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Datasheet for the decision of 9 March 2026

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Title of invention:
Drug eluting medical device

Patent Proprietor:
Invatec Technology Center GmbH

Opponents:
Ahrens, Gabriele Dr.
BARD PERIPHERAL VASCULAR, INC.

Relevant legal provisions:
EPC Art. 76(1), 123(2), 83, 54, 56

Keyword:
Amendments
Sufficiency of disclosure
Novelty
Inventive step

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Boards of Appeal

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Case Number: T 1171/24 - 3.3.02

D E C I S I O N
of Technical Board of Appeal 3.3.02
of 9 March 2026

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Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted/ electronically transmitted on 16 July 2024 concerning maintenance of the European Patent No. 2962706 in amended form.**

Composition of the Board:

Chairman	M. O. Müller
Members:	A. Lenzen
	B. Burm-Herregodts

Summary of Facts and Submissions

I. The patent proprietor and opponent 2 lodged an appeal against the opposition division's decision (decision under appeal) that European patent No. 2 962 706 (patent) in amended form meets the requirements of the EPC.

Since the patent proprietor and opponent 2 are both appellant and respondent, the board refers to them below as the patent proprietor and opponent 2.

II. The patent is based on European patent application No. 15158846.4 (application) which is a divisional application of European patent application No. 10700525.8 (parent application).

III. Reference is made in the present decision to the following documents filed with the opposition division:

D1 WO 2009/018816 A2
D11 WO 2008/089730 A2
D12 Experimental report (9 pages)

IV. With the statement of grounds of appeal, the patent proprietor filed, *inter alia*, the sets of claims of auxiliary requests 1 and 2.

V. In preparation for the oral proceedings, which had been arranged at the patent proprietor's and opponent 2's request, the board issued a communication under Article 15(1) RPBA. In that communication, it summarised the parties' previous substantive submissions and expressed its preliminary opinion on several issues.

VI. By letter dated 11 December 2025, the patent proprietor filed a further substantive submission.

VII. Oral proceedings before the board were held by videoconference on 9 March 2026 in the presence of the patent proprietor and opponent 2. At the end of the oral proceedings, the chair announced the order of the present decision.

VIII. The parties' final requests at the end of the oral proceedings relevant to this decision were as follows.

- The patent proprietor requested that the decision under appeal be set aside and that the oppositions be rejected implying that the patent be maintained as granted (main request). In the alternative, it requested that the patent be maintained in amended form based on one of the sets of claims of auxiliary request 1 or 2, filed with the statement of grounds of appeal.
- Opponent 2 requested that the decision under appeal be set aside and that the patent be revoked in its entirety.
- Opponent 1 did not file any submission or request on appeal.

IX. Summaries of the patent proprietor's and opponent 2's submissions relevant to the present decision and key aspects of the decision under appeal are set out in the reasons for the decision below.

Reasons for the Decision

Main request (patent as granted)

1. Claim 1 of the main request reads as follows:

> "*A catheter balloon completely or partially coated with paclitaxel in crystalline hydrated form or in crystalline hydrated solvated form, having an immediate release and bioavailability of a therapeutically effective amount of paclitaxel at the site of intervention, and wherein paclitaxel is present in the catheter balloon coating layer in amounts ranging between 2 and 7 µg/mm^2, or between 3 and 5 µg/mm^2.*"

2. Novelty (Article 54 EPC)

2.1 Opponent 2 argued that the subject-matter of claim 1 of the main request lacked novelty over example 9 of D1.

2.2 In example 9 of D1, a Falcon Bravo RX catheter balloon (diameter: 3.5 mm; length: 20 mm) is coated once with 18 µL of a solution consisting of urea (70 mg), water (1 mL), THF (9 mL) and paclitaxel (500 mg) using a Hamilton CR-700 microdosing syringe followed by drying.

