

**Internal distribution code:**

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

**Datasheet for the decision  
of 3 June 2024**

**Case Number:** T 2643/16 - 3.3.07

**Application Number:** 08732818.3

**Publication Number:** 2203462

**IPC:** A61K31/7064, A61K31/7076

**Language of the proceedings:** EN

**Title of invention:**  
NUCLEOSIDE PHOSPHORAMIDATE PRODRUGS

**Patent Proprietor:**  
Gilead Pharmasset LLC

**Opponents:**  
MEDECINS DU MONDE  
Fleischer, Holm Herbert  
ELLIS IP LTD  
Pharmaceutical Works POLPHARMA  
Generics [UK] Ltd (trading as Mylan)  
Teva Pharmaceutical Industries Ltd.  
I P S Intellectual Property Services  
STADA Arzneimittel AG  
ZBM Patents - Zea, Barlocchi & Markvardsen  
Actavis Group PTC ehf

**Headword:**  
Sofosbuvir/GILEAD

**Relevant legal provisions:**

EPC 1973 Art. 87, 83

**Keyword:**

Priority - (yes)

Sufficiency of disclosure - (yes)

**Decisions cited:**

G 0001/22, G 0002/22, T 2643/16



**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 2643/16 - 3.3.07**

**D E C I S I O N**  
**of Technical Board of Appeal 3.3.07**  
**of 3 June 2024**

**Appellant:**  
(Patent Proprietor)  
Gilead Pharmasset LLC  
Gilead Sciences, Inc.  
333 Lakeside Drive  
Foster City, CA 94404 (US)

**Representative:**  
J A Kemp LLP  
80 Turnmill Street  
London EC1M 5QU (GB)

**Appellant:**  
(Opponent 1)  
MEDECINS DU MONDE  
62 Rue Marcadet  
75018 Paris (FR)

**Representative:**  
Jorget, Quentin  
J-INVENT  
110, rue Vieille du Temple  
75003 Paris (FR)

**Appellant:**  
(Opponent 2)  
Fleischer, Holm Herbert  
Am Lingenstock 17  
51515 Kürten (DE)

**Representative:**  
Altmann Stößel Dick Patentanwälte PartG mbB  
Isartorplatz 1  
80331 München (DE)

**Appellant:**  
(Opponent 5)  
Generics [UK] Ltd (trading as Mylan)  
Albany Gate  
Darkes Lane  
Potters Bar  
Hertfordshire EN6 1 AG (GB)

**Representative:**  
Elkington and Fife LLP  
Prospect House  
8 Pembroke Road  
Sevenoaks, Kent TN13 1XR (GB)

**Appellant:** Actavis Group PTC ehf  
(Opponent 10 ) Reykjavikurvegi 76-78  
220 Hafnarfjörður (IS)

**Representative:** D Young & Co LLP  
3 Noble Street  
London EC2V 7BQ (GB)

**Party as of right:** ELLIS IP LTD  
(Opponent 3 ) Newbyth House  
East Linton  
East Lothian  
EH40 3DU (GB)

**Representative:** Ellis, Michael James  
Ellis IP Ltd  
53/4 George Street  
Edinburgh EH2 2HT (GB)

**Party as of right:** Pharmaceutical Works POLPHARMA  
(Opponent 4 ) Pelplinska Str. 19  
83-200 Starogard Gdanski (PL)

**Representative:** Elkington and Fife LLP  
Prospect House  
8 Pembroke Road  
Sevenoaks, Kent TN13 1XR (GB)

**Party as of right:** Teva Pharmaceutical Industries Ltd.  
(Opponent 6 ) 124 Dvora HaNevi'a St.  
6944020 Tel Aviv (IL)

**Representative:** D Young & Co LLP  
3 Noble Street  
London EC2V 7BQ (GB)

**Party as of right:** I P S Intellectual Property Services (OP7)  
(Opponent 7 ) 11 Rue La Fayette  
75009 Paris (FR)

**Representative:** Casalonga  
Casalonga & Partners  
Bayerstraße 71/73  
80335 München (DE)

**Party as of right:** STADA Arzneimittel AG (OP8)  
(Opponent 8 ) Stadastrasse 2-18  
61118 Bad Vilbel (DE)

**Representative:** Hamm & Wittkopp Patentanwälte PartmbB  
Jungfernstieg 38  
20354 Hamburg (DE)

**Party as of right:** ZBM Patents - Zea, Barlocchi & Markvardsen (OP9)  
(Opponent 9 ) Rambla Catalunya, 123  
08088 Barcelona (ES)

**Representative:** ZBM Patents - Zea, Barlocchi & Markvardsen  
Rambla Catalunya, 123  
08008 Barcelona (ES)

**Decision under appeal:** **Interlocutory decision of the Opposition  
Division of the European Patent Office posted on  
31 October 2016 concerning maintenance of the  
European Patent No. 2203462 in amended form**

