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(54) **Title:** MANUFACTURE OF DEGARELIX

(57) **Abstract:** The present invention provides methods for producing a lyophilized degarelix product which, upon reconstitution with water for injection in an amount of 20 mg/ml, shows a viscosity of up to 15 mPas. The present invention also provides a lyophilized degarelix drug substance which shows, upon dissolution in water in an amount of 20 mg/ml, a viscosity of up to 3.2 mPas, and processes for providing this lyophilized degarelix drug substance.



INTERNATIONAL SEARCH REPORT

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PCT/EP2013/061264

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61K38/09 A61K47/12 A61K9/00
ADD.
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED
Minimum documentation searched (classification system followed by classification symbols)
A61K
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, WPI Data, BIOSIS, EMBASE

C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	CN 102 204 889 A (BENGBU BBKA TUSHAN PHARMACEUTICAL CO LTD) 5 October 2011 (2011-10-05) abstract claims paragraph [0007] - paragraph [0015] examples	1-15,20, 21
X	WO 2011/004260 A2 (FERRING INTERNAT CT SA [CH]; PETRI AXEL NICLAS [DK]; ERICHSEN LARS [DK]) 13 January 2011 (2011-01-13) page 2, line 8 - page 3, line 2 page 4, line 6 - line 14 page 5, line 8 - line 20 page 7, line 26 - page 9, line 12 ----- -/--	1-15,20, 21

Further documents are listed in the continuation of Box C.

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Date of the actual completion of the international search 18 December 2013	Date of mailing of the international search report 07/01/2014
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Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Authorized officer Giró, Annalisa
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C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
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X	<p>WO 2010/125468 A1 (FERRING INTERNAT CT SA [CH]; OLESEN TINE KOLD [DK]; CANTOR PER [DK]; E) 4 November 2010 (2010-11-04) page 3, line 19 - page 4, line 2 page 5, line 11 - line 18 page 8, line 19 - page 9, line 13 page 14, line 16 - page 15, line 27 page 6, line 6 - line 8</p> <p style="text-align: center;">-----</p>	1-15,20, 21
X	<p>US 2005/282731 A1 (BAUER HORST [DE] ET AL) 22 December 2005 (2005-12-22) paragraph [0008] - paragraph [0010] paragraph [0019] paragraph [0047] paragraph [0069] - paragraph [0075] paragraph [0080] - paragraph [0087]</p> <p style="text-align: center;">-----</p>	1-15,20, 21
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X	<p>WO 2012/013331 A2 (GP PHARM SA [ES]; PARENTE DUENA ANTONIO [ES]) 2 February 2012 (2012-02-02) example 10</p> <p style="text-align: center;">-----</p>	16-22
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