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Verne, B. Michael

From: [redacted]
Sent: Thursday, January 16, 2014 1:49 PM
To: Verne, B. Michael
Cc: [redacted]
Subject: Exclusive Pharmaceutical Licenses

Mike:

We have a few questions regarding HSR reportability of various assignments and exclusive licenses to existing and to be developed intellectual property ("IP") contained in a proposed Collaborative Research Agreement, intended to facilitate the discovery and development of new pharmaceutical active ingredients ("New Compounds") (anticipated to be 10 in all), which agreement will be executed simultaneously with related transactions. We also want to confirm that our analysis set forth below is not affected by the FTC's 2013 guidance regarding the transfer of "all commercially significant rights" to a pharmaceutical patent.

Background

Under the Collaborative Research Agreement, the Parties will work together to research and identify a targeted number of New Compounds, with Party A entitled to select a set number of the New Compounds (three) identified for exclusive development and commercialization within a defined Field and Territory (which includes the United States), and Party B entitled to select the remaining New Compounds identified, as well as select Party A's New Compound selections outside the defined Field or Territory, for exclusive development and commercialization. Party A will fund at least a portion of Party B's research and identification expenses.

Party B will give Party A an exclusive, royalty bearing license to patents and know-how necessary or useful for Party A to make, have made, use, develop, offer for sale, sell, import, export or otherwise exploit its selected New Compounds within the defined Field and Territory (which includes the United States). In addition, Party A will own any composition of matter patents claiming its selected New Compounds in the territory. This Field expands (to include additional indications) following the first regulatory approval of a New Compound by Party A. Similarly, Party A will give Party B an exclusive, royalty bearing license to patents and know-how necessary for Party B to make, have made, use, develop, offer for sale, sell, import, export or otherwise exploit the remaining New Compounds, as well as Party A's selected New Compounds outside the defined Field or Territory. In addition, Party B will own any composition of matter patents claiming (i) Party A's selected New Compounds outside of the territory and (ii) the remaining New Compounds worldwide.

Party A will make milestone and royalty payment to Party B on the development and sale of the New Compounds selected by Party A, and Party B will make royalty payments to Party A on the sales of New Compounds selected by Party B and sales of New Compounds outside of Party A's Field or Territory.

In one related transaction, Party A will also acquire voting securities of Party B. The consideration for these non-publicly traded voting securities has been determined and would not trip a notification threshold for the acquisition of voting securities. Party B will have the right to put a second tranche of voting securities to Party A after one year, also at a determined price. If that second tranche is acquired by Party A, that acquisition would most likely (based on current valuation) trip a notification threshold for the acquisition of voting securities.

2

In a second related transaction, the Parties will amend an existing License and Collaboration Agreement, pursuant to which Party A acquired an exclusive license to Party B's know how and patents regarding a specific Compound X, to make, have made, use, import, export, offer for sale and sell Compound X in a Field and Territory (that previously did not include the U.S.). The amendment to this License and Collaboration Agreement will expand the Territory to include the U.S., with Party A having the exclusive right to develop and commercialize Compound X in the U.S. in a limited field of use with such field expanding (to include additional indications) after Party A achieves its first regulatory approval for Compound X in North America. The consideration for this amendment adding U.S. rights consists of milestone and royalty payments on the development and sales of Compound X (although Party A made an upfront cash payment to Party B at the time this License and Collaboration Agreement was executed).

Analysis

Under Informal Interpretation 0911004 (http://www.ftc.gov/enforcement/premerger-notification-program/informal-interpretations/1006004), it appears that each Party should make a FMV estimate of the exclusive IP rights it is acquiring relating to the New Compounds, even if the New Compounds have not yet been identified. These FMV estimates would address the FMV of the assignment or exclusive license of IP rights being acquired for the U.S. market only (as any IP rights to non-U.S. markets are not relevant to the HSR analysis).

If Party B's FMV estimate does not exceed $50 million (as adjusted), there would be no obligation for Party B to notify its acquisition, and there would be no requirement that Party B analyze or revisit in the future its acquisition of rights relating to the New Compounds, when and if New Compounds might actually be identified and commercialized by Party B. Conversely, if Party B determines that the FMV of the New Compounds exceeds the size of transaction threshold, it could make an HSR filing now, even though the New Compounds have not been specifically identified. Such filing would cover the acquisition of the IP rights to the New Compounds, even if the specific New Compounds are not identified until a year after the HSR filing is made.

Party A, in contrast, under Rule 801.14, would aggregate: (a) the FMV of the U.S. rights to the assignment or exclusive license of IP rights it is acquiring relating to the New Compounds; (b) the value of the voting securities being currently acquired; and (c) the FMV of the exclusive IP rights in the U.S. relating to Compound X. If the aggregated value of those assets and voting securities exceeds $50 million (as adjusted), Party A would be obligated to notify. This notification would include notification as to (c), even though Party A's exclusive right to commercialize Compound X in the U.S. attaches after Party A achieves its first regulatory approval for Compound X in North America – in other words, Party A would not be subject to any additional filing in the future related to Compound X, if and when Party A achieves its first regulatory approval for Compound X in North America. And, as with Party B, there would be no requirement that Party A analyze or revisit in the future its acquisition of rights relating to the New Compounds, when and if New Compounds might actually be identified and commercialized by Party B.

Party A would not cross a notification threshold for the acquisition of voting securities with the first voting securities acquisition (although the value of that acquisition still gets counted for filing fee threshold purposes). Party A would (likely) cross a notification threshold for the acquisition of voting securities if and when the second tranche is acquired, but that would be after one year. Under Informal Interpretation 1003002 (http://www.ftc.gov/enforcement/premerger-notification-program/informal-interpretations/1003002), it appears that Party A would have a second filing obligation at the time of the second tranche acquisition, in order to cross a notification threshold for the acquisition of voting securities, despite the fact Party A had already notified the first voting securities acquisition.

Are we reading correctly the referenced Informal Notifications, in combination with the FTC's 2013 guidance regarding the transfer of "all commercially significant rights" to a pharmaceutical patent?

Happy to discuss by phone, if you need further detail.

[redacted]

Agree
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1/17/14

No Concurs