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Verne, B. Michael

From: [redacted]
Sent: Monday, July 14, 2008 4:40 PM
To: [redacted] Verne, B. Michael
Subject: HSR - Exclusive License Analysis

Mike,

I have been analyzing whether an HSR filing would be required for the grant of a particular exclusive license to a drug patent. I have reached a tentative conclusion as to whether a filing would be required, but would be grateful for your concurrence or contrary opinion. In sum, I have concluded based on the analysis below, that no filing would be required as long as the licensee's board of directions concludes that the fair market value of the license is less than $63.1 million.

Here is an informal outline of the facts and my analysis.

I. Parties

Licensor -- A European pharmaceutical company (with little U.S. presence)

Licensee -- A European pharmaceutical company (also with little U.S. presence)

License -- An exclusive license to a drug patent for exploitation in the U.S., Canada and Mexico.

I believe that the U.S. aspect of the exclusive license would render it, for HSR purposes, an acquisition of an asset in the U.S. (regardless of the fact that the parties are both foreign, with little U.S. assets or revenue).

II. Size of the Person Test

A. The transaction size is small enough to require application of the size of the person test.

B. Licensee and Licensor are both public companies and their own UPEs.

C. Licensor exceeds the $12.6 million asset and revenues tests, assuming there is no reduction for assets and revenues outside of the U.S. for purposes of the size of the person test.

D. Licensee exceeds the $126.2 asset test, given the same assumption I made in IIC.

E. Therefore, the size of the person test would be satisfied.

III. Size of the Transaction Test

A. The size of the transaction would be determined based upon one of two valuation methods applicable to exclusive licenses, i.e., either (i) if determined, the gross, undiscounted sum of future royalties, or, (ii) if royalty amounts are speculative, then fair market value. (Int. 86 in 4th ed. of the ABA Premerger Notification Practice Manual).

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B. Gross Royalties Test:

1. I have assumed that payments characterized as "milestone" payments would be treated the same as royalty payments for purposes of the first test.

2. There is no minimum guaranteed royalty, or if there is one, the minimum would not be sufficient to reach the size of the transaction threshold.

3. The drug requires FDA approval, which has not yet been obtained, before sales can begin.

4. If the first test were applied, then the gross sum of future, undiscounted royalties and milestone payments would probably be exceeded **if** the Licensee's sales projections are ultimately realized.

5. I would conclude, however, that although the Licensee might have a reasonable basis for its projections, they are simply that, and the contingency of FDA approval or and any uncertainty regarding the ability to achieve sales projections, would render the gross royalty payments test to be "undetermined," or too speculative to be used for the HSR test.

C. Fair Market Value Test:

1. Applying the fair market value test, the Board of Directors of the Licensor (or its qualified nominee) will have to determine whether the fair market value of the U.S. portion of the exclusive license transaction exceeds US$63.1 million.

2. This determination is made on a present day basis, appropriately discounting potential payments for time value and the risks involved.

3. This determination would also assume no other contingent payments required in the future (i.e. the potential value represented by such payments must be incorporated into the fair market value figure).

4. If the Board determines in good faith and on a reasonable basis that the fair market value of the exclusive license is less than $63.1 million, then the size of the transaction test would not be satisfied and no filing would be required.

5. This result is not impacted by the fact that application of the gross royalties test, if it had been applied, might have yielded greater than $63.1 million, assuming the Licensee's conclusion that the royalties were speculative was based on the facts as described and not simply a tactic to avoid an HSR filing.

D. I have not found any guidance that would lead to a different result simply because we have here two entities that are not currently active in the U.S. licensing a drug not currently sold in the U.S. (thus bringing a new product and participant into the relevant drug market) but would appreciate your insight as to whether there is anything on that point that would change the analysis.

[redacted]

Agree.
BM
7/16/08