2.3 Thus, D1 discloses in example 9 a catheter balloon which is completely or partially coated with paclitaxel. However, it does not explicitly disclose the following features of claim 1 of the main request.

(a) The paclitaxel is in crystalline hydrated or in crystalline hydrated solvated form.

(b) The catheter balloon provides immediate release and bioavailability of a therapeutically effective amount of paclitaxel at the site of intervention.
(c) The paclitaxel is present in the catheter balloon coating layer in an amount ranging from 2 to 7 µg/mm^2.

2.4 As argued by opponent 2, the catheter balloon of D1 (see above, point 2.2) and the balloons according to claim 1 of the main request (see the patent, example 1A) are manufactured in the same way. In both cases, a solution of urea and paclitaxel (the latter at a concentration of 50 mg/mL or 50 µg/µL) in THF/water (9:1) is applied to a catheter balloon followed by drying.

Since identical processes yield identical products, both the paclitaxel and the balloon coated with it according to D1 must necessarily satisfy features (a) and (b) of claim 1 of the main request. This is because these features concern properties inherent to the paclitaxel obtained by that process or attributable to the paclitaxel produced in this manner.

As regards feature (b), this was not contested by the patent proprietor. Nor did it contest that the paclitaxel in example 9 of D1 is present in hydrated or hydrated solvated form (see feature (a)). With respect to the crystallinity specified in feature (a), the patent proprietor merely submitted that D1 referred to crystalline paclitaxel coatings only for the preferred embodiments. It therefore argued that no conclusion could be drawn as to whether the catheter balloon in example 9 of D1 was coated with paclitaxel in crystalline form. This argument, however, is not persuasive since crystallinity is not inferred from D1

itself but rather from a comparison of the manufacturing processes disclosed in D1 and the patent.

2.5 As regards feature (c), in example 9, D1 does not specify the amount of paclitaxel that is ultimately deposited on the balloon. However, as argued by opponent 2, D1 (page 19, lines 18 to 26; page 20, lines 19 to 22) generally teaches that, to achieve a uniform coating, the entire balloon membrane should be wetted with the coating solution without any of it being lost in the process. Therefore, the board agrees with opponent 2 that the ratio of the amount of paclitaxel that is ultimately deposited on the balloon to the amount used for coating, i.e. the coating efficiency, can reasonably be assumed to be 100%. Under this assumption, and in line with opponent 2's submission, the amount of paclitaxel in the catheter balloon coating layer of example 9 of D1 can be calculated by dividing the total amount of paclitaxel used for coating (m = (concentration of solution applied) · (volume of solution applied) = 50 µg/µL · 18 µL = 900 µg) by the surface area to which it is applied (A = (length of balloon) · (circumference of balloon) = (length of balloon) · 2π · (diameter of ballon)/2 = 20 mm · 2π · 3.5/2 mm ≈ 220 mm^2). This gives m/A ≈ 4.1 $µg/mm^2$, i.e. a value that squarely falls within the range of claim 1 of the main request. The board therefore agrees with opponent 2 that, apart from features (a) and (b), feature (c) of claim 1 of the main request is also implicitly disclosed in example 9 of D1.

2.6 The patent proprietor did not agree with the conclusion above that feature (c) of claim 1 of the main request is implicitly disclosed in example 9 of D1. It essentially argued as follows.

In example 2 of D1, a balloon was coated using the same syringe as that used in example 9. However, unlike example 9 (single application), example 2 involved a double application of a paclitaxel solution with an intermediate drying step. Furthermore, in example 2, the amount of paclitaxel ultimately deposited was determined experimentally, allowing the coating efficiency to be accurately assessed. In example 2, however, the coating efficiency was only 76.8%, i.e. significantly lower than 100%. Given that the coating efficiency in example 2 was significantly below 100%, it would not be reasonable to assume a coating efficiency of 100% for example 9 as otherwise there would be no need for a double application. In other words, if the coating efficiency were 100% for a single application, there would be no reason to carry out a second application instead of simply increasing the amount of paclitaxel applied in the first application. Therefore, it had to be concluded that the coating efficiency of the single application in example 9 was even lower than that calculated for example 2, and that the amount of paclitaxel in the catheter balloon coating layer obtained in example 9 could not fall within the range defined in claim 1 of the main request.

