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Datasheet for the decision of 21 November 2023

Case Number: T 2019/20 - 3.3.10

Application Number: 06787258.0

Publication Number: 1909973

IPC: B05D3/00, A61L2/00, A61L31/10, A61L31/16

Language of the proceedings: EN

Title of invention:
POLYMER COATINGS CONTAINING DRUG POWDER OF CONTROLLED MORPHOLOGY

Patent Proprietor:
Micell Technologies, Inc.

Opponent:
BIOTRONIK AG

Headword:

Relevant legal provisions:
EPC Art. 56, 83, 123(2)
RPBA 2020 Art. 11, 12(1), 12(2), 12(3), 12(4), 12(5), 13(1), 13(2), 15(3)

Keyword:
Main request - Inventive step - (no)
Remittal - special reasons for remittal (no)
Amendment to appeal case - amendment within the meaning of Art. 12(4) RPBA (no)
Auxiliary request 1 - Inventive step - (yes)
Sufficiency of disclosure - (yes)
Amendments - allowable (yes)

Decisions cited:
T 2295/19

Catchword:
The substance of the request filed during the oral proceedings before the board - i.e. the claimed subject-matter and the attacks against it - is fully encompassed by both the appellant's and the respondent's initial appeal case within the meaning of Article 12(1) to (3) RPBA. The request certainly limits the potential issues for discussion. This means that, in view of the totality of the facts of the present case, the filing of this request, although formally an amendment and as such potentially subject to the strict provisions of Article 13(2) RPBA, in substance does not constitute an amendment of a party's case within the meaning of Article 12(4) RPBA, but rather a partial abandonment of the initial appeal case. There is no apparent reason not to admit such a request under any of the Articles 12(5), 13(1) or 13(2) RPBA. (Reasons 23.)

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Case Number: T 2019/20 - 3.3.10

D E C I S I O N
of Technical Board of Appeal 3.3.10
of 21 November 2023

Appellant: (Opponent)	BIOTRONIK AG Ackerstrasse 6 8180 Bülach (CH)
Representative:	Keil & Schaafhausen Patentanwälte PartGmbB Friedrichstraße 2-6 60323 Frankfurt am Main (DE)
Respondent: (Patent Proprietor)	Micell Technologies, Inc. 7516 Precision Drive Raleigh, NC 27617 (US)
Representative:	Wichmann, Hendrik Wuesthoff & Wuesthoff Patentanwälte PartG mbB Schweigerstraße 2 81541 München (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 9 November 2020 rejecting the opposition filed against European patent No. 1909973 pursuant to Article 101(2) EPC.**

Composition of the Board:

Chairman	M. Kollmannsberger
Members:	A. Zellner
	T. Bokor

Summary of Facts and Submissions

I. The opponent lodged an appeal against the decision of the opposition division to reject the opposition against European patent No. 1 909 973 under Article 101(2) EPC.

II. Notice of opposition has been filed on the grounds of lack of novelty and lack of inventive step (Articles 100(a), 54 and 56 EPC), lack of sufficiency of disclosure (Article 100(b) EPC) and added subject-matter (Article 100(c) EPC).

III. Reference is made to the following documents:

D1: EP 1 810 665 A1
D2: WO 00/32238
D3: WO 2006/063021
D4: Medinol, NIRflex Premounted Coronary Stent System, Instructions for Use, 2003
D6: WO 2004/101017 A2
D7: US 2004/0181278 A1
D8: US 5,605,696
D15: Jiyeon Choi, *et. al.*; Effect of Solvent on Drug Release and a Spray-Coated Matrix of a Sirolimus-Eluting Stent Coated with Poly(lactic-*co*-glycolic acid), *Langmuir* 2014, 30, 10098-10106
D16: Medinol, Products, X-Suit NIR, 2017
D22: Handbook of Coronary Stents, Serruys, P.W. (Editor-in-Chief); Rotterdam Thoraxcentre Group, 1997

IV. In its decision the opposition division came to the conclusion that the objections brought forward by the

opponent did not prejudice the maintenance of the patent as granted. In particular, the opposition division considered independent claims 1 and 17 of the patent as granted to be based on the application as filed (Article 100(c) EPC) and the claimed subject-matter to be sufficiently disclosed in order to be carried out by the skilled person (Article 100(b) EPC). Novelty of the claimed subject-matter was acknowledged with respect to the disclosure of documents D1, D2 and D8 (Articles 100(a) and 54 EPC). The claimed subject-matter was also considered to be based on an inventive step starting from document D2 as closest prior art (Articles 100(a) and 56 EPC).

