

Internal distribution code:

- (A) [-] Publication in OJ
- (B) [-] To Chairmen and Members
- (C) [-] To Chairmen
- (D) [X] No distribution

**Datasheet for the decision
of 18 March 2022**

Case Number: T 0476/18 - 3.3.10

Application Number: 10700525.8

Publication Number: 2385848

IPC: A61L29/06, A61L29/16, A61M25/10

Language of the proceedings: EN

Title of invention:
DRUG ELUTING MEDICAL DEVICE

Patent Proprietor:
Invatec Technology Center GmbH

Opponent:
Cook Medical Technologies LLC

Headword:
DRUG ELUTING DEVICE / INVATEC

Relevant legal provisions:
RPBA 2020 Art. 13(2)

Keyword:
New main request filed during oral proceedings - admitted (no)

Decisions cited:

T 0752/16

Catchword:



Beschwerdekammern
Boards of Appeal
Chambres de recours

Boards of Appeal of the
European Patent Office
Richard-Reitzner-Allee 8
85540 Haar
GERMANY
Tel. +49 (0)89 2399-0
Fax +49 (0)89 2399-4465

Case Number: T 0476/18 - 3.3.10

D E C I S I O N
of Technical Board of Appeal 3.3.10
of 18 March 2022

Appellant: Invatec Technology Center GmbH
(Patent Proprietor) Hungerbühlstrasse 12A
8500 Frauenfeld (CH)

Representative: Zimmermann & Partner
Patentanwälte mbB
Postfach 330 920
80069 München (DE)

Appellant: Cook Medical Technologies LLC
(Opponent) 750 North Daniels Way
Bloomington, IN 47404 (US)

Representative: Mathys & Squire
The Shard
32 London Bridge Street
London SE1 9SG (GB)

Decision under appeal: **Interlocutory decision of the Opposition
Division of the European Patent Office posted on
5 December 2017 concerning maintenance of the
European Patent No. 2385848 in amended form.**

Composition of the Board:

Chairman P. Gryczka
Members: M. Kollmannsberger
T. Bokor

Summary of Facts and Submissions

- I. The appeals lie from the decision of the Opposition Division to maintain European Patent EP 2 385 848 in amended form, Article 101(3)(a) EPC.

The patent had been opposed raising grounds for opposition under Articles 100(a), 100 (b) and 100(c) EPC. In its decision the Opposition Division came to the conclusion that the subject matter of the claims of the granted patent as well as of the first auxiliary request was not novel over document WO 2009/018816 (D1). The claims of the second auxiliary request were found to comply with the provisions of the EPC.

- II. In its statement of grounds of appeal the appellant-patentee requested the appealed decision to be set aside and the patent to be maintained as granted.

As auxiliary request he requested the patent to be maintained on the basis of the claim sets of one of the first to eleventh auxiliary requests, already filed during the opposition procedure and re-filed with the statement of the grounds of appeal.

- III. In its statement of grounds of appeal the appellant-opponent requested the appealed decision to be set aside and the patent to be revoked.

- IV. On 30 July 2020 the Board issued a communication under Rule 100(2) EPC setting out its preliminary opinion as regards the legal and factual issues under dispute. With respect to unallowable amendments the Board's preliminary opinion was that the process claims of all requests contravened Article 123(2) EPC, whereas the

product claims appeared not to contain added subject matter. With respect to novelty the Board's preliminary opinion was that the product claims of at least the main request and of auxiliary requests 1-3 and 11 lacked novelty over D1.

V. On 8 March 2021 the Board summoned the parties for oral proceedings which were to take place, together with two other related cases, on 24. and 25 February 2022. The date of the oral proceedings was later changed to 17 and 18 March 2022.

VI. Oral proceedings were held on 18 March 2022 in the form of a videoconference.

VII. During oral proceedings the Board came to the conclusion that not only the process claim, but also the product claim of the granted patent contained added matter, contrary to the provision of Article 123(2) EPC. This finding applied equally to the product claims of auxiliary requests 1-10. Auxiliary request 11 on the other hand contained no added subject-matter.

The appellant-patentee then filed a new main request, replacing all pending requests. This new main request was based on previous auxiliary request 11 wherein in the independent claim the subject-matter of two dependent claims was incorporated.

