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December 7, 2009

BY EMAIL

Re: HSR Advice

Mr. Mike Verne
Federal Trade Commission
Premerger Notification Office
Bureau of Competition
600 Pennsylvania Avenue, N.W.
Room 303
Washington, DC 20580

Dear Mike:

Thank you for taking the time to speak with us last Tuesday. We are writing to provide you with further details regarding the license transaction that we discussed, and to set forth more specifically our view as to why no HSR filing should be required for the transaction.

Here are the basic facts: the original owner of certain intellectual property rights, A, granted an exclusive license to B, a transaction for which HSR filings were made. Those exclusive rights subsequently were transferred to a 50/50 joint venture of A and B, and later to other entities that were 50% or more controlled by B. **After a restructuring of the Agreements, the license grant included an optional mechanism for returning the rights to A upon a specified cash payment from A to B.** Since the restructuring, entities controlled by A have had the exclusive right to sell the patented products. In the proposed transaction, the intellectual property would return to A via the implementation of this mechanism contained in the restructured Agreements.

The specifics of the Agreements, in somewhat greater detail, are as follows:

A. Original Agreements

- Companies A and B entered into certain Agreements pursuant to which the parties formed a 50/50 joint venture corporation, AB, for purposes of conducting clinical evaluations, obtaining regulatory approval, and marketing in the US certain products to which A currently held patent rights and certain other products later discovered, developed, or acquired by A ("Products").

- As part of those Agreements, A granted exclusive licenses in the US to B and AB with respect to the Products.

- A and B each submitted an HSR filing for the above-referenced transactions. The filings described the exclusive US license grants from A to B "for a period of years," the formation of AB, and the subsequent contributions to AB of intellectual property and other assets. After expiration of the waiting period, the transaction proceeded.

B. Contribution of the license to AB

- Several years later, upon satisfying certain minimum sales requirements set forth in the Agreements, B's exclusive license rights terminated and AB's exclusive license rights became effective. Counsel for B confirmed with the PNO that the original HSR filing covered both the formation of AB *and* the future contributions of assets – including exclusive licenses – to AB. Accordingly, no new filing was required.

C. Restructuring of the license

- A number of years later, A and B restructured the Agreements. Company A then consummated a merger with another entity by means of an exchange offer pursuant to which Successor A+ was formed and A became a subsidiary of A+.

- In the restructuring, AB (in which B's voting control increased from 50% to 90%) assigned the exclusive license rights, which it obtained under the Agreements, to a subsidiary, AB-Sub, which then granted AB non-exclusive rights to make and have made Products. Company A and Company B agreed to manufacture the Products (or perform specified manufacturing stages therefor) on behalf of AB.

- AB agreed to supply those products to a newly created limited partnership (of which an A-controlled entity holds more than 50% of the rights to profits and rights, in the event of dissolution, to assets, and is the general partner, and in which a B-controlled entity is the minority limited partner), which was granted an exclusive right to distribute the products.

- Under the restructured Agreements, A reserved the option to have AB-Sub's rights assigned back to A:

    - The option involves a transfer back to A, upon a cash payment by A to B, of the exclusive license rights to three Products currently on the market and certain other Products in development, as described in the Agreements (the "Option Products"). In exchange for this payment, A would receive: (i) all of AB-Sub's license rights to the Option Products and (ii) certain of AB-Sub's rights to the Option Products under a manufacturing agreement and a supply agreement. AB-Sub had the right to exercise this option in 2008 but did not do so. Company A now has the right to exercise this option.

    - Company A would not be acquiring any voting securities of AB or AB-Sub (or any other entity) as a result of the exercise of this option.

    - Company B would have the right to manufacture certain Option Products on behalf of AB (or perform specified manufacturing stages therefor, such as formulating and packaging) for a limited transition period, commencing on the closing of the exercise of the option and terminating on the later of the expiration of market exclusivity of the relevant product or April 2012, depending on the product being manufactured, and Company A would have the obligation to purchase those Option Products manufactured by Company

B for that same limited period.

- AB-Sub would also retain the right to continue to receive contingent payments with respect to one of the Option Products, also for a limited period, following closing of the exercise of the option.

D. The proposed transaction

- In the proposed transaction, A would exercise its contractual rights under the option described above to have AB-Sub's license rights to the Option Products assigned back to A in exchange for a cash payment, pursuant to the terms of the Agreements.

- B would perform certain of the manufacturing stages for certain Option Products, specifically formulating and packaging one Product and packaging another Product. B's right to manufacture and to perform those manufacturing stages, and A's obligation to purchase those products manufactured by B, would continue only for a limited transition period, and terminate at various points in 2012 depending on the product.

HSR Analysis

In our view, the proposed transaction would not be an acquisition of an asset for HSR purposes.

First, as we have discussed, the PNO has advised that the expiration of a patent license does not constitute an acquisition of the rights by the original licensor.[1] We believe the same analysis should apply here. In this case, the parties essentially negotiated the optional *acceleration* of the expiration date in exchange for a fee. As in the expiration scenario, the contractual terms for ending the license are set forth in the Agreements. The option is a limitation on the license grant, and thus should not be characterized as an acquisition of any new rights in the patent. These are, instead, reserved rights that A retained in the restructured Agreements. As such, the fact that A has an option as to whether or not to exercise that right should not change the fundamental nature of the transaction – it is still not the acquisition of an asset.

By contrast, if a license was perpetual or otherwise contained no pre-set right to accelerate expiration, it is understandable why an affirmative decision to "buy back" the license could be deemed an acquisition. In that scenario, the licensee owned the rights outright and the re-acquisition is a separate transaction (just as if it was being acquired by a third party). In our case, however, the rights being acquired were reserved to the licensor in the Agreements and thus are not new rights. Requiring a filing in these circumstances could lead to uncertainty in any number of situations in which agreements provide for termination of license rights on various grounds triggered by, or at the option of, the licensor.

Second, this result is particularly sensible here because A has – beginning with the contribution of the license to AB – retained rights to make and sell the patented products (exclusive in the case of selling the products), initially through AB and later (and now) through an A-controlled partnership. Thus, as a practical matter, the principal substantive change brought about by the transaction is the cessation of ongoing payments to a B-controlled entity – and at a later date the cessation of B's rights to participate in manufacturing – under the Agreements in exchange for a lump sum payment. (You raised the question whether A's retention of rights suggested that a filing may not have been required for the original transaction. We were not involved in that transaction, but note that the PNO's guidance with respect to the characterization of exclusive licenses has been clarified over the years.

[1] See http://www.ftc.gov/bc/hsr/informal/opinions/0312007.htm (December 11, 2003).

In addition, B held exclusive license rights prior to the contribution of the license rights to AB (though that contribution was provided for in the original agreement). Of course, if the grant of rights to B did not convey an exclusive license under the PNO's current interpretation of the Rules, or if A's later retention of rights renders the license non-exclusive, then the reversal of the existing license grant similarly should not be deemed to be an acquisition of an asset that A never relinquished.

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We are of course happy to discuss this further, and look forward to hearing your views on whether the transaction described above would be reportable.

Very truly yours,

[redacted]

AGREE - NOT REPORTABLE
K. WALSH / K. BERG CONCUR

12/8/09