

March 8, 2004

**Via E-Mail**

Nancy M. Ovuka  
FTC Premerger Notification Office  
Federal Trade Commission  
600 Pennsylvania Ave, NW  
Washington, D.C. 20580


Dear Nancy:

Thank you for taking the time to speak with me today and on Friday, March 5, regarding my questions on the application of the Hart-Scott Rodino Antitrust Improvements Act (the "HSR Act"), 15 U.S.C. §18a. I am writing this letter to confirm the conclusion that Company X in the following fact situation would not have to file a Notification and Report Form for Certain Mergers and Acquisitions pursuant to the HSR Act. The facts that we discussed are as follows.

Company X is a foreign entity engaged in the research, development and sale of pharmaceutical products. Company X owns patents and know-how in an active ingredient that Company X hopes to develop or have developed into a marketable drug product in the United States for human use in all dosage forms.

Company X has decided to grant to Company Y, a U.S. entity, an exclusive license under the patents and know-how to use the active ingredient to conduct development of the drug product in the United States and Canada. Company X will continue to manufacture (or have manufactured) the active ingredient.

Under the terms of the agreement, Company Y shall use its commercially reasonable efforts to conduct all development activities necessary to obtain the regulatory approvals needed to launch the drug. Once the necessary approvals have been obtained and the drug product has been launched, Company Y shall have the exclusive right to manufacture and sell the drug in the United States from the active ingredient supplied by or on behalf of Company



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X. The research is currently in Phase 3 studies and a new drug application has not yet been filed.

It is my understanding from our conversations that this is not a reportable transaction. First, the exclusive license to develop the active ingredient is not deemed the transfer of an asset, since no right to manufacture the active ingredient is being conveyed. Second, while the acquiring party, Company Y, is also being granted an exclusive right to manufacture and sell any approved drug derived from the development of the active ingredient, no HSR filing is required since the acquisition of a future right to manufacture a product that does not currently exist does not constitute the transfer of an asset.

Please let me know at your earliest convenience whether the conclusions in this letter correctly reflect our conversations and the view of the Premerger Notification Office of the Federal Trade Commission. I can be reached at [REDACTED]. Thank you again for your time and attention.

Sincerely,

[REDACTED]

3/10  
Advised writer that  
conclusions are correct.

n. Ovuka  
m. Verse concm

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