

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
26 January 2006 (26.01.2006)

PCT

(10) International Publication Number
WO 2006/007850 A1

(51) International Patent Classification⁷: **C07K 16/34**,
A61K 39/395

(21) International Application Number:
PCT/DK2005/000501

(22) International Filing Date: 18 July 2005 (18.07.2005)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
PA 2004 01133 20 July 2004 (20.07.2004) DK
PA 2004 01992 22 December 2004 (22.12.2004) DK

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(81) Designated States (unless otherwise indicated, for every
kind of national protection available): AE, AG, AL, AM,
AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN,
CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI,
GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE,
KG, KM, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA,
MD, MG, MK, MN, MW, MX, MZ, NA, NG, NI, NO, NZ,
OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL,
SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC,
VN, YU, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every
kind of regional protection available): ARIPO (BW, GH,
GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM,
ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM),
European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI,
FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT,
RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA,
GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

- with international search report
- before the expiration of the time limit for amending the
claims and to be republished in the event of receipt of
amendments

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: ANTI-RHESUS D RECOMBINANT POLYCLONAL ANTIBODY AND METHODS OF MANUFACTURE

(57) Abstract: The invention relates to a method for manufacturing an anti-RhD recombinant polyclonal antibody composition (anti-RhD rpAb). The method comprises obtaining a collection of cells transfected with a library of anti-RhD antibody expression vectors, wherein each cell in the collection is capable of expressing from a VH and VL comprising nucleic acid segment, one member of the library, which encodes a distinct member of anti-RhD recombinant polyclonal antibody composition and which is located at the same site in the genome of individual cells in said collection. The cells are cultured under suitable conditions for expression of the recombinant polyclonal antibody, which is obtained from the cells or culture supernatant. The nucleic acid segments encoding the anti-RhD rpAb is introduced into the cells by transfection with a library of vectors for site-specific integration. The present method is suitable for manufacturing anti-RhD rpAb, thereby making available a superior replacement of plasma-derived prophylactic and therapeutic immunoglobulin products.



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