VIII. Claim 1 of the new 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, wherein the coating layer of paclitaxel comprises urea,

wherein said paclitaxel crystalline hydrated or crystalline solvated hydrated form can 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

iii) letting the solvent to evaporate;

wherein said paclitaxel solution of the step i) comprises urea, preferably in amounts ranging between 1 and 100 mg/mL. or between. 4 and 10 mg per mL solvent or about 7 mg per mL solvent, and

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."

The underlined part has been added compared to claim 1 of previous auxiliary request 11 upon which is it based. The added features are taken from dependent claims 6 and 10 of previous auxiliary request 11, corresponding to claims 7 and 11 as granted. They were also recited in claim 1 of previous auxiliary requests 4 and 5.

IX. In the view of the appellant-patentee this new request had to be admitted into the proceedings under Article 13(2) RPBA 2020 since the preliminary opinion on added

matter set out in the Board's communication under Rule 100(2) EPC was changed during oral proceedings. A patent proprietor could not be expected to file, from the outset, auxiliary requests taking account of all possible combinations of objections that the Opposition Division or the Board might later find convincing. The new request took account of the added matter as well as the novelty objections. It did not give rise to any additional discussion since the features of the new independent claim were likewise present in the independent claims of at least auxiliary requests 11 and 5. The opponent could thus not be surprised by the new main request.

X. The appellant-opponent referred to Rule 13(2) RPBA 2020 which required the presence of exceptional circumstances for the admittance of an amendment in the patentee's appeal case at such a late stage of the proceedings. No such circumstances were present. In particular a change of the preliminary opinion did not qualify as being exceptional since the opinion was, according to Article 17(2) RPBA 2020, not binding. The added matter and the novelty objection in question were on file since the start of opposition procedure; the Opposition Division had accepted the novelty objection, but not the added matter objection. The patentee had thus enough time to file a request taking account of both of the objections; no multitude of requests would have been necessary.

XI. The final requests of the parties were as follows:

The appellant-patentee requested the impugned decision to be set aside and the patent to be maintained in amended form based on the claims of the new main request filed during oral proceedings.

The appellant-opponent requested the newly filed main request not to be admitted into the proceedings under Article 13(2) RPBA and to revoke the patent.

XII. At the end of the oral proceedings the Board announced the decision.

Reasons for the Decision

1. The appeals are admissible.
2. The present decision hinges on the admission of the patentee's new main and sole request into the proceedings.

This request was filed during oral proceedings after the announcement of the Board's conclusion that, in contrast to what was set out in the Board's preliminary opinion in the communication under Rule 100(2) EPC, the opponent's objection under Article 123(2) EPC against claim 1 of the patent as granted was valid. This applied in the same way to claim 1 of each of auxiliary requests 1-10. Since claim 1 of auxiliary request 11, which overcame the added matter objection, was according to the Board's preliminary opinion not novel, the patentee felt the need to file a request based on auxiliary request 11 with additional features from dependent claims which in his view overcame the novelty objection.

However, the new main request cannot be admitted into the proceedings, for the reasons set out below.

3. The appeals were filed in 2018, i. e. before the entry into force of the present Rules of Procedure. The

Board's communication under Rule 100(2) EPC was issued on 30 July 2020, i. e. after the entry into force of the present Rules of Procedure. Thus, according to the transitional provisions in Article 25(3) RPBA 2020 Article 13(2) 2020 applies to the present case.

This was undisputed.

4. Article 13(2) RPBA 2020 reads as follows:

"Any amendment to a party's appeal case made after the expiry of a period specified by the Board in a communication under Rule 100, paragraph 2, EPC (...) shall, in principle, not be taken into account unless there are exceptional circumstances, which have been justified with cogent reasons by the party concerned."

It was undisputed that the patentee's new main request constitutes an amendment of its appeal case in the sense of Rule 13(2) RPBA 2020. It was also undisputed that the request was filed after the expiry of a period specified by the Board in a communication under Rule 100(2) EPC, namely at an advanced stage of the oral proceedings.

5. The patentee submitted that the exceptional circumstances justifying an amendment of its case under this provision was the unexpected change in the Board's opinion regarding the assessment of the opponent's objection under Article 123(2) EPC against the independent product claim of the main and most of the auxiliary requests, in combination with the fact that the RPBA had been amended after the filing of the appeal. This change of opinion only became apparent during oral proceedings, and could only have been pre-

empted with an unreasonably high number of auxiliary requests.

