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Datasheet for the decision of 29 July 2021

Case Number:	T 3139/19 - 3.3.01
Application Number:	10174985.1
Publication Number:	2269604
IPC:	A61K45/06, A61K31/436, A61K31/337, A61K31/475, A61K31/502, A61K31/555, A61K31/5685, A61K31/704, A61K31/7068, A61P35/00
Language of the proceedings:	EN

Title of invention:
Treatment of solid kidney tumours with a rapamycin derivative

Patent Proprietor:
Novartis Pharma AG

Opponents:
Synthon Biopharmaceuticals B.V.
Fresenius Kabi Deutschland GmbH
KRKA, d.d., Novo mesto
Teva Pharmaceutical Industries Ltd
STADA Arzneimittel AG
Wittkopp, Alexander
Generics [UK] Ltd
Intas Pharmaceuticals Ltd.

Headword:
Solid kidney tumours/NOVARTIS

Relevant legal provisions:
EPC Art. 100(c), 76(1)

Keyword:
Subject-matter extends beyond content of earlier application (yes) - all requests

Decisions cited:
G 0002/10, T 0197/08

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Beschwerdekammern

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Case Number: T 3139/19 - 3.3.01

D E C I S I O N
of Technical Board of Appeal 3.3.01
of 29 July 2021

Appellant: (Opponent 4)	Teva Pharmaceutical Industries Ltd 5 Basel Street 49131 Petach-Tikva (IL)
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Representative:	Hamm&Wittkopp Patentanwälte PartmbB Jungfernstieg 38 20354 Hamburg (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 12 September 2019 rejecting the oppositions filed against European patent No. 2269604 pursuant to Article 101(2) EPC.**

Composition of the Board:

Chairman	A. Lindner
Members:	J. Molina de Alba
	M. Blasi

Summary of Facts and Submissions

I. The decision under appeal is the opposition division's decision rejecting the eight oppositions filed against European patent No. 2 269 604.

II. The patent stems from European patent application 10 174 985.1, which was filed as a divisional application of European patent application 02 719 864.7 (earlier application). The patent was granted with two claims. Claim 1 as granted reads as follows:

"*40-O-(2-hydroxyethyl)-rapamycin for use in the treatment of solid tumors other than lymphatic cancer, wherein the solid tumor is a kidney tumor and 40-O-(2-hydroxyethyl)-rapamycin is administered as the sole active ingredient.*"

In the following, the compound 40-O-(2-hydroxyethyl)-rapamycin is referred to by its common name, everolimus.

III. The oppositions were filed against the patent on the grounds that the claimed subject-matter lacked novelty and inventive step, was not disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art, and extended beyond the content of both the earlier application and the application as filed (Article 100(a), (b) and (c) EPC).

In the appealed decision, the opposition division concluded that none of the grounds for opposition raised prejudiced the maintenance of the patent as granted. It held, among other things, that the subject-

matter of claim 1 as granted was directly and unambiguously derivable from the content of the earlier application as filed (Article 100(c) EPC) because it resulted from a single selection, namely kidney tumour as the solid tumour type.

IV. Each of opponents 4, 5, 7 and 8 (appellant-opponents 4, 5, 7 and 8, respectively) filed an appeal against the decision. They requested that the decision be set aside and that the patent be revoked in its entirety.

V. A third party filed observations.

VI. In its reply to the statements of grounds of appeal and to the third-party observations, the patent proprietor (respondent) requested that the appeals be dismissed (main request). It also filed 14 sets of claims as auxiliary requests 1 to 14: auxiliary requests 1 to 12 on 19 December 2017 and auxiliary requests 13 and 14 on 11 April 2019.

Claim 1 of auxiliary request 1 differs from claim 1 as granted in that the kidney tumour is specified as not being a renal pelvis tumour.

Claim 1 of auxiliary request 2 differs from claim 1 as granted in that the solid tumour is specified to be an advanced solid tumour.

Claim 1 of auxiliary request 3 differs from claim 1 as granted in that the treatment is limited to inducing regression of tumours.

Claim 1 of auxiliary request 4 differs from claim 1 as granted in that it specifies that everolimus is administered orally.

Claim 1 of auxiliary request 5 differs from claim 1 as granted in that it specifies that everolimus is administered daily.

Claim 1 of auxiliary request 6 differs from claim 1 as granted in that the treatment is limited to inhibiting or controlling deregulated angiogenesis of the tumours.

