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Datasheet for the decision of 18 February 2025

Case Number: T 1271/23 - 3.3.02

Application Number: 16180589.0

Publication Number: 3150586

IPC: C07D277/28, C07D417/14, A61K31/427, A61P31/12

Language of the proceedings: EN

Title of invention:
MODULATORS OF PHARMACOKINETIC PROPERTIES OF THERAPEUTICS

Patent Proprietor:
Gilead Sciences, Inc.

Opponents:
STADA Arzneimittel AG
Teva Pharmaceutical Industries Ltd.
Cooke, Richard

Relevant legal provisions:
EPC Art. 76(1)
RPBA 2020 Art. 11

Keyword:

Decisions cited:
T 1160/18, T 1442/19, T 3139/19

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Case Number: T 1271/23 - 3.3.02

D E C I S I O N
of Technical Board of Appeal 3.3.02
of 18 February 2025

Appellant: (Patent Proprietor)	Gilead Sciences, Inc. 333 Lakeside Drive Foster City, CA 94404 (US)
Representative:	Carpmaels & Ransford LLP One Southampton Row London WC1B 5HA (GB)
Respondent 1: (Opponent 1)	STADA Arzneimittel AG Stadastraße 2-18 61118 Bad Vilbel (DE)
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Respondent 2: (Opponent 2)	Teva Pharmaceutical Industries Ltd. 124 Dvora HaNevi'a St. 6944020 Tel Aviv (IL)
Representative:	Eder, Michael df-mp Patentanwälte Rechtsanwälte PartG mbB Theatinerstraße 16 80333 München (DE)
Respondent 3: (Opponent 3)	Cooke, Richard Elkington and Fife LLP Patents Department 3-4 Holborn Circus London EC1N 2HA (GB)
Representative:	Elkington and Fife LLP Prospect House 8 Pembroke Road Sevenoaks, Kent TN13 1XR (GB)

Decision under appeal: **Decision of the Opposition Division of the European Patent Office posted on 19 May 2023 revoking European patent No. 3150586 pursuant to Article 101(2) and Article 101(3)(b) EPC.**

Composition of the Board:

Chairman M. O. Müller
Members: A. Lenzen
M. Blasi

Summary of Facts and Submissions

I. This decision concerns the appeal filed by the patent proprietor (appellant) against the opposition division's decision (decision under appeal) to revoke European patent No. 3 150 586 (patent).

II. The patent was granted on European patent application No. 16 180 589.0 (application), which is a divisional application of European patent application No. 12 167 589.6 (parent application). The parent application itself is a divisional application of European patent application No. 08 743 531.9 (grandparent application). The grandparent application was filed as an international application published as WO 2008/103949 A1.

III. The decision under appeal is based on the patent as granted (main request) and the sets of claims of auxiliary requests 1 to 8, filed with the reply to the notices of opposition (letter dated 24 February 2021). According to this decision, the subject-matter of claim 1 of the main request and auxiliary requests 1 to 8 extended beyond the content of the grandparent application as filed (Article 100(c) EPC and Article 76(1) EPC, respectively).

IV. Each of opponents 1 to 3 (respondents 1 to 3; collectively referred to as respondents, if applicable) filed a reply to the statement of grounds of appeal. Further substantive submissions were filed by the appellant and respondent 1, respectively by letters dated 6 March 2024 and 11 April 2024.

V. In preparation for the oral proceedings, which had been arranged at the parties' request, the board issued a communication under Article 15(1) RPBA.

VI. By letter dated 20 December 2024, respondent 2 announced that it would not attend the scheduled oral proceedings.

VII. Oral proceedings before the board were held by videoconference on 18 February 2025 in the presence of the appellant, respondent 1 and respondent 3. At the end of the oral proceedings, the chair announced the order of the present decision.

VIII. The parties' requests at the end of the oral proceedings were as follows.

The appellant requested that the decision under appeal be set aside and that the case be remitted to the opposition division for further prosecution.

All the respondents requested that the appeal be dismissed, with the implication that the decision under appeal on the revocation of the patent be confirmed.

Respondent 3 also requested that the appellant's submission according to which the examples in the grandparent application as filed served as a pointer not be admitted into the proceedings.

