without those particular features, for instance coil stents such as those disclosed in document (9) or document (32) could be dip-coated without any pooling, so that no detachment would occur during expansion, implying no improvement of the spraying- versus the dipping-coating method.

Furthermore, the claimed subject-matter was not inventive in view of the combination of document (9) with document (1).

Document (1) taught the solution proposed as such. There were only very few methods of coating described in that document. Accordingly the skilled person following the teaching in document (1) would automatically and inevitably arrive at the proposed solution. The fact that this coating method provided an enhancement of the coating adhesion was merely a bonus effect, which according to the established case law of the Boards of Appeal could not contribute to an inventive step.

VI. The Respondent indicated that claim 1 was based on the combination of original claims 1, 2, 4 and 6, and on page 5, line 3 of the application as filed where the stent was specified to be of the balloon-expandable type.

The Respondent concurred with the Appellant that document (9) was the closest prior art. The coated stents were, however, disclosed in that document as being prepared by assembling coated filaments.

In view of document (9), the technical problem underlying the patent in suit consisted in providing a simplified process of making a coated balloon expandable intravascular stent having an improved attachment of the coating during stent expansion and an improved control over the rate of drug delivery.

It was well-established that the problem/solution approach to the assessment of inventive step often required reformulation of the problem to be solved once the closest prior art document had been identified. Furthermore, this technical problem was clearly

foreshadowed in paragraph [0006] on page 2, lines 37 to 39 of the patent in suit, corresponding to the bottom of page 2 of the application as filed, where the problem of keeping an active substance on the stent during expansion of the stent until it made contact with the blood vessel wall was addressed. It was also disclosed on the top of page 4 of the patent in suit that spraying provided a coating, which was furthermore improved by multiple applications, with a greater uniformity and control over the amount of the therapeutic substance.

The comparative test data (Annex A of the letter of 24 November 2006) showed that spraying in multiple application steps, a solution as defined in claim 1 of the patent in suit, rather than dipping it, provided a uniform drug-eluting coating that remained attached to the stent after expansion. The images of the coated stents clearly showed that coatings produced by spraying were more uniform over the stent surface than those produced by dipping. The coating was even and adhered to the stent struts on spray coated stents whereas the coating was pulled away or missing from dip coated stent struts. The improvement of the coating attachment was independent of the nature and concentration of the polymer, since it was obtained with formulations having different polymers in different amounts. Contrary to the Appellant's submission, though the values were not provided in this comparative test, the dip-coated and spray-coated stents had roughly the same thickness.

The comparative tests provided by the Appellant with letter of 22 August 2008 were not pertinent since the

method of dipping used in this test did not reflect the prior art method. It comprised a step of high speed spinning which was not disclosed in document (1) and led to stents having a very low coating weight of about 60 µg as opposed to the coating weights of 600 to 1500 µg obtained according to the claimed method in examples 6 and 7 of the patent in suit.

None of the prior art documents taught the skilled person that spraying the coating solution instead of dipping it would yield a coating that remains better attached to the stent surface on expansion. There was no reason to choose among the methods of coating a medical device disclosed in document (1) to coat an intravascular stent by a method comprising spraying in multiple steps. On the contrary, document (1) taught that grafts, the sole medical device disclosed in that document like a stent, should be coated by agitation and/or vacuum suction in a single step dipping process leading the skilled man away from the claimed process.

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

The Respondent requested that the decision under appeal be set aside and the patent be maintained upon the basis of claims 1 to 11 of claims 1 to 12 of the main request filed on 24 November 2006.

VIII. At the end of the oral proceedings, the decision of the Board was announced.

Reasons for the Decision

1. The appeal is admissible.

2. *Amendments*

Claim 1 is based on the combination of original claims 1, 2, 4 and 6, and on page 5, line 3 of the application as filed where the (expandable) stent according to step (a) is specified to be of the balloon-expandable type. These amendments restrict the protection conferred. Therefore, there are no objections to the amendments made in present claim 1, which finding was not contested by the Appellant. Furthermore, dependant claims 2 to 11 are backed up by original claims 7 to 16 respectively.

The requirements of Article 123(2) and (3) EPC are thus satisfied.