Claim 1 of auxiliary request 7 differs from claim 1 as granted in that it specifies that everolimus is administered orally in the form of a unit dose comprising 10 mg everolimus together with one or more pharmaceutically acceptable diluents or carriers.

Claim 1 of auxiliary request 8 is identical to claim 1 as granted.

Claim 1 of auxiliary request 9 differs from claim 1 as granted in that it specifies that everolimus is used as a monotherapy.

Claim 1 of auxiliary request 10 differs from claim 1 of auxiliary request 9 in that the feature that everolimus is administered as the sole active ingredient has been deleted.

Claim 1 of auxiliary request 11 differs from claim 1 as granted in that the feature "as the sole active ingredient" has been inserted after the word "use", and the phrase after "kidney tumor" has been deleted.

Claim 1 of auxiliary request 12 differs from claim 1 as granted in that the following phrase has been added at the end:

"*and 40-O-(2-hydroxyethyl)-rapamycin is not used in combination with an antimetabolite antineoplastic agent or with an antineoplastic alkylating agent*".

Claim 1 of auxiliary requests 13 and 14 derives from claim 1 of auxiliary requests 3 and 6, respectively, and indicates that everolimus is administered in a therapeutically effective amount.

VII. With a letter dated 22 August 2020 appellant-opponent 7 made additional submissions.

VIII. At the request of appellant-opponents 7 and 8, and in view of ongoing arbitration proceedings in Portugal between appellant-opponent 7 and the respondent in relation to the patent in suit, the board decided to accelerate the appeal proceedings pursuant to Article 10(3) RPBA 2020. It informed the parties accordingly and summoned them to oral proceedings.

In preparation for the oral proceedings, the board issued a communication drawing the parties' attention to salient issues that might be debated at the oral proceedings.

IX. At the request of the respondent, a transfer of the patent was recorded in the European Patent Register with effect from 29 July 2020, and the appeal proceedings were continued with the newly recorded patent proprietor as the respondent to the proceedings.

X. In response to the board's preliminary opinion, appellant-opponents 5 and 7 and the respondent made additional submissions. Those from appellant-opponent 7 and the respondent focused on the issue of added subject-matter. Appellant-opponent 5 concentrated on

the admittance of documents filed with its statement of grounds of appeal.

XI. Opponents 1 to 3 and 6 (parties as of right) did not file any requests or arguments relating to the patent in these appeal proceedings.

XII. Oral proceedings were held by videoconference on 29 July 2021 in the absence of appellant-opponent 4 and the parties as of right, opponents 1 to 3 and 6. They had all previously informed the board of their absence. None of the parties had objected to holding the oral proceedings by videoconference.

XIII. At the end of the oral proceedings, the board's decision was announced.

XIV. The appellant-opponents' arguments, where relevant to the present decision, can be summarised as follows.

Claim 1 as granted added subject-matter because the earlier application as filed disclosed neither explicitly nor implicitly the combination of everolimus monotherapy with the treatment of solid kidney tumours: the earlier application did not individualise this specific combination of features, did not present general preferences that could lead to their combination, and did not contain any pointer to linking the two choices. Thus, claim 1 resulted from at least two selections: kidney as the solid tumour type and everolimus monotherapy as the treatment type.

Kidney tumours were an option within the long list of solid tumour types bridging pages 2 and 3. Everolimus monotherapy was one of two options: mono- and combination therapy, which were disclosed at the same

level of preference throughout the earlier application. Regarding the examples, none of the in vivo tests and clinical trials in sections B and C of the earlier application related to solid kidney tumours, and they were equally directed to mono- and combination therapy. Furthermore, the clinical trials in section C were not real trials but mere proposals for investigation. They neither referred to a specific tumour type nor were suitable for drawing general conclusions; clinical trials had to be carried out under very specific conditions. Therefore, it could not be concluded from the heading of section C.1 that everolimus monotherapy was generally applicable to each of the tumours recited in the list bridging pages 2 and 3. The general statement on page 11, paragraph 3, did not help either, because it still required two selections: the examples directed to monotherapy and solid kidney tumours from the list on pages 2 and 3.

Contrary to the respondent's view, and in line with decision T 197/08 (Reasons, 3.2, paragraph 1), a disclosure of the therapeutic effect of a compound did not amount to a disclosure of its use as monotherapy; it encompassed both mono- and combination therapy. The reason the board in case T 197/08 (Reasons, 3.3) had decided that the choice of monotherapy was not a selection from a list was that monotherapy could be considered to be preferred on the basis of the examples. The case in hand did not allow the same conclusion, because the earlier application as filed, including its examples, disclosed mono- and combination therapy at the same level of preference. Hence, a choice had to be made between two equally preferred options.

