DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

www.nih.gov

April 26, 2016

Zack Struver
Knowledge Ecology International
1621 Connecticut Ave., NW
Washington, D.C. 20009

Re: NIH FOI Case No. 44773

Dear Mr. Struver:

This is the final response to your February 23, 2016, Freedom of Information Act (FOIA) request addressed to the National Cancer Institute (NCI) FOIA Office and received in that office the same day. Your request was forwarded to this office for processing because of our responsibilities under the FOIA. Department of Health and Human Services (HHS) policy calls for the fullest possible disclosure provided by the FOIA, 5 U.S.C. §552, consistent with the protections contained therein. The implementing HHS Regulations establish the criteria pursuant to which the FOIA is administered, *see* 45 C.F.R. Part 5. Copies of the FOIA and the HHS FOIA Regulations are located at: http://www.nih.gov/icd/od/foia/efoia.htm and http://www.nih.gov/icd/od/foia/cfr45.htm. You requested the following records from the period of October 1, 2009 to present:

1. All documents, correspondence, and notes from the National Cancer Institute (NCI) at the National Institutes of Health (NIH) regarding an exclusive patent license to HUIYU Pharmaceuticals Co, Ltd located in Neijiang City, CHINA, to practice inventions related to the treatment of HER2 positive breast cancer using Antibody Drug Conjugates (ADCs).
2. All documents, correspondence, and notes that were generated internally or may have been submitted or sent to NCI by other offices, institutes, or components of the NIH; the United States Department of Health and Human Services and any other federal departments or agencies; Chinese government officials or agencies; other foreign governments; and non-governmental persons or entities, regarding the above exclusive license.
3. Any documents related to the patent landscape of the invention, any communications with HUIYU regarding the terms of the license, and any documents or communications that describe research and development costs for HUIYU related to FDA marketing approval of the invention.

With regard to Item 3, on February 29, 2016 you clarified that you were referring to any patents or patent applications related to the practice of the invention(s) specified in the prospective grant of the exclusive license.

We searched the files of the NCI Technology Transfer Office and the National Human Genome Research Institute (NHGRI) Technology Transfer Office for records responsive to your request.

Our search produced a total of 131 pages of responsive records, consisting of an unexecuted license agreement and other related documents, which I have determined to withhold in their entirety pursuant to Exemptions 4 and 5 of the FOIA, 5 U.S.C. §§552(b)(4) and (b)(5) and sections 5.65 and 5.66 of the HHS FOIA Regulations, 45 C.F.R. Part 5. Exemption 4 protects from disclosure trade secrets and commercial or financial information that is privileged and confidential. Exemption 5 protects the integrity of the deliberative or policy-making processes within an agency by exempting from mandatory disclosure opinions, conclusions, and recommendations included within interagency or intra-agency memoranda or letters.

Portions of these records are also protected from release pursuant to Exemptions 3 and 6 of the FOIA, 5 U.S.C. §§552(b)(3) and (b)(6) and sections 5.64 and 5.67 of the HHS FOIA Regulations, 45 C.F.R. Part 5. Exemption 3 applies to documents which are exempt from disclosure by another statute; in this instance, 35 U.S.C. §209, which protects from disclosure the commercial development plans submitted by potential licensees. Exemption 6 protects from disclosure records that if released would cause a clearly unwarranted invasion of personal privacy.

With regard to Item 3, please note that the patent landscape consists of the following patent applications only: 1) US 61/833,732; 2) PCT PCT/US2014/041492; and 3) US 14/897,389. These patent application files are available from the United States Patent and Trademark Office (USPTO) via Public Patent Application Information Retrieval (PAIR) at http://portal.uspto.gov/pair/PublicPair.

Please also note that the Federal Register Notice associated with your request can be found at http://www.federalregister.com/Browse/AuxData/C5FF30B6-E020-435C-8D1A-5DB5D6479C3E.

You have the right to appeal this determination to deny you access to records in the agency's possession. Should you wish to do so, you must send your appeal within thirty (30) days of receipt of this letter, following the procedures outlined in Subpart C of the HHS FOIA Regulations http://www.nih.gov/icd/od/foia/cfr45.htm) to:

Deputy Agency Chief FOIA Officer
United States Department of Health and Human Services
5600 Fishers Lane, Room 19-01
Rockville, MD 20857
foiarequest@psc.hhs.gov
fax (301) 480-5862

Clearly mark both the envelope and your letter "Freedom of Information Act Appeal."

In certain circumstances provisions of the FOIA and HHS FOIA Regulations allow us to recover part of the cost of responding to your request. Because no unusual circumstances apply to the processing of your request, there is no charge associated with our response.

Sincerely,

Susan R. Cornell

Susan R. Cornell, J.D.
Freedom of Information Officer, NIH
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