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**Datasheet for the decision
of 5 July 2022**

Case Number: T 0372/19 - 3.3.02

Application Number: 12167596.1

Publication Number: 2487166

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:

Teva Pharmaceutical Industries Ltd.
Cooke, Richard

Relevant legal provisions:

EPC Art. 76(1)

Keyword:

Divisional application - added subject-matter

Decisions cited:

T 2037/17, T 2635/18, T 0735/19



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Case Number: T 0372/19 - 3.3.02

D E C I S I O N
of Technical Board of Appeal 3.3.02
of 5 July 2022

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Decision under appeal: **Interlocutory decision of the Opposition
Division of the European Patent Office posted on
11 December 2018 concerning maintenance of the
European Patent No. 2487166 in amended form.**

Composition of the Board:

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

Summary of Facts and Submissions

I. This decision concerns the appeals filed by opponents 1 and 2 and the patent proprietor against the opposition division's interlocutory decision (decision under appeal), according to which European patent No. 2 487 166 (patent) in amended form meets the requirements of the EPC. Since all the parties are simultaneously appellant and respondent, they are referred to as opponents and patent proprietor for the sake of simplicity.

The patent originates from European patent application No. 12 167 596.1, which is a divisional application of European patent application No. 08 743 531.9.

II. In preparation for the oral proceedings, scheduled at the parties' request, the board issued a communication pursuant to Article 15(1) RPBA 2020.

III. With the statement of grounds of appeal, the patent proprietor filed the set of claims of auxiliary request 1.

IV. With the reply to the statements of grounds of appeal, the patent proprietor filed the set of claims of auxiliary request 3.

V. The parties' final requests relevant to this decision were as follows:

- Opponent 1 and opponent 2 requested that the decision under appeal be set aside and the patent be revoked in its entirety.

- The patent proprietor requested that the decision under appeal be set aside and the patent be maintained in amended form based on
 - the set of claims of the main request, filed before the opposition division on 19 December 2017, or alternatively
 - the set of claims of auxiliary request 1, filed with the statement of grounds of appeal.

Alternatively, the patent proprietor requested that the opponents' appeals be dismissed, implying that the patent be maintained in amended form as held allowable in the decision under appeal (auxiliary request 2).

In the further alternative, the patent proprietor requested that the decision under appeal be set aside and the patent be maintained in amended form based on the set of claims of auxiliary request 3, filed with the reply to the statements of grounds of appeal.

VI. The parties' appeal cases relevant to the present decision can be summarised as follows:

Opponents 1 and 2

- The subject-matter of claim 1 of the main request and auxiliary requests 1 to 3 was the result of a double selection from the parent application as filed without there being any pointer to this effect. This view was supported by decisions T 1255/18 and T 3139/19. The main request and auxiliary requests 1 to 3 therefore did not meet the requirements of Article 76(1) EPC.

Patent proprietor

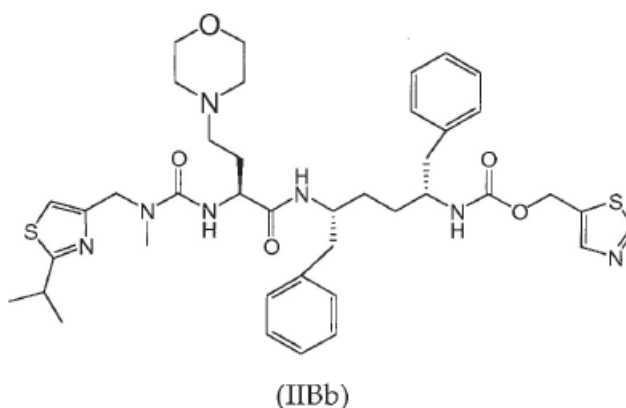
- Summaries of the patent proprietor's arguments are contained in the reasons for this decision.

Reasons for the Decision

Main request

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

"A pharmaceutical composition comprising a compound of formula IIBb



or a pharmaceutically acceptable salt, and/or solvate thereof, a pharmaceutically acceptable carrier or excipient and at least one additional therapeutic agent which is selected from the group consisting of a HIV nucleotide inhibitor of reverse transcriptase."

The compound whose structure is shown in claim 1 is example S of the parent application as filed. In agreement with the parties, it is referred to as cobicistat hereinafter. Thus claim 1 relates to a

pharmaceutical composition comprising, *inter alia*, cobicistat and an HIV nucleotide inhibitor of reverse transcriptase.

