801.2

Verne, B. Michael

From: [redacted]
Sent: Wednesday, June 29, 2011 10:42 AM
To: Verne, B. Michael
Subject: HSR Questions - Collaboration and License Agreement

Dear Mike,

I would appreciate your views as to the reportability under HSR of the following Collaboration and License Agreement for the development of pharmaceuticals:

1. The Licensee will receive an exclusive license under licensed technology to develop, have developed, make, have made, use, offer for sale, sell, have sold, import, export, commercialize and otherwise exploit Products, subject to other terms and conditions in the agreement, including those summarized in #2 below.

2. The Licensor shall be responsible for conducting certain activities to develop the Products, including preclinical development and manufacture for preclinical testing. Licensee, however, will be solely responsible for commercialization of the Products (subject to a co-promote agreement in a specific field of use).

3. Upon completion of Licensor's development of the initial manufacturing process, Licensor will transfer to Licensee the manufacturing process, information, documentation and materials to establish manufacturing in Licensee's or its designee's facilities.

In light of ABA Premerger Notification Practice Manual (4th ed.) Interp. 27, and the PNO's informal interpretations, including http://www.ftc.gov/opinions/0212016.pdf, http://www.ftc.gov/opinions/0803005.pdf, http://www.ftc.gov/bc/hsr/informal/opinions/0702018.pdf, http://www.ftc.gov/bc/hsr/informal/opinions/0912004.pdf, and the more recent May 27, 2011 informal interpretation pasted below, which has been shared with me, we seek your view as to whether the PNO would view the retained rights as compromising the exclusivity of the license, such that it would be considered non-exclusive and therefore non-reportable, or if it would be considered exclusive and therefore reportable under HSR if the "size-of-person" and "size-of-transaction" tests are met.

We further seek your view as to whether the PNO might view the license as becoming an "asset" at some point during the life of the agreement, which could require the parties to value the license and potentially have to file under HSR at some future date, and if so, at what point would the license have to be valued to determine if a filing is required, taking into account the informal interpretations at http://www.ftc.gov/bc/hsr/informal/opinions/0612014.pdf and http://www.ftc.gov/bc/hsr/informal/opinions/1006004.pdf, and the more recent informal interpretation below.

Would the PNO advice be different if the Licensor retained the right to make and use Products solely for the purpose of conducting further research and development, for the life of the license?

Kind regards.

[redacted]

Right-click here to

From: [redacted]
Sent: Friday, May 27, 2011 6:21 AM
To: [redacted]
Cc: [redacted]
Subject: RE: HSR questions

We think the "retained" manufacturing right do not compromise the exclusivity of the license. You should file before the licensing agreement is entered into.

Right-click here to

From: [redacted]
Sent: Thursday, May 26, 2011 8:08 PM
To: Verne, B. Michael
Cc: [redacted]
Subject: HSR questions

Mike,

Can you share your views on the below scenario?

We would like to determine whether a license, with the provisions described below, constitutes an "asset" for HSR purposes upon execution of the Licensing Agreement or only at a later point:

1. The Licensee receives an exclusive right to make, use and sell the Product, subject to the limitation set forth in 2 below.

2. The Licensor retains the right to make (or have made) the Product to the extent necessary for it to satisfy its obligations under the development agreement as well as to manufacture Product at the request of Licensee during the commercialization period if the Licensee requests.

3. The Licensee can, at any time, require the Licensor to transfer the manufacturing technology to the Licensee or its designee.

Although the Licensor's right or obligation to manufacture product is described as a "retained" right in the agreement, Licensee ultimately controls whether Licensor will in fact manufacture the licensed product because it has the unfettered right to demand the transfer of the manufacturing technology to it or a designee at will. Accordingly, it is our view that the license should be treated as exclusive for HSR purposes upon execution of the licensing agreement.

In the event that you conclude that the license is not exclusive for HSR purposes upon execution of the licensing agreement, does it become an "asset" at the time that Licensee requires that Licensor transfer the manufacturing rights and related IP to it or a third party? If this is not the case, under what circumstances would these licensing rights become sufficiently exclusive that they would constitute the acquisition at that time of an "asset"?

Best,
[redacted]

Neither the licensor "retaining" the right to limited manufacture during the preclinical testing period nor for the purpose of R&D for the life of the license would compromise the license's exclusivity. The parties should file prior to entering into the licensing agreement.

6/29/11