2.7 However, the validity of the assumption made with regard to example 9, as well as the coating efficiency observed in example 2 of D1, are essentially confirmed by the experimental report D12.

D12 describes the repetition of examples 2 (double application) and 9 (single application) from D1. Each example was repeated three times. In the repetitions of example 2, the amounts of paclitaxel deposited on the

balloons (see D12, page 3, table 1: 3.0, 3.7 and 3.5 µg/mm^2), when related to the maximum deposited amount possible (3.9 µg/mm^2), correspond to an average coating efficiency of 88%, i.e. a value consistent with the coating efficiency observed in D1, which is well below 100% for a double application. In contrast, in the repetitions of example 9, the amounts of paclitaxel deposited on the balloons (see D12, page 7, table 2: 4.4, 3.6 and 3.5 µg/mm^2), when related to the maximum deposited amount possible (4.0 µg/mm^2), correspond to an average coating efficiency of 96%, i.e. a value very close to the maximum possible coating efficiency of 100%. The results of D12 therefore align both with the lower coating efficiency observed in example 2 of D1 for the double application and with the coating efficiency of 100% reasonably assumed by opponent 2 for the single application in example 9. Moreover, D12 (page 2, penultimate paragraph) gives a plausible explanation for the different coating efficiencies observed for the single versus double application, namely that during the second application, the coating device, when in contact with the balloon, interacts with the paclitaxel coating resulting from the first application, thereby reducing the overall coating efficiency. In view of the results described in D12, the board sees no reason to doubt opponent 2's position that a coating efficiency of 100% is achieved in example 9 of D1 using a single application.

It is true that, as submitted by the patent proprietor, the measured values obtained in the repetitions described in D12 vary more or less from one another and that the three measured values obtained in the repetition of example 9 were averaged incorrectly (note: the above value of 96% is based on the correct average). However, the board sees no reason in this

alone to doubt the above conclusion since the measured values obtained in the repetition of example 9 still all lie squarely within the range of claim 1 of the main request.

The board acknowledges that - as also argued by the patent proprietor - D12 does not reproduce example 9 in every detail and that it also supplements it (e.g. with regard to the size and material of the balloon, the amount of the coating solution as well as the type of syringe and its needle). However, at least in the absence of any counter-evidence from the patent proprietor, the board considers these deviations and additions not to be of such significance as to have a material impact on the outcome.

2.8 In summary, the board concludes, in line with the opposition division and opponent 2, that the subject-matter of claim 1 of the main request lacks novelty over example 9 of D1. The main request is not allowable.

Auxiliary request 1

3. Claim 1 of auxiliary request 1 differs from claim 1 of the main request only in the following additional feature:

> "*wherein said paclitaxel in crystalline hydrated or crystalline solvated hydrated form can be obtained by means of a method comprising:*
> *i) dissolving paclitaxel in an aqueous solvent so as to form a paclitaxel solution;*
> *ii) completely or partially wetting the balloon surface with such solution; and*
> *letting the solvent to evaporate.*"

This additional feature relates to a method of manufacture of the paclitaxel forms recited in claim 1.

4. However, as is evident from the foregoing discussion, this additional feature is also anticipated by example 9 of D1 (see point 2.2 above).

Consequently, the subject-matter of claim 1 of auxiliary request 1 also lacks novelty over example 9 of D1. Auxiliary request 1 is not allowable.