3. *Novelty*

In the opposition proceedings the Opposition Division found the subject-matter of the patent in suit to be novel. The Appellant did not raise any objections in the appeal proceedings to the novelty of the claimed process. The Board on its own does not see any reason to take a different view, and thus the claims are considered to be novel.

4. *Inventive step*

According to the established jurisprudence of the Boards of Appeal it is necessary, in order to assess

inventive step, to establish the closest state of the art, to determine in the light thereof the technical problem which the invention addresses and successfully solves, and to examine the obviousness of the claimed solution to this problem in view of the state of the art. This "problem-solution approach" ensures that inventive step is assessed on an objective basis and avoids an *ex post facto* analysis.

4.1 *Closest prior art*

The Board considers, in agreement with the Opposition Division and the Parties, that document (9) represents the closest state of the art, and, hence, takes it as the starting point in the assessment of inventive step.

4.1.1 Document (9) discloses a cylindrical, balloon-expandable, intravascular coated metallic stent, the coating being formed from a polymer into which a drug which limits acute or chronic closure (restenosis) is compounded (claim 1, page 10, lines 32 to 36, figure 2). The coating can also be made of at least two separate layers, each of said layers including a therapeutic compound (claim 2).

Document (9) thus discloses all the features of the stent which is prepared by the method of claim 1 of the patent in suit, but does not disclose its method of preparation.

4.1.2 The Respondent argued that the stents of document (9), including the balloon-expendable stent (20) of figure 2, are disclosed as being preparing by assembling coated filaments.

However the passages of document (9) relating to that method, i.e. page 10, lines 22 to 27 and page 11, lines 4 to page 12, line 7, exclusively refer to the preparation of the self-expandable stent (10) as depicted in figure 1, but not to a balloon-expandable stent such as depicted in fig. 2. Accordingly, the Respondent's arguments with respect to the disclosure of a method of preparation in document (9) are solely valid for the self expandable stent 10 of figure 1 and do not apply to the balloon-expandable stents.

Hence, the Respondent's interpretation of that document as disclosing a method for the preparation of balloon expandable stents by first coating single wires and then forming these into a stent is not supported by the facts. Thus document (9) does not disclose any method of preparation of balloon-expandable stents.

4.2 *Technical problem underlying the patent in suit*

In view of document (9), the Respondent submitted during the oral proceedings that the technical problem underlying the patent in suit consisted in providing a simplified process of making a coated balloon expandable intravascular stent having an improved attachment of the coating during its expansion and an improved control rate of drug delivery.

4.2.1 However, the problem underlying the patent in suit is to be formulated vis-à-vis the closest prior art, i.e. document (9). The part of the proposed technical problem, "simplification" of the known preparation method, cannot be accepted as being part of the

objective technical problem as document (9) does not disclose any method of preparation for a balloon-expandable stent. The Respondent's interpretation with respect to the method of preparation of stent (20) according to document (9) is not supported by the facts (see point 4.1.2 above). Thus, the alleged problem of "simplifying" the method of document (9) is to be discarded when assessing inventive step.

4.2.2 The Appellant objected to a violation of the requirement of Article 123(2) EPC with respect to the above formulation of the technical problem submitting that any amendment of that technical problem vis-à-vis its formulation in the patent in suit should be in line with those requirements relying *inter alia* on the decision of the Enlarged Board of Appeal G 1/93 (*supra)*.

4.2.2.1 Article 123(2) EPC, however, governs amendments of a European patent. It is not concerned with the issue whether or not an objectively reformulated technical problem may be used in the course of the "problem-solution approach" which was developed by the Boards as a tool for achieving objectivity and to avoid *ex post facto* analysis in the assessment of inventive step. Therefore, Article 123(2) EPC would only come into play if an amended technical problem was incorporated into the description itself, which is not the case here (see decision T 564/89, point 4.3 of the reasons; T 284/98, point 1.3.2 of the reasons; neither published in OJ EPO).

4.2.2.2 Decision G 1/93 deals with the conflicting requirements of Article 123(2) and (3) EPC. Point 16 of the reasons which was referred to by the Appellant is solely

concerned with the issue of whether or not the adding of an undisclosed limiting feature to a claim has to be considered as subject-matter extending beyond the content of the application as filed. The formulation of the technical problem for assessing inventive step pursuant to Article 56 EPC according to the problem-solution approach is not addressed in that decision with the consequence that it does not apply to the present case.