IX. Summaries of the parties' 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

Continuation of proceedings in respondent 2's absence

Although duly summoned, respondent 2 did not attend the oral proceedings, as communicated to the board by letter dated 20 December 2024. The board therefore decided to continue the proceedings in respondent 2's absence pursuant to Rule 115(2) EPC. In accordance with Article 15(3) RPBA, respondent 2 was treated as relying on its written case.

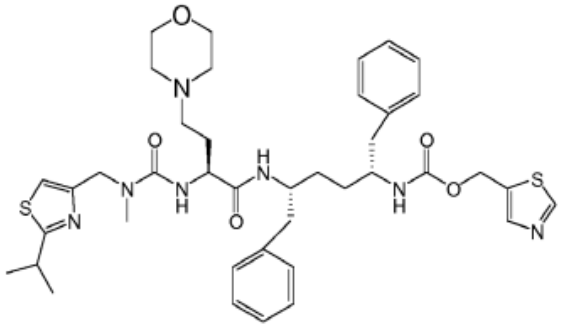
Main request (patent as granted) - Amendments
(Article 100(c) EPC)

1. The main request consists of two claims. The parties disagreed on whether their subject-matter extends beyond the content of the grandparent application as filed. In this respect, they referred to the grandparent application as published, i.e. to WO 2008/103949 A1. The board does the same below. References in this decision to "earliest application" thus relate to the published version of the grandparent application. Claims 1 and 2 of the main request are assessed in succession.

Claim 1 of the main request

2. Claim 1 reads as follows:

"*A compound of formula IIBb*



(IIBb)

or a pharmaceutically acceptable salt or solvate thereof,

in combination with one or more additional therapeutic agents selected from the group consisting of HIV protease inhibiting compounds, HIV non-nucleoside inhibitors of reverse transcriptase, HIV nucleoside inhibitors of reverse transcriptase, HIV nucleotide inhibitors of reverse transcriptase, HIV integrase inhibitors, gp41 inhibitors, CXCR4 inhibitors, gp120 inhibitors, G6PD and NADH-oxidase inhibitors, CCR5 inhibitors, other drugs for treating HIV, and mixtures thereof,

for use in treating an HIV infection."

In line with the parties, the compound of formula IIBb is referred to as cobicistat below. Claim 1 of the main request thus requires a combination of cobicistat with one or more additional therapeutic agents.

3. The appellant relied on independent claim 28 of the earliest application as the basis for claim 1 of the main request. It reads as follows:

> "*A method for treating an HIV infection comprising administering to a patient in need thereof*
>
> *a therapeutically effective amount of a compound of claim 1, or a pharmaceutically acceptable salt, solvate, and/or ester thereof,*
>
> *in combination with a therapeutically effective amount of one or more additional therapeutic agents selected from the group consisting of HIV protease inhibiting compounds, HIV non-nucleoside inhibitors of reverse transcriptase, HIV nucleoside inhibitors of reverse transcriptase, HIV nucleotide inhibitors of reverse transcriptase, HIV integrase inhibitors, gp41 inhibitors, CXCR4 inhibitors, gp120 inhibitors, G6PD and NADH-oxidase inhibitors, CCR5 inhibitors, other drugs for treating HIV, and mixtures thereof.*"

4. It was common ground between the parties that the additional therapeutic agents recited in claim 28 of the earliest application are identical to those of claim 1 of the main request. It was also common ground that the structural definition of the "compound of claim 1" referred to in claim 28 of the earliest application encompasses cobicistat and that, therefore, on the basis of claim 28 of the earliest application, one single selection was needed to arrive at claim 1 of the main request, namely the selection of cobicistat as the "compound of claim 1". According to established case law, such a single selection does not result in added matter.

5. The respondents argued that starting from claim 28 of the earliest application in itself already implied a first selection. The earliest application disclosed methods for treating an HIV infection (claim 28) and for treating an HCV infection (claim 30), each of which used a different group of additional therapeutic agents. However, claim 1 of the main request related only to the treatment of an HIV infection and the additional therapeutic agents as recited in claim 28. Thus, in order to arrive at the subject-matter of claim 1 of the main request, two selections were necessary from the earliest application, namely not only the selection of cobicistat as the "compound of claim 1", but also the selection of the infection to be treated and the group of additional therapeutic agents required therefor, i.e. in other words the selection of claim 28 over claim 30. The fact that a second selection was necessary with regard to claims 28 and 30 of the earliest application was indeed fully in line with the present board's reasoning in decisions T 358/19, T 372/19, T 1260/19 and T 1442/19.