Auxiliary request 2

5. Claim 1 of auxiliary request 2 reads as follows (the additional feature compared with claim 1 of the main request is shown in bold):

> "*A catheter balloon completely or partially coated with paclitaxel in crystalline hydrated form or in crystalline hydrated solvated form, having an immediate release and bioavailability of a therapeutically effective amount of paclitaxel at the site of intervention, and wherein paclitaxel is present in the catheter balloon coating layer in amounts ranging between 2 and 7 µg/mm^2, or between 3 and 5 µg/mm^2,*
> ***wherein said balloon is made of a polyether-polyamide block copolymer, or compound thereof with a polyamide, or wherein said balloon is made of polyamide-12, or wherein said balloon is made of polyester amide.***"

Thus, claim 1 of auxiliary request 2 now additionally specifies the material from which the catheter balloon may be made.

6. Amendments (Articles 76(1) and 123(2) EPC)

6.1 Since the claims of the parent application as filed are appended as "*clauses*" to the description of the application as filed, the parties agreed that the assessment of added subject-matter will yield the same result, regardless of whether it is conducted with respect to the application or the parent application as filed. In line with opponent 2's submissions, the board concentrates on the application as filed below.

6.2 Claim 1 of auxiliary request 2 is based on clauses 1, 2, 13, 19, 20, and 24 of the application as filed, with clauses 1, 2, and 24 providing a basis in so far as the wording of claim 1 of auxiliary request 2 is identical to that of claim 1 of the main request (not in bold above), and clauses 13, 19 and 20 providing a basis for the additional feature, i.e. the balloon materials (in bold above).

6.3 Clauses 1, 2 and 24 of the application as filed read as follows:

> "*1. A catheter balloon completely or partially coated with paclitaxel in crystalline hydrated form, having an immediate release and bioavailability of a therapeutically effective amount of paclitaxel at the site of intervention.*"
>
> "*2. The catheter balloon completely or partially coated with paclitaxel in crystalline hydrated solvated form, having an immediate release and bioavailability of a therapeutically effective amount of paclitaxel at the site of intervention.*"

"*24. The catheter balloon according to any one of the clauses 1 to 23, wherein paclitaxel is present in the catheter balloon coating layer in amounts ranging between 1 and 20 µg/mm^2, or between 2 and 7 µg/mm^2, or between 3 and 5 µg/mm^2.*"

Independent clause 1 recites paclitaxel in crystalline hydrated form; independent clause 2, paclitaxel in crystalline hydrated solvated form. The subject-matter of these two independent clauses has been combined in claim 1 of auxiliary request 2 with an "*or*". Furthermore, the two narrower quantitative ranges ("*between 2 and 7 µg/mm^2, or between 3 and 5 µg/mm^2*") from clause 24, which refers back to both clauses 1 and 2, have been selected and incorporated in claim 1 of auxiliary request 2.

Thus, in so far as the subject-matter of claim 1 of auxiliary request 2 is identical to that of claim 1 of the main request, it requires only a single selection from the combination of clauses 1, 2 and 24 of the application as filed. This single selection does not result in added subject-matter.

6.3.1 Opponent 2 did not agree. In its written submissions, it argued that the application as filed disclosed two distinct and non-overlapping embodiments: one in which paclitaxel was present in crystalline hydrated form (clause 1), and another in which it was present in crystalline hydrated solvated form (clause 2). By contrast, claim 1 of auxiliary request 2 encompassed the possibility that both forms were present. This possibility was not disclosed in the application as filed. At the oral proceedings before the board, opponent 2 further elaborated on this argument by also referring to clause 24 of the application as filed. In

claim 1 of auxiliary request 2, the amount of paclitaxel present in the coating layer referred collectively to both forms. For instance, claim 1 of auxiliary request 2 encompassed a coating layer comprising 0.5 µg/mm^2 of the crystalline hydrated form and 1.5 µg/mm^2 of the crystalline hydrated solvated form. By contrast, the clauses of the application as filed required that each form be present in an amount of at least 2 µg/mm^2.