2. Amendments (Article 76(1) EPC)

2.1 In line with the parties, the board refers to the published version (WO 2008/103949 A1) for the disclosure of the parent application as filed.

2.2 The patent proprietor acknowledged that the HIV nucleotide inhibitor of reverse transcriptase is the result of a selection from the parent application as filed. The only dispute between the parties concerned the question of whether or not cobicistat involves a further selection.

2.2.1 As regards cobicistat, the following parts of the parent application as filed are relevant (it should be recalled that example S is cobicistat):

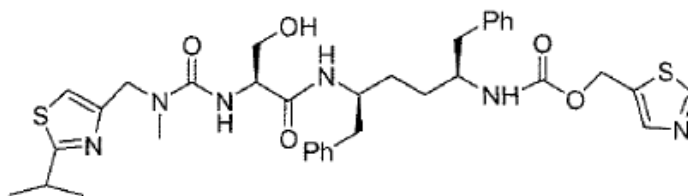
(a) page 217, line 1 to page 393, line 5, with syntheses of compounds according to the invention; four methods of synthesis for example S are disclosed on pages 251 to 259

(b) page 194, lines 21 ff.; this passage reads:

"For example, such combinations can comprise Example P, S, or X, or a pharmaceutically acceptable salt, solvate, and/or ester thereof in combination with two or three additional therapeutic agents selected from the group consisting of [...]"

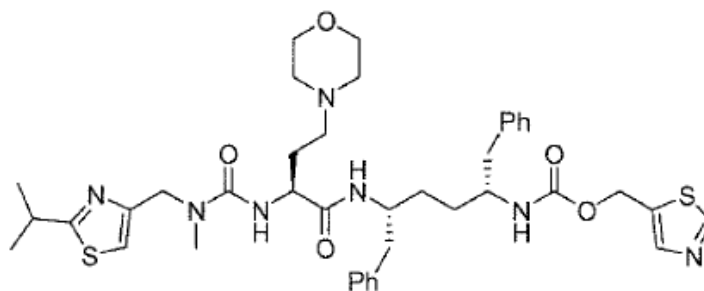
(c) claims 19 to 21; these claims read as follows:

"19. A compound which is:



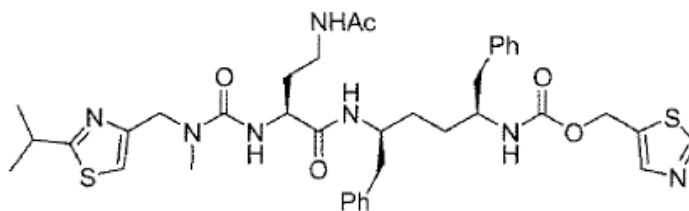
or a pharmaceutically acceptable salt, ester, and/or solvate thereof.

20. A compound which is



or a pharmaceutically acceptable salt, ester, and/or solvate thereof.

21. A compound which is



or a pharmaceutically acceptable salt, ester, and/or solvate thereof."

Each of these claims is an independent claim. They relate to examples P (claim 19), S (claim 20) and X (claim 21).

(d) page 401, lines 3 to 7; this passage reads:

"Experimental data based on representative Examples P, S, and T have a CYP450 3A4 inhibition activity in a range represented by an IC₅₀ from about 80-150 nM, a CYP450 2C9 inhibition activity in a range represented by an IC₅₀ from about 1000-10,000 nM, and a protease inhibition activity in a range represented by HIV EC₅₀ greater than about 30,000 nM."

2.2.2 Part (a) does not present cobicistat as preferred to the other examples of the parent application as filed.

In parts (b) and (d), cobicistat is presented at the same level of preference as two other examples, namely examples P and X and examples P and T, respectively.

As regards part (c), claims 19 to 21 have essentially the same wording. They only differ from each other with respect to the compounds claimed, but do not in any way suggest that one of their compounds is preferred over the other two. Thus, similarly to part (b), part (c) also presents cobicistat at the same level of preference as examples P and X.

It follows that in each of the above cases cobicistat must be selected from an indication of equally preferred examples, i.e. an enumeration of items ("list"), to arrive at the subject-matter of claim 1.