XV. The respondent's arguments, where relevant to the present decision, can be summarised as follows.

The issue of added subject-matter had to be assessed using the "gold standard". The principle of selection from different lists was not a legal requirement and did not apply to the case in hand. Applying the gold standard led to the conclusion that claim 1 as granted did not add subject-matter, because it did not present the skilled person with any new technical teaching; the treatment of solid kidney tumours with everolimus as the sole active agent was directly and unambiguously derivable from the earlier application as filed.

From the introduction and the experimental section of the earlier application, the skilled person would have understood that everolimus could be used on its own for treating solid tumours. This was an implicit disclosure that everolimus treated solid tumours as the sole active ingredient, i.e. without needing to be provided as part of a combination therapy. This general teaching was applicable to all of the solid tumour types according to the invention - namely those disclosed in the paragraph bridging pages 2 and 3, which included kidney tumours.

Furthermore, the introduction of the experimental part on page 11, paragraph 3, linked the general teaching that everolimus treated solid tumours with the experimental work then presented. Within that experimental work, the heading of section C.1 was particularly relevant, since it explicitly referred to the clinical benefit of everolimus (compound A) as monotherapy in solid tumours. Thus, the passage on page 11, paragraph 3, provided a direct link between everolimus monotherapy and the solid tumours listed on

pages 2 and 3, i.e. a choice between mono- and combination therapy was not needed.

Moreover, the earlier application disclosed a preference for monotherapy in claim 9. The claim was directed to the treatment of solid tumours with a compound of formula I and referred to the use of additional chemotherapeutic agents (combination therapy) only as an option. Accordingly, the main and preferred disclosure of claim 9 was the use of the compound of formula I as the sole active ingredient.

Regarding decision T 197/08 (Reasons, 3.3), the application as filed in that case did not explicitly disclose the use of a sole active ingredient. Therefore, the board had had to look for an implicit basis. It had held that the application implicitly related to both mono- and combination therapy, but that, because there were examples only of monotherapy, it did not need to be selected. In the case in hand, the earlier application disclosed monotherapy not only implicitly but also explicitly, and it contained several examples illustrating it. Hence, in line with T 197/08, a selection was not necessary. The respondent should not be put in a worse situation than the patent proprietor in T 197/08 just because the earlier application in the present case showed that, in addition to monotherapy, combination therapy was also suitable for treating solid tumours. Mono- and combination therapy were two separate, individualised embodiments which did not make a list from which a selection was required; each embodiment was individually applicable to each of the solid tumour types listed on pages 2 and 3.

XVI. The parties' final requests, as far as relevant to the present decision, were as follows.

- Appellant-opponents 4, 5, 7 and 8 requested that the decision under appeal be set aside and that the patent be revoked in its entirety.

- The respondent requested that the appeals be dismissed (main request).

  Alternatively, it requested that, if the decision under appeal was to be set aside, the case be remitted to the opposition division for further prosecution on the basis of any of the sets of claims filed as auxiliary requests 1 to 14, 1 to 12 having been filed on 19 December 2017 and 13 and 14 on 11 April 2019.

  As a further alternative, it requested that the patent be maintained in amended form on the basis of one of auxiliary requests 1 to 14.

Reasons for the Decision

1. The appeals are admissible. They meet the requirements of Articles 106 to 108 and Rule 99(2) EPC.

2. Absence of parties at the oral proceedings - Rule 115(2) EPC and Article 15(3) RPBA 2020

The oral proceedings before the board took place in the absence of appellant-opponent 4 and the parties as of right, opponents 1 to 3 and 6. They had been duly

summoned but chose not to attend. All of them had informed the board of their absence before the oral proceedings.

In accordance with Rule 115(2) EPC and Article 15(3) RPBA 2020, the board decided to continue the proceedings in those parties' absence. The absent parties, especially appellant-opponent 4, were treated as relying on their written cases. Hence, the board was in a position to announce a decision at the conclusion of the oral proceedings, in accordance with Article 15(6) RPBA 2020.

3. Claim 1 as granted - Article 100(c) EPC

3.1 The patent in suit stems from European patent application 10 1749 85.1, which was filed as a divisional application of the earlier European patent application 02 719 864.7.