6.3.2 The board does not find this convincing. Opponent 2's objections ultimately concern the interpretation of clauses 1, 2 and 24 of the application as filed, namely the questions of (i) whether the fact that the two paclitaxel forms are mentioned in two independent clauses excludes their simultaneous presence on the balloon, and (ii) whether the back-references in clause 24 imply that the amounts specified in that clause must relate to only one of the two paclitaxel forms alone. However, as set out above, in so far as the wording of claim 1 of auxiliary request 2 is identical to that of claim 1 of the main request, it corresponds exactly to the combination of clauses 1, 2 and 24 of the application as filed. There can therefore be no issue of added subject-matter for logical reasons alone. If anything, it would have to be concluded that the ambiguities contained in the clauses of the application as filed with regard to the two questions of interpretation identified above are likewise present in claim 1 of auxiliary request 2.

Irrespective of the foregoing, and merely by way of additional argument, the board notes the following. Assuming that the two forms mentioned in clauses 1 and 2 of the application as filed are distinct and non-overlapping as argued by opponent 2, each clause

nevertheless still provides only for a partial coating. Therefore, as correctly set out by the patent proprietor, each clause explicitly encompasses the possibility that the respective other form is likewise present on the catheter balloon. The skilled person would therefore not understand the amount of paclitaxel in clause 24 as being limited to one of the forms mentioned in clause 1 or 2 but rather as relating to the combination of both forms. The skilled person's understanding of clauses 1, 2 and 24 of the application as filed therefore corresponds to opponent 2's own interpretation of these clauses when combined in claim 1 of auxiliary request 2. Thus, also from this perspective, there can be no added subject-matter.

6.4 Of the clauses in the application as filed, clauses 13 to 22 relate to materials suitable for the balloon catheter. Clauses 13, 19, and 20 relate to different groups of materials in their most general form. These are, where applicable, further defined, i.e. limited, by the clauses dependent on them (clauses 14 to 18, 21 and 22). In claim 1 of auxiliary request 2, all the materials mentioned in clauses 13, 19, and 20 - and only those - have now been incorporated. Thus, claim 1 of auxiliary request 2 has been limited to all possible groups of materials in their most general form which are mentioned in the clauses of the application as filed. The board agrees with the patent proprietor that this does not require any selection from the clauses of the application as filed.

6.5 Therefore, the subject-matter of claim 1 of auxiliary request 2 results from a single selection of the two narrower quantitative ranges ("*between 2 and 7 µg/mm^2, or between 3 and 5 µg/mm^2*") from the application as filed and - contrary to opponent 2's view - not from a

double selection, the second selection allegedly consisting of the balloon materials recited in claim 1 of auxiliary request 2.

6.6 In opponent 2's view, the dependent claims contained added subject-matter for the same reasons as claim 1 (see above, point 6.3.1). However, as far as the dependent claims are concerned, this objection is not convincing either for the reasons set out above (see point 6.3.2).

6.7 In summary, the claims of auxiliary request 2 do not contain added subject-matter.

7. Sufficiency of disclosure (Article 83 EPC)

7.1 Opponent 2 essentially argued that claim 1 of auxiliary request 2 defined the catheter balloon in terms of achieving an effect, namely as "*having an immediate release and bioavailability of a therapeutically effective amount of paclitaxel at the site of intervention*". However, the patent did not provide any means for determining whether the effect was achieved. The definition of the term "*immediate release and bioavailability*" given in the patent, i.e. "*a release from the balloon surface in periods of time ranging between 1 second and 1.5 minutes*", was so unclear that it gave rise to a *prima facie* issue of sufficiency. The examples of the application did not help as they did not say how long the balloon was inflated for or how much paclitaxel was present in crystalline hydrated or in crystalline hydrated solvated form. Therefore, it was not possible to conclude if a therapeutically effective amount of paclitaxel was released from the balloon within the time range of 1 second to 1.5 minutes.

