801.2

Verne, B. Michael

From: [redacted]
Sent: Tuesday, October 25, 2005 11:22 AM
To: Verne, B. Michael
Cc: [redacted]
Subject: HSR Reportability of License Agreement

Mike:
This is to confirm that you indicated this morning that the transaction described below would not be considered an "exclusive" license for purposes of HSR reportability. I would appreciate it if you could get back to me if my understanding is not correct. [redacted] and I appreciate your assistance.

Regards,

[redacted]

Brand pharmaceutical company ("Brand") is entering into an agreement to license two drugs, ABC Drug and XYZ Drug, to Generic pharmaceutical company ("Generic"). The principal question presented by the agreement is whether a pharmaceutical license qualifies as "exclusive" for HSR reporting purposes when the licensor retains full rights (e.g., to manufacture, use, offer for sale, sell, market, import and have imported) to the brand version of the drug and the licensee acquires rights only with respect to a generic version of the drug. [Assume for purposes of this question that the other reporting requirements are satisfied.]

License for ABC Drug

Effective on the earlier of a number of alternative dates (the "Entry Date), Brand grants Generic what is termed an "exclusive non-transferable" license, without the right to sublicense, under the ABC Drug IP, to (1) use, offer for sale, sell, import and have imported the A/B Rated* Generic ABC Drug and the Brand-Supplied ABC Drug (i.e., not including the ABC Drug Reference Product) solely for sale in the United States and (2) manufacture and have manufactured Generic ABC Drug in the US, Canada, and potentially other countries. Brand agrees that it will not, and will not license a third party to, market, sell, supply, distribute or manufacture any Authorized Generic version of ABC Drug. Brand will, however, retain at all times the right to manufacture, market, sell, supply, and distribute a brand version of ABC Drug as well as other formulations of ABC Drug. Brand also retains all rights to the ABC Drug trademark, which are not conveyed to Generic.

* This A/B rating means that the generic version is bioequivalent to the brand version of the drug [it contains the same active ingredient

in the same amount and dosage form as the brand version of the drug], and pharmacies may substitute the generic version when filling a prescription for the drug.

License for XYZ Drug

Effective on the earlier of a number of alternative dates (the "Entry Date"), Brand grants Generic what is termed an "exclusive non-transferable" license, without the right to sublicense, under the XYZ Drug IP, to (1) use, offer for sale, sell, import and have imported the A/B Rated* Generic XYZ Drug solely for sale in the United States and (2) manufacture and have manufactured Generic XYZ Drug in the US, Canada, and potentially other countries. The exclusive license terminates six months after the Entry Date, and becomes non-exclusive at that point. During the period of exclusivity, Brand agrees that it will not, and will not license a third party to, market, sell, supply, distribute or manufacture any Authorized Generic version of XYZ Drug. Brand will, however, retain at all times the right to manufacture, market, sell, supply, and distribute a brand version of XYZ Drug as well as other formulations of XYZ Drug. Brand also retains all rights to the XYZ Drug trademark, which are not conveyed to Generic.

* This A/B rating means that the generic version is bioequivalent to the brand version of the drug [it contains the same active ingredient in the same amount and dosage form as the brand version of the drug], and pharmacies may substitute the generic version when filling a prescription for the drug.

AGREE -
B [redacted]
10/25/05

[redacted]

For more information about [redacted], click here:
[redacted]