6. The board does not agree for the following reasons.

6.1 As is disclosed in the section "BACKGROUND OF THE INVENTION" starting on page 1 of the earliest application, the grandparent application as filed deals generally with the problem that it can be difficult to maintain therapeutically effective blood plasma levels of therapeutic agents ("drugs") which are rapidly metabolised by cytochrome P450 enzymes. This problem is solved in the earliest application by providing the compounds of claim 1 of the earliest application, which inhibit cytochrome P450 enzymes and thus the metabolism of therapeutic agents by these enzymes while at the

same time not having appreciable biological activity other than cytochrome P450 inhibition (first full paragraph and "SUMMARY OF THE INVENTION" on page 2 of the earliest application).

Claims 28 and 30 of the earliest application are two independent claims directed at methods for treating viral infections. They make use of the unique properties of the compounds of claim 1. As set out in the above-mentioned introductory passages of the earliest application, their inhibitory activity on cytochrome P450 enzymes prolongs the activity of co-administered drugs which are metabolised by these enzymes. Which actual viral infection is treated is not determined by the compounds of claim 1 but by the co-administered drug - the additional therapeutic agents of claim 28 are active against HIV, those of claim 30 against HCV. Thus, the methods of claims 28 and 30 each relate to separate applications of the compounds of claim 1, i.e. to different distinct aspects of the invention disclosed in the grandparent application as filed or, more simply, different inventions. The board agrees with the appellant that pursuing only one invention, i.e. the method of claim 28, does not amount to a selection from the earliest application.

Against this background, it is irrelevant whether or not, as argued by respondent 1, the earliest application discloses other groups of additional therapeutic agents relating to the treatment of HIV which are different from the group of claim 1 of the main request.

6.2 Notwithstanding the above, the board also agrees with another of the appellant's lines of argument: a set of claims comprising independent claims 28 and 30 of the

earliest application, each limited to cobicistat, is not objectionable for reasons of added subject-matter under Article 100(c) EPC, nor is the deletion of one of those independent claims, namely limited claim 30, from this hypothetical set of claims. Since this leads to claim 1 of the present main request, it is also not objectionable under Article 100(c) EPC.

7. In its decision, the opposition division agreed with the respondents' view based on T 358/19, T 372/19, T 1260/19 and T 1442/19 that the subject-matter of claim 1 of the main request extended beyond the content of the earliest application.

In those cases, the patents in question were granted on applications which are divisional applications of European patent application No. 08 743 531.9, i.e. the grandparent application in the present case. Also in these four previous cases, the board had to decide whether the claimed subject-matter extended beyond the content of the earliest application (within the meaning of Article 100(c) EPC and Article 76(1) EPC, respectively).

7.1 More specifically, in case T 1442/19, claim 3 of the main request essentially related to a pharmaceutical composition comprising cobicistat and an additional therapeutic agent generally defined as an HIV protease inhibiting compound.

In that case, the patent proprietor relied on the passage on page 192, lines 9 to 17 of the earliest application as the basis for the subject-matter of claim 3 of the main request. The pharmaceutical compositions disclosed in this passage comprise a "compound of the present invention" and at least one

additional therapeutic agent. The additional therapeutic agent is stated in this passage to be selected from a group of agents including, amongst others, HIV protease inhibiting compounds. The "compound of the present invention" referred to in this passage is defined in the earliest application in varying degrees of specificity. Amongst the most specific teachings of the earliest application are claims 19 to 21. Each of these independent claims relates to one specific compound, claim 20 to cobicistat.

In that decision, the deciding board held that the subject-matter of claim 3 of the main request was the result of a double selection. The HIV protease inhibiting compounds had to be selected from the group of additional therapeutic agents recited in the passage on page 192, lines 9 to 17. Furthermore, the compounds claimed individually in independent claims 19 to 21 were equally preferred items and constituted a list. Cobicistat had to be selected from this list as the "compound of the present invention". As there were no pointers to this double selection, the subject-matter of claim 3 of the main request extended beyond the content of the earliest application.

