Haynes, Lanea

From: Shaffer, Kristin
Sent: Wednesday, March 01, 2017 7:19 AM
To: [redacted]
Cc: Walsh, Kathryn E.; Berg, Karen E.; Gillis, Diana L.; Storm, Evan; Carson, Timothy
Subject: RE: 802.51 Question

[redacted]

The data are inextricably linked to the value of both the foreign and US IP. Therefore, we think that a reasonable valuation of the US assets should include the value of any data or other intangible asset that would relate to the US IP.

Best regards,
Kristin

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From: [redacted]
Sent: Monday, February 27, 2017 10:22 AM
To: Walsh, Kathryn E.; Berg, Karen E.; Gillis, Diana L.; Storm, Evan; Carson, Timothy
Cc: [redacted]
Subject: 802.51 Question

Dear PNO team:

I hope this finds you all well and ready for Spring.

I'm writing to seek clarification with regard to whether certain clinical data held by a foreign corporation could be classified as an asset "located in the United States" for purposes of the foreign voting securities exemption set forth at §802.51.

Here are the basic hypothetical facts:

Corporation A intends to acquire 100% of the outstanding voting securities of Corporation B. Both A and B are foreign entities and each is its own Ultimate Parent Entity. Corporation B is a life sciences company that currently has products in development. It has no tangible US assets or offices, and it has less than $1 million in current US revenues. Corporation B does hold certain US and foreign patents, along with clinical data used to support its regulatory applications in various jurisdictions, including the US. All clinical data were collected outside the United States (as B's clinical trials were conducted in Europe). Moreover, the data are maintained by B at its facilities outside the United States. No rights of use currently have been granted in the US (though the data have been made available to Corporation A for the limited purpose of due diligence review, which may include reviewers based in the US). As noted, the data are being used to support B's global regulatory approval efforts, including its filings before the FDA for new drug approval in the US.

The exemption set forth at 16 CFR §802.51 states, in relevant part:

The acquisition of voting securities of a foreign issuer by a foreign person shall be exempt from the requirements of the act unless the acquisition will confer control of the issuer and the issuer (including all entities controlled by the issuer) either: holds assets located in the United States (other than investment assets, voting or nonvoting securities of another person, and assets included pursuant to §801.40(d)(2) of this chapter) having an aggregate total value of over $50 million (as adjusted) [currently $80.8 million]; or made aggregate sales in or into the United States of over $50 million (as adjusted) [currently $80.8 million] in its most recent fiscal year.

In our hypothetical the fair market value of the US patents held by B would be less than $80.8 million; however the fair market value of the patents and the clinical data combined would exceed $80.8 million. (Acquiring the clinical data supporting FDA regulatory approval is expected to allow the buyer to obtain regulatory approval in the US substantially sooner than if it owned the patents only and had to conduct new clinical trials to develop new data Thus the clinical data hold significant value.) If the data comprise assets "located in the United States" the exemption would not apply and the transaction would be reportable; but if the data are not located in the US the exemption applies and the transaction would not be reportable.

Our view is that the data are not assets located in the US, even though they are used to support regulatory approval in the US (among other jurisdictions). This is in part because the ownership rights to the data, as well as other rights regarding its collection and use (i.e., data privacy protections, etc.) primarily would be enforced overseas (see, e.g., Informal Interpretation #1309004 (accounts receivable are located in the jurisdiction in which rights to payment would be enforced)). But we have found no direct guidance on this point, and thus would appreciate your insight.

Thanks very much in advance for your consideration

Best regards,

[redacted]

[redacted]

[redacted]