V. In support of its appeal, the appellant (opponent) argued that the opposition division's decision was erroneous with respect to all grounds of opposition.

VI. The appellant withdrew its request for oral proceedings with letter dated 20 January 2022, and stated that it would not participate in any oral proceedings.

VII. In a communication under Article 15(1) RPBA the board informed the parties of its preliminary opinion on the factual and legal issues of the case. In particular, it saw amended claims 1 and 17 of the main request to be based on the application as filed (Article 100(c) EPC), the claimed subject-matter of the main request to be sufficiently disclosed to be carried out by a skilled person (Article 100(b) EPC) and novel in view of the disclosure of documents D1 and D2 (Articles 100(a) and 54 EPC). It saw the need to discuss inventive step for claims 1 and 17 (Articles 100(a) and 56 EPC) in the oral proceedings.

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

"A coated coronary stent, comprising:
a stent framework; and
a macrolide immunosuppressive drug-polymer coating wherein at least 50% of the drug is in crystalline form."

IX. Claim 1 of auxiliary request 1 is identical with claim 17 of the main request (patent as granted) and reads as follows:

"A method for coating a coronary stent comprising a stent framework, said coating comprising

at least one polymer; and

at least one pharmaceutical agent, which comprises a macrolide immunosuppressive drug, in a therapeutically desirable morphology;

said method comprising the following steps:
a) discharging the at least one pharmaceutical agent in dry powder form through a first orifice; discharging the at least one polymer in dry powder form through a second orifice; depositing the polymer and pharmaceutical agent particles onto said coronary stent, wherein an electrical potential is maintained between the coronary stent and the polymer and pharmaceutical agent particles, thereby forming said coating; and then

b) sintering said coating under conditions that do not substantially modify the morphology of said pharmaceutical agent, wherein the therapeutically

desirable morphology of said pharmaceutical agent is at least 50% crystalline."

X. The appellant argued essentially as follows:

Claim 1 of the main request did not meet the requirements of Article 56 EPC, because the provision of the claimed coated coronary stent was not based on an inventive step. Document D2 was closest prior art. It disclosed in example 1 a coated stent, from which the claimed stent only differed in the nature of the drug in the coating. Since document D2 suggested the use of rapamycin as an alternative drug, the skilled person would have replaced paclitaxel in example 1 with the macrolide immunosuppressive drug rapamycin and thus provided a stent as claimed. The respondent's argumentation that document D2 was non-enabling with respect to the formation of rapamycin in crystalline form was not convincing. There was also no obligation for the appellant to prove that D2 was enabling.

Claim 1 of auxiliary request 1 (identical to claim 17 of the main request) did not find a basis in the application as filed. The claimed subject-matter was not sufficiently disclosed. The request did furthermore not meet the requirements of the EPC since the provision of the claimed method was not based on an inventive step considering either of documents D6 or D7 as closest prior art.

XI. The respondent argued essentially as follows:

The provision of a coated coronary stent according to claim 1, and of a method for coating of a coronary stent according to claim 17 of the main request involved an inventive step. Document D2, the closest

prior art for claim 1 of the main request, was non-enabling concerning the disclosure of a coated stent comprising rapamycin, wherein at least 50% thereof was in crystalline form. This was confirmed by the disclosure of document D15. The request also fulfilled the requirements of Articles 54, 83 and 123(2) EPC.

The case should be remitted to the opposition division for further prosecution in case the main request could not be allowed, because the content of any of the auxiliary requests has not been discussed yet during the opposition proceedings.

Auxiliary request 1 should be admitted into the proceedings, since it only consisted of claims already present in the patent as granted. The request was also allowable, in particular because the provision of a method according to claim 1 involved an inventive step. None of documents D6 or D7 led the skilled person to the claimed method.

XII. The party's final requests are as follows:

The appellant (opponent) requests in writing that the decision under appeal be set aside and that the patent be revoked.

