Gillis, Diana L.

From: Walsh, Kathryn E.
Sent: Wednesday, December 03, 2014 1:11 PM
To: Gillis, Diana L.
Subject: FW: HSR Question -- Pharma License

From: Verne, B. Michael
Sent: Wednesday, December 03, 2014 1:03 PM
To: [redacted] Walsh, Kathryn E.
Cc: [redacted]
Subject: RE: HSR Question -- Pharma License

[redacted]- we have made a distinction between a licensee having the exclusive right to the drug for a specific indication or therapeutic area with the licensor retaining the right to the same drug for other indications or therapeutic areas, and the licensee having the exclusive right to a particular formulation of a drug for certain indications and the licensor retaining the right to other formulations of the same drug for the same indications. We agree this is not reportable

From: [redacted]
Sent: Wednesday, December 03, 2014 11:33 AM
To: Verne, B. Michael; Walsh, Kathryn E.
Cc: [redacted]
Subject: HSR Question -- Pharma License

Dear Mike and Kate:

We would like your guidance as to whether a pharmaceutical collaboration agreement including the transfer of IP would be viewed as transfer of an exclusive license, and therefore potentially reportable under the HSR Act. The facts are as follows:

Company A and Company B will enter into a collaboration agreement for the global development and commercialization of Company B's proprietary pharmaceutical compound, including as nebulized products, in other presentations, and as combination products. In the U.S. Company A and Company B will co-develop and co-commercialize this compound in nebulized form only (Product X). Subject to these U.S. co-development and co-commercialization rights, Company B will grant Company A an exclusive, royalty-bearing license to make, have made, use, sell or offer for sale Product X (in nebulized form) in the US, and in any form outside the US. Company B will retain all rights to the compound for use in the same therapeutic area in non-nebulized form in the US.

In the US, the parties will jointly develop a marketing plan through a joint product committee and joint steering committee. Each party will have its own sales force to sell and market Product X. It is anticipated that both Company A and Company B will sell Product X in the US, but they will split the profits or losses.

Consideration will be in the form of cash, milestone payments, and royalty payments (and Company B will get a share of the profits or losses).

Specific issues:

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1. Is the license to Product X "exclusive" when both parties will sell Product X in the U.S. (splitting profits or losses according to a determined formula)?

2. Is the license to Product X "exclusive" because it only covers one method of administration (i.e., a nebulized form) in the therapeutic area, when there are other presentations or methods of administration anticipated, including combination products?

The licensor is not reserving largely theoretical rights (e.g., the ability to manufacture but only for the licensee), which we understood to be the impetus behind the recent pharmaceutical rulemaking and adoption of the "all commercially significant rights" test. But in any event, we wanted to get your views in light of some of the commentary regarding the effect on the analysis of the retention of co-rights.

Thank you in advance.

Best regards,

[redacted]

[redacted]

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