4.2.2.3 Consequently, the Appellant's objection based on a violation of Article 123(2) EPC with respect to the formulation of the technical problem fails on these grounds.

4.2.3 It is established jurisprudence of the Boards of Appeal that the objective problem underlying the claimed invention is to be solely determined on the basis of the technical results or effects successfully achieved vis-à-vis the closest state of the art (cf. point 4.1 above). When doing so it is permissible to (re)formulate the arising technical problem in particular in more ambitious terms (see decisions T 184/82, OJ EPO 1984, page 261, point 5 of the reasons; T 39/93, OJ EPO 1997, page 134, point 5.3.2 of the reasons). In the present case, inventive step can be assessed on the basis of the technical problem as defined in the paragraph 4.2 above, as it amounts only to a more elaborated formulation of the problem already indicated in the patent in suit, as well as in the application as filed, where the problem of keeping the therapeutic substance on the stent during its expansion and of controlling the rate of drug delivery was already addressed (see page 2, lines 36 to 39 of the

patent in suit, corresponding to the last six lines of page 2 of the application as filed). Thus, in the Board's judgment, this technical problem is derivable from the patent in suit as well as from the application as filed.

4.3 *Solution*

The proposed solution is the method according to claim 1 characterized by steps (b) spraying onto the stent body in a plurality of application and drying steps a solution which comprises a solvent, a polymer dissolved in the solvent and a therapeutic substance dispersed in the solvent, and (c) evaporating said solvent.

4.4 *Success*

4.4.1 There are no comparative examples in the specification of the patent in suit showing that a coated stent prepared according to the method according to the invention would lead to a stent with an improved rate of drug delivery. According to the jurisprudence of the Boards of Appeal, alleged but unsupported advantages cannot be taken into consideration in respect of the determination of the problem underlying the invention (see e.g. decision T 20/81, OJ EPO 1982, 217, point 3, last paragraph of the reasons). Since in the present case the alleged improvement, namely the better control rate of drug delivery lacks the required experimental support, the part of technical problem relating to the improvement of the control rate of drug delivery cannot be considered as being solved. The technical problem must therefore be reduced to that of improving the

attachment of the coating on the stent during expansion of the stent.

4.4.2 In order to show that the problem of improving the attachment of the coating on the stent was successfully solved the Respondent referred to the comparative test submitted in annex A of the letter dated 24 November 2006.

4.4.3 According to established jurisprudence, in the case where comparative tests are chosen to demonstrate an inventive step with an improved effect over a claimed area, the nature of the comparison with the closest state of the art must be such that the effect is convincingly shown to have its origin in the distinguishing feature of the invention. For this purpose it may be necessary to modify the elements of comparison so that they differ only by such a distinguishing feature (see T 197/86, EPO OJ 1989, 371, points 6.1.2 and 6.1.3 of the reasons).

In the present circumstances, since document (9) does not disclose any method of preparation of balloon-expandable stents, in order to make a comparison of the properties of the balloon-expandable stents prepared according to the claimed method with those stents of document (9), it is necessary to supplement the teaching of document (9) with the teaching of a conventional method of preparing coated stents that the skilled person would have used for preparing the coated balloon-expandable stents disclosed in document (9). According to the submissions of both Parties, coating by dipping belongs to the conventional methods for

preparing coated balloon-expandable stents (also see document (1), column 14, lines 54 to 57).

4.4.4 In this comparative test, coated stents prepared according to the claimed method, i.e. by spraying in 15 short bursts the stents suspended from a mandrel with a coating solution comprising a polymer and a therapeutic substance, while rotating on the mandrel and drying, were compared with coated stents prepared by rapidly dipping the stents 15 times in the same coating solution, the only difference between the two methods being the way of application of the coating solution onto the stent, i.e. by spraying as opposed to by dipping.

Hence, the comparative test provided by the Respondent is pertinent since it truly reflects the impact of the essential technical feature characterising the claimed method, namely coating the stent by spraying.

4.4.5 The Appellant argued that this test report did not represent a fair comparison. The method illustrating the invention comprised a step of rotating the stent suspended from a mandrel and thus was not carried out in a usual way. In the method illustrating the prior art, the coating solution was not optimized for a coating by dipping, in particular with regard to its viscosity, so that the amounts of the coating onto the stents obtained in the compared methods significantly differed. Furthermore it was not clear what was meant by the expression "stents were dipped rapidly", so that it was not possible to reproduce the experiment with accuracy.

