

Application No.: **08 732 818.3**  
Patent No.: **EP-B-2 203 462**

Direct decision:

yes  no

**Interlocutory decision in opposition proceedings (Art. 101(3)(a) and 106(2) EPC)**

The Opposition Division - at the oral proceedings dated 05.10.2016 - has decided:

Account being taken of the amendments made by the patent proprietor during the opposition proceedings, the patent EP-B-2 203 462 and the invention to which it relates are found to meet the requirements of the Convention.

The currently valid documents are:

**Auxiliary Request 1**

**Description, Pages**

2-46 of the patent specification

**Description, Paragraphs**

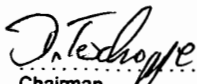
52 handwritten amendments filed during Oral Proceedings on 05-10-2016

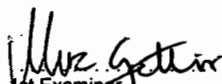
**Claims, Numbers**


1, 2 received on 03-08-2016 with letter of 03-08-2016

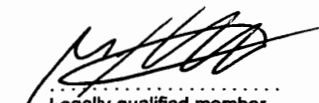
The Grounds for the decision (Form 2916) are enclosed.

24/10/16  
Date

  
Chairman  
Tzschoppe, Dieter

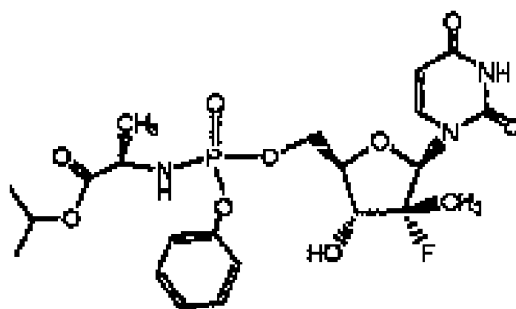
  
1st Examiner  
Gettins, Marc

  
2nd Examiner  
Härtlinger, Stefan

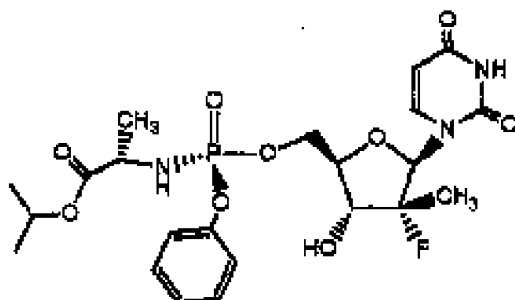
  
Legally qualified member  
Schauwecker, Marko

## Facts and Submissions

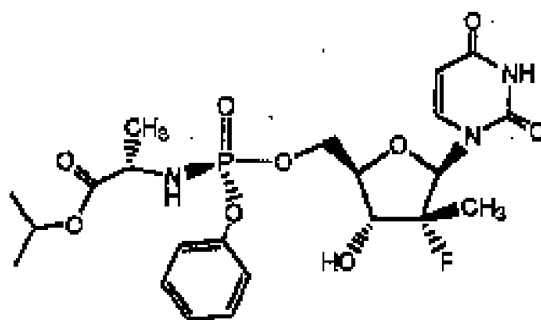
- 1 The contested patent has the patent number EP2203462 and is based upon the application number 08732818 with the title "NUCLEOSIDE PHOSPHORAMIDATE PRODRUGS". The patent proprietor is Gilead Pharmasset LLC. The patent has 3 priority dates namely: 30.03.2007; 24.10.2007 and 21.03.2008.
- 2 Claim 1 of the patent in suit is directed to the following racemate



Claims 2-3 are directed to the enantiomers of this compound and have the following formulae:



claim 2



claim 3

Claims 4-6 relate to compositions corresponding to claims 1-3 respectively.

