(12) **Translation of European patent specification**

(11) **NO/EP 3421033 B1**

(19) NO

NORWAY

(51) Int Cl.

A61K 9/24 (2006.01) ***A61K 31/5377 (2006.01)*** ***A61P 31/18 (2006.01)***
A61K 31/4418 (2006.01) ***A61P 31/12 (2006.01)*** ***A61P 43/00 (2006.01)***

Norwegian Industrial Property Office

(45)	Translation Published	2022.11.07
(80)	Date of The European Patent Office Publication of the Granted Patent	2022.07.27
(86)	European Application Nr.	18179796.0
(86)	European Filing Date	2014.10.06
(87)	The European Application's Publication Date	2019.01.02
(30)	Priority	2013.10.07, US, 201361887574 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
(62)	Divided application	EP3054926, 2014.10.06
(73)	Proprietor	Bristol-Myers Squibb Holdings Ireland Unlimited Company, Hinterbergstrasse 16, 6312 Steinhausen, Sveits
(72)	Inventor	KOO, Otilia May Yue, c/o Bristol-Myers Squibb Company 1 Squibb Drive, New Brunswick, New Jersey 08903, USA NIKFAR, Faranak, c/o Bristol-Myers Squibb Company 1 Squibb Drive, New Brunswick, New Jersey 08903, USA TAO, Jing, c/o Bristol-Myers Squibb Company 1 Squibb Drive, New Brunswick, New Jersey 08903, USA KOTTALA, Niranjan Kumar, Flat 502 PVR Grand Apt. Simon Nagar Kurmannapalem, AP 530056 Visakhapatnam, India VARIA, Sailesh A., c/o Bristol-Myers Squibb Company 1 Squibb Drive, New Brunswick, New Jersey 08903, USA
(74)	Agent or Attorney	ZACCO NORWAY AS, Postboks 488, 0213 OSLO, Norge

(54) Title **HIV TREATMENT FORMULATION OF ATAZANAVIR AND COBICISTAT**

(56) References Cited:

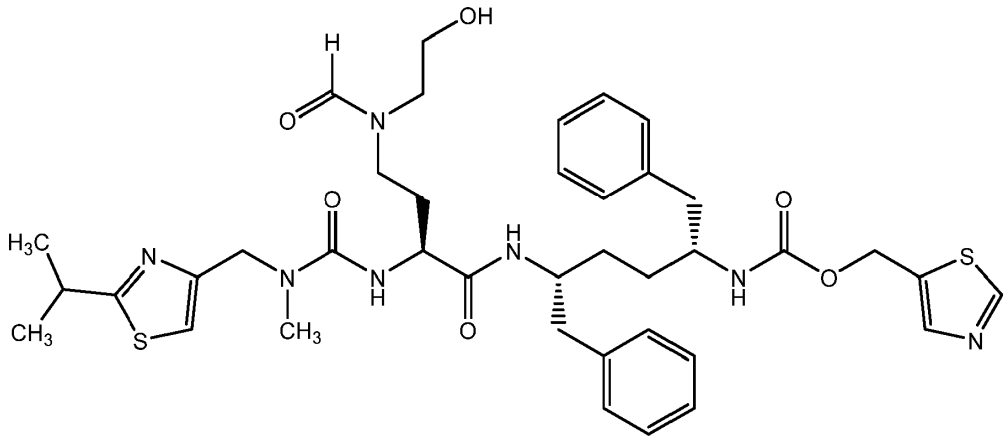
US-A1- 2010 178 339, WO-A2-2009/084036, WO-A2-2011/127244,
RICHARD ELION ET AL: "Phase 2 study of cobicistat versus ritonavir each with once-daily atazanavir and fixed-dose emtricitabine/tenofovir df in the initial treatment of HIV infection", AIDS, vol. 25, no. 15, 1 September 2011 (2011-09-01), pages 1881-1886, XP055051636, ISSN: 0269-9370, DOI: 10.1097/QAD.0b013e32834b4d48
FDA: "Guidance for Industry Fixed Dose Combination and Co-Packaged Drug Products for Treatment of HIV", INTERNET CITATION, May 2004 (2004-05), XP002417855, Retrieved from the Internet: URL:http://www.fda.gov/oc/initiatives/hiv/ hivguidance.html [retrieved on 2007-01-31]

PUJARI S ET AL: "Safety and long-term effectiveness of generic fixed-dose formulations of nevirapine-based HAART amongst antiretroviral-naive HIV-infected patients in India", INTERNET CITATION, 16 December 2003 (2003-12-16), XP002417803, Retrieved from the Internet: URL:http://libdoc.who.int/publications/200 3/a86263.pdf [retrieved on 2007-01-31]
Gilead Sciences International Ltd: "Tybost: International non-proprietary name: Cobicistat", European Medecines Agency , 25 July 2013 (2013-07-25), XP002732922, Retrieved from the Internet: URL:http://www.ema.europa.eu/docs/en_GB/do cument_library/EPAR_-_Public_assessment_re port/human/002572/WC500153016.pdf [retrieved on 2014-11-24]

Patentkrav

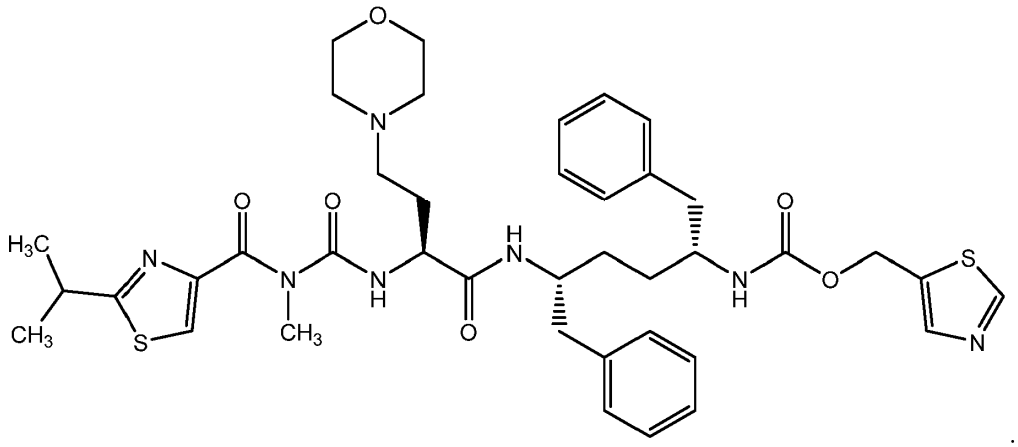
1. En tolagstablett som omfatter atazanavir og kobicistat og en farmasøytisk akseptabel bærer, hvor nevnte tablett omfatter mindre enn eller lik med rundt 0,2 % av nedbrytningsmiddel.

BMT-115982



eller

BMT-089290



2. Tolagstabletten som definert i krav 1, hvor nevnte tablett omfatter mindre enn eller lik med rundt 4,0 % totale kobicistat-urenheter.

3. Tolagstabletten som definert i krav 2, hvor nevnte tablett har mindre enn rundt 2 % totale kobicistat-urenheter ved rundt 12 måneder.

4. Tolagstabletten som definert i krav 3, hvor nevnte tablett har mindre enn rundt 1,4 % kobicistat-urenheter ved rundt 12 måneder.

5. Tolagstabletten som definert i krav 4, hvor nevnte tablett ikke sprekker ved frigjøring fra en tablettpresse.

6. Tolagstabletten som definert i krav 1, hvor nevnte tablett omfatter mindre enn rundt 3 % totale kobicistat-urenheter etter 8 uker ved 40 °C og 75 % relativ fuktighet.