A cylindrical stent is a three dimensional object. Accordingly, in order to spray a uniform coating on it, either the spray or the stent must rotate. Hence, allowing the stent to rotate by fixing it from a rotating mandrel, while spraying represents a sensible way of coating a stent by spraying.

Claim 1 is directed to a method of making a stent. Accordingly, in order to provide a fair comparison all features of the methods to be compared should be identical apart from the characterising feature, in the present case, the step of spraying as opposed to the step of dipping. Thus, in order to provide a fair comparison, it is therefore not objectionable to use the same coating composition. Besides, the Board observes that in the written statement setting out the grounds of appeal filed on 8 May 2006 (see points 1.4 and 1.5), the Appellant objected to the comparative tests provided in the patent in suit because the coating compositions used differed from each other.

The differences of the stent coating obtained by the methods compared in the report, including the alleged difference of coating weight on the stent objected to by the Appellant, are the direct consequences of the distinguishing feature of the compared processes. For this reason, any differences in the products obtained by the methods of preparation to be compared are not relevant as regards the fairness of the experiment which compares these methods.

The Appellant furthermore objected to the term "rapidly" in the test protocol as being not precise without, however, providing any evidence that a

difference in the rapidity of the dipping would have a significant impact on the resulting coating. Mere unsubstantiated doubts expressed by the Appellant are not sufficient. Accordingly, in the absence of any proof to the contrary, the Board does not accept this objection as being a basis for disregarding the Respondent's comparative test report.

4.4.6 Thus, for the above reasons, the Board holds that the comparison provided by the Respondent in its comparative test report is fair and to be taken into consideration when assessing inventive step.

4.4.7 The comparative test report, i.e. annex A to the letter dated 24 November 2006, reveals that dip coated stents show a high degree of coating pooling whereas spray coated stents prepared according to the invention have an initial coating that is more uniform over the stent surface. After the stent has been crimped onto the balloon and/or final deployment, the coating is pulled away and/or missing from portions of dip coated stent struts whereas the coating of a spray coated stent remains uniform and adheres to the stent struts (see the optical and SEM images of annex A to the letter of 24 November 2006).

Hence, the Respondent's comparative tests reveal that the coating obtained by dipping, which lacks homogeneity (pooling), leads to detachment of the coating during expansion of the stent whereas no detachment occurs during the expansion of a coated stent obtained by spraying according to the claimed method, thereby indicating the better attachment of the coating.

4.4.8 The Appellant argued that the detachment was due to the unsuitable conditions used in this comparative test, in particular due to a difference in the coating weight obtained. In support of its argument, it relied on its own comparative tests filed on 22 August 2008 purportedly showing that there was no difference in the detachment of a coating between a spray-coated stent and a dip-coated stent.

In these comparative tests the stent was dip-coated according to a "Dip-High Speed Spin-Low speed Dry-Weight" process which, according to the Appellant, is disclosed in US-A-4955899. Thus, after dipping and before drying the stents were rotated about their longitudinal axis at approximately 1600-2000 rpm for 15 seconds.

Since this particular dip-coating technique only appears in a particular patent it cannot be considered as a conventional method for preparing a coated stent by dipping. Furthermore, this technique includes the additional feature of high speed spinning with the consequence that the methods compared not only differ by the characterising feature, namely the spraying step as opposed to the dipping step, but further differ by the spinning step occurring between the dipping and drying steps. These comparative tests therefore do not represent a fair comparison since they do not reflect the impact of the essential technical feature characterising the claimed method vis-à-vis that of the prior art, namely the impact of the step of spraying the coating solution onto the stent rather than dipping the stent into the solution.

Hence, the comparative tests filed on 22 August 2008 are not fair and must be discarded.

4.4.9 *Breadth of the claim*

A purported technical effect, in the present case the improved attachment of the coating onto the stent obtained by the claimed methods, can only form the basis for the assessment of inventive step if it would be credible that this technical effect occurs across the whole scope claimed (see decision T 939/92, OJ 1996, 309, point 2.5.4 of the reasons). Therefore, it must be examined whether or not the improvement shown is likely to apply over the whole breadth of the claim.