Under Article 100(c) EPC, the subject-matter of a European patent which was granted on a divisional application may not extend beyond the content of the earlier application as filed. In the present proceedings the parties disputed, among other things, whether claim 1 as granted met this requirement. In particular, the parties disputed whether the earlier application as filed directly and unambiguously disclosed the combination of features in claim 1: "everolimus as the sole active ingredient" and "solid kidney tumours".

3.2 Regarding the feature "as the sole active ingredient", the parties did not contest the opposition division's interpretation in the appealed decision (point 2.3) that, in line with decision T 197/08 (Reasons, 3.1),

the feature only excluded compounds other than everolimus that had pharmacological activity suitable for treating solid kidney tumours. Thus, it was common ground that "as the sole active ingredient" was synonymous with "monotherapy". The board saw no reason to take another stance and uses the term "monotherapy" in this decision as equivalent to the feature "as the sole active ingredient".

3.3 The respondent argued that the issue of added subject-matter needed to be examined using the "gold standard" rather than by looking at selections from lists; the latter principle was allegedly not suitable for assessing the present case. For the application of the gold standard, the respondent referred to the following elements in the earlier application as filed:

(i) the general teaching that everolimus is suitable for treating solid tumours on its own, namely in the sentence bridging pages 1 and 2, on page 17, lines 26 to 27, and in the examples;
(ii) the mention of kidney tumours as one of the solid tumour types recited in the paragraph bridging pages 2 and 3;
(iii) the mention of everolimus (compound A) as monotherapy in solid tumours in the heading of section C.1 (page 16); and
(iv) the passage on page 11, paragraph 3, referring to the treatment of solid tumours previously specified in accordance with the methods disclosed afterwards.

According to the respondent, the general teaching in the earlier application that everolimus is suitable for treating solid tumours on its own (element (i)) is an

implicit disclosure of the treatment of solid tumours with everolimus as the sole active ingredient. This teaching was applicable to each of the tumour types recited in the paragraph bridging pages 2 and 3 (element (ii)). Moreover, the heading of section C.1 on page 16 (element (iii)) explicitly disclosed the use of everolimus monotherapy for treating solid tumours. This use was applicable to each of the solid tumour types according to the invention (element (ii)) by virtue of the statement on page 11, paragraph 3 (element (iv)), which linked the treatment of solid tumours with the experimental part of the description.

Thus, although the earlier application disclosed mono- and combination therapy, there was no need to choose between them to arrive at the claimed subject-matter: both therapies were individualised as separate embodiments and each of them was individually applicable to each of the tumour types of the invention. This conclusion was in line with decision T 197/08.

Moreover, if the principle of selection from lists were applied, the conclusion would be the same because only one selection would be necessary, namely kidney as the solid tumour type. Claim 9 of the earlier application as filed demonstrated that monotherapy had preference over combination therapy.

3.4 The board agrees with the respondent that the principle to be applied for the assessment of added subject-matter is the so-called "gold standard", i.e. the claimed subject-matter must remain within the limits of what a skilled person would derive directly and unambiguously, using common general knowledge, and seen objectively and relative to the date of filing, from

the whole of the application as filed - in the case in hand, the earlier application as filed (see also, in the context of Article 123(2) EPC, Enlarged Board of Appeal decision G 2/10, OJ EPO 2012, 376, Reasons, 4.3). Nevertheless, this does not rule out the principle of selection from different lists, although not compulsory, being a useful tool for assessing whether the earlier application as filed discloses a direct link between features in the claims, especially in the absence of generally preferred embodiments or allowable generalisations.

In the case in hand, claim 1 as granted adds subject-matter when the gold standard is applied, and this conclusion is confirmed by the principle of selection from different lists, for the following reasons.

3.5 Regarding element (i), the board disagrees with the respondent's argument that the disclosure that everolimus is suitable for treating solid tumours is necessarily an implicit disclosure of everolimus monotherapy. On this point, the board endorses the view in decision T 197/08 (Reasons, 3.2, paragraph 1) that a generic disclosure of a compound being active against a disease is not a disclosure of the treatment with that compound as monotherapy; it encompasses both mono- and combination therapy.

With regard to the specific passages cited by the respondent in this context, namely the sentence bridging pages 1 and 2, the passage on page 17, lines 26 to 27, and the examples, the board notes the following.

