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802.50

Verne, B. Michael

From: [redacted]
Sent: Friday, May 19, 2006 3:35 PM
To: Verne, B. Michael
Subject: Product Development Agreement

Dear Mike:

I am interested in your views as to the reportability under HSR of a product development agreement between my client, a Foreign Company, and a U.S. Company.

Both the Foreign Company and the U.S. Company have intellectual property relating to the development of a new pharmaceutical product. They propose to enter into a Commercialization Agreement which will enable the parties to develop and commercialize the intellectual property more quickly and effectively. Under the proposed Agreement each party grants to the other certain licenses to use and exploit the intellectual property described above for a specified "field", and in the event the product development is successful, to sell the resulting product in specified territories. The Agreement contemplates the grant of "research licenses" upon execution and "commercialization licenses" upon regulatory approval in any country. Under the commercialization licenses the U.S. Company will be granted the exclusive right to sell the product in a Country, and the Foreign Company will be granted the exclusive right to sell the product in the rest of the world.

Both the research and commercialization licenses contemplate that only the Foreign Company will have the right to manufacture the product except that the U.S. Company will have the right to use or sublicense its technology for other "fields". The U.S. Company agrees to purchase its supply of the product from the Foreign Company for sale in its territory. In the event that the Foreign Company defaults in its supply of the product to the U.S. Company, the U.S. Company is entitled to assume the manufacturing of the product (or have the product made by a third party) until the Foreign Company demonstrates that it is able to resume supply to the U.S. Company. In the event of termination of the Agreement (except for breach by the U.S. Company), the U.S. Company will have the exclusive right to develop and commercialize the product worldwide.

As compensation for the licenses from the U.S. Company to the Foreign Company, the Foreign Company agrees to make a number of payments over a period of time. They include: (1) upfront payments over a two year period; (2) clinical development payments over a six year period; (3) milestone payments if and when sales of the product hit certain sales targets; and (4) royalty payments based on revenues or sales from the product in its territory. Obviously, payments (3) and (4) relate to the commercialization licenses and are contingent upon development and regulatory approval of the product, and the specific amounts to be paid under (3) and (4) are dependent upon the sales, which are unknown at this time.

As compensation for the commercialization license from the Foreign Company to the U.S. Company, the U.S. Company agrees to pay royalties based on the sales, if any, of the product in its territory.

In considering whether this transaction is reportable under HSR, I understand the issues to be:

(1) Would the licenses from the U.S. Company to the Foreign Company be considered exclusive licenses and therefore acquired assets for HSR purposes?
(2) Does it matter that the research licenses are granted upon execution whereas the commercialization licenses are only granted upon regulatory approval in a country?

(3) If either or both licenses are considered acquired assets, how should they be valued? Which of the payments should be taken into account in valuing the asset? If future sales are to be taken into account, are they limited to sales in the U.S.?
(4) Would either of the licenses by the Foreign Company to the U.S. Company be considered an exclusive license?
(5) If so, would it be exempt as a foreign asset?

Please advise if you need any additional information. I look forward to hearing from you at your earliest convenience.

Thanks very much.

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1) The research licenses are non-exclusive. The commercialization licenses are exclusive.
2) The potential filing obligation occurs at the time the exclusive commercialization licenses are granted.
3) The licenses are valued by the Board of the licensee, based on fair market value, taking into account projected future royalties based on US sales only.
4) Only the commercialization licenses are exclusive.
5) The license to commercialize outside of the US is a foreign asset and would be exempt under Section 802.50 because it has no nexus with US commerce.

5/19/06