DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
National Institutes of Health

Office of Technology Transfer
National Institutes of Health
6011 Executive Boulevard
Rockville, MD 20852

February 13, 2013

Sent by Electronic Mail and US Mail

Dr. C. Allen Black
1579 Montgomery Road
Allison Park, Pennsylvania 15101

Subject: 2010 Request to HHS to Exercise its Bayh-Dole March-In Authority on U.S. Patent No. 5,356,804

Dear Dr. Black:

In a letter dated August 2, 2010, you requested on behalf of your clients that NIH use its march-in authority on U.S. Patent No. 5,356,804, a "Subject Invention" made using NIH funds and owned by The Mount Sinai School of Medicine ("Mount Sinai"). The patent is licensed exclusively to Genzyme Corporation ("Genzyme") for the production of Fabrazyme® (agalsidase beta). On December 6, 2010, NIH informed you of its decision not to proceed with march-in under 35 U.S. C. § 203(a)(2) because any licensing plan that might result from such a proceeding would not, in the judgment of NIH, address the problem you identified (see www.ott.nih.gov/policy/March-In-Fabrazyme.pdf). Notwithstanding this decision, NIH stated it would re-evaluate the need for march-in if a third party expressed interest in manufacturing agalsidase beta or if progress towards restoring the supply of Fabrazyme® to meet patient demand was not proceeding as represented by Genyzme. Due to the seriousness of Fabry patients' need to obtain their full prescribed dose of Fabrazyme®, NIH required Mount Sinai to report on the status of Fabrazyme® availability. To that end, both Mount Sinai and Genzyme reported each month to the NIH: (1) the status of Genzyme's progress toward addressing the supply shortage of Fabrazyme® until such time as U.S. Fabry patients' needs had been met; and (2) Genzyme's reports on the allotment of Fabrazyme® to Fabry patients. These parties were also required to notify NIH within two business days after having received any request from a third party for a license to Mount Sinai's Subject Invention to market agalsidase beta during the Fabrazyme® shortage.

From January 2011 through December 2012, both Mount Sinai and Genzyme provided monthly reports responsive to the above criteria. Neither Mount Sinai nor Genzyme informed NIH that they had received a request from a third party to license the Subject Invention, and at no point did a third party contact NIH with such a request. The December 2012 report from Genzyme stated that: (1) U.S. Fabry patients remain on full dose regimens, (2) Genzyme continues to accommodate new patients with full dosing and without placing them on a waiting list; and (3) Genzyme is able to provide full doses of Fabrazyme® to patients transitioning to Fabrazyme® as

a result of the Shire PLC's decision to withdraw its FDA Biologics License Application for Replagal®.

Based on Mount Sinai's and the Genzyme's representations in their respective December 2012 reports and the ability of U.S. Fabry patients to obtain full doses of Fabrazyme®, NIH has closed the above march-in case.

Sincerely,

/s/

Mark L. Rohrbaugh, Ph.D., J.D.
Director, Office of Technology Transfer

MLR:sf