It appears conceivable that the improvement of the claimed method compared to a method representing the closest prior art is due to the step of spraying as opposed to that of dipping. The Board *prima facie* sees no technical reasons why an improvement of the coating adhesion which was shown in the comparative test to be due to the step of application of the coating solution, i.e. by spraying as opposed to by dipping, as shown in the comparative test, should not be present over the whole scope of claim 1 which is limited to that way of application of the coating.

Nevertheless the Appellant submitted that the comparative test was carried out with fine spraying, with only one specific drug, with a single ratio drug/polymer, with one type of balloon-expandable stent, and with only two different polymers, solvents and concentrations. Hence, there was no proof that the

improvement shown was achieved with all ways of spraying, with all drugs, solvents, polymers, ratios drug/polymer, concentrations and types of balloon-expandable stent. More particularly. the Appellant relied on the passage on page 3, lines 6 to 9 of the patent in suit, indicating a relationship between adhesion of the coating and nature of the polymer in the coating solution, and argued that a solvent evaporating too quickly or too slowly might not be appropriate. Since the detachment of the coating was due to pooling and that pooling was due to a particular form of the stent (e.g. presence of struts, sharp curves), it was to be expected that coil stents which lack those parts leading to pooling, such as those disclosed in documents (9) and (32), could be dipped-coated without any pooling, so that no detachment would occur during expansion. Thus, an improvement due to the step of spraying instead of dipping could not be implied.

According to the established jurisprudence of the Boards of Appeal, each of the parties to the proceedings carries the burden of proof for the facts it alleges. If a party, whose arguments rest on these alleged facts, does not discharge its burden of proof, this goes to the detriment of that party and such a party may not shift the onus of proof onto the other party (see T 270/90, OJ EPO 1993, 725, point 2.1 of the reasons; T 355/97, point 2.5.1 of the reasons; T 836/02, point 4.5 of the reasons; T 176/04, point 5.6.3 of the reasons; all but T 270/90 not published in OJ EPO).

With regard to the allegation of non-achievement of a better effect with conventional spraying or with a

coating solution comprising any other drugs, concentrations and/or ratios, the Appellant merely expressed doubts that the claimed method would achieve an improvement. However, the Appellant neither substantiated its objection nor filed evidence for its allegation that those variations necessarily would destroy the improvement shown by the comparative tests of the Respondent. As there is no apparent and compelling technical reason why this should be the case, and in the absence of any supporting evidence, the Appellant has not discharged its burden of proof, with the consequence that this unsubstantiated allegation is not to be taken into account by the Board.

The Appellant has also not provided any supporting evidence showing that the improved adhesion of the coating on the stent was linked to the chosen polymer, but relied merely on the passage on page 3, lines 7 to 9 of the specification of the patent in suit indicating that the adhesion of the coating could be controlled by the selection of an appropriate polymer.

However, the problem underlying the patent in suit is to provide a method which improves the adhesion of the coating, i.e. a relative property. That this problem was solved was demonstrated in the Respondent's comparative tests showing that the improvement of the adhesion was the result of the method of application of the coating onto the stent, i.e. by spraying as opposed to dipping, regardless of the polymer used, namely poly L-lactic acid or polycaprolactone, thus indicating that the improvement was not due to the nature of the polymer *per se*. The Appellant's argument that the claimed method encompassed polymers that also provide

low coating attachment is therefore not convincing in the present case, since a relative improvement of the coating has been shown on account of the different method of application of the coating, irrespective from the nature of the polymer.

As regards the argument that the improved adhesion of the coating is dependant on the form of the stent, the Appellant referred to coil stents and relied on documents (9) and (32) to show that they were balloon-expandable stents not having the drawback of pooling.

However, the coil stent described in document (9) is the stent (10) of figure 1 which is a self-expandable stent, and, thus, excluded from the claimed method which requires a balloon-expandable stent (see point 4.1.2 above).

The stent disclosed in document (32) is a wire having a balloon-expandable serpentine configuration formed into a cylindrical shape, and thus comprises curved sections (see figures 1 to 5) on which pooling is likely to occur when the stent is dipped into a coating solution. Accordingly, in the absence of any substantiation or evidence to the contrary, it is plausible that a balloon-expandable stent necessarily comprises sections, such as curves, which lead to pooling when the stent is dipped into a coating solution thereby rendering credible for any balloon-expandable stent that the improvement of the adhesion of a coating obtained by spraying rather than by dipping is achieved.

