Sheinberg, Samuel I.

From: HSRHelp
Sent: Friday, May 19, 2023 10:17 AM
To: Berg, Karen E.; Musick, Vesselina; Shaffer, Kristin; Sheinberg, Samuel I.; Six, Anne; Whitehead, Nora; Fetterman, Michelle
Subject: FW: Informal Interpretation Request re: exclusive pharma license

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From: Walsh, Kathryn E. <kwalsh@ftc.gov>
Sent: Friday, May 19, 2023 10:17:15 AM (UTC-05:00) Eastern Time (US & Canada)
To: [redacted]
Cc: HSRHelp <HSRHelp@ftc.gov>
Subject: FW: Informal Interpretation Request re: exclusive pharma license

We disagree. Your filing will cover whatever exclusive licenses will become effective during the year after filing. Any licenses that become effective after that are potentially reportable.

From: [redacted]
Sent: Thursday, May 18, 2023 12:36:32 PM (UTC-05:00) Eastern Time (US & Canada)
To: HSRHelp <HSRHelp@ftc.gov>
Cc: [redacted]
Subject: Informal Interpretation Request re: exclusive pharma license

Dear PNO Staff,
We respectfully request the PNO's confirmation that it agrees with each of the following two conclusions relating to a Collaboration and License Agreement ("License Agreement") that is the subject of the proposed transaction and discussed further below: 1) a single HSR Filing is sufficient to meet the parties' notification obligation under the HSR Act as it relates to the License Agreement and 2) the year-to-close rule is satisfied when the exclusive licenses contemplated by the License Agreement are granted at signing even if only one of the exclusive licenses becomes effective within the year while the others may become effective after the year has lapsed. These conclusions are appropriate because, unlike the agreement that was the subject of invalidated Informal Interpretation 1709004, the License Agreement under discussion here is not an option contract because the exclusive licenses are granted at the outset and become automatically effective upon designation of a compound as a Development Candidate. Therefore, we think it appropriate to consider the License Agreement a single, upfront acquisition of exclusive rights to yet-to-be identified products for which only one HSR Filing is required.
Company A, a pharmaceutical company, intends to enter into a License Agreement with Company B, another pharmaceutical company. Company B has patent rights, know-how, technology, and expertise relating to novel, very early-stage potential treatments. Upon signing the License Agreement, Company A is granted two types of licenses: a non-exclusive research license that is effective immediately and exclusive exploitation (meaning development and commercialization) licenses that do not become effective until later. Company A and Company B will agree to a joint research plan to identify compounds and select as Proposed Development Candidate(s) pursuant to Development Candidate Criteria set out in an Agreed Research Plan. Company A and Company B will be equally represented on a committee that has decision-making authority to designate a Proposed Development Candidate as a Development Candidate and to make any updates to the Development Candidate Criteria but in case of deadlock Company A has ultimate decision-making authority except in circumscribed circumstances. Upon designation of a Development Candidate, under the terms of the License Agreement the exclusive license previously issued to Company A automatically becomes effective even as to Company B for that specific Development Candidate. By the terms of the License Agreement, the previously issued exclusive license will become effective upon the designation of each Development Candidate on a Development Candidate-by-Development Candidate Basis. Once a Development Candidate is designated, Company A is responsible for all further development and commercialization activities at Company A's own cost.
Upon execution of the License Agreement Company A will pay Company B an upfront fee. Company A will pay an additional fee to Company B for up to two Development Candidate designations (which is when the previously issued exclusive licenses become effective). Company A will also pay specified amounts upon the achievement of specified milestones in the drug development and approval process for a certain number of Licensed Products covered by the

Agreement. In the event a Licensed Product covered by the License Agreement is commercialized, Company A will pay Company B a royalty based on annual worldwide net sales for the first Licensed Product that achieves those commercial milestones, and the License Agreement further specifies Company A's obligations to commercialize the License Product(s).

Please do not hesitate to let us know if you require further facts to aid you in your evaluation of our analysis.

Sincerely,

[redacted]