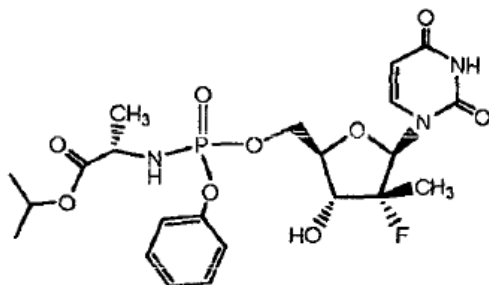
**Composition of the Board:**

**Chairwoman** M. Blasi  
**Members:** J. Molina de Alba  
S. Albrecht  
E. Duval  
Y. Podbielski

## Summary of Facts and Submissions

- I. This is a final decision following interlocutory decision T 2643/16, dated 16 February 2023.
- II. The following documents are cited in this decision:
- D1 US 60/909,315 (priority application 1)
  - D2 US 60/982,309 (priority application 2)
  - D6 H. Ma *et al.*, *The Journal of Biological Chemistry*, 2007, 282(41), 29812-20
  - D8 M.J. Sofia *et al.*, poster presented at the 14th International Symposium on Hepatitis C Virus and Related Viruses, Glasgow (UK), 9-13 September 2007
  - D9 E. Murakami *et al.*, *Antimicrobial Agents and Chemotherapy*, 2008, 52(2), 458-64
- III. The decision under appeal is the opposition division's interlocutory decision rejecting the patent proprietor's main request (patent as granted) and finding that the patent as amended in the form of auxiliary request 1 met the requirements of the EPC.
- IV. The patent had been granted with six claims. Claim 1 as granted read as follows:

"1. A compound represented by the formula



Claim 2 was directed to the diastereomer of the compound of claim 1 having the (S)-configuration at the phosphorous atom.

Claim 3 was directed to the diastereomer of the compound of claim 1 having the (R)-configuration at the phosphorous atom.

Claims 4, 5 and 6 were directed to a composition comprising the compound of claim 1, 2 or 3, respectively, and a pharmaceutically acceptable medium.

V. Auxiliary request 1 in these appeal proceedings is identical to the auxiliary request held allowable by the opposition division. It contains only two claims, which are identical to claims 1 and 4 as granted.

VI. Oral proceedings were held before the Board on 24 November 2022. At the oral proceedings, the Board did not deal with the inventive-step objections involving documents D6, D8 and D9 because the assessment of whether these documents belonged to the prior art depended on the outcome of then pending referral cases G 1/22 and G 2/22.

VII. The Board issued interlocutory decision T 2643/16, dated 16 February 2023, which dealt with all the matters on which the Board had come to a conclusion at the oral proceedings of 24 November 2022. In the interlocutory decision, the Board decided that:

- the ground for opposition of Article 100(c) EPC prejudiced the maintenance of the patent as granted,
- priority applications D1 and D2 disclosed the invention claimed in auxiliary request 1 in an enabling manner, and
- the subject-matter of auxiliary request 1 was inventive if only the cited documents published before the earliest priority date were considered.

VIII. A decision on referrals G 1/22 and G 2/22 was issued on 10 October 2023. The Board sent a communication to the parties with its preliminary opinion. It considered that auxiliary request 1 enjoyed the priority dates of 30 March 2007 and 24 October 2007. Therefore, D6, D8 and D9 did not belong to the prior art under Article 54(2) EPC and could not be considered for assessing inventive step. The Board also gave the reasons why the remaining sufficiency objection against auxiliary request 1 should be rejected. Therefore, the Board informed the parties that it could take a decision on the case without holding further oral proceedings.

The Board gave the parties two months from notification of the communication to submit comments or requests. If no replies or requests were received within that period, the parties could expect the Board to issue a



decision in writing without holding further oral proceedings. The outcome would be dismissal of the appeals.

IX. No replies or requests were received.

X. The parties' final requests relevant for the present decision were as follows.

The appellant-patent proprietor requests:

- that the decision under appeal be set aside and that the oppositions be rejected, i.e. that the patent be maintained as granted (main request),
- alternatively, that the opponents' appeals be dismissed and that the decision under appeal be upheld, i.e. that the patent be maintained as amended in the form of auxiliary request 1 as considered allowable by the opposition division (claims resubmitted as auxiliary request 3 with the appellant-patent proprietor's statement of grounds of appeal, and renumbered as auxiliary request 1 during the oral proceedings on 24 November 2022).

Appellant-opponents 1, 2, 5 and 10 request that the decision under appeal be set aside and that the patent be revoked in its entirety.

Respondent-opponents 7, 8 and 9 withdrew their appeals, neither maintaining their earlier requests nor submitting any new request.

Respondent-opponents 3, 4 and 6 did not file any request in these appeal proceedings.

## Reasons for the Decision

### 1. *Priority - auxiliary request 1*

1.1 The Board decided in interlocutory decision T 2643/16 (Reasons 5.1 and 5.2) that D1 and D2 disclose the same invention in an enabling manner as claimed in auxiliary request 1. The only issue that remained open with regard to the requirements of Article 87(1) EPC was whether the applicant, Pharmasset, Inc., was entitled to claim priority from previous applications D1 and D2 when filing the application on which the patent in suit was granted.

