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Datasheet for the decision of 18 December 2023

Case Number: T 2156/21 - 3.3.07

Application Number: 15164931.6

Publication Number: 2932970

IPC: A61K31/5365, A61K31/505, A61P31/18

Language of the proceedings: EN

Title of invention:
ANTIVIRAL THERAPY

Patent Proprietor:
VIIV Healthcare Company

Opponents:
Teva Pharmaceutical Industries Ltd.
Cooke, Richard

Headword:
Antiviral therapy/VIIV

Relevant legal provisions:
RPBA 2020 Art. 12(4), 12(6)
EPC Art. 76(1)

Keyword:
Admission of documents (No)
Basis in the parent application (No)

Decisions cited:
T 0197/08, T 0045/12, T 0264/16, T 0207/17, G 0002/10

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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 2156/21 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 18 December 2023

Appellant: (Opponent 1)	Teva Pharmaceutical Industries Ltd. 124 Dvora HaNevi'a St. Tel Aviv 6944020 (IL)
Representative:	D Young & Co LLP 120 Holborn London EC1N 2DY (GB)
Appellant: (Opponent 2)	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)
Respondent: (Patent Proprietor)	VIIV Healthcare Company 251 Little Falls Drive Wilmington, DE 19808 (US)
Representative:	Gladwin, Amanda Rachel GlaxoSmithKline Global Patents (CN925.1) 980 Great West Road Brentford, Middlesex TW8 9GS (GB)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 20 October 2021 rejecting the opposition filed against European patent No. 2932970 pursuant to Article 101(2) EPC.**

Composition of the Board:

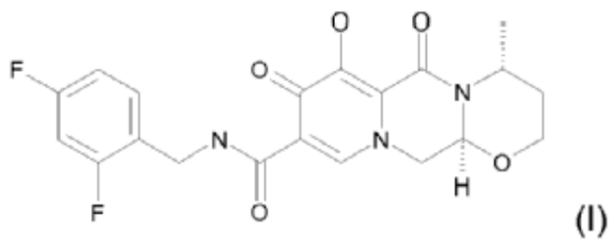
Chairman	A. Usuelli
Members:	D. Boulois
	S. Ruhwinkel

Summary of Facts and Submissions

I. European patent No. 2 932 970 was granted on the basis of a set of 9 claims. The patent had the application number 15164931.6 and is a divisional application from the application EP 11737484.3 (EP 2 531 027) published as WO2011094150..

Independent claim 1 as granted read as follows:

"1. A combination comprising a compound of formula (I)



(I)

or a pharmaceutically acceptable salt thereof, and rilpivirine or a pharmaceutically acceptable salt thereof."

II. The patent was opposed under Article 100 (a), (b), (c) EPC on the grounds that its subject-matter lacked novelty and inventive step, was not sufficiently disclosed and extended beyond the content of the application as filed.

III. The appeal lies from the decision of the opposition division to reject the oppositions.

IV. The documents cited during the opposition proceedings included the following:

D2: Azijn et al., Antimicrob Agents Chemother, 54(2), 718-727, 2009
D10: WO 2011/094150 (Parent application)

V. According to the decision under appeal, the claims as granted complied with Article 123(2) and 76(1) EPC, since only a selection in one list had to be made for rilpivirine, as the parent application D10 contained a clear pointer to the compound of formula (I) (dolutegravir).

The priority was found to be valid and the claims as granted were found to be inventive over D2. The opposition division also considered that the grounds pertaining to Art 100(a) EPC for lack of novelty and Art 100(b) EPC for lack of sufficiency were not substantiated.

VI. Opponents 01 and 02 (hereinafter appellants 01 and 02) filed an appeal against said decision.

VII. Third party observations were filed on 24 March 2022.

VIII. With its reply to the statements of grounds of appeal dated 28 June 2022, the patent proprietor (hereinafter the respondent) submitted the following evidences:

D13a: Guidelines for the use of ARVs (December 2009)
D33: Arts et al
D34: Garvey et al
D35: Jones et al
D36: Declaration of Arlene Cannon

IX. A communication from the Board, dated 21 September 2023, was sent to the parties. In it the Board expressed its preliminary opinion that the main request did not meet the requirements of Article 76(1) EPC.

X. With a letter dated 16 October 2023, the respondent filed auxiliary request 1. Claim 1 of auxiliary request was identical to claim 1 of the main request, this request differing from the main request in the suppression of claims 2-9.

XI. Oral proceedings took place on 18 December 2023 by videoconference. In the course of the discussion, appellant 02 withdrew his objection against the admittance of document D13a

XII. The arguments of the appellants may be summarised as follows:

Admission of D34 and D35

According to appellant 02, D34 and D35 were allegedly filed by the respondent in order to demonstrate the context in which the claimed application was written, and were filed in response to the opponents' objection regarding added subject-matter, while these arguments had been on file since the beginning of the present proceedings. Moreover, it was difficult to see how documents other than the application as filed could address the issues on Article 76(1) EPC raised by the opponents.

