Sheinberg, Samuel I.

From: [redacted]
Sent: Tuesday, June 9, 2020 11:48 AM
To: Berg, Karen E.; Carson, Timothy; Sheinberg, Samuel I.; Six, Anne; Whitehead, Nora; Musick, Vesselina
Subject: FW: Licensing Inquiry

From: Walsh, Kathryn E.
Sent: Tuesday, June 9, 2020 11:47:40 AM (UTC-05:00) Eastern Time (US & Canada)
To: [redacted]
Cc: [redacted]
Subject: FW: Licensing Inquiry

The collaboration involves co-exclusive licenses, so there is nothing reportable at the outset. But if either party acquires exclusive rights over IP discovered or developed as a result of the collaboration, those acquisitions might be reportable.

From: [redacted]
Sent: Friday, June 5, 2020 1:42:00 PM (UTC-05:00) Eastern Time (US & Canada)
To: [redacted]
Subject: Licensing Inquiry

Hi PNO Team –

We are hoping to get your guidance on the HSR reportability of the hypothetical transaction, a collaboration and license agreement involving three products. One product is reaching the end of Phase I/II development; the others are in an earlier stage of clinical development. All are several years from commercialization even if they succeed in the clinical development process.

Because we do not believe the license would result in the transfer of all commercially significant rights, we do not believe it is reportable. Please let us know if you agree with our analysis or if you need additional details or information in order to provide a response.

Facts/Transaction Details

Company B ("B" or "Licensee"), a pharmaceutical company, intends to enter into a collaboration and license agreement with Company A ("A" or "Licensor"), also a pharmaceutical company, to jointly research, develop, manufacture, and commercialize three of A's patented compounds. For purposes of this fact pattern, assume that both the size of transaction and size of persons tests are met.

Generally speaking, the transaction apportions the parties' rights and obligations on a 50/50 basis, with the Licensor retaining certain key ownership rights and/or final decision-making authority on certain key matters. The rights of the parties in the U.S. are as follows:

Intellectual Property Rights. Licensor grants a co-exclusive license to its patents, allowing both parties to exploit the licensed patents for purposes of the collaboration. Licensor retains the first right

to prepare, file, prosecute, validate, maintain, defend, and extend its patent rights on a global basis. The parties will jointly determine the enforcement and extension of certain Licensor patent rights with other Licensor patent rights being enforced and extended by Licensor solely. Additionally, Licensor will obtain exclusive ownership over certain IP rights discovered or developed by either or both parties during the term of the agreement, with other such IP rights discovered or developed by both parties being jointly owned. Certain IP rights discovered or developed by Licensee only will be owned by Licensee.

Profits, Losses, and Costs. The parties will share profits and losses equally. They will also split the costs of development, manufacturing, and commercialization.

Sales. Licensor will book sales to the products produced from the first proposed licensed product; after that, the parties will alternate booking sales from each licensed product.

Pricing. A joint committee will develop and decide on pricing strategy, including pricing bands (the "Global Pricing Strategy"). The parties will alternate responsibility for obtaining pricing and reimbursement approvals on a product-by-product basis in accordance with the Global Pricing Strategy depending on which is booking sales of the relevant licensed product. The Licensor will be responsible for obtaining prices and reimbursement approvals for the first proposed licensed product, which is the first product in the collaboration that has entered the clinic for development, in accordance with the Global Pricing Strategy.

Regulatory Filings. A joint committee will make decisions regarding regulatory filings, but where it cannot decide, Licensor will have final decision making authority in respect of those products it is booking sales for and Licensee will have final decision making authority in respect of those products it is booking sales for. Additionally, Licensor will submit and own all regulatory filings and regulatory approvals in respect of those products it is booking sales for and vice versa.

Pharmacovigilance. Licensee will be responsible for establishing and maintaining a global safety database which Licensor will contribute to and will have shared access to. The parties will jointly agree whether to perform any recall of the licensed product(s) save that, if the parties cannot agree, each party will have final decision making authority in respect of those licensed product(s) it is booking sales for.

Commercialization and Promotion. A joint committee will develop a commercialization plan, including a promotion plan, for each licensed product. Both parties will be equally responsible for activities allocated to the respective parties.

Manufacturing. A joint committee will develop a manufacturing plan in respect of each licensed product. Licensor will be responsible for manufacturing initially, but Licensee will assume responsibility at some point in the future, with the exception that Licensor retains manufacturing rights to certain antibodies incorporated as part of two of the licensed products for use in any non-competing products outside the scope of the agreement.

Clinical Development. A joint committee will develop a plan for clinical development. Both parties are equally responsible for execution of the activities assigned to them in that plan. Licensor will retain responsibility for certain studies and activities while Licensee will assume responsibility for

certain other studies, with the understanding that Licensor will be conducting the majority of the phase III clinical studies.

