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June 10, 2004

FEDERAL TRADE COMMISSION
PREMERGER NOTIFICATION OFFICE
JUN 10 AM 11:09

HAND DELIVERY

Mr. Michael Verne
Compliance Specialist
Premerger Notification Office
Federal Trade Commission
Washington, DC 20580

Re: Exclusive Supply and Distribution Agreement

Dear Mr. Verne

This is to confirm our telephone conversation of May 6, 2004, in which you agreed that an agreement, the terms of which we described to you and which are substantially as set forth below, represents a supply and exclusive distribution agreement and not the acquisition of an asset under the Hart-Scott-Rodino Act, HSR rules of practice and related interpretations of the Premerger Notification Office.

FACTS:

Company A is a foreign person with a limited United States presence. It has developed and holds certain Patents and Know-How relating to an active ingredient that can be incorporated into a number of formulated finished products. It has also developed a number of finished products incorporating this active ingredient. Company B is a United States person that will commercialize some of the finished products that have been developed by Company A. Company B may also develop other finished products utilizing the active ingredient.

Company A and Company B intend to enter into an exclusive agreement whereby Company A will manufacture the active ingredient and supply Company B with 100 percent of its requirements for the active ingredient for use in Company B's finished products. Company B will then have the right to sell to the ultimate customer finished products containing the active ingredient for certain uses. Company A will retain the right to sell finished products containing the active ingredient for other uses. Company B's rights to market and sell finished product containing the active ingredient will be limited to certain geographic territories (including the United States). Company A will retain rights to use the product it manufactures in finished products to be sold in all parts of the world other than Company B's territory.

Under the terms of the agreement, Company B does not have rights to manufacture the active ingredient. In addition, Company B does not have the right under the agreement to use the

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Patents and Know-How of Company A in order to develop a new product that would otherwise infringe Company A's Patents or Know-How. The proposed license is restricted to Company A's Patents and Know-How as they relate to the active ingredient manufactured by Company A and any products incorporating that product to be manufactured by Company B.

Company A holds all Patents related to the active ingredient and is "primarily" responsible for filing, prosecuting and maintaining the Patents. Company B will have the primary right to enforce the Patents against third party infringers in its geographic territory. Company A will pay all costs incurred by Company B relating to pre-clinical and clinical trials necessary to obtain regulatory approvals for finished products to be sold by Company B in its assigned territory.

The proposed supply agreement will be exclusive; that is, Company A will sell only to Company B and Company A will provide Company B with "know how" as it relates to the active ingredient. This is necessary in order for Company B to produce its finished products. The license is strictly limited to how the active ingredient is formulated into the finished product and Company B does not have the right to utilize any of Company A's Patents or Know-How regarding Company A's product other than noted herein. Finally, Company B must make available to Company A for use in its retained geographic territories any Patents or Know-How it develops related to the finished product(s) that Company B develops.

ANALYSIS AND CONCLUSION:

Based on our review of the above facts, we concluded that the agreement between Company A and Company B is in effect an exclusive supply and distribution arrangement and not an exclusive patent or know-how license otherwise subject to the HSR Act. We came to this conclusion based principally on the following: (1) Company B would not have rights to manufacture the active ingredient to be manufactured by Company A; (2) the license to Company A's Patents and Know-How would be only as they relate to the product manufactured by A for B and the products to be manufactured by B incorporating A's product, and not any broader to encompass, for example, any additional inventions that B might create and that would otherwise infringe the Patents and Know-How held by A; and (3) Company B's right to commercialize finished products incorporating Company A's active ingredient is limited to certain fields of use. These limitations are so substantial that it is impossible to conclude that Company B has acquired an exclusive license to the Patents and Know-How owned by Company A. Thus, there is no asset acquisition under the HSR Act and related rules of practice. Rather, the transaction should be regarded as an exclusive supply and distribution agreement, which is exempt from premerger filing requirements under section 7A(c)(1) as a transaction in the ordinary course of business.

We are relying on this advice in advising our clients with respect to their HSR obligations regarding this agreement. If we have made an error in our summary of the discussion, or if you

disagree with our conclusions, please let us know as soon as possible. Thank you for taking the time to speak with us on the phone and for reviewing our recollection of that discussion.

Sincerely,

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AGREE -
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