The same logic was applied, *mutatis mutandis*, in cases T 358/19, T 372/19 and T 1260/19.

7.2 The respondents argued that the methods of claims 28 and 30 were equally preferred and it was possible to subsume them under the same generic method. Hence, following the logic with regard to claims 19 to 21 according to the four decided cases (see point 7.1 above), claims 28 and 30 also formed a list. The method of claim 28 had to be selected from this list.

7.3 The board agrees with the respondents that the methods of claims 28 and 30 can conceivably be subsumed under a more general method encompassing both and that these claims can therefore be regarded as a list. However, the present case is distinguished from that of T 1442/19 in that the appellant does not rely on a passage of the description as filed as the basis from which it would be confronted with the list of claims 28 and 30 and from which a selection would then ultimately have to be made. Instead, the appellant relies on independent claim 28 itself as the basis. This was not done in case T 1442/19 and was not meaningfully possible, since claim 20 refers to cobicistat as such, without any connection to an additional therapeutic agent. Although claim 28 is conceptually a member of a list of claims 28 and 30, it is nevertheless an independent/stand-alone embodiment (or invention as set out above) and starting from it does not entail a first selection.

8. Respondent 3 additionally referred to decision T 3139/19 where the competent board had to decide on whether a claim essentially reading "everolimus for use in the treatment of solid kidney tumors by monotherapy" contained added subject-matter. According to respondent 3, the board held in that decision that monotherapy had to be selected from among two possible treatment options (monotherapy and combination therapy). This showed that, contrary to the appellant's and the board's view in the present case, the use aspects of claims 28 and 30 did indeed form a list from which a selection was necessary. Another example in support of this conclusion was decision T 1160/18.

The board agrees in principle with respondent 3 that the restriction to a particular use may also require a selection. However, as set out above, this is not the case here. The cases cited by respondent 3 are not inconsistent with the board's conclusion in the present case, as the underlying facts are different. In particular, unlike the present case, the competent board in the cases cited by respondent 3 did not start from an independent claim as the basis from which a single selection leads to the claimed subject-matter. For example, in case T 3139/19, the board started from the passage bridging pages 2 and 3 and concluded that solid kidney tumours had first to be selected from the list of solid tumours recited in that passage. The further restriction to monotherapy required a second selection (point 3.8 of the Reasons). In this board's view, the situation underlying case T 3139/19 is therefore, if at all, more comparable to the situation described above under point 7.1.

9. Therefore, the respondents' arguments do not change the conclusion above that the subject-matter of claim 1 of the main request does not extend beyond the content of the earliest application.

10. As set out above, starting the assessment of added subject-matter from claim 28 of the earliest application does not amount to a selection from the earliest application or the list of claims 28 and 30.

Hence, the parties' arguments on the presence of pointers to the alleged selection of claim 28 were not relevant to this decision. Therefore, it was not necessary at the oral proceedings to decide on respondent 3's request not to admit the appellant's

submission that the examples of the earliest application were pointers to the selection of claim 28.

Claim 2 of the main request

11. For the subject-matter of claim 2 of the main request, the appellant relied on the following parts of the earliest application as the basis: the paragraph bridging pages 214 to 215; claim 29, referring back to claim 28.

12. The parties agreed that the subject-matter of claim 2 of the main request differs from these parts of the earliest application in at least the following respects.

(a) The earliest application refers to the "compound of claim 1" (claims 28/29 of the earliest application) and the "compound of the present invention" (passage on pages 214 to 215). By contrast, claim 2 of the main request refers to cobicistat.
(b) According to the earliest application, the "compound of claim 1"/"the compound of the present invention" is to be combined with "one or more additional therapeutic agents" selected from a group of specific agents, i.e. 1, 2, 3, 4 or more. The wording in claim 2 of the main request is different and provides for the combination of cobicistat with "more than one additional therapeutic agent", i.e. 2, 3, 4 or more.

The parties also agreed that difference (a) amounts to a selection of cobicistat as the "compound of claim 1"/"compound of the present invention". However, there was disagreement as to whether difference (b)

resulted in an additional selection from the earliest application.

