Exemption under FDCA § 505(i) became effective	October 7, 1999
Patent was granted	June 18, 2002
Biologics License Application (BLA) under PHSA § 351 was filed	December 29, 2005
BLA was approved	June 30, 2006

(ii) The '213 patent was granted during the period specified in § 156(g)(1)(B)(i) (*i.e.*, the period from the date of the grant of the exemption under § 505(i) of the FDCA until the date of submission of the BLA). Pursuant to § 156(b) and (c)(2), the calculated regulatory review period therefore includes a component of time between when the patent was granted and when the BLA was submitted (1/2 of 1289 days or 644 days).

(iii) The patent was granted prior to the start of the period specified in § 156(g)(1)(B)(ii) (*i.e.*, the period from the date of submission of the BLA until the date of approval). The regulatory review period under § 156(b) therefore includes a component equal to the total number of days in that period that are after the BLA was submitted (184 days).

(iv) The period determined according to § 156(b), (c)(2), and (g)(1) for the approved product (*i.e.*, the number of days following the date of issue of the patent between the dates of submission and of approval of the BLA for LUCENTIS™) is 828 days.

(v) The '213 patent will expire on June 18, 2019.

(vi) The date of approval of the approved product is June 30, 2006.

(vii) The date that is fourteen years from the date of approval of the approved product is June 30, 2020.

(viii) The period measured from the date the patent expires (*i.e.*, June 18, 2019) until the end of the fourteen-year period specified in §156 (c)(3) (*i.e.*, June 30, 2020) is approximately 1 year and 13 days or 378 days.

(ix) The number of days in the regulatory review period determined pursuant to § 156(g)(1)(B)(ii) (i.e., 828 days) exceeds the number of days that the

patent may be extended pursuant to §156(c)(3). As such, the period by which the patent may be extended is limited by the fourteen-year rule of §156(c)(3) to **378 days**.

(x) The '213 patent issued after the effective date of Public Law No. 98-417. As such, the two- or three-year limit of 35 U.S.C. § 156(g)(6)(C) does not apply.

13. Statement Pursuant to 37 C.F.R. § 1.740(a)(13)

Pursuant to 37 C.F.R. § 1.740(a)(13), Applicant acknowledges its duty to disclose to the Director of the PTO and to the Secretary of Health and Human Services any information which is material to the determination of entitlement to the extension sought, particularly as that duty is defined in 37 C.F.R. § 1.765.

14. Applicable Fee [§ 1.740(a)(14)]

Our check in payment of the fee prescribed in 37 C.F.R. § 1.20(j) for a patent term extension application under 35 U.S.C. § 156 accompanies this application. Please deduct any additional required fees from, or credit any overpayments to our deposit account no. 18-1260.

15. Name and Address for Correspondence [§ 1.740(a)(14)]

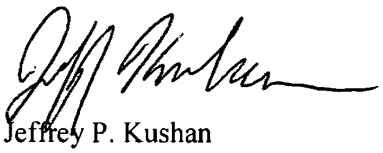
Please direct all inquiries, questions, and communications regarding this application for term extension to:

Jeffrey P. Kushan
SIDLEY AUSTIN LLP
1501 K Street, N.W.
Washington, D.C. 20005
Phone: 202-736-8914
Fax: 202-736-8111
email: jkushan@sidley.com

The correspondence address for U.S. Patent No. 6,407,213 is unchanged for all other purposes. A Power of Attorney granted to the undersigned by the patent assignee, a copy of which is included with this application as Attachment K, accompanies this communication.

Two additional copies of this application are enclosed, in compliance with 37 C.F.R. § 1.740(b). Applicant also provides herewith two further copies of the application for the convenience of the Office, pursuant to M.P.E.P. § 2763.

Sincerely,



Jeffrey P. Kushan
Attorney for Applicant
Registration No. 43,401

Sidley Austin LLP
1501 K Street, N.W.
Washington, D.C. 20005

Dated: August 25, 2006

INDEX OF ATTACHMENTS

Attachment A: Lucentis™ Product Label

Attachment B: Lucentis™ Biologics' License Application Approval

Attachment C: U.S. Patent No. 6,407,213

Attachment D: Certificate of Correction of U.S. Patent No. 6,407,213

Attachment E: Receipt of Maintenance Fee Payment for U.S. Patent No. 6,407,213

Attachment F: Chen *et al.*, "Selection and Analysis of an Optimized Anti-VEGF Antibody: Crystal Structure of an Affinity-Matured Fab in Complex with Antigen." *J. Mol. Bio.*, 293:865-881 (1999).

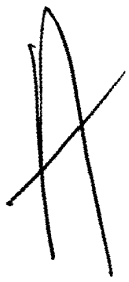
Attachment G: Figures 1A, 1B, 10A and 10B of WO 98/45331

Attachment H: 10/13/99 Letter from FDA to Genentech regarding IND acceptance/effective date

Attachment I: 01/27/06 Letter from the FDA to Genentech regarding receipt and acceptance of BLA Application

Attachment J: 03/14/06 Letter from the FDA to Genentech regarding 02/28/06 filing of BLA, and 06/30/06 assignation of User Fee Goal Date

Attachment K: Power of Attorney by Assignee



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