The respondent (patent proprietor) requests that the appeal be dismissed and that the patent be maintained as granted (main request) or that the patent be maintained on the basis of one of auxiliary requests 1 to 9, whereby auxiliary request 1 was filed during the oral proceedings before the board, and auxiliary requests 2 to 9 were filed as auxiliary requests 1 to 8 on 2 December 2019, and re-filed with the reply to the appellant's statement setting out the grounds of

appeal. The respondent furthermore requests remittal to the opposition division for the examination of the auxiliary requests in case the main request is not allowed.

XIII. The decision was announced at the end of the oral proceedings before the board held on 21 November 2023.

Reasons for the Decision

1. The appeal is admissible.

2. With submission of 20 January 2022 the appellant withdrew its request for oral proceedings and agreed to a decision in writing. The appellant also declared that it would not attend oral proceedings, should such proceedings be held. A decision can thus be taken without infringing the appellant's right to be heard (Article 113(1) EPC, Article 15(3) RPBA).

Main request (patent as granted)
Inventive step (Article 100(a) and 56 EPC)

3. The opposition division came to the conclusion that claim 1 of the main request complied with the requirements of Article 56 EPC. Example 4 of document D2 was considered to represent the closest prior art. According to the opposition division, the difference between the claimed stent and the stent according to example 4 of D2 was that the active agent combined with a coronary stent was a macrolide immunosuppressive agent having a degree of crystallinity above 50%, instead of crystalline paclitaxel. No technical effect was recognised, and the technical problem was seen in the provision of an alternative restenosis inhibiting drug eluting coronary stent.

The opposition division found that the claimed solution involved an inventive step. Document D2 did not disclose how to coat with rapamycin in crystalline form, and was thus non-enabling in that respect.

According to the division, it was the opponent's duty to prove that stents coated with crystalline macrolides could be formed when following the teaching of document D2. Since the opponent did not fulfill this duty, and since document D15 furthermore showed that coating of a stent with crystalline rapamycin could not be achieved, the provision of the claimed alternative was held to involve an inventive step. Even more so since none of documents D1, D3 or D8 provided any hint of a successful coating with crystalline rapamycin.

4. The appellant contested the opposition division's conclusions. It also argued lack of inventive step based on document D2 as closest prior art. The only differing feature was seen in the use of a macrolide immunosuppressive drug instead of paclitaxel. Since this difference did not lead to a particular technical effect, the technical problem was the provision of an alternative to a coated stent as disclosed in example 1 of D2. The solution provided according to claim 1 of the main request did not involve an inventive step, since D2 suggested the use of any drug that could be crystallized, and explicitly disclosed rapamycin as an example of such a drug. In addition, D2 disclosed that the use of a drug in crystalline form had considerable advantages compared to other morphologies.

The appellant disagreed in particular with the reasoning of the opposition division concerning the burden of proof concerning the disclosure of document

D2. According to the appellant, there was no reason why the opponent (appellant) should have brought any evidence to prove that the disclosure of document D2 was enabling. It certainly had no obligation to do so.

The appellant did not consider the disclosure of document D15 to be pertinent either, because the teaching of that document could not be applied to the closest prior art represented by D2. A different polymer was used in the coating method of D15, and the method did not contain the step of exposing the drug coated stent which was initially formed to water. Both features, however, were essential in the method according to D2. D15 could thus not demonstrate that the disclosure of document D2 was not enabling.

Furthermore, the appellant argued that crystalline rapamycin containing stent coatings were also suggested by documents D1 and D3.

5. The respondent submitted that the essence of the invention was the provision of stents coated with a macrolide immunosuppresive drug, such as rapamycin, wherein at least 50% of the drug was in crystalline form, and referred to paragraph [0006] of the patent in dispute. Although similar stents were known in the art, like those disclosed in document D2, they comprised a polymer coating containing paclitaxel, rather than containing a macrolide such as rapamycin. Since rapamycin and paclitaxel were structurally very different, their crystallisation behaviour was not comparable. Paclitaxel could easily be crystallised, in contrast to rapamycin. It was also not possible to deposit crystalline rapamycin using a solvent based method such as the one disclosed in D2. Even paclitaxel crystals were only formed on some of the stents, as

disclosed in example 1 of D2. Document D2 did even less disclose a coating comprising at least 50% of paclitaxel in crystalline form. Document D15, on the other hand, proved that stents having a coating with rapamycin in crystalline form could not be manufactured at all without the knowledge of the contested patent.

