

801-2

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Via E-Mail and U.S. Mail

July 9, 2007

Mr. Michael Verne
Premerger Notification Office
Bureau of Competition
Federal Trade Commission
7th Street & Pennsylvania Avenue, N.W.
Washington, DC 20580

RE: Reportability of Licensing Arrangement For Combination Product

Dear Mike:

I am writing to confirm my understanding of our telephone conversation on July 9, 2007, concerning whether the transaction described below is exempt from the requirements of the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended ("HSR Act").

- Company X and Company Y propose to enter into a combination product development and commercialization agreement. For the purpose of this letter, assume that the license that Company X will receive to "manufacture" the combination product is exclusive and that the parties satisfy all of the jurisdictional tests under the HSR Act.
- Under the proposed transaction, Company X and Company Y have retained the sole right to manufacture and will separately provide all quantities of their respective products needed to produce the combination product. Each of these separate products is already on the market and sold by the companies. In order to produce a combination product, both companies will provide their pharmaceutical compound in bulk form which has not been formulated for administration to a patient and has not been filled into vials or other delivery devices.
- The "manufacturing" that is being undertaken by Company X is that it will take these bulk products and formulate them for stability and most likely fill them into dual chamber cartridges (one chamber for each drug) for delivery to patients. (It is possible that the drugs will be "mixed" into one formulation for delivery to patients, but it is unlikely as stability is much harder to achieve for such a mix.)

Under previous informal advice given by the Premerger Notification Office, it appears that the steps being taken by Company X to create the combination drug do not constitute "manufacture" and that the license grant enabling Company X to produce the combined product is therefore not reportable under the HSR Act, given that insufficient rights have been granted to



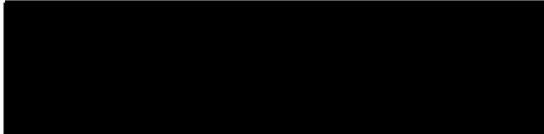
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constitute the transfer of beneficial ownership of the underlying intellectual property (see, e.g., <http://www.ftc.gov/bc/hsr/informal/opinions/0205013.htm>).

As we discussed during our call today, you agreed that the above-described arrangement is not reportable under the HSR Act. If you disagree, or would like to discuss further, please do let us know.

Sincerely,



AGREE -
BV
7/9/07

