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December 22, 2006

B. Michael Verne
Premerger Notification Office
Bureau of Competition, Room 303
Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Washington, D.C. 20580

Dear Mr. Verne:

Thank you very much for speaking with me by telephone yesterday. I write in order to confirm my understanding of our discussion.

I posed the following transaction: Party A is a foreign corporation which owns certain patents, know-how and patent applications (the "IP"). Party B is a U.S. company engaged in the development of potential pharmaceutical products and the management of such potential pharmaceutical products through the U.S. FDA regulatory process.

Party A and Party B will enter into a License Agreement pursuant to which Party A would grant an exclusive license of the IP for a Territory which includes the United States (among other countries) for a field of use for the treatment, prevention and diagnosis of certain specified indications in human beings. No pharmaceutical product comprising the claims of the patents or other licensed IP has been approved by the FDA or by an equivalent regulatory agency in any other jurisdiction.

The license agreement would provide for Phase II and Phase III human clinical trials and, if those clinical trials are successful, pursuance of a New Drug Application ("NDA") with the FDA. During the period of clinical development Party A will manufacture or have manufactured by an entity other than Party B such quantities of the products or active ingredient as may comprise the patents or other IP as are needed for the clinical trials. Party A will supply such products or active ingredient to Party B pursuant to a purchase agreement for use during the clinical studies.

Under the License Agreement Party A will grant an exclusive license to Party B to develop the compound and the licensed products and (among other countries) the United States. Under the License Agreement Party A will also grant an exclusive license to make the patented active ingredient but only for the purpose of making approved pharmaceutical products. Such manufacturing right would take effect at such time as Party B (or its sublicensee) is to commence commercial manufacturing of licensed pharmaceutical products, which we anticipate would be significantly more than one year after the signing of the license agreement and the purchase agreement.

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The License Agreement contemplates a development process running in excess of twelve months during which Party A would be supplying products and compound pursuant to the purchase agreement and Party B would not be manufacturing. The Parties anticipate that commercial product launch would occur - - provided the clinical trials come up with a development process and the FDA regulatory process are successful - - approximately five years after signing the license agreement.

During the phase of clinical development Party A is simply supplying finished products to Party B for a price in sufficient quantities to conduct the clinical trials and complete the regulatory process. This aspect of the transaction is therefore analogous to a distribution agreement and no manufacturing rights would take effect nor be implemented by the licensee until it begins to prepare for commercial launch of an FDA approved product.

Therefore, it is such exercise of a licensed right to manufacture that would viewed as the sale of an asset for HSR purposes and would, provided that the size of the parties and the size of the transaction tests then in effect are met, trigger an HSR filing requirement.

No HSR filing is required before signing the License Agreement and the Purchase Agreement (i.e., distribution agreement).

I believe this letter accurately reflects our conversation of December 21, 2006. I would be grateful if you could confirm to me that the signing of this License Agreement and Purchase Agreement is exempt from HSR filing until such time as the licensee's manufacturing rights may be implemented to produce a commercial product.

Sincerely,

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Agree
12/22

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