The respondent agreed with the opposition division that the appellant had the burden of proof for the disclosure of document D2, who relied on its content.

The respondent considered the nature of the stent to be a further differing feature, as supported by D16.

6. The board concludes that a coated coronary stent according to claim 1 of the main request does not involve an inventive step for the following reasons:

The claimed invention

7. Claim 1 of the main request relates to a coated coronary stent. The stent comprises a stent framework and a macrolide immunosuppressive drug-polymer coating, wherein at least 50% of the drug is in crystalline form. According to patent, the morphology of the drug in the coating is of importance for a variety of properties of the coated stent (see paragraph [0006]).

The closest prior art

8. The parties agreed with the opposition division in that document D2 represented the closest prior art for claim 1 of the main request. The parties, however, considered example 1 to be more relevant than example 4, since it disclosed a stent coating comprising a drug as well as a polymer. The board agrees.

Differing features

9. Example 1 of document D2 discloses the preparation of a NIR® stent comprising a polymer-drug coating, the coating comprising paclitaxel crystals (see line 13 of page 9). The parties also agreed that the coated coronary stent according to claim 1 differed therefrom on account of the drug comprised in the drug-polymer coating, *i.e. "... a macrolide immunosuppressive drug ..."* instead of paclitaxel. The board agrees.

10. The board also agrees with the respondent in that example 1 of D2 does not directly and unambiguously disclose that at least 50% of the drug is in crystalline form, nor that the stent is a coronary stent. Although paclitaxel crystals were formed on the surface of the coated stents according to example 1 of D2, there is no information whether all, or only a part of the drug deposited on the stent is in crystalline form. Documents D4 and D22 disclose NIR® coronary stents. However, document D16 discloses that the NIR® designation also refers to other products, such as biliary stents. Document D2 does thus not disclose that the stent coated in example 1 is a coronary stent.

11. The coated coronary stent according to claim 1 of the main request thus differs from the stent disclosed in example 1 of document D2 in that the drug in the coating is a macrolide immunosuppressive drug instead of paclitaxel, in that specifically at least 50% of the drug in the coating is in crystalline form, and in that the stent is a coronary stent.

Technical problem

12. The opposition division saw the technical problem in the provision of alternative restenosis inhibiting drug eluting coronary stents. The appellant agreed that the technical problem was the provision of an alternative, whereas the respondent saw the objective technical problem in the provision of an improved coronary stent with macrolide immunosuppressive drugs having better storage stability and better drug release properties, which avoided a large drug burst after administration.

13. The board does not see any particular technical effect associated with the differing features. It was undisputed that the presence of the drug in crystalline form leads to advantages. However, D2 already disclosed stents with a coating comprising a polymer and a drug in crystalline form (see example 1) and mentioned advantages of stents wherein the drug is in crystalline form (see page 2, lines 15 to 28). There is no evidence on file that the value of at least 50%, should it not have been achieved in D2, leads to any further unexpected technical effect. It was also undisputed that the use of a macrolide immunosuppressive drug as part of a coronary stent coating was known. Finally, although - as submitted by the respondent - different stents may well differ in the nature of their surface or other properties, no arguments were provided that coating a specific stent, *i.e.* a coronary stent, rather than any other stent, would bring unexpected effects.

14. The objective technical problem is thus to provide a further stent comprising a drug-polymer coating, wherein the drug in the coating is in crystalline form.

Solution provided

15. The problem is solved by providing a coated coronary stent according to claim 1 of the main request. The claimed coronary stent comprises a macrolide immunosuppressive drug in the drug-polymer coating, wherein at least 50% of the drug is in crystalline form. It was not disputed that the provision of such a stent solves the technical problem. The board agrees.

Obviousness of the claimed solution

16. The remaining question is whether the prior art suggest the provision of a coronary stent according to claim 1 in order to solve the technical problem.

17. The board comes to the conclusion that this is the case. The reasons are as follows:

17.1 Concerning the specific type of stent according to claim 1 (a coronary stent), the board notes that example 1 of document D1 does not specify which particular stent of the NIR® type is used. The respondent did not provide any arguments, however, why the selection of a coronary stent out of the different NIR® stents available to the skilled person (see documents D4, D16 and D22) leads to a particular technical effect. The board thus concludes that this choice is the direct result of the intended use, and that the selection of a coronary stent out of the known range of stents does not involve an inventive step.

