801-1(P)
801-2

Verne, B. Michael

From: [redacted]
Sent: Thursday, November 07, 2013 3:15 PM
To: Verne, B. Michael; Walsh, Kathryn
Subject: Pharma license question

Hi Mike and Kate,

I have a question regarding a scenario we discussed over a year ago, and wanted to check to see what impact the new rules have on the previous conclusion that no filing would be required.

The scenario is this:

1. Subject to the right retained in 2. below, Company X will receive from Company Y an exclusive license under Y IP to "make, use and sell" the products in the US for a specific indication within a therapeutic area.
2. Company Y will retain the right to manufacture in the US for third parties who are selling the products outside the US for the same indication.

In the new rules, the term "limited manufacturing rights" is defined as rights "retained by the patent holder *solely to provide the recipient of the patent rights* with product(s) covered by the patent" (italics mine). In the above scenario, the licensor would be retaining rights to manufacture the products for someone other than the recipient of the patent rights, though only products for sale outside of the US.

Would the retention of these manufacturing rights go beyond "limited manufacturing rights" and thus render the transaction non-reportable (as it was prior to these new rules)?

Many thanks for your guidance.

Best,

[redacted]

Our current position is that X is still getting an exclusive license for a specific indication in the U.S. geographic market. Y is retaining the right to manufacture the product for the non-US geographic market, which doesn't affect the exclusivity of Y's license with respect to the US market, even though it is for the same indication.

BM

11/7/13

KW concurs