7.2 This is not convincing. Example 1 of the application as filed discloses how a coating layer of paclitaxel in crystalline hydrated or in crystalline hydrated solvated form can be applied to a catheter balloon. It is this form to which the claimed effect ("*having an immediate release and bioavailability of a therapeutically effective amount of paclitaxel at the site of intervention*") is attributable (see application as filed, page 27, lines 2 to 9, corresponding to paragraph [0100] of the patent). This was also not disputed by opponent 2. Example 2 of the patent, which both the opposition division in its decision and the patent proprietor relied on for sufficiency, describes the *in vivo* use of catheter balloons provided with such a coating and explains how the amount of paclitaxel released from the balloon is to be determined, namely indirectly by measuring the amount of paclitaxel still adhering to the balloon after use. Table I discloses the corresponding amounts of paclitaxel absorbed by the vascular tissue, i.e. amounts that are, within the context of the invention, to be regarded as therapeutically effective. The board agrees with the patent proprietor and finds no reason to doubt that the release of such amounts can be achieved using balloon inflation times within the range specified in the application as filed (1 second to 1.5 minutes). In any event, the board agrees with the opposition division that the selection of suitable inflation times for this purpose falls within the routine practice of the skilled person.

Thus, the invention defined in claim 1 of auxiliary request 2 is sufficiently disclosed.

8. Novelty (Article 54 EPC)

8.1 Opponent 2 put forward novelty objections to the subject-matter of claim 1 of auxiliary request 2 based on example 9 of D1 and examples 1 and 2 of D11. These objections are addressed in turn below.

8.2 D1, example 9

While opponent 2 had argued a lack of novelty based on example 9 of D1 in its written submissions, it acknowledged at the oral proceedings before the board that the subject-matter of claim 1 of auxiliary request 2, which specifies the material from which the catheter balloon may be made, is novel over example 9 of D1 since the material of the Falcon Bravo RX catheter balloon used in this example is not disclosed in D1.

8.3 D11, examples 1 and 2

8.3.1 In example 1 of D11, a solution of paclitaxel (50 mg/mL) in DMSO is sprayed onto a catheter balloon. A fine water mist with a pH of 3.5 is then sprayed onto the surface of the catheter balloon already wetted with the paclitaxel/DMSO solution until paclitaxel precipitation begins. After drying, the coating process with paclitaxel in DMSO followed by precipitation with the water mist is repeated two more times. The amount of paclitaxel on the catheter balloon is specified as 3 $\mu g/mm^2$.

In example 2 of D11, a catheter balloon is immersed in a solution of paclitaxel (80 mg) in DMSO/MeOH (1.0 mL/ 0.1 mL) and sprayed with a water mist having a pH of 4.0. As soon as the first fine paclitaxel crystals

begin to form, the catheter balloon is allowed to dry slowly in air. After drying, the initially coated catheter balloon is immersed three more times in the paclitaxel solution and then dried, without being sprayed with water mist again. The fine paclitaxel crystals on the balloon surface serve as crystallisation nuclei for the newly applied paclitaxel. D11 states that the resulting loading is typically in the range of 1 to 20 µg/mm^2.

8.3.2 Novelty over example 1 of D11

Example 1 of D11 thus discloses the precipitation of paclitaxel; example 2, its crystallisation.

Opponent 2 argued that paclitaxel crystals were also formed during the precipitation in example 1. However, as argued by the patent proprietor, these examples are consistent with the overall disclosure of D11, which does not equate the precipitation of paclitaxel with its crystallisation (see: D11, page 6, lines 16 to 19; page 7, first paragraph).

Moreover, contrary to opponent 2's argument, it cannot be inferred from example 2 that example 1 must also provide crystalline paclitaxel as the two examples do not employ the same procedure for producing the paclitaxel coating. Differences exist, for example, with regard to the composition of the paclitaxel solution and the pH value of the water mist.