2.3 Thus to arrive at the subject-matter of claim 1 both the HIV nucleotide inhibitor of reverse transcriptase and cobicistat have to be selected from lists of the parent application as filed. It is established case law that such a double selection results in subject-matter which extends beyond the content of the (parent) application as filed unless there is a pointer to the specific combination claimed. However, in the present case there is no such pointer.

2.4 The patent proprietor took the view that the subject-matter of claim 1 of the main request was directly and unambiguously disclosed in the parent application as filed for the following reasons:

2.4.1 According to the patent proprietor, the parent application as filed disclosed (see e.g. part (a) above) and encompassed (see e.g. claim 1 as filed) a multitude of different compounds. Of these compounds, three, including cobicistat, were elevated above all the others in the parent application as filed. At least parts (b) to (d) of the parent application as filed, therefore, were not to be understood according to case law as lists from which cobicistat had to be selected. This was particularly true of claims 19 to 21. As they contained cobicistat in individualised form in claim 20, cobicistat was a standalone embodiment of the invention and did not require a selection. This view was confirmed by decisions T 735/19 and T 2635/18. At the very least, the fact that cobicistat was individualised in claim 20 had to be understood as a pointer to precisely this compound.

The board cannot agree with this argument. The concept of lists does not require a list necessarily to have a particular format, for example a table or with each

item introduced with a number or bullet point, nor is it applicable only to such formats. Rather, the information conveyed to the skilled person is crucial. If the skilled person is confronted with an indication of equally preferred items, this indication of items forms an enumeration or "list". Although it may be more obvious for parts (a), (b) and (d) that their indication of compounds forms a list, it is also true of part (c), i.e. claims 19 to 21. This can be illustrated by the fact that, as far as the disclosure is concerned, there is no difference between part (c), mentioning examples P, S and X in individual claims, and the hypothetical situation in which these examples are all contained in a single claim, the latter situation being more akin to what is usually referred to as a list.

Since claims 19 to 21 form a list, the mere fact that cobicistat is individualised in claim 20 cannot be understood as a pointer to this compound as argued by the patent proprietor - a view that might possibly have been accepted if cobicistat had been the only compound mentioned in the claims.

That claims 19 to 21 form a list, of which limitation to only one constitutes a selection, is precisely what distinguishes the present case from those underlying decisions T 735/19 and T 2635/18, on which the patent proprietor relied to support its argument that a claim was a standalone embodiment and that a limitation to its subject-matter did not constitute a selection.

In T 2635/18 (Reasons, point 3.1.1), it was indeed held that starting from the embodiment of a dependent claim of the application as filed did not constitute a selection. However, contrary to the present case, with

regard to the dependent claim in question, there were no other dependent claims with regard to which a selection would have had to be made. A similar assessment was made in case T 735/19 (Reasons, point 1.2), albeit with regard to Article 54 EPC. The claim at issue was directed to a contact lens comprising, *inter alia*, a hydrogel comprising phosphorylcholine groups. Dependent claim 32 of the prior-art document relevant to novelty of the subject-matter of the claim at issue disclosed a contact lens comprising as a component a polymer of hydroxyethyl methacrylate and a phosphorylcholine derivative. The competent board held that starting from the embodiment of claim 32 did not constitute a selection. This conclusion again is not in contradiction to that in the present case because in T 735/19 there were no other dependent claims in the relevant prior-art document relating to compounds which were preferred equally to that of dependent claim 32.

- 2.4.2 The patent proprietor also argued that even if claims 19 to 21 were considered as a list, this list was very short. In this context, decision T 2037/17 was relevant. This decision found a double selection from two very short lists to be an allowable amendment.

The board cannot agree with this argument either. The fact that the lists in passages (b) to (d) and in particular in claims 19 to 21 comprise only three compounds and are thus to be regarded as very short, as submitted by the patent proprietor, does not render a selection superfluous. Even if decision T 2037/17 (Reasons, point 1.3) were understood to mean that a double selection from two lists of only two items was allowable, as argued by the patent proprietor, this has no bearing on the present case, where the lists including cobicistat and the HIV nucleotide inhibitor

of reverse transcriptase comprise three and significantly more than two items, respectively.

2.5 It follows that claim 1 does not meet the requirements of Article 76(1) EPC. The main request is not allowable.

Auxiliary requests 1 to 3

3. Claim 1 of auxiliary requests 1 to 3 is identical to claim 1 of the main request. These auxiliary requests are therefore not allowable for the same reasons as given above for the main request.

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

M. O. Müller

Decision electronically authenticated