3.5.1 The generic statement bridging pages 1 and 2 that "*[c]ompounds of formula I have potent antiproliferative*

properties which make them useful for cancer chemotherapy, particularly of solid tumors" and the in vitro examples in section A.2 disclose the anti-proliferative and anti-angiogenic effect of everolimus. Although compounds with anti-proliferative and anti-angiogenic properties may be suitable for treating solid tumours, the description of these properties associated with everolimus cannot be equated with a disclosure of the treatment of solid tumours with everolimus as the sole active agent. In line with decision T 197/08 (Reasons, 3.2, paragraph 1), this teaching concerns both mono- and combination therapy. Therefore, these passages do not establish a direct link between everolimus monotherapy and solid kidney tumours.

3.5.2 The in vivo tests in sections B.1 to B.3 show the treatment of lung, epidermoid and pancreatic tumours with everolimus as the sole active ingredient. They are indeed examples of everolimus monotherapy. However, they constitute highly specific embodiments and their teaching cannot go beyond the treatment of the mentioned tumours, which do not include solid kidney tumours. Thus, the tests in sections B.1 to B.3 do not support the argument that everolimus monotherapy is applicable to solid kidney tumours.

3.5.3 The passage on page 17, line 26 onwards, is part of the description of a clinical trial proposed for testing combination therapy (section C.2). It nevertheless discloses how the compounds of formula I should be dosed when used alone. The passage is in itself ambiguous because it refers to monotherapy in a context of combination therapy. Furthermore, rather than disclosing a real clinical trial, section C.2 proposes a generic procedure for carrying out clinical trials

and is silent on any specific tumour type. Hence, the passage does not unambiguously disclose the combination of everolimus monotherapy with solid kidney tumours.

3.6 Elements (ii) to (iv) do not disclose the combination of features in claim 1 either.

3.6.1 The respondent's argument that element (iv) linked elements (ii) and (iii) to disclose everolimus monotherapy for each of the solid tumours of the invention is not convincing.

The heading of section C.1 (element (iii)) reads: "*C.1 Investigation of clinical benefit of a compound of formula I, e.g. Compound A* [everolimus] *as monotherapy in solid tumours*".

Although this element explicitly proposes a clinical trial to investigate the treatment of solid tumours with everolimus as monotherapy, it does not refer to any specific tumour type or to all of the tumour types recited before. The skilled person would need to read the element in its context to assess the scope of its proposal.

A reading of section C.1 makes it immediately apparent that it does not disclose a real clinical trial, let alone its results; rather, section C.1 proposes a generic procedure for investigating the optimal dose of a compound according to the invention, e.g. everolimus, for treating (unspecified) advanced malignant solid tumours by way of once-weekly oral administration. It is self-evident that a clinical trial cannot be generic; clinical trials are by their nature highly specific with respect to at least the active ingredient, the mode of administration, the dose

regime, the treated disease and the patients involved. The primary aim of the study of C.1 is the identification of the optimal dose of the compound. This dose is assumed to be the minimum dose for obtaining an anti-tumour effect equivalent to that observed in the in vivo preclinical tests. In vivo preclinical tests in which everolimus was tested as the only active ingredient are disclosed exclusively in sections B.1 to B.3. They relate to the treatment of lung, epidermoid and pancreatic tumours, respectively.

Thus, a reading of the whole disclosure of section C.1 leads to the conclusion that the proposal in element (iii) is directed to the solid tumours tested in sections B.1 to B.3 rather than to each of the tumour types disclosed in element (ii). However, sections B.1 to B.3 do not provide any information on kidney tumours.

3.6.2 This disclosure gap cannot be remedied by element (iv), which introduces the experimental part of the earlier application with the following text:

"*Utility of the compounds of formula I in treating solid tumors as hereinabove specified, may be demonstrated in animal test methods as well as in clinic, for example in accordance with the methods hereinafter described.*"

The text vaguely refers to "solid tumors as hereinabove specified". It fails to explicitly mention any tumour type or to clearly state that it refers to each of the tumour types previously cited, i.e. those listed in the paragraph bridging pages 2 and 3. The reference to the methods described afterwards does not help to clarify the situation: as outlined above, the animal (in vivo)

test methods relate to lung, epidermoid and pancreatic tumours (sections B.1 to B.3), and the clinical trials are unspecific (section C.1).

Hence, elements (ii) and (iii), even when read in the light of element (iv), fail to establish a link between solid kidney tumours and everolimus monotherapy.

3.7 Thus, the application of the gold standard leads to the conclusion that claim 1 as granted adds subject-matter beyond the content of the earlier application as filed.

