801.2(g)

Verne, B. Michael

From: [redacted]
Sent: Wednesday, March 12, 2014 10:18 AM
To: Verne, B. Michael; Walsh, Kathryn
Cc: [redacted]

Subject: Inquiry re reportability of a license under 801.2(g)

Mike and Kate:

We are writing to obtain your view on the non-reportability of a proposed pharmaceutical commercialization agreement ("Agreement"). Although the Agreement transfers some patent rights, we do not believe that it transfers "all commercially significant rights" as that phrase is used in 801.2(g) in several aspects. Rather, like those agreements cited by Comment 2 to the Notice of Proposed Rulemaking (see Footnote 16 of the Final Rule at Fed. Reg. Vol. 78, No. 221 p. 68708), the proposed Agreement is substantively the same as an exclusive product distribution agreement that is excluded from the new rule.

The subject of the proposed Agreement involves a pharmaceutical chemical compound ("RX") that is approved by the FDA and is currently marketed and sold outside the U.S. As a result of the proposed Agreement, Licensee would begin exclusively distributing RX in the U.S. as of mid-2015.

Below are the relevant facts:

- Licensor will manufacture RX and sell the finished RX to Licensee for its use, sale and distribution in the U.S.
- Licensor grants to Licensee an exclusive (even to Licensor except as otherwise provided herein with respect to Licensor's research and development activities) right and license under Licensor's Trademarks, Patent Rights, Know-How and interest in the Joint Patent Rights and Joint Know-How to "register, have registered, use, have used, promote, have promoted, commercialize, have commercialized, sell and have sold" RX in the U.S. "For clarity, this grant shall not include researching, having researched, developing, have developed, making, having made, manufacturing, having manufactured and/or supplying of the RX and/or for using any Licensor Know-How for such purposes. Notwithstanding the foregoing exclusive license grant, the Parties rights under the Licensor Patent Rights and Licensor Know-How shall be co-exclusive with respect to research and development activities relating to the RX in the Field in the Territory (U.S.)."
- Licensor retains all manufacturing rights, including the right to manufacture RX for sale inside and outside the U.S.
- Licensor retains the right to its own inventions related to RX and will share with Licensee the rights to joint inventions.
- Notwithstanding the foregoing, any Licensee inventions and joint inventions in connection with RX relating to (a) a pharmaceutical with the same chemical composition as RX; (b) a pharmaceutical composition comprising the same active ingredient of RX; (c) any amendment or improvements to the process or specifications provided by Licensor to Licensee; (d) a medical use of the RX; (e) any amendment or improvement regarding the production cell line or the production medium; and/or (f) any combination of the RX, each shall be the exclusive property of the Licensor and the corresponding Patent Rights shall be assigned to Licensor.
- Licensor retains rights in the RX to carry out its obligations to certain studies required by the FDA.

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- After the effective date, the expense of a defined set of studies required by the FDA that the Licensee is required to conduct under the Agreement will be borne equally by Licensee and Licensor.
- After the effective date, Licensee is solely responsible for U.S. regulatory approvals, e.g., BLA maintenance, labeling, dosage, etc.
- If, at any time during the term of the Agreement, Licensor intends to license, sublicense, assign, transfer, sell, divest or otherwise dispose of the RX outside the U.S., Licensee will have the right of first negotiation.
- Licensor shall, at its own expense and discretion, be solely responsible for the preparing, filing, prosecuting, and maintaining of its Patent Rights in the RX.
- If Licensor wishes to abandon any Patent Rights in the U.S. that are licensed to Licensee under the Agreement, it will offer Licensee a right of first refusal.
- Licensor will, during the term of the Agreement, have primary responsibility for litigating any known infringement or suspected infringement by a third-party of its Patent Rights, its Know-How, Joint Patent Rights or Joint Know-How.

Notably, a licensor's retained manufacturing rights are only "limited" under 801.1(p) if "all other exclusive rights to the patent" have been transferred. In this case, there are several patent rights held by Licensor that will not be transferred to Licensee exclusively. Accordingly, we do not believe the Agreement transfers "all commercially significant rights" and, therefore, is not an exclusive license that constitutes an asset transfer that is potentially reportable under the HSR Act. Moreover, the Agreement does not involve a pipeline compound that the new rules were seemingly meant to address.

Please confirm that the proposed Agreement is not reportable under the HSR Act.

Regards,

[redacted]

[redacted]

[redacted]

AGREE - NOT REPORTABLE

BW

3/12/19

KW CONCURS