FISH.
FISH & RICHARDSON

Fish & Richardson P.C.
1000 Maine Avenue, S.W.
Suite 1000
Washington, DC 20024
202 783 5070 main
202 783 2331 fax

Ahmed J. Davis
Principal
adavis@fr.com
202 626 6379 direct

VIA CM/ECF

May 14, 2024

Hon. Magistrate Judge Erin Aslan
United States District Court for the District of Maryland
101 W. Lombard Street, 7B
Baltimore, MD 21201

Re: *Merck Sharp & Dohme LLC v. The Johns Hopkins University*, Civ. Act. No. 22cv3059 (JRR)

Dear Magistrate Judge Aslan:

The Johns Hopkins University ("JHU") requests the Court compel Merck to produce documents responsive to JHU's discovery requests concerning Merck's sales of the accused drug, Keytruda, and its licensing of Keytruda and other cancer therapies. *See* Exhs. A, B. These documents are directly relevant to JHU's patent infringement damages claim. JHU also requests the Court order Merck to reimburse JHU $28,600 in costs incurred to remedy Merck's violation of the Court's ESI Order. While Merck continues to stonewall compliance with JHU's other discovery requests, JHU is hopeful that resolution of these key issues will facilitate resolution of those other disputes.

Merck's Refusal to Produce Sales Information. JHU requested production of Merck's U.S. Keytruda sales information. JHU's request (RFP 10) seeks information from March 2, 2021 (the date of first infringement) to present, narrowed to the specific indications implicated by JHU's claims (generally, treatment based on the determination that the patient's cancer is MSI-H or dMMR). Within these parameters, JHU seeks unit sales, unit pricing, revenue, costs, profits (gross, net, margins), market share, pricing and pricing strategies. Production of such financial information is standard fare in patent cases. Certainly, Merck's annual Keytruda sales of over $20 billion would generate the requested financial information. After months of delay, Merck produced a two-page document containing only monthly and yearly Keytruda sales amounts without indication information; but Merck refused to commit to producing data responsive to the full scope of JHU's request. Moreover, despite the importance of identifying the portion of sales related to the accused indications, counsel conceded that they had not investigated whether Merck maintains this information or whether third-party vendors provide it to Merck. In view of passage of the deadline for substantial completion of document production without resolution of these issues, JHU requests the Court to order Merck to produce the requested financial information.

Merck's Refusal to Produce Licenses. JHU seeks reasonable royalty damages for Merck's infringement of JHU's patented methods for treating cancer patients using Keytruda (pembrolizumab). On October 23, 2023, JHU served RFP Nos. 6, 21 and 22 seeking licenses involving Keytruda and other cancer therapies. Discovery of an infringer's existing licenses is routine and relevant to quantifying the royalty damages in a patent case. JHU tried repeatedly to resolve this dispute, but Merck has refused to even search for the requested information. For example, JHU identified relevant licenses and settlement agreements with Bristol-Meyers Squibb, Avaxis, Inc., Pfizer, Inc., Agilent Technologies, Inc., Dynavax Technologies Corp., and Eisai R&D

FISH.
FISH & RICHARDSON

Management Co., Ltd. Despite JHU's efforts to focus Merck's investigation, Merck has maintained its objections based on overbreadth and burden. According to Merck, "all sorts" of agreements exist relating to Keytruda across multiple departments. Despite this abundance of responsive documents, Merck has refused to provide even a list of known responsive licenses and their subject matter, such that the parties might make progress to resolving this dispute. Accordingly, and given that the deadline for substantial completion of document production has passed without resolution of this issue, JHU requests the Court Order Merck's production of all license documents responsive to JHU's discovery requests without objection.

Merck's Refusal to Produce its BLA in Compliance With the ESI Order. JHU's RFP No. 1 seeks production of Merck's Keytruda Biologics License Application ("BLA"), which is a set of regulatory documents, including draft labeling and marketing information, submitted to FDA to gain approval to market Keytruda. Production of the BLA in a patent case is routine, as it contains documents relevant to infringement, including induced infringement (e.g., drug labelling and marketing materials). Merck delayed compliance with this basic request for months, claiming undue burden. Initially, Merck alleged that the size of BLA made production impracticable. In response, JHU identified certain sections of the BLA that Merck could produce instead of the entire BLA, and Merck agreed. Merck delayed for two more months. Merck finally produced a hard drive containing a "drag-and-drop" copy of 2.3 terabytes of unprocessed documents, but Merck's production in this form does not comply with mandates of § II.B.3 of the ESI order (D.I. 55) or the Protective Order (D.I. 56, ¶¶ 21-22). The files are not text searchable and do not have extracted metadata, Bates page numbering or confidentiality designations, rendering them effectively useless without further processing. In subsequent discussions, Merck attorneys have conceded that they did not abide by the ESI Order. Instead, they sought to justify this failure, contending that processing would break the hyperlinks in the produced documents. Merck never discussed this deviation from the ESI Order with JHU *before* making the production. Importantly, as produced, the documents cannot be efficiently searched, creating the very needle-in-a-haystack situation the ESI Order aims to avoid. JHU has obtained a third-party estimate of $28,600 to process the data into a form compliant with the ESI and Protective Orders. Rather than shoulder this financial burden, JHU requested Merck either pay the $28,600 costs or promptly process and reproduce the data. Merck declined both options. Because processing and reviewing this information must be done before JHU can pursue most deposition discovery within the Scheduling Order deadline, JHU seeks an order compelling Merck to reimburse JHU $28,600 for bringing Merck's production into compliance with the ESI order.

Respectfully,

Ahmed J. Davis

cc: ECF Counsel of Record