1.2 At the date of the oral proceedings before the Board, referral cases G 1/22 and G 2/22 were pending before the Enlarged Board of Appeal. The following questions were posed by the referring board:

*"I. Does the EPC confer jurisdiction on the EPO to determine whether a party validly claims to be a successor in title as referred to in Article 87(1) (b) EPC?*

*II. If question I is answered in the affirmative*

*Can a party B validly rely on the priority right claimed in a PCT-application for the purpose of claiming priority rights under Article 87(1) EPC*

*in the case where*

*1) a PCT-application designates party A as applicant for the US only and party B as applicant*

*for other designated States, including regional European patent protection and*

*2) the PCT-application claims priority from an earlier patent application that designates party A as the applicant and*

*3) the priority claimed in the PCT-application is in compliance with Article 4 of the Paris Convention?"*

It is apparent from the questions that the outcome of G 1/22 and G 2/22 was relevant for the Board's decision on the validity of the priorities claimed in the case in hand.

1.3 On 10 October 2023, the Enlarged Board handed down its decision on referrals G 1/22 and G 2/22. In the order, it decided that:

(a) *"The European Patent Office is competent to assess whether a party is entitled to claim priority under Article 87(1) EPC.*

*There is a rebuttable presumption under the autonomous law of the EPC that the applicant claiming priority in accordance with Article 88(1) EPC and the corresponding Implementing Regulations is entitled to claim priority."*

(b) *"The rebuttable presumption also applies in situations where the European patent application derives from a PCT application and/or where the priority applicant(s) are not identical with the subsequent applicant(s).*

*In a situation where a PCT application is jointly filed by parties A and B, (i) designating party A for one or more designated States and party B for one or more other designated States, and (ii) claiming priority from an earlier patent application designating party A as the applicant, the joint filing implies an agreement between parties A and B allowing party B to rely on the priority, unless there are substantial factual indications to the contrary."*

- 1.4 In accordance with this order, the Board is competent to assess whether a party is entitled to claim priority under Article 87(1) EPC. In this context, there is a rebuttable presumption that the applicant claiming priority in accordance with Article 88(1) EPC and the corresponding Implementing Regulations is entitled to claim priority. This rebuttable presumption also applies in situations such as the one in hand, in which the European patent application derives from a PCT application and the priority applicants differ from the subsequent applicant.

The opponents did not rebut the presumption that the applicant, Pharmasset, Inc., was entitled to claim the priority from applications D1 and D2. Therefore, the Board concludes that Pharmasset, Inc. was entitled to claim the priority of applications D1 and D2, with the consequence that auxiliary request 1 enjoys the priority dates of 30 March 2007 and 24 October 2007.

2. *Inventive step - auxiliary request 1*

Auxiliary request 1 enjoys the priority date of 30 March 2007. Therefore, documents D6, D8 and D9,

published on 12 October 2007, September 2007 and February 2008, respectively, do not belong to the prior art under Article 54(2) EPC and cannot be considered for assessing inventive step of the claimed subject-matter of auxiliary request 1.

Having regard to the Board's conclusion in interlocutory decision T 2643/16 that the subject-matter of auxiliary request 1 is inventive when considering the documents published before 30 March 2007, the subject-matter of auxiliary request 1 is inventive and meets the requirements of Article 56 EPC.

3. *Sufficiency of disclosure - auxiliary request 1*

An additional issue that could not be discussed at the oral proceedings of 24 November 2022 was sufficiency of disclosure of auxiliary request 1.

3.1 The opponents had argued that the diastereomers in claims 2 and 3 of the patent as granted were not sufficiently disclosed. In their opinion, the skilled person could neither separate the diastereomers from the mixture of claim 1 as granted nor determine the absolute stereochemistry of each diastereomer without undue burden.

As claims 2 and 3 as granted were deleted in auxiliary request 1, the objection was moot.

3.2 Appellant-opponent 2 (reply to the patent proprietor's appeal, point II.2b) nevertheless argued that the sufficiency objection still applied to auxiliary request 1 if claim 1 was interpreted as encompassing not only the mixture but also the pure diastereomers.

This was indeed the appellant-patent proprietor's interpretation of claim 1 (statement of grounds of appeal, points 2.2 and 2.7).

- 3.3 Irrespective of the interpretation of the scope of claim 1, the Board agrees with the appellant-patent proprietor (statement of grounds of appeal, points 4.5 and 4.9) that, on the filing date, diastereoisomers could be routinely separated by column chromatography, e.g. using a chiral column as suggested in Example 81 of the application as filed. The absolute configuration of diastereomers could also be routinely determined by spectroscopic techniques, e.g. by X-ray diffraction.

The sufficiency objection of appellant-opponent 2 relied on allegations not supported by evidence raising serious doubts as to the skilled person's ability to separate diastereomers and assign their corresponding configurations without undue burden. Consequently, the objection is rejected.

- 3.4 Therefore, the subject-matter of auxiliary request 1 is sufficiently disclosed and meets the requirements of Article 83 EPC.

**Order**

**For these reasons it is decided that:**

The appeals are dismissed.

The Registrar:

The Chairwoman:



S. Sánchez Chiquero

M. Blasi

Decision electronically authenticated