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(71) Applicant: **GLAXOSMITHKLINE INTELLECTUAL PROPERTY (NO.2) LIMITED** [GB/GB]; 980 Great West Road, Brentford Middlesex TW89GS (GB).

(72) Inventors: **CROTTS, George**; 709 Swedeland Road, King of Prussia, Pennsylvania 19406 (US). **MORAR-MITRICA, Sorina**; 709 Swedeland Road, King of Prussia, Pennsylvania 19406 (US).

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- as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))
- as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))
- of inventorship (Rule 4.17(iv))

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(54) Title: LOW CONCENTRATION ANTIBODY FORMULATIONS

(57) Abstract: The present invention is directed formulations for low concentrations of therapeutic proteins and methods of making the same. In one aspect the present invention is directed to a formulation for a therapeutic protein comprising: a) the therapeutic protein; and b) a surfactant; wherein the molar ratio of surfactant to therapeutic protein is at least 100. In another aspect the present invention is directed to a formulation for a therapeutic protein comprising: a) the therapeutic protein; and b) an antioxidant, wherein the molar ratio of antioxidant to therapeutic protein is at least 750.



INTERNATIONAL SEARCH REPORT

International application No

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A. CLASSIFICATION OF SUBJECT MATTER

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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)

EP0-Internal, WPI Data, BIOSIS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	DEECHONGKIT SONGPON ET AL: "Physical and Biophysical Effects of Polysorbate 20 and 80 on Darbepoetin Alfa", JOURNAL OF PHARMACEUTICAL SCIENCES, vol. 98, no. 9, September 2009 (2009-09), pages 3200-3217, XP002729734, ISSN: 0022-3549	1,2,4,9, 20-22
Y	the whole document ----- -/--	1-28



Further documents are listed in the continuation of Box C.



See patent family annex.

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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

Merlos, Ana Maria

INTERNATIONAL SEARCH REPORT

International application No
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C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

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Y	HYO JIN LEE ET AL: "Molecular origins of surfactant-mediated stabilization of protein drugs", ADVANCED DRUG DELIVERY REVIEWS, ELSEVIER, AMSTERDAM, NL, vol. 63, no. 13, 29 June 2011 (2011-06-29), pages 1160-1171, XP028320149, ISSN: 0169-409X, DOI: 10.1016/J.ADDR.2011.06.015 [retrieved on 2011-07-06] the whole document	1-28
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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.
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