Governance and Decision Making. The parties will establish joint committees for governance, development, and commercialization. Each party shall have one vote in respect of any decisions made by the respective committees and decisions must be made by consensus. Under each joint committee, the parties will establish subteams for chemistry, manufacturing, controls, regulatory, medical affairs, finance, intellectual property and translational research (with others to potentially follow). Each party shall have one vote in respect of any decisions made by the respective subteams and decisions must be made by consensus. Where a dispute between a joint committee or a subteam cannot be resolved, the governance committee will resolve the dispute based on consensus. If the governance committee cannot resolve the dispute, the executive officers of both companies will resolve the dispute based on consensus. Where they cannot resolve the dispute, the issue goes to arbitration, unless otherwise noted in the agreement.

Analysis

The nature of the rights conveyed to the Licensee, as well as those retained by the Licensor, suggests that this is, at best, a non-reportable co-exclusive license. The PNO has indicated that a co-exclusive license is one where "both the licensor and the licensee have exclusive rights to the patent, making the license non-exclusive for HSR purposes." Federal Trade Commission, Informal Interpretation 1311003 (dated Nov. 7, 2013), available at https://www.ftc.gov/enforcement/premerger-notification-program/informal-interpretations/1311003

In litigation defending its rule-making on pharmaceutical patent licenses, the FTC explained that a transfer of "all commercially significant rights" can occur where a licensor retains limited rights, including manufacturing rights, but conveys "the **sole** right to decide if and when to commercialize the patent and how to market and price the product covered by the license." Brief of Appellee at 7-8, *Pharm. Research and Mfrs of Am. v. FTC*, No. 14-5182 (D.C. Cir. June 9, 2015)(emphasis added).

Here, the Licensee has not obtained the sole control over *any* individual commercially significant right. There is not a single function or right over which Licensee has sole control across the collaboration. Thus, there has been no transfer of any individual right of commercial significance. This does not involve a situation where, for example, the Licensor has retained control over development, but the Licensee obtains control and final decision making authority over pricing and commercialization. The Licensee would have *no* final authority over any of the commercially significant functions and rights described above.

Nor would the Licensee's acquisition of joint decision making and equal responsibility constitute a "transfer of all commercially significant rights." By definition, if each of Licensor and Licensee retains equal control over, and responsibility for, decision making (with only a few exceptions where one party has a final decisive vote as defined in the agreement), then *neither* has "all commercially significant rights." That structure represents a classic collaboration, not the kind of license tantamount to a pharmaceutical acquisition.

We realize that a licensee's mere retention of limited commercial rights, like co-promotion, has never made an otherwise reportable transaction non-reportable. But that is the case only when the

retention of some co-exclusive rights is in the shadow of a transfer of all commercially significant rights. It is the transfer of sole control over all commercially significant rights, not the equal sharing of commercially significant rights, that gives rise to reportability. In justifying the extension of reportability to transfers of all commercially significant rights in pharmaceutical products, the FTC explained that mere retention of such rights is often done for licensors to aid licensees who otherwise control the timing and nature of the commercialization of the product, are solely responsible for pricing and selling it, and book revenues, paying a royalty to the licensee. *See* Premerger Notification; Reporting and Waiting Period, 78 Fed. Reg. 68705, 68707 (Nov. 11, 2013); *see also* Brief of Appellee at 7, *Pharm. Research and Mfrs of Am. v. FTC*, No. 14-5182 (D.C. Cir. June 9, 2015).

That would certainly not be the case here. For the lead and most mature product in the collaboration, the parties would have joint decision making authority over development and commercialization, but the Licensor would book the sales, the Licensor would be responsible for obtaining pricing and reimbursement in accordance with the Global Pricing Strategy, and the parties would split the profits equally. The Licensor would not be a passive royalty recipient standing by with theoretical rights to help the Licensee commercialize a product over which the Licensee would have sole control over all commercially significant rights.

In this case, and with respect to all of commercialization, marketing, and pricing, both parties must jointly agree except for certain enumerated instances described above where the Licensor retains certain key ownership rights and/or has final decision making authority. Where the Licensee cannot proceed on these key commercial matters on its own, there can be no transfer of all commercially significant rights.

Further, the PNO has previously found that where profits, losses, and development costs are shared equally there has been no transfer of all commercially significant rights. *See* Federal Trade Commission, Informal Interpretation 1401007 (dated Feb 4, 2014), available at https://www.ftc.gov/enforcement/premerger-notification-program/informal-interpretations/1401007 (parties shared profits 50/50, costs of commercialization 50/50, and licensor retained responsibility to control prosecution, maintenance, and enforcement of the key patent covering the core IP).

Question(s)

Based on the facts provided, please confirm that you agree that all commercially significant rights have not passed to the Licensee and, as a result, the transaction is not reportable.

Thank you for your consideration.

[redacted]

[redacted]