13. The opposition division shared the appellant's view and saw no problem with the change in wording from "one or more additional therapeutic agents" to "more than one additional therapeutic agent". In its view, this change merely resulted in the deletion of one option. No specific selection was made and the whole disclosure remained generic.

14. However, the board agrees with the respondents' view. Even if the wording of claim 2 of the main request could still be considered generic, this does not alter the fact that by changing "one or more additional therapeutic agents" to "more than one additional therapeutic agent" a selection was made at the expense of a particular option, namely the combination with only one additional therapeutic agent. It follows, that the subject-matter of claim 2 of the main request is the result of a double selection.

15. There was agreement between the parties that the earliest application does not disclose a pointer to the selection of cobicistat. The appellant did not argue either that the earliest application disclosed a pointer to the selection considered in point 14. Hence, there are no pointers to the two selections made.

16. The appellant argued that the deletion of one option could be viewed as a disclosed disclaimer in which the embodiment "and one additional therapeutic agent" was disclaimed from the open-ended range of "one or more additional therapeutic agents". In decision T 712/16 the exclusion of a lower limit was held to be allowable

because the claimed subject-matter changed only marginally as a result.

Even if one were to adopt the appellant's view, i.e. to assume, despite the absence of a corresponding disclaimer wording, that the exclusion of a combination would be equivalent to a disclosed disclaimer, it would still have to be examined whether the remaining subject-matter, i.e. ultimately the subject-matter of claim 2, is directly and unambiguously disclosed (G 2/10, OJ EPO 2012, 376, order). As set out above, this examination leads to the conclusion that claim 2 of the main request contains added subject-matter.

17. Thus, it must be concluded that the subject-matter of claim 2 extends beyond the content of the earliest application and the ground for opposition under Article 100(c) EPC thus prejudices maintenance of the patent as granted. The main request is not allowable.

Auxiliary request 1 - Amendments (Article 76(1) EPC)

18. Claim 2 of auxiliary request 1 differs from claim 2 of the main request only in that the therapeutic agents deleted from the list of specific therapeutic agents are those which are derivatives of other agents mentioned in this list. This does not change the reasoning given above in relation to the subject-matter of claim 2 of the main request.

Thus, the subject matter of claim 2 of auxiliary request 1 extends beyond the content of the earliest application, contrary to Article 76(1) EPC. Auxiliary request 1 is not allowable.

Auxiliary request 2 - Amendments (Article 76(1) and Article 123(2) EPC)

19. The set of claims of auxiliary request 2 differs from that of the main request only in that in claim 2 the wording "more than one additional therapeutic agent" has been changed back to that of claim 28 of the earliest application ("one or more additional therapeutic agents"). As a consequence, the reasoning set out above for claim 2 of the main request with regard to the additional selection beyond that of cobicistat is no longer applicable. Claim 1 of auxiliary request 2 is identical to claim 1 of the main request. For the reasons given above, it does not add subject-matter either.

20. It was common ground between the parties that - provided the claimed subject-matter of auxiliary request 2 did not extend beyond the content of the grandparent application as filed - the same conclusion had to be drawn with regard to the two earlier applications.

Thus, it can be concluded that the claimed subject-matter of auxiliary request 2 does not extend beyond the content of the grandparent application as filed, the parent application as filed and the application as filed.

Remittal (Article 111(1) EPC and Article 11 RPBA)

21. Before the opposition division, the respondents submitted objections under Article 100(a), (b) and (c) EPC. However, the decision under appeal only assesses objections under one ground for opposition, namely Article 100(c) EPC. It would be contrary to

Article 12(2) RPBA if the board were now to decide, conclusively and without any previous substantive review, on objections under those grounds for opposition which were not the subject of the decision under appeal.

In its communication under Article 15(1) RPBA, the board had already indicated that it intended to remit the case in the event of one of the sets of claims not containing added subject-matter. At the oral proceedings, none of the parties objected to the remittal of the case.

Therefore, there are special reasons in the present case in favour of a remittal of the case to the opposition division for further prosecution.

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 for further prosecution.

The Registrar: The Chairman:

U. Bultmann M. O. Müller

Decision electronically authenticated