Haynes, Lanea

From: [redacted]
Sent: Tuesday, September 12, 2017 11:17 AM
To: Walsh, Kathryn E.; Berg, Karen E.; Gillis, Diana L.
Cc: [redacted]
Subject: RE: Request for Informal Interpretation re Pharmaceutical Collaboration Involving Exclusive Licenses

Will do, thanks!

From: Walsh, Kathryn E. [mailto:kwalsh@ftc.gov]
Sent: Tuesday, September 12, 2017 11:16 AM
To: [redacted] Berg, Karen E. <KBERG@ftc.gov>; Gillis, Diana L. <dgillis@ftc.gov>
Cc: [redacted]
Subject: RE: Request for Informal Interpretation re Pharmaceutical Collaboration Involving Exclusive Licenses

We agree with your analysis. In the future, please copy the entire PNO team on your questions.

From: [redacted]
Sent: Thursday, September 07, 2017 1:51 PM
To: Walsh, Kathryn E.; Berg, Karen E.; Gillis, Diana L.
Cc: [redacted]
Subject: Request for Informal Interpretation re Pharmaceutical Collaboration Involving Exclusive Licenses

Kate, Karen and/or Diana,

We are writing to confirm our proposed approach with respect to the HSR analysis of a potential collaboration in the pharmaceutical sector. The collaboration may result in up to three exclusive licenses from the licensor to the licensee, as described in more detail below. The terms of each exclusive license are specified in the initial agreement, but they will not become effective until the exercise of an exclusive option trigged by the completion of initial development work required by the collaboration. While we acknowledge that the grant of an option does not generally result in an HSR reportable transaction, we believe that on these particular facts it is appropriate to consider the entire collaboration for purposes of the HSR Act as a single, upfront acquisition of exclusive rights to both identified and yet to be identified products utilizing the intellectual property subject to the collaboration.

Company A is a global branded pharmaceutical company. It intends to enter into a Research, Option and License Agreement ("the Agreement") with Company B, a pharmaceutical company that has a development stage pharmaceutical product ("the Lead Product") that utilizes a particular proprietary technology to increase its effectiveness. Company B is currently conducting early stage clinical trials of the Lead Product. The Agreement will outline a collaboration that will specify the detailed terms under which Company B will complete certain clinical trials for the Lead Product. Upon completion of those trials, Company A can exercise an exclusive option to acquire an exclusive license to the Lead Product and take over future development activities. Concurrently, the collaboration also provides for Company A to identify multiple potential targets for investigation by Company B for possible therapeutic use in conjunction with the same Company B proprietary technology. Company A will have the rights to exercise an exclusive option to take an exclusive license to up to two pre-clinical products created by Company B based on the designated research targets identified by Company A ("Additional Products") and take over all development activities related thereto. Both

the Lead Product and the Additional Product(s) will incorporate the proprietary technology developed by Company B and depend on the overall development program contemplated under the Agreement.

Company A will pay Company B an upfront fee upon signing of the collaboration. Company A will pay an additional fee upon exercise of its option to acquire an exclusive license to the Lead Product or any Additional Product(s). Company A will also pay specified amounts upon the achievement of specified milestones in the drug development and approval process for Products covered by the Agreement. In the event Products covered by the Agreement are commercialized, Company A will pay Company B a royalty based on annual worldwide net sales. The Agreement also contains exclusivity provisions (effective upon the effective date of the Agreement) intended to secure Company A's exclusive rights to exclusively license the Lead Product and identify targets for development into potential Additional Products. The Agreement further specifies Company A's obligations to commercialize the products developed under the collaboration.

We have reviewed interpretation #26 in the PreMerger Notification Practice Manual (Fifth Edition) and believe that it is consistent with our proposed approach. In particular, it confirms that the parties can evaluate the FMV of exclusive licenses to specific intellectual property that the parties anticipate will be identified in the future through operation of the proposed collaboration. We also believe that it is appropriate, although not required in all cases, to consider the exercise of an option to take an exclusive license that relates to technology developed pursuant to the Agreement as an acquisition contemplated under the original Agreement. Under such a view, the Parties would not need to assess whether the future potential option exercises to acquire exclusive licenses triggered any notification requirement. We understand that the PNO has accepted filings for collaboration and licensing agreements that involve future transfers of intellectual property rights outside of the normal one-year HSR threshold where those future transfers are an integral part of the overall collaboration and anticipated to occur assuming scientific and technical goals are met.

Please let us know if you have any questions or concerns regarding our proposed analysis, which will result in a single-up front filing for the entire collaboration following signing of the Agreement.

Regards,

[redacted]