



(12) Translation of new
European patent specification
After opposition procedure

(11) NO/EP 2709613 B2

NORWAY

(19) NO
(51) Int Cl.

A61K 31/381 (2006.01)
A61K 31/4184 (2006.01)
A61K 31/4196 (2006.01)
A61K 31/513 (2006.01)
A61P 31/14 (2006.01)

Norwegian Industrial Property Office

(45)	Translation Published	2018.05.22
(80)	Date of The European Patent Office Publication of the Granted Patent	2017.11.29
(45)	Decision of the opposition in EPO	2020.08.12
	Decision of the opposition in NIPO	2020.12.28
(86)	European Application Nr.	12768967.7
(86)	European Filing Date	2012.09.14
(87)	The European Application's Publication Date	2014.03.26
(30)	Priority	2011.09.16, US, 201161535885 P 2011.11.18, US, 201161561753 P
(84)	Designated Contracting States:	AL ; AT ; BE ; BG ; CH ; CY ; CZ ; DE ; DK ; EE ; ES ; FI ; FR ; GB ; GR ; HR ; HU ; IE ; IS ; IT ; LI ; LT ; LU ; LV ; MC ; MK ; MT ; NL ; NO ; PL ; PT ; RO ; RS ; SE ; SI ; SK ; SM ; TR
	Designated Extension States:	BA ; ME
(73)	Proprietor	Gilead Pharmasset LLC, c/o Gilead Sciences, Inc. 333 Lakeside Drive, Foster City, CA 94404, USA
(72)	Inventor	RAY, Adrian S., c/o Gilead Pharmasset LLC333 Lakeside Drive, Foster City, CA 94404, USA WATKINS, William J., c/o Gilead Pharmasset LLC333 Lakeside Drive, Foster City, CA 94404, USA LINK, John O., c/o Gilead Pharmasset LLC333 Lakeside Drive, Foster City, CA 94404, USA OLDACH, David W., 9111 Laurel Springs Drive, Chapel Hill, North Carolina 27516, USA DELANEY, IV, William E., c/o Gilead Pharmasset LLC333 Lakeside Drive, Foster City, California 94404, USA
(74)	Agent or Attorney	TANDBERG INNOVATION AS, Postboks 1570 Vika, 0118 OSLO, Norge

(54) Title **METHODS FOR TREATING HCV**

(56) References

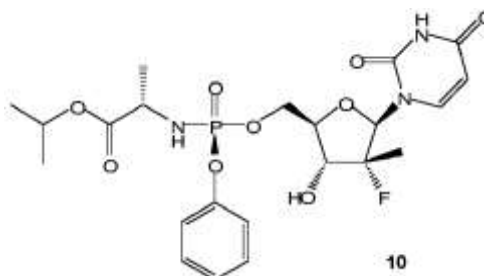
Cited:

- WO-A1-2012/087596
 US-A1- 2011 306 541
 US-A1- 2011 178 129
 WO-A1-2010/132601
 EP-A2- 2 583 680
 EP-A2- 2 583 677
 Soriano et al: Journal of Antimicrobial. Chemotherapy, vol. 66, 2011, pages 1673-1686,
 DELANG et al.: Viruses, vol. 2, no. 4, 2010, pages 826-866,
 sss.clinicaltrial.gov NCT01260350
 Sofia et al: Antiviral Chemistry and Chemotherapy, vol. 22, 2011, pages 23-49,
 LAM ANGELA M ET AL: "PSI-7851, a pronucleotide of .beta.-D-2'-deoxy-2'-fluoro-2'-C-methyluridine monophosphate, is a potent and pan-genotype inhibitor of hepatitis C virus replication", ANTIMICROBIAL AGENTS AND CHEMOTHERAPY, AMERICAN SOCIETY FOR MICROBIOLOGY, US, vol. 54, no. 8, 1 August 2010 (2010-08-01) , pages 3187 -3196, XP009151247, ISSN: 0066 -4804, DOI: 10.1128/AAC.00399 -10 [retrieved on 2010 -06-01]
 ERIC J LAWITZ ET AL: "A phase 1, randomized, placebo-controlled, 3-day, dose-ranging study of GS-5885, an NS5A inhibitor, in patients with genotype 1 hepatitis C", JOURNAL OF HEPATOLOGY, ELSEVIER, AMSTERDAM, NL, vol. 57, no. 1, 29 December 2011 (2011-12-29), pages 24-31, XP028493090, ISSN: 0168 -8278, DOI: 10.1016/J.JHEP.2011.12.0 29 [retrieved on 2012-02-05]
 E. MURAKAMI ET AL: "Mechanism of Activation of PSI-7851 and Its Diastereoisomer PSI-7977", JOURNAL OF BIOLOGICAL CHEMISTRY, vol. 285, no. 45, 26 August 2010 (2010-08-26), pages 34337 -34347, XP055004551, ISSN: 0021 -9258, DOI: 10 .1074/jbc.M110.161802
 P. FERENCI et al.: "Treatment of chronic hepatitis C - are interferons really necessary?", Liver International, vol. 32, 1 February 2012 (2012 -02-01), pages 108 -112,

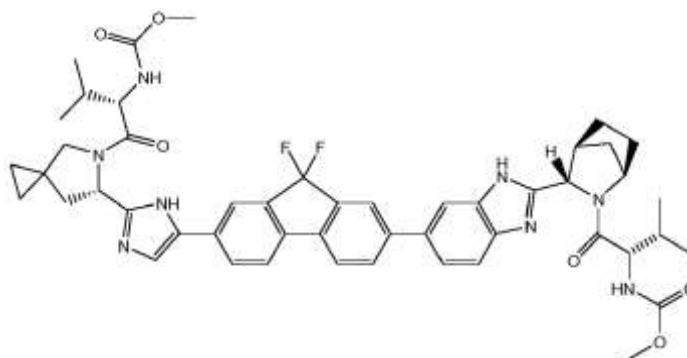
Enclosed is a translation of the patent claims in Norwegian. Please note that as per the Norwegian Patents Acts, section 66i the patent will receive protection in Norway only as far as there is agreement between the translation and the language of the application/patent granted at the EPO. In matters concerning the validity of the patent, language of the application/patent granted at the EPO will be used as the basis for the decision. The patent documents published by the EPO are available through Espacenet (<http://worldwide.espacenet.com>) or via the search engine on our website here: <https://search.patentstyret.no/>

Patentkrav

1. Sammensetning som omfatter: 1) forbindelse 10



eller et farmasøytisk akseptabelt salt derav, og 2) forbindelse 6



eller et farmasøytisk akseptabelt salt derav.

3. Sammensetningen ifølge krav 1 som videre omfatter ett eller flere farmasøytisk akseptable fortynningsmidler eller bærere.

3. Sammensetningen ifølge krav 2, som er formulert som en enhetsdoseringsform for administrering én gang daglig.

4. Sammensetningen ifølge krav 2 eller 3 som er formulert for oral administrering; som eventuelt er formulert som en tablett.

- 5.** Sammensetning som beskrevet i ett av kravene 1-4 for anvendelse ved medisinsk behandling.
- 6.** Sammensetning som beskrevet i ett av kravene 1-4 for anvendelse ved profylaktisk eller terapeutisk behandling av en HCV-infeksjon.
- 7.** Sammensetningen for anvendelse ifølge krav 6, som skal administreres sammen med ribavirin.