



(12) Translation of
European patent specification

(11) NO/EP 2486051 B1

NORWAY

(19) NO
(51) Int Cl.
C07K 14/59 (2006.01)
A61K 38/24 (2006.01)

Norwegian Industrial Property Office

(45) Translation Published 2020.08.17

(80) Date of The European Patent Office Publication of the Granted Patent 2020.03.25

(86) European Application Nr. 10763000.6

(86) European Filing Date 2010.10.04

(87) The European Application's Publication Date 2012.08.15

(30) Priority 2009.10.05, EP, 09252360

(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

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(54) Title **PHARMACEUTICAL PREPARATION COMPRISING RECOMBINANT HCG**

(56) References Cited: WO-A2-2005/017130
WO-A-2004/105788
WO-A-2005/076013
WO-A-2005/080585
WO-A1-85/01958
WO-A-03/038100
WO-A1-2009/127826
HARD K ET AL: "The carbohydrate chains of the [beta] subunit of human chorionic gonadotropin produced by the choriocarcinoma cell line BeWo. Novel O-linked and novel bisecting-GlcNAc-containing N-linked carbohydrates", EUROPEAN JOURNAL OF BIOCHEMISTRY 1992 DE, vol. 205, no. 2, 1992, pages 785-798, XP009127868, ISSN: 0014-2956
KESSLER M J ET AL: "STRUCTURE AND LOCATION OF THE O GLYCOSIDIC CARBOHYDRATE UNITS OF HUMAN CHORIONIC GONADOTROPIN", JOURNAL OF BIOLOGICAL CHEMISTRY, vol. 254, no. 16, 1979, pages 7909-7914, XP002563495, ISSN:

0021-9258

C Sen Gupta ET AL: "Hyperexpression of biologically active human chorionic gonadotropin using the methylotropic yeast, *Pichia pastoris* INTRODUCTION", *Journal of Molecular Endocrinology*, 1 January 1999 (1999-01-01), pages 273-283, XP055364066, Retrieved from the Internet: URL:<http://jme.endocrinology-journals.org/content/22/3/273.full.pdf> [retrieved on 2017-04-12]

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Patentkrav

1. Fremgangsmåte for fremstilling av rekombinant hCG (rhCG) inkludert α 2,3- og α 2,6-
5 sialylering omfattende et trinn av å produsere eller uttrykke nevnte rhCG i en Per.C6-
cellelinje, hvor nevnte Per.C6-cellelinje er modifisert til over-uttrykke α 2,3-
sialyltransferase.

2. En fremgangsmåte ifølge krav 1, hvor nevnte Per.C6-cellelinje inkluderer endogen
10 sialyltransferase-aktivitet.