Therefore, example 1 does not directly and unambiguously disclose that the paclitaxel is in crystalline form, as is the case in example 2.

This reasoning had been set out in the board's communication under Article 15(1) RPBA and was not contested by opponent 2 at the oral proceedings.

8.3.3 Novelty over example 2 of D11

The opposition division took the view - and opponent 2 reiterated this on appeal - that the paclitaxel crystals formed in the initially applied coating solution in example 2 had to be in hydrated or in hydrated solvated form. The reason for this was that a water mist was used to induce the crystallisation of paclitaxel. However, for the following reasons, which were discussed during the oral proceedings, the board shares the patent proprietor's view that this conclusion cannot, in fact, be drawn.

Example 2 of D11 is based on the crystallisation of paclitaxel from a solution by the addition of an anti-solvent, the solvent being a mixture of DMSO and methanol and the anti-solvent being water. Such an approach does not necessarily imply that the anti-solvent must form part of the crystals obtained by this method.

Opponent 2 argued that since a hydrated form of paclitaxel was obtained according to claim 3 of the patent, it had to be assumed that the same was true also for example 2 of D11. However, this argument is not convincing. Claim 3 essentially states that paclitaxel in crystalline hydrated or in crystalline hydrated solvated form can be obtained by i) dissolving paclitaxel in DMSO/water; ii) completely or partially wetting the balloon surface with this solution; and iii) letting the solvent evaporate. However, not only the solvents used in example 2 but also the

crystallisation method itself differ significantly from those recited in claim 3 of the patent. Example 2 employs DMSO, water and, crucially, methanol, whereas claim 3 of the patent refers only to DMSO and water. Furthermore, example 2 is based on the addition of a water mist to a solution containing DMSO and methanol, whereas claim 3 of the patent is based on the use of a solution comprising DMSO and water. Hence, contrary to opponent 2's assertion, it cannot be concluded from claim 3 of the patent that the paclitaxel in example 2 of D11 is present in the hydrated form.

Thus, the subject-matter of claim 1 of auxiliary request 2 differs from example 2 of D11 at least in that the paclitaxel is in crystalline **hydrated** or in crystalline **hydrated**solvated form.

9. Inventive step (Article 56 EPC)

9.1 The parties agreed that D1 constitutes prior art under Article 54(3) EPC and therefore cannot be taken into account in the assessment of inventive step.

9.2 Opponent 2's only inventive-step objection started from example 2 of D11 as the closest prior art.

9.3 As set out above, the subject-matter of claim 1 of auxiliary request 2 differs from example 2 of D11 at least in that the paclitaxel is in crystalline **hydrated** or in crystalline **hydrated** solvated form.

9.4 In table I, the patent compares catheter balloons according to claim 1 of auxiliary request 2 (entries 1 to 4) with one that is coated with paclitaxel in a crystalline but non-hydrated form (entry 5). Compared with the latter, the catheter balloons according to

claim 1 show an improvement in release to vascular tissue. These results were not questioned by opponent 2.

9.5 Therefore, the board concurs with the patent proprietor that the objective technical problem is to provide a catheter balloon having an improved release performance.

9.6 Opponent 2 only ever argued that the solution to a less ambitious objective technical problem (namely, to provide an alternative catheter balloon) was obvious. In the absence of any arguments from opponent 2 as to why the solution to the more ambitious objective technical problem formulated above, as reflected in claim 1 of auxiliary request 2, should be obvious, the board agrees with the patent proprietor that the subject-matter of claim 1 and its dependent claims 2 to 9 of auxiliary request 2 involves an inventive step. Consequently, auxiliary request 2 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 and a figure possibly to be adapted thereto:

   Claims 1 to 9 according to auxiliary request 2, filed with the proprietor's statement of grounds of appeal

The Registrar: The Chairman:

U. Bultmann M. O. Müller

Decision electronically authenticated