17.2 Concerning the level of at least 50% of the drug being in crystalline form, it is noted that document D2 generally suggests the use of coated stents comprising a therapeutic agent in crystalline form (see claim 1). According to the D2, this leads to several advantages, such as a controlled release rate of the therapeutic

agent from a localized drug delivery system (see page 2, lines 15 to 28). The advantageous properties of stent coatings comprising drugs in crystalline form were not disputed. Although D2 does not refer to a specific minimum amount of the drug being in crystalline form, there is no suggestion to stay below a certain value either. Selecting a minimum value of at least 50% according to claim 1 can thus not contribute to inventive step.

17.3 Furthermore, D2 discloses that the therapeutic agent used in the invention includes any pharmaceutically active material that can be crystallized (see page 4, line 11 to page 4, line 9). The document specifically mentions rapamycin - which is a macrolide immunosuppressive drug according to paragraph [0010] of the disputed patent - as an example of such a pharmaceutically active material (see page 4, line 16). The skilled person, starting from example 1 of D2, thus finds in the same document a suggestion to use rapamycin as an alternative to paclitaxel.

17.4 The parties disagreed, whether - despite the specific disclosure of *"rapamycin"* in the description of D2 - the provision of the claimed solution should be considered obvious, or not. The respondent argued that the skilled person was not in a position to provide a coated coronary stent where rapamycin comprised in the coating was in crystalline form, in particular not at least 50% thereof. In the respondent's view, document D2 was not enabling, because it did not disclose how such a stent could be prepared. The respondent furthermore argued that it would have been the appellant's duty to provide evidence thereof.

17.5 The board disagrees with the respondent's argumentation concerning the burden of proof.

The appellant challenged the presence of an inventive step for the coated coronary stent according to claim 1 of the main request. In support of its objection the appellant submitted document D2 and argued, based on the disclosure of that document, in particular example 1 and the passage on page 4, lines 11 to 16, that inventive step should not be acknowledged. The appellant has thus fulfilled its duty to provide evidence in support of its allegation. At that stage, the appellant is not required to provide further evidence that the disclosure of D2 is enabling, at least not unless there are indications to the contrary.

Document D2 itself does not raise any doubt about the credibility of the disclosure relied upon by the appellant. It does not dissuade the skilled person from using rapamycin as an alternative to paclitaxel of example 1. Rather the contrary is stated, namely that rapamycin may be used. There is thus no reason for the appellant to provide evidence as to the enablement of its disclosure. On the contrary, it is the respondent who challenges the explicit disclosure of D2, so it is upon the respondent to prove that the disclosure of D2 cannot be put into practice.

17.6 However, there is no evidence on file that may throw doubts on the disclosure of D2.

17.6.1 It is uncontested that rapamycin exists in crystalline form (see document D15, page 10102, figure 3 and lines 7 to 11 below figure 3).

17.6.2 The contested patent does not disclose that the use of rapamycin rather than paclitaxel in a solvent based method as the one used in D2 would lead to any particular difficulty. Paragraph [0006] of the description of the patent in suit refers to difficulties in the preparation of coated stents by using solvent based methods in general. No specific pharmaceutical agent is referred to. In particular the patent does not state that, or explain why, rapamycin or any other macrolide immunosuppressive drug should be handled differently from paclitaxel.

17.6.3 The respondent did not provide any experimental data showing that carrying out the process disclosed in example 1 of D2 using rapamycin instead of paclitaxel, or following the teaching on page 5, line 28 to page 7, line 15 correspondingly, did not lead to rapamycin crystals being formed.

17.6.4 Instead, the respondent relied on document D15. According to the respondent, D15 showed that rapamycin crystals could not be formed on the surface of stents coated with a polymer.

17.6.5 However, in D15 the coated stents are not prepared with the methods described in D2. A different polymer is used than in example 1 of D2 (PLGA instead of polyurethane). The stents were not exposed to any non-solvent either. According to documents D15 and D2, both of these features have an effect on the morphology of the drug in the drug-polymer coating (see D15, page 10102, left column, lines 4 to 8; see D2, page 9, lines 13 to 15). In particular, in example 1 of D2 crystals are formed only after the exposure to water as a non-solvent. Document D15 does not support the respondent's allegation that a rapamycin-polymer coated stent

comprising rapamycin in crystalline form cannot be prepared following the teaching of document D2.

