801.2

Verne, B. Michael

From: [redacted]
Sent: Wednesday, June 09, 2010 11:19 PM
To: Verne, B. Michael
Subject: Collaboration and License Agreement

Mike:

I hope all is well. Sorry to bother you but I have a few questions related to a Collaboration and License Agreement. The agreement is between a pharmaceutical company (Licensor) and a company that possess certain patent rights, know-how and technology with respect to certain therapeutic compounds (Licensee).

Under the terms of the agreement, the Licensor will grant to the Licensee an exclusive worldwide, royalty bearing, license under the Licensor's know-how and patents, to research, develop, make , have made, use, gain NDA approval, commercialize, sell, offer for sale, have sold, export and import Licensed Compounds and Products in the specific targeted fields. The Licensor has identified one specific compound for which it will use the Licensor's patents and know-how to develop and hopefully commercialize a product. The value of the license for this compound as it relates to the U.S. is well below $63.4 million.

In addition, the Licensee has the right under the agreement to identify up to three additional compounds during the three year research period provided for in the agreement. This period may be extended for two additional one year periods by agreement of the parties. At this point, the Licensee has not identified any additional compounds.

The Licensor is responsible for the manufature and supply of all therapeutic compounds for use in support of the research program. The Licensor will transfer to the Licensee the manufacturing technolgoy upon the filing of the NDA and the Licensee will be solely responsible for the manufacture of the compound for cllinical trials and commerciaal supply.

In addition, the Licensee has agreed to make an equity investment of $10 million in the Licensor acquiring preferred voting shares. The Licensee intends to hold the shares solely for the purpose of investment.

My questions concern the effect of the designation by the Licensee of additional compounds for which it will have an exclusive license to use the Licensor's patents and know-how. The value of the exclusive rights as it relates to these additional compounds cannot be determined at this time since they have not yet been identified. It also does not seem appropriate to include them in the initial HSR analysis because the assets will be transferred at a later time, if at all.

Query should the designation of a each new compound be treated and analyzed as a separate asset acquisition? Or should the value of the license as it relates to all of the compounds be aggregated over the course of the license? Or should only the value of the licenses for compounds desigaated within 180 days of each other be aggregated under a 801.13 theory?

Note - Further complicating the analysis is the fact that the right to manufacture a specific compound does not occur until the NDA for the compound has been filed. Consequently, the Licensee is not acquiring asset under exisiting interpretations until it receives the right to manufacture the compound in question.

Despite the fact that the additional compounds have not been specifically identified, I think you would have to put some value on the possibility that they will be identified in the future. I think the appropriate time to do this analysis is when the NDA for the initial compound is filed and the licensee receives the right to manufacture. If at that point the value of the license for the first compound plus the value of potential additional compounds is less than $50 million (as adjusted), there is no need to analyze the transaction again when additional compounds are identified. Alternatively, if the value at that point exceeds $50 million (as adjusted), the filing will cover the initial compound and any future compounds that are identified.

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K. WALSH CONCURS