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Law Offices

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December 4, 2009

801 Exclusive License
Agree 3-4
JJ-KB agree.
12/4/09

BY ELECTRONIC MAIL

James H. Ferkingstad, Esq.
Premerger Notification Office
Federal Trade Commission
Sixth & Pennsylvania Avenue, N.W.
Washington, D.C. 20580

Dear Mr. Ferkingstad:

Thank you for your time yesterday and today to discuss the applicability of the Hart-Scott-Rodino (HSR) Act reporting requirements to a particular technology licensing arrangement, which the parties have described in their agreement as "exclusive," but which we believe, under the facts and circumstances described, should be considered "non-exclusive" for purposes of determining reportability under the HSR Act.

My client, a specialty pharmaceutical company (Company A), proposes to enter into a License, Development and Asset Transfer Agreement (the Agreement) with another pharmaceutical company (Company B).

Under the proposed Agreement, Company B would grant Company A exclusive rights to market and sell a biologic product extracted from bacterial cells approved for sale as a medical device by the Food and Drug Administration in the United States and by regulatory authorities in other jurisdictions, along with a follow-on product under development which would require less frequent dosing.

Specifically Company B would grant to Company A an exclusive license in certain territories, including the United States, under Company B intellectual property, including all patents, patent applications and know-how owned, licensed or controlled by Company B relating to the product and the product under development, to offer for sale, sell, import, market and promote the product and the product under development, in a particular field of use. In addition, Company B would grant to Company A, an exclusive license to develop, make, have made and use the product and the product under development, *except that* Company B would retain the right (including the right to sublicense) to make and develop the product and the product under development in the field to provide manufacturing services to Company A and to conduct certain specified clinical studies. Company B would provide manufacturing services to Company A to supply finished or semi-finished product for an initial 10 year term, renewable for subsequent five year terms at Company A's option.

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At the same time, Company A will acquire certain other assets from Company B, including trademarks, certain product data, product registrations, marketing materials, accounts receivable and inventory, but Company A expects that, and before closing

would make a good faith determination that, the fair market value of those assets alone would not meet the size-of-transaction threshold.

The *Premerger Notification Practice Manual*, Interpretation 27, advises that the grant of an exclusive intellectual property license is the transfer of an asset to the licensee, which may be reportable under the HSR Act, and the Premerger Notification Office (PNO) has extended that position to partial or limited exclusivity, or "field-of use" exclusivity, so that if a license grants exclusive geographic territories or exclusivity for specific uses, it may be considered the acquisition of an asset. *Premerger Notification Practice Manual* Interpretation 27 also teaches that to be treated as an acquisition, a license must be exclusive even against the grantor, as the PNO has taken the position that the grant of a nonexclusive license does not involve the acquisition of an asset, since the grantor retains the right to use the intellectual property. Interpretation 27 also instructs that the grant of marketing and distribution rights, even if exclusive, does not constitute the acquisition of an asset.

You advised us in December 2002 that no filing was required where a firm was granted an exclusive right to market and sell certain drugs under development, where the licensor retained the right to manufacture the products for sale to such firm, which would only obtain a right to manufacture in the event of certain future events. See http://www.ftc.gov/opinions/0212016.htm. The PNO has more recently advised that if a company grants an "exclusive" license but retains the right to manufacture the product covered by the license, then the license is not sufficiently exclusive to be treated as the transfer of an asset for purposes of the HSR Act and would not be reportable. See http://www.ftc.gov/opinions/0803005.htm.

Based on the above facts and precedents, you have advised that the intellectual property license described above would not be reportable and the value of that license need not be included in determining whether the transaction meets the size-of-transaction threshold.

If this letter does not accurately summarize your advice, I ask that you contact me promptly. Thank you again for your guidance and assistance in this matter.

Very truly yours,

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