4.4.10 The Appellant raised an objection under Article 123(2) EPC, since there was no disclosure in the application

as filed of a causal link between the step of spraying and the degree of attachment of the coating. The application as filed disclosed that all coating methods were equivalent so that there was no disclosure permitting the Respondent to base inventive step on the selection of one of the coating methods.

This objection is in fact a repetition of the point already dealt with in point 4.2.2 above. There is no basis for this objection. In particular Article 123(2) EPC does not apply to the assessment of technical effects in the problem/solution approach, but exclusively governs formal requirements to be satisfied by amendments made to a European patent (application), which text in the present case however has not been amended in this respect. Therefore the Appellant's argument is not convincing.

4.4.11 For theses reasons, the Board is satisfied that the partial technical problem underlying the patent in suit relating to the improvement of the attachment of the coating on the stent has been successfully solved by the proposed solution, i.e. by the method according to claim 1 characterized by the spraying step (b).

4.5 *Obviousness*

Finally, it remains to be decided whether or not the proposed solution to this objective technical problem is obvious in view of the cited state of the art.

4.5.1 During the oral proceedings before the Board, the Appellant exclusively addressed document (1) in order to object to obviousness.

Document (1) relates to coated medical devices, in particular coated arterial grafts. Although this document addresses the importance of the adhesion of the coating to the device (column 7, lines 26 to 31), it lacks any hint on how to improve this adhesion. In particular, document (1) does not teach that an improvement of adhesion can be obtained by the choice of a particular coating technique, all techniques taught as being equivalent (see column 14, lines 54 to 57). Accordingly, document (1) does not point to the claimed solution, which is characterized by the use of a particular coating method, namely spraying (step (b)), for solving the technical problem underlying the patent in suit.

4.5.2 The Appellant argued that document (1) taught the solution proposed as such. There were only a few methods of coating described in document (1). The skilled person when following the teaching in document (1) would automatically and inevitably arrive at the proposed solution. The fact that this coating method provided an enhancement of the coating adhesion was merely a bonus effect, which could not contribute to an inventive step.

However, in order for the "bonus effect" approach of the Appellant to succeed it would need to demonstrate that the person skilled in art was effectively on a "one-way street" (see decision T 192/82, OJ EPO 1984, 415). This "one-way street" should have inevitably led him to adopt exclusively the spraying method instead of the other coating methods under consideration in

document (1), however, all coating methods are taught therein to be equivalent.

The Appellant's argumentation implies that the skilled person would have taken into consideration document (1) to solve the underlying problem. However, this is not the case, because document (1) does not address the problem of improving the coating adhesion, so that, as already stated in point 4.5.1 above, the solution to this problem is not rendered obvious by document (1).

It is the established jurisprudence of the Boards of Appeal that, when assessing inventive step according to the problem/solution approach, the decisive question is not whether the skilled person **could** have arrived at the invention, in the present case by using the spraying coating technique disclosed in document (1), but whether he **would** have done so for solving the problem underlying the patent in suit with a reasonable expectation of success. Thus, as is clear from the preceding considerations, the latter condition has not been met since the decisive fact remains that document (1) lacks any hint on how to solve the problem underlying the invention, i.e. to enhance the adhesion of the coating. Therefore, the Appellant's argument fails because the skilled person would not have considered document (1) in order to solve the technical problem underlying the patent in suit, the solution of coating the stent by spraying disclosed *inter alia* in document (1) can be only the result of an inadmissible *ex post facto* analysis.

4.5.3 In respect of obviousness, the Appellant did not rely on any further documents and the Board is not aware of

further documents relevant in this respect. Thus, the Board is satisfied that none of the other documents in the proceedings renders the proposed solution obvious.

4.5.4 Therefore, the subject-matter of claim 1, and for the same reason, that according to dependent claims 2 to 11 involve an inventive step within the meaning of Article 56 EPC.

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 with the order to maintain the patent on the basis of claims 1 to 11 of the main request filed on 24 November 2006 and a description yet to be adapted.

The Registrar: The Chairman:

C. Rodríguez Rodríguez R. Freimuth