17.6.6 Moreover, document D2 suggests various different solvent based coating methods. There is no evidence on file either that any of these methods may not work.

17.7 In summary, the respondent's allegation that the disclosure of D2 would be non-workable is not backed by any evidence. It has not been shown that a drug-polymer coated coronary stent comprising at least 50% of rapamycin in crystalline form cannot be prepared following the disclosure of D2. Thus its disclosure must be taken as it is, and the conclusion drawn in point 6. of this decision remains valid. The provision of a coated coronary stent according to claim 1 of the main request does not involve an inventive step, so that the main request does not meet the requirements of Article 56 EPC and is thus not allowable.

Request for remittal to the opposition division for the examination of the auxiliary requests

18. The respondent requested remittal to the opposition division for the examination of the auxiliary requests in case its main request were not allowed.

19. According to Article 11 RPBA, the board shall not remit a case to the department whose decision was appealed, unless special reasons present themselves for doing so. No special reasons have been referred to by the respondent, nor can the board see any special reasons. Although none of the auxiliary requests were discussed during the opposition proceedings, given that the opposition division allowed the main request, the impugned decision dealt with all grounds of opposition.

20. The board thus refuses the respondent's request for remittal to the opposition division for the examination of the auxiliary requests (Article 11 RPBA).

Auxiliary request 1
Admittance

21. Auxiliary request 1 was filed during the oral proceedings before the board. As such its admittance is to be examined pursuant to Articles 13(1) and (2) RPBA. The request contains one independent and 10 dependent claims. Claims 1 to 16 of the granted patent, *i.e.* all product claims, are deleted. Claim 1 of auxiliary request 1 is identical to independent claim 17 of the main request (patent as granted). The remaining 10 claims are identical to claims 18 to 27 thereof.

22. In its notice of opposition, the opponent requested revocation of the patent based on the grounds of opposition under Articles 100(a), (b) and (c) EPC. In particular, independent claim 17 was attacked for lack of inventive step (Article 56 EPC). In the impugned decision, the opposition division specifically addressed objections based on Articles 100(a) and (c) EPC which were raised against claim 17 as granted (see points II.2.2 and II.7.3). In the statement setting out the grounds of appeal, the appellant reiterated its objections and argued that the method according to claim 17 of the main request was not based on the application as filed (Article 100(c) EPC), that the claimed invention was not sufficiently disclosed (Article 100(b) EPC), and that the method according to claim 17 was not based on an inventive step (Article 100(a) and 56 EPC).

23. All the issues to be discussed for the auxiliary request 1 would also have had to be discussed for the main request if claim 1 had been found to involve an inventive step, a not implausible outcome in view of the findings of the contested decision.The filing of auxiliary request 1 during the oral proceedings before the board does not bring in unexpected new issues to be dealt with. The substance of this request - i.e. the claimed subject-matter and the attacks against it - is fully encompassed by both the appellant's and the respondent's initial appeal case within the meaning of Article 12(1) to (3) RPBA. The request certainly limits the potential issues for discussion. This means that, in view of the totality of the facts of the present case, the filing of this request, although formally an amendment and as such potentially subject to the strict provisions of Article 13(2) RPBA, in substance does not constitute an amendment of a party's case within the meaning of Article 12(4) RPBA. It rather constitutes a partial abandonment of the initial appeal case. There is no apparent reason not to admit the request under any of the Articles 12(5), 13(1) or 13(2) RPBA, and the board decides to admit the request under its discretionary powers pursuant to Article 13(1) RPBA(similarly decided in T 2295/19, albeit under Article 13(2) RPBA and with a different reasoning, see Reasons 3.4.1 to 3.4.14 and the further decisions there cited).

Amendments (Article 123(2) EPC)

24. The opposition division found the method of claim 17 of the granted patent (claim 1 of auxiliary request 1) to be based on the disclosure of claim 31 in combination with paragraphs [0085] and [0010] to [0013] and with claim 58, of the application as filed. In particular,

it found that the method of claim 31 as filed also applied to the coating of a coronary stent comprising a stent framework, and that claim 58 as filed provided a basis for the value of at least 50% crystallinity.