3.8 This conclusion is confirmed by the principle of selection from different lists.

3.8.1 It was common ground among the parties that the treatment of solid kidney tumours constitutes a selection from the passage bridging pages 2 and 3. Thus, the ground for opposition under Article 100(c) EPC would not prejudice the maintenance of the patent as granted if the subject-matter of claim 1 could be derived from the earlier application as filed without having to make an additional selection. However, as argued by the appellant-opponents, the administration of everolimus as monotherapy constitutes an additional selection.

3.8.2 The parties concurred that the earlier application discloses both mono- and combination therapy (see the respondent's letter dated 26 May 2021, page 2, paragraph 3).

3.8.3 However, they disputed whether mono- and combination therapy were disclosed as equivalent options or whether monotherapy was preferred over combination therapy.

On this issue, the board concurs with the appellant-opponents that the general disclosure and the examples of the earlier application disclose mono- and combination therapy without giving preference to either of them. The only element in the earlier application cited by the respondent as an indication that monotherapy would be preferred is claim 9.

Claim 9 of the earlier application reads:

"*A method for treating solid tumors in a subject in need thereof, comprising administering to said subject a therapeutically effective amount of a compound of formula I as defined in claim 1, optionally concomitantly or sequentially with a chemotherapeutic agent*."

According to the respondent, combination therapy is defined by the optional part of the claim. Hence, monotherapy, which was defined by the essential part of the claim, would be preferred.

The board disagrees. The part of claim 9 which is not optional does not refer to monotherapy but encompasses both mono- and combination therapy. This becomes apparent when the optional part is dispensed with, since the claim would then still encompass mono- and combination therapy. The optional feature in claim 9 merely makes it explicit that the claim encompasses combination therapy; it does not suggest in any form that combination therapy is the less preferred of the two possible options implicit in the essential part of the claim. Thus, claim 9 of the earlier application as filed does not disclose any general preference for monotherapy.

3.8.4 This makes the case in hand different from the one underlying decision T 197/08 (Reasons, 3.3), which was also discussed by the parties in this context.

In T 197/08, the board had to decide whether the feature monotherapy constituted a selection between mono- and combination therapy. The board considered that both therapies were implicitly disclosed but, because the application as filed disclosed examples only of monotherapy, the latter was generally preferred. Therefore, a selection between mono- and combination therapy was not necessary.

In contrast, in the case in hand, there is no indication that one of the two options is preferred; both therapies are equally disclosed and illustrated in the examples, such that a selection is unavoidable to arrive at monotherapy.

3.8.5 Hence, the combination of everolimus monotherapy with solid kidney tumours requires a selection from two different lists and would present the skilled person with new technical information.

3.9 In conclusion, the earlier application as filed does not directly and unambiguously disclose a link between the treatment of solid kidney tumours and everolimus as the sole active agent. Therefore, the subject-matter of claim 1 as granted extends beyond the content of the earlier application as filed, and the ground for opposition under Article 100(c) EPC prejudices the maintenance of the patent as granted, with the consequence that the decision under appeal is to be set aside.

4. Remittal - Article 111 EPC

The respondent requested that, if the decision under appeal was to be set aside, the case be remitted to the opposition division for further prosecution on the basis of any of the auxiliary requests. Appellant-opponent 7 requested that the case not be remitted to the opposition division under any circumstances.

The reasons why claim 1 as granted adds subject-matter apply equally to all requests on file (see point 5 below). Therefore, it would not have been reasonable to remit the case to the opposition division. This is even more true considering that the case had been accelerated and that, at the point in time of taking the decision, the patent was only some months before the expiry of its term. Hence, as there were no special reasons for remitting the case, the board decided to deal with the auxiliary requests pursuant to Article 11 RPBA 2020, in exercise of the powers within the competence of the opposition division in accordance with Article 111(1), second sentence, EPC.

5. Auxiliary requests - Article 76(1) EPC

At the oral proceedings before the board, the respondent chose not to present any arguments as to why any of the auxiliary requests would overcome the problems of added subject-matter identified in the main request.

Claim 1 of each of auxiliary requests 1 to 14 contains the combination of features "everolimus as the sole active agent" (or "everolimus as monotherapy") and "solid kidney tumours". As outlined above in relation

to claim 1 as granted, this combination of features was not directly and unambiguously disclosed in the earlier application as filed.

Hence, none of auxiliary requests 1 to 14 meets the requirements of Article 76(1) EPC.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

The Registrar: The Chairman:

M. Schalow A. Lindner

Decision electronically authenticated