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— as to the applicant's entitlement to claim the priority of the
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For two-letter codes and other abbreviations, refer to the "Guid-
ance Notes on Codes and Abbreviations" appearing at the begin-
ning of each regular issue of the PCT Gazette.

(54) Title: METHODS FOR THE STABILIZATION OF ATORVASTATIN

(57) Abstract: Stabilization of the pharmaceutical active solid substance atorvastatin alone or in a mixture with other solid sub-
stances embedded in a gaseous mixture is carried out in such a manner that in the surrounding gaseous mixture a partial pressure
of oxygen of at most 2 kPa, preferably less than 1 kPa, more preferably less than 0.4 kPa is maintained. The corresponding partial
pressure is achieved either by use of oxygen absorbers, by packaging under a pressure of 0.3 - 10 kPa, or by packaging under a slight
overpressure of an inert gas, preferably nitrogen, the gas being introduced, by means of nozzles, into the cavities, optionally also
into the space of the press roller and of the wiper station.

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INTERNATIONAL SEARCH REPORT

International Application No
PCT/CZ2004/000045

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61K9/20 A61K31/40

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)
IPC 7 A61K A01J

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 practical, search terms used)

EPO-Internal, WPI Data, PAJ, BIOSIS, EMBASE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P, X	WO 2004/032920 A (LEK PHARMACEUTICALS D.D; BASTARDA, ANDREJ; SALOBIR, MATEJA) 22 April 2004 (2004-04-22) page 3, line 17 - page 4, line 36 page 6, line 8 - page 7, line 4 examples claims	1-10, 14, 15, 21-23
X	US 2003/042166 A1 (WATERMAN KENNETH C) 6 March 2003 (2003-03-06) paragraph '0010! paragraph '0022! examples claims	1-13
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Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

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Date of the actual completion of the international search <p style="text-align: center; font-weight: bold;">9 August 2005</p>	Date of mailing of the international search report <p style="text-align: center; font-weight: bold;">19/08/2005</p>
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Authorized officer <p style="text-align: center; font-weight: bold;">Epskamp, S</p>

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International Application No

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 01/93859 A (LEK PHARMACEUTICAL AND CHEMICAL COMPANY D.D; PFLAUM, ZLATKO; MILIVOJEV) 13 December 2001 (2001-12-13) cited in the application page 3, line 26 - page 6, line 4 examples claims -----	1-23

INTERNATIONAL SEARCH REPORT

Information on patent family members

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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2004032920 A	22-04-2004	SI 21302 A	30-04-2004
		AU 2003280361 A1	04-05-2004
		WO 2004032920 A1	22-04-2004
		US 2004077708 A1	22-04-2004
US 2003042166 A1	06-03-2003	CA 2376709 A1	16-09-2002
		EP 1243524 A2	25-09-2002
		JP 2002320662 A	05-11-2002
WO 0193859 A	13-12-2001	WO 0193859 A1	13-12-2001
		AU 5096000 A	17-12-2001
		CZ 20024015 A3	16-04-2003
		EP 1296672 A1	02-04-2003