3 A total of ten oppositions have been filed by the following opponents:

- 3.1 Médecins du Monde (Opponent 1) on 10.02.2015;
- 3.2 Mr H. H. Fleischer (Opponent 2) on 19.02.2015;
- 3.3 Ellis IP Ltd. (Opponent 3) on 19.02.2015;
- 3.4 Pharmaceutical Works Polpharma S.A. (Opponent 4) on 20.02.2015;
- 3.5 Generics [UK] Ltd (Opponent 5) on 20.02.2015;
- 3.6 Teva Pharmaceutical Industries Ltd; (Opponent 6) on 20.02.2015;
- 3.7 Intellectual Property Services (IPS) (Opponent 07) on 23.02.2015;
- 3.8 Stada Arzneimittel AG (Opponent 8) on 23.02.2015;
- 3.9 ZBM Patents S.L. (Opponent 9) on 23.02.2015;
- 3.10 Actavis Group PTC ehf (Opponent 10) on 23.02.2015

4 The following documents have been cited:

- A1 assignment of D1
- A2 assignment of D2
- A3 assignment of D3
- D1 US prov. appl. 60/909315 = 1st priority document of contested patent

- D2 US prov. appl. 60/982309 = 2nd priority document of contested patent
- D3 US prov. appl. 12/053015 = 3rd priority document of contested patent
- D4 WO2005/012327
- D5 Thesis entitled "Design, Synthesis and Biological Evaluation of Novel Nucleotide Prodrugs as Potential Anti-Hepatitis C Virus Agents" submitted by Plinio Perrone
- D6 Ma et al 2007, J. Biol. Chem. 282: pp29812-29820
- D7 Perrone et al 2007 J. Med. Chem. 50, pp1840-1849
- D7a Extract from website of J. Med. Chem. to confirm publication date of document D7
- D8 Poster presented at the 14th International Symposium on Hepatitis C Virus and Related Viruses which was held in Glasgow (Scotland) on 9-13 September 2007
- D9 Murakami et al 2008 Antimicrob. Agents Chemother. 52:458-464
- D10 Clark et al 2005, J. Med. Chem. 48, pp5504-5508
- D11 Zemlicka 2002 Biochemica Acta 1587:276-286
- D12 WO2005/003147
- D13 WO2008/121634 application document of contested patent
- D14 Lehsten et al, Org. Proces Res. Dev. 2002, 6, 819-822
- D15 WO2011/123645
- D16 Cahard et al, Mini-Reviews in Medicinal Chemistry, 2004, 4, pp:371-381
- D17 Jones et al., Minireview: Nucleotide Prodrugs. Antiviral Research 27 (1995), pp. 1-17
- D18 Lee et al, Antimicrobial Agents and Chemotherapy 2005. pp 1898-1906
- D19 WO 02/08241
- D20 McGuigan et al, J. Med. Chem, 2006, 49, pp 21 5-7226
- D21 Sofia et al. J, Med. Chem, 2010, 53, pp7202-7218
- D22 Abstract 100 "Design, synthesis, and Biological evaluation of Novel Nucleoside PPAs as Potential Anti-HCV Agents' presented at the 14th international Conference on Antiviral Research May 7-11, 2006
- D23 W02004/002999

- D24 W02006/121820
- D25 W02006/012078
- D26 WO2006/065335
- D27 Gunic et al Bioorg & Med Chem. Letts 17(9) pp2456-2458 14.02.2007
- D28 US6475985
- D29 WO03/000713
- D30 WO2007/020193
- D31 US2006/0241064
- D32 WO2007/095269
- D33 Ma et al "Characterization of the Intracellular metabolism of 3-D-2'-deoxy-2'-fluoro-2'-C-methylcytidine. ... ." Antiviral Research 2007 74 A36 Abstract 23
- D34 Evidence as to the priority date of D33 and D35
- D35 McGuigan et al "Sub Micromolar Inhibitors of HCV Generated from Inactive Nucleosides by Application of ProTide Technology" Antiviral Research 2007 74 A36 Abstract 24
- D36 McGuigan et al FEBS Letter (1994) 11-14
- D37 McGuigan et al, J. Med. Chem. 2005, pp3504-3515
- D38 Klumpp et al, J. Biol. Chem., 2006, vol. 281, pp3793-3799
- D40 US12/053015
- D42 Declaration of Dr Michael Sofia
- D43 Declaration of Dr Valentino Stella
- D44 Declaration of Professor John R. Thomas
- D45 Declaration of Dr Adrian Ray
- D45A Second Declaration of Dr Adrian Ray
- D46 Declaration of Dr Phillip Furman
- D47 Declaration of Dr William Delaney
- D48A Email exchange dated 14 May 2015 regarding publication date of D14
- D48B Email exchange dated 12 November 2015 regarding the period

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