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January 31, 2014

Mr. B. Michael Verne
Ms. Kathryn E. Walsh
Premerger Notification Office
Bureau of Competition
Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Washington, DC 20580

Re: Commercial Arrangement Between Company A and Company B

Dear Mr. Verne and Ms. Walsh:

This email is to seek your view on whether the below-mentioned transaction would be reportable under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended (the "HSR Act"). We are counsel to Company A, a pharmaceutical company. Company A will shortly enter into a Collaboration Agreement (the "Agreement") with Company B, also a pharmaceutical company. Both of the ultimate parent entities of Company A and Company B meet their respective HSR Act size-of-person thresholds. Please assume, for the purposes of this letter, that the consideration to be received by Company A is an amount in excess of the size-of-transaction threshold.

The proposed Agreement relates to two pharmaceutical products currently under development by Company A (the "Products"). All of the current and future core intellectual property rights to the Products are and will be owned or controlled by Company A. In the Agreement, Company A will grant certain limited rights to Company B to the extent necessary to enable Company B to do certain mutually agreed-upon activities for the Products, as further described below, in many major markets worldwide including the U.S. We believe that the limited rights granted to Company B are substantially and materially different from the "exclusive rights with the right to co-develop, co-promote, co-market and co-commercialize the product along with the licensee" which would be reportable under the "all commercially significant rights" test of the HSR Premerger Notification Rules.

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The U.S. aspects of the proposed Agreement will include the following provisions:

Product Development and Regulatory Matters

- Company A will, both strategically and operationally, control, have the lead role and have final decision-making authority for development of the Products, other than for the limited circumstance of changing the primary clinical endpoints on certain presently contemplated clinical studies, which change would require mutual agreement of the parties. Therefore, no development of the Products may occur without Company A's consent. In addition, if certain pre-defined development milestones are met, both parties would be obligated to continue to develop the Products in accordance with the terms of the Agreement;

- As permitted by Company A, Company B may collaborate in activities for development of the Products, and Company B will share the development costs of all development activities with Company A on a 50/50 sharing basis, subject to certain limitations; and

- Company A will, both strategically and operationally, control, have the lead role and will have final decision-making authority over all regulatory actions relating to the Products that need to be undertaken before the FDA, including being responsible for the filing and holding investigative new drug applications and filings seeking marketing approval (i.e., IND, NDA/BLA).

Intellectual Property

- Company A, as owner, will be responsible for and control prosecution, maintenance and enforcement of the key patent covering Composition of Matter of the Products ("Core Intellectual Property"); and

- Company B will be provided with a limited right to this Core Intellectual Property in order to carry out the limited activities assigned to Company B under the Collaboration, and as such, there shall be no transfer of rights to the Core Intellectual Property to Company B.

Commercialization

- Company A will, both strategically and operationally, control, have the lead role in and have final decision-making authority for the commercialization of the Products, subject to certain restrictions on each party's ability to unilaterally commercialize combination products containing the Product without the consent of the other Party;

- Company A will market and sell the Products and be the only party booking the sales of the Products;

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- Company B will co-promote the Products with Company A and share the commercialization cost on a 50/50 sharing basis in accordance with a commercialization plan and budget to be agreed between Company A and Company B; and

- Company B will receive 50 percent of the operating profit generated from the Products for a certain number of years as consideration for its investment in the development of the Products, sharing the commercialization costs as well as performing the agreed-upon co-promotion activities.

Manufacturing

- Company A will be responsible for the manufacturing of the Products; provided, that Company B will provide certain contract manufacturing services to Company A to support the manufacturing and supply of the Products; and

- Company A will be responsible for distribution of the Products and be responsible for key contracting activities with key distributors, wholesalers and payors.

No Transfer of Rights upon Termination of Agreement

- Upon termination of the Agreement for any reason, Company A will retain ownership and control of the Products, including any regulatory filings and approvals for the Products and Company A's Core Intellectual Property.

The above-described arrangements are in significant contrast to a more traditional pharmaceutical licensing development and collaboration arrangement, where a licensee is granted exclusive rights to a pharmaceutical product and with those rights gains the majority of decision-making control over the development and commercialization of the licensed product.

Please allow us to restate that, to our belief, the granted rights described above with respect to the contemplated Agreement would transfer far less than "all commercially significant rights" of the patent rights owned by Company A. Importantly, in the Commission's Statement of Basis and Purpose[1] for its new HSR Rule regarding pharmaceutical licensing transactions, the Commission explains that a key factor for determining whether "all commercially significant rights" have been conveyed, is whether the licensee, as the recipient of the exclusive rights to a patent, can commercially use the patent and generate revenue from those exclusive patents. As contemplated by the Agreement, Company A (the licensor) is the sole party that will consummate and book all sales and will retain final decision-making authority over many or all

[1] 78 Fed. Reg. 68705, 68707 (November 15, 2013).

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the collaboration's commercially important matters relating to the development and commercialization of the Products. Although both parties will share eventual profits on a 50/50 basis, these profits will result from the transfer to the licensee of less than all commercially significant rights to the licensor's patents. Thus, we believe that the rights retained by Company A and the limitations imposed upon Company B's activities and involvement relating to the Products, as contemplated by the Agreement, would not constitute a conveyance or transfer of all commercially significant rights of Company A's patents relating to the Products.

Based upon our description of the facts and circumstances as described above, would you agree with our view that this transaction is not reportable under the HSR Act?

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AGREE - THIS IS NOT REPORTABLE.

BMV

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