Main request - Article 76(1) EPC

The broadest disclosure of the parent application as filed related to the combinations on pages 2 to 3 of

the application as filed of either compound (I) (dolutegravir), compound II (cabotegravir), or compound III; and one or more additional therapeutic agent selected from several therapeutic classes. The parent application disclosed a long list of possible specific additional therapeutic agents including rilpivirine (paragraph bridging pages 5 and 6), which was the only disclosure of rilpivirine in the parent application as filed. There was no indication in these passages that dolutegravir was the preferred embodiment.
Moreover, the parent application identified several preferred combinations in the examples which included dolutegravir, but did not identify dolutegravir as preferred in itself, or in combination with any other compounds different from the examples.

XIII. The arguments of the respondent may be summarised as follows:

Admission of D34 and D35

D34 and D35 were cited during the appeal procedure to explain the context in which the application as filed would have been read at the filing date by one of skill in the art, and were provided in response to the discussion in the opponents' grounds of appeal regarding the content of the application as filed.

Main request - Article 76(1) EPC

Of the three integrase inhibitors identified as compounds "of the invention", the application as filed pointed to a clear preference for the compound of formula (I) (dolutegravir), over the compounds of formulae (II) and (III) for following reasons:

- the compound of formula (I) was the only compound used in the combinations that were tested in the working examples;
- the claims as originally filed were directed only to combinations in which the compound of formula (I) was claimed.

Consequently, only one selection from a single list was required to arrive at the presently claimed subject matter from the specification as filed, namely the selection of rilvipirine. The claimed subject matter was therefore directly and unambiguously derivable from the specification as filed and from the parent application as filed.

XIV. Requests

Appellants 01 and 02 (opponents 01 and 02) requested that the decision under appeal be set aside and the patent be revoked. Appellant 02 also requested that documents D34 and D35 not be admitted into the appeal proceedings.

Respondent (patent proprietor) requested that the appeal be dismissed or alternatively that the decision under appeal be set aside and the patent be maintained on the basis of auxiliary request 1 filed on 16 October 2023.

Reasons for the Decision

1. Admission of D34 and D35 into the appeal proceedings

1.1 These documents were filed by the respondent in its response to the statements of grounds of appeal of

appellants 01 and 02. Their admission into the appeal proceedings is objected to by appellant 02.

1.2 D34 and D35 are documents on file on the related opposition to EP 3 127 542, relating to the combination of the same compound of Formula (I) with abacavir. According to the respondent, D34 and D35 are cited to explain the context in which the application as filed would have been read at the filing date by a skilled person, and are provided in response to the opponent's grounds of appeal regarding the content of the application as filed.

1.3 D34 and D35 do not appear to be relevant to the case. The Board did not identify the appellant's arguments that could justify the filing of these documents. The appellants' arguments regarding the addition of subject-matter have been on file since the beginning of the opposition proceedings. The assessment of Articles 123(2) EPC and 76(1) EPC is furthermore only performed in view of the patent or parent application, and not in view of parallel cases. Whether or not a claim has direct and unambiguous basis in the application as filed cannot indeed be decided on the basis of the disclosure of any other document.

Thus, D34 and D35 documents do not address the objection under Article 76(1) EPC put forward by the opponents and their admission would be harmful to procedural economy and for this reason cannot be admitted into the appeal proceedings (Article 12(4) RPBA 2020). Accordingly, the Board decides not to admit D34 and D35 into the appeal proceedings.

2. Main request - Article 76(1) EPC

2.1 The subject-matter of claim 1 of the main request is the combination of the compound of formula (I) with rilpivirine.

2.2 The parent application WO 2011/094150 (D10) relates to combinations of HIV integrase inhibitors and other therapeutic agents.

It discloses more particularly general combinations of either a compound of formula (I), i.e. GSK1349572 or dolutegravir, or a compound of formula (II) or a compound of formula (III) with one or more therapeutic agents selected from nucleotide reverse transcriptase inhibitors, nucleoside reverse transcriptase inhibitors (NRTIs), non-nucleoside reverse transcriptase inhibitors (NNRTIs), protease inhibitors, CCR5 antagonists, CXCR4 antagonists, fusion inhibitors, maturation inhibitors and integrase inhibitors (see D10, page 2, line 30 to page 3, line 19, page 4, line 34 to page 5, line 6). The parent application gives a long list of examples of such therapeutic agents to be combined with compounds of formula (I), (II) or (III) in the paragraph bridging pages 5 and 6. Rilpivirine is one of the compound mentioned in this list. This is the only disclosure of rilpivirine in the parent application as filed.

Thus, the parent application comprises several possible combinations of active ingredients, said combinations being the result of the selection of compounds disclosed in two lists of equal alternatives. The compound of formula (I) and rilpivirine have been singled out from their list among other equal alternatives. The combination of the compound of

formula (I) and rilpivirine results therefore from a double selection among two lists of alternative compounds.

