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Verne, B. Michael

From: [REDACTED]
Sent: Wednesday, November 04, 2009 12:30 PM
To: Verne, B. Michael
Subject: Exclusive pharmaceutical license

Mike:

Hope all is well. I have a question regarding the an exclusive license whereby the Licensor will grant the Licensee the exclusive right under the Licensor's patents and know-how owned or controlled by the Licensor to research, develop, manufacture, have manufactured, use, sell, offer for sale, and import the Product in the Field worldwide. Product is a specific compound and Field means the use of the Product for prophylactic and therapeutic uses in animals and humans for oral formulation or dosage form for a specific named diseases. The term of the license is until the patent rights owned by the Licensor expire.

Under the license, the Licensor and Licensee would have co-exclusive rights to manufacture the API (the active ingredient) but the Licensor will only be allowed to sell whatever it produces to the Licensee and the Licensee has no obligation to acquire any of its API requirements from the Licensor should it choose to make the API itself.

The question is whether under these facts, the exclusive license is the equivalent of an asset transfer under the HSR Act and Rules. The Licensee will receive the right to manufacture the API but the right will not be exclusive for all purposes or for a specific field of use.

The PNO has advised that the grant of an exclusive license must include the right to manufacture the API to constitute an asset transfer but it is not clear whether this right to manufacture the API must be exclusive for all purposes, exclusive for the purpose of manufacturing a specific compound or pharmaceutical product (Interpretation 0612014), or merely the right to manufacture the API on a non-exclusive basis. If you could add some clarification regarding the PNO's views on these questions, it would be much appreciated.

Thanks in advance for the guidance on these issues.

[REDACTED]

[REDACTED]

I think under our current position, if the licensor has the right to manufacture the API co-exclusively for the licensee in the field of use that the licensee has rights to, it would not be reportable. If the Licensor only had rights to manufacture for other fields of use and the licensee had the exclusive right to manufacture for its licensed field of use, it would be reportable.

BN
11/04/09