The Board cannot agree, for the following reasons:

- 5.1 The Board's opinion on the appreciation of substantive and legal issues as set out in a communication to the parties is preliminary and non-binding, see Article 17(2) RPBA 2020. Although the Board's preliminary opinion is based on a thorough analysis of the case, it may still change during oral proceedings based on the submissions made by the parties there. If parties could not expect to change the Board's preliminary opinion by presenting and refining their arguments during oral proceedings, oral proceedings would be pointless. It is established jurisprudence of the Boards that a change of the Board's preliminary opinion during oral proceedings does not qualify as exceptional circumstance under Article 13(2) RPBA 2020 (T 0752/16, points 3.3 and 3.4 of the reasoning).

- 5.2 That the new Rules of Procedure came into force while the present appeal was pending is correct, and transitional provisions are provided for in Article 25 RPBA 2020. That, according to Article 25(3) of these Rules, the new provision of Article 13(2) RPBA 2020 applied from 1 January 2020 on for all pending cases in which no summons to oral proceedings or no communication under Article 100(2) EPC had been notified did not come as a surprise, since the new Rules had been published well before their entry into force. This situation cannot qualify as "exceptional" already because it applies to all cases pending before the Boards at the time of entry into force of the RPBA 2020.

5.3 The patentee argued that the new Rules of Procedure put a disproportionate burden on the patentee in that auxiliary requests covering all combinations of objections would have to be filed at an early stage of even the opposition proceedings, not knowing which of the objections would be considered convincing by the Opposition Division or by the Boards of Appeal. This would lead to a multitude of auxiliary requests being on file, most of which would later turn out to be superfluous. It should at least be permitted to combine requests already on file, also at a late stage of the proceedings.

The Board does not deny that the Rules of Procedure aim at presenting the Board and the parties with the complete appeal case at an early stage of the appeal proceedings. The Board also acknowledges that parties may be confronted with a higher workload upfront. But however this may be, this is not decisive in the present case. Here, the number of objections against which the patentee intended to defend the patent by means of auxiliary requests is limited, namely one novelty objection, one added matter objection each for the product and the process claim and one objection concerning insufficient disclosure. Addressing these objections by means of amended claim sets would not have necessarily led to a disproportionate number of auxiliary requests. The added matter objection and the novelty objection having been on file from the outset of the opposition proceedings and being objects of the appeal, an auxiliary request addressing both these objections clearly could have been filed earlier than at an advanced stage of oral proceedings in appeal.

6. In the patentee's view the Rules of Procedure stipulate that amendments should *in principle* not be admitted,

thus giving the Boards still some discretionary power to admit or not amendments to a party's appeal case also at a late stage of the proceedings even in the absence of an exceptional situation.

However, independent of the question of whether such a discretionary power exists and how far it may go, the Board finds the arguments brought forward by the patentee unconvincing for the present case.

The patentee submitted that the new main request streamlined the proceedings and did not give rise to any additional discussion. The features of the new independent claim were present in the independent claims of some of the auxiliary requests on file, so the opponent would have been prepared to discuss them.

That a request filed at an advanced stage of oral proceedings does not raise new issues is certainly a pre-requisite, but is in itself not sufficient for admitting it into the proceedings.. Requests raising new issues would be inadmissible anyway, also under the previous provision of Article 13(3) RPBA 2007.

The filing of the new request at the point in time it was submitted did by no means streamline the proceedings. At the time of its filing the granted patent as well as auxiliary requests 1-10 had been found to contravene Article 123(2) EPC. Compared to the request on file that still would have to be discussed, auxiliary request 11, the newly filed request would not have cut short any of the remaining issues. The patentee argued that at least the novelty discussion could have been avoided, since the newly introduced features, corresponding to the ones of auxiliary requests 4 or 5, provided novelty. However, the

preliminary opinion of the Board stated that whether these features provided novelty would have to be discussed during the oral proceedings (see point 6.4 there).

7. The claim set filed during oral proceedings before the Board being the basis for the appellant-patentee's request to maintain the patent in amended form is not admitted into the proceedings under Article 13(2) RPBA 2020.

Since there is no admissible and allowable request for maintaining the patent in amended form under Article 101(3)(a) EPC the Board must follow the appellant-opponent's request to revoke the patent.

Order

For these reasons it is decided that:

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

The Registrar:

The Chairman:



C. Rodríguez Rodríguez

P. Gryczka

Decision electronically authenticated