Consequently, the claimed subject-matter is not derivable directly and unambiguously from the parent application and the main request does not meet the requirements of Article 76(1) EPC.

2.3 The respondent argued that, when a feature is identified as preferred in an application, its incorporation into the claims cannot constitute a selection, since the claims did not present any new information. In the present case, it was clear that one feature was the core feature of the parent application and that this feature could not constitute an option. This feature was the compound of formula (I), which was disclosed as the preferred compound in the parent application. The respondent cited decisions T 197/08, T 45/12, T 264/16 and T 207/17 in support of its line of argumentation.

2.4 The Board considers this argument not convincing in the present case.

2.4.1 First, it is not at all apparent from the description of the parent application that the compound of formula (I) is the preferred compound. There is in particular no explicit statement in the description of the parent application that the compound of formula (I) has a general preference.

As discussed above under point 2.2, the general disclosure of the parent application on pages 2-6 relates to combinations useful in the inhibition of HIV replication and generally to a combination between

either compound of formula (I), or compound of formula (II) or compound of formula (III) with another therapeutic agent disclosed in a long list (see D10, pages 2-6).

The following pages of the parent application disclose the more specific combinations with again either the compound of either formula (I), (II) or (III) with specifically lamivudine, abacavir, tenofovir, efavirenz, GSK2248761, lersivirine, lopinavir, fosamprenavir and atazanavir, and more particularly with abacavir, efavirenz or lopinavir (see page 6, lines 8-27; page 7, lines 10-29; page 8, lines 15-30).

Hence, there is no passage in the description of the parent application which indicates that the compound of formula (I) is the preferred compound.

2.4.2 The Board acknowledges that the claims and the sole example of the parent application relate to combinations comprising systematically the compound of formula (I) with another anti-HIV compound, but considers that said example and claims cannot serve as pointer for a general preference to the compound of formula (I).

The example of the parent application studies indeed the biological activity of the compound (I) with several combined therapeutic agents; the compound of formula (I) was found to be additive with raltegravir, adefovir, and maraviroc and was not affected by the presence of ribavirin, while it was found to be synergistic with stavudine, abacavir, efavirenz, nevirapine, lopinavir, amprenavir, enfuvirtide. Figures 1-3 show the experimental results of HIV inhibition by the combinations of abacavir, efavirenz and lopinavir

with the compound of formula (I). These specific and limited preferences demonstrated by the example is reflected by the claims of the parent application, which are directed to a combination of the compound (I) with specifically and exclusively abacavir, efavirenz or lopinavir, namely three active ingredients for which a synergistic effect has been shown (see claims 1 or 5 of D10).

The Board considers however that the disclosure of the original application does not allow to isolate the compound of formula (I) from the context of the example or the claims and then to combine it with a feature disclosed in a distinct part of the description of the parent application, namely the compound riplipvirine. In the Board's view, the disclosure of the claims and the example highlights that the compound of formula (I) is preferred only in combination with specific additional active ingredients and provides therefore a direct basis for these specific combinations, but cannot serve as a basis for a combination with rilpivirine.

2.4.3 The respondent cited several decisions from the EPO jurisprudence in support of its arguments, namely T 197/08, T 45/12, T 264/16 and T 207/17. The Board considers that none of said decisions can apply to the present case.

In all these decisions, it was considered either that a specific feature constituted *de facto* the only possibility envisaged by the application (see T 197/08 point 3.3), or that an one-dimensional selection did not introduce added subject-matter (see T 45/12 point 3.2.2), and/or that the restriction to a preferred compound was not to be considered as a selection (see

T45/12 point 3.2.2, T264/16 point 2.1.1 and T207/17 point 3.2).

In the present case the compound of formula (I) is not the only compound envisaged in the original application for forming a combination with a further anti-HIV (cf. point 2.4.1 above). Moreover, as argued above, the sole example and the claims of the parent application can only be seen as pointers for specific **combinations** of the compound of formula (I) with the other specific anti-HIV agents disclosed in the example or in the claims, but not for the singling out of the compound (I) and combining it with any other therapeutic agent disclosed in the remaining part of the parent application.

According to the "gold standard", any amendment can only be made 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 documents as filed, here the parent application (G 2/10, OJ 2012, 376). In the present case, the compound rilpivirine is disclosed in the parent application **only** in the context of a long list of anti-HIV products which may be associated with any equal alternative compound of formula (I), (II) or (III). As discussed above, this represents a multiple selection from different lists which is not derivable directly and unambiguously from the parent application.

3. Auxiliary request 1 - Article 76(1) EPC

Claim 1 of auxiliary request is identical to claim 1 of the main request, this request differing from the main request in the suppression of claims 2-9. The

conclusions reached for the main request apply therefore *mutatis mutandis* to auxiliary request 1 which does not meet 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:

B. Atienza Vivancos A. Usuelli

Decision electronically authenticated