25. The appellant contested this finding and argued that claim 17 of the patent as granted (claim 1 of auxiliary request 1) required two selections to be made from the application as filed. First, a coronary stent with a stent framework had to be selected as the *"substrate"* according to filed claim 31. Second, the method steps had to be selected. Furthermore, filed claim 31 did not define the pharmaceutical agent to be a macrolide immunosuppressive drug, and the passages cited by the opposition division did not provide a link between these features. Finally, the degree of crystallinity as well as the crystalline form as such had to be selected. Even the value of 50% as such was not based on the disclosure of claim 58, since that claim only related to the crystallinity of the pharmaceutical agent to be used as a starting material, but not to the desirable morphology of the agent in the coating.

26. The board is not convinced by the arguments of the appellant and comes to the conclusion that claim 1 of auxiliary request 1 meets the requirements of Article 123(2) EPC. The reasons are as follows:

26.1 Claim 31 of the application as filed is directed to a method for coating a substrate. Claim 1 of auxiliary request 1 differs therefrom in that:

(a) the term *"substrate"* is replaced by *"coronary stent comprising a stent framework"*,
(b) the expression *"and/or at least one biological agent"* is deleted,

(c) the *"pharmaceutical agent comprises a macrolide immunosuppressive drug"*, and in that

(d) the *"therapeutically desirable morphology of said pharmaceutical agent is at least 50% crystalline"*.

26.2 According to paragraph [0085] of the description as filed, the term *"substrate"* generally refers to any surface upon which it is desirable to deposit a coating comprising a polymer and a pharmaceutical or biological agent. This includes in particular the surface of a coronary stent as disclosed in paragraphs [0009] and [0010]. Also, part of the drug - which is a macrolide immunosuppressive in the embodiment according to paragraph [0010] - is in crystalline form (see also paragraph [0010]). Claim 58, dependent on claim 31, as filed, further defines that at least 50% of the drug used for the coating is crystalline or semicrystalline. The skilled person will understand that this also applies to the macrolide immunosuppressive being part of the coating of a coronary stent according to paragraph [0010]. The application as filed does not contain any information to the contrary either.

27. The opposition division's finding concerning the ground of opposition under Article 100(c) EPC is thus correct.

Sufficiency of disclosure (Article 83 EPC)

28. According to point II.3 of the impugned decision, the opposition division found that the granted patent met the requirements of Article 83 EPC. The division in particular referred to example 26 of the patent, which showed that a crystallinity of at least 50% could be achieved.

29. The appellant argued that example 26, in combination with figure 21 could not show that at least 50% of the drug in the coating was in crystalline form. In particular, figure 21 did not allow to quantify the degree of crystallinity.

30. The board agrees with the opposition division and the respondent and comes to the conclusion that the skilled person is able to perform a method for coating a coronary stent according to claim 1, wherein the coating of the stent framework comprises a macrolide immunosuppressive drug in a therapeutically desirable morphology which is at least 50% crystalline.

In order to show a lack of sufficiency, it is necessary to demonstrate serious doubts substantiated by verifiable facts. In the present case, the appellant has alleged that a crystallinity value according to claim 1, *i.e.* at least 50% crystalline, cannot be achieved. This allegation, however, has not been substantiated by any evidence. On the other hand, the patent as granted discloses examples on how to obtain a coated coronary stent according to claim 1, which has the required value of more than 50% of the drug in crystalline form (see, in particular, example 26). Even if, as submitted by the appellant, figure 21 was not suitable to quantify the degree of crystallinity of rapamycin comprised in the drug-polymer coating prepared according to example 26, the figure does not prove either that a crystallinity of at least 50% cannot be achieved. It would still have been incumbent on the appellant to provide evidence and to support its claim with verifiable facts. However, no such evidence was provided.

31. The objection of the appellant is thus unfounded. Auxiliary request 1 meets the requirements of Article 83 EPC.

Inventive step (Article 56 EPC)

32. The appellant argued lack of inventive step for the method according to claim 17 of the patent as granted (claim 1 of auxiliary request 1) in view of either of documents D6 or D7 as closest prior art. According to the appellant, the difference was either that an immunosuppressive drug, whose morphology is at least 50% crystalline, was present in the final stent (with respect to documents D6 and D7), or additionally that the stent comprised a stent framework (with respect to document D6). These features were known from documents D2 and D3. The skilled person would adapt the methods of D6 or D7 by including these features, and provide stents with a rapamycin-polymer coating comprising rapamycin in at least 50% crystalline form. The claimed method thus did not involve an inventive step.

33. This argumentation does not convince the board for the following reasons:

Claim 1 of auxiliary request 1

33.1 The patent under dispute relates to coated coronary stents and methods for their preparation (see paragraph [0001]). Claim 1 of the auxiliary request 1 is directed to a method for coating a coronary stent by electrodeposition and sintering. The coating comprises a polymer and a macrolide immunosuppressive drug in a therapeutically desirable morphology, which is at least 50% crystalline. The method comprises the steps of discharging the drug and the polymer, both in dry

powder form, on the coronary stent, wherein an electrical potential is maintained between the coronary stent and the polymer and drug particles (see paragraph [0011] and claim 1). The patent mentions various problems encountered with other methods known in the art, such the difficulty to achieve uniform coating thickness and consistency of the coating, resulting in poor bioavailability, insufficient shelf life, low in vivo stability or uncontrollable elution of the drug (see paragraphs [0005] to [0008]).

The closest prior art

33.2 Document D7 discloses stents comprising a polymer coating and mentions the problem of attachment of the polymer to the stent (see paragraphs [0002], [0012], [0016] and claim 1), as well as methods for their preparation (see paragraphs [0031], [0032]). D7 does not disclose stents comprising a pharmaceutical agent in the coating. It is thus not a promising starting point for the preparation of a coronary stent with a coating comprising at least one pharmaceutical agent which comprises a macrolide immunosuppressive drug.

33.3 Document D6 also relates to the preparation of coated stents, *e.g.* coronary stents (see claim 3). In addition, pharmaceutical agents, such as sirolimus (rapamycin) may be applied to the coating (claim 23). D6 is a more suitable as closest prior art than D7.

The differing feature and the technical problem

33.4 The method according to claim 1 of auxiliary request 1 differs from the method disclosed in claim 1 of D6 in that a stent is prepared, in which the morphology of the pharmaceutical agent in the drug-polymer coating is

at least 50%. D6 does not disclose the morphology of the pharmaceutical agent in the coating. Furthermore, the polymer coating according to D6, which is applied in a first step and before the pharmaceutical agent is applied, is heated in order to obtain a carbonised layer (see claims 1 and 17). The final product obtained according to D6 does thus not contain a polymer-drug coating, but a carbon-containing layer, which may contain an applied pharmaceutical agent (claim 17).

33.5 As indicated in point 17.2 above, it was undisputed that the presence of the drug in crystalline form leads to advantages, such as a controlled release rate (see document D2, page 2, lines 3 to 18).

33.6 The technical problem is thus the provision of a method for the preparation of a drug coated coronary stent which allows for a controlled release rate of the drug.

The claimed solution

33.7 In order to solve the technical problem, a method according to claim 1 is suggested. The method is directed to the preparation of a coated coronary stent comprising a polymer-drug coating, wherein the morphology of the pharmaceutical agent is at least 50%. The board is satisfied that the claimed method solves the technical problem.

Inventiveness of the claimed solution

33.8 Document D6 does not lead the skilled person to the claimed solution. In particular, the method disclosed in the document does not allow for the preparation of a coating comprising a polymer, since the polymer, once applied to the surface of a stent, is heated to a

temperature of between 200°C and 2500°C in order to form a carbon layer (claim 1). The polymer is thus destroyed in the process. Although the preparation of drug-polymer stents is known in the art (see *e.g.* D1, claim 1), it is not obvious to modify the method according to D6 and avoid the formation of a carbon layer, because this step is essential in the teaching of D6 (page 2, lines 21 to 22, page 3, line 27 to page 4, line 2, also page 5, line 19 to page 6, line 7).

34. The provision of a method according to claim 1 of auxiliary request 1 thus involves an inventive step, and auxiliary request 1 meets the requirements of Article 56 EPC.

35. Since none of the objections brought forward by the appellant prejudices the maintenance of the contested patent in amended form under Article 101(3)(a) EPC on the basis of auxiliary request 1, this request is allowable.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the opposition division with the order to maintain the patent with the following claims and a description to be adapted thereto:

Claims: Nr. 1 to 11 of the auxiliary request 1 filed in the oral proceedings before the board.

The Registrar: The Chairman:

C. Rodríguez Rodríguez M. Kollmannsberger

Decision electronically authenticated