801.2

[redacted]

[redacted]

March 19, 2009

Mr. B. Michael Verne
Premerger Notification Office
Bureau of Competition
Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Washington, DC 20580

Re: Hard Tablet Formulation Technology License

Dear Mr. Verne:

We are submitting this letter in order to see if you agree with our view that the grant of a license under the facts and circumstances described below would not require a filing under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended (the "Act").[1] Although the license is fairly described in the parties' agreement as exclusive, for purposes of determining compliance under the Act we believe that the license is non-exclusive.

We are counsel to a pharmaceutical company ("Grantee") which has entered into a licensing agreement with another corporation ("Grantor"). By its terms, the licensing agreement will not become effective until the waiting period under the Act, if applicable to the transaction, has expired or been terminated. Grantor will license to Grantee certain patent rights related to the manufacturing and marketing of two different pharmaceutical products which incorporate a "technology." That technology includes a hard delayed-release tablet formulation having physical properties which may increase the difficulty of tampering (hereafter, the technology is referred to as the "Hard Tablet Formulation" or "HTF").[2]

More specifically, the proposed agreement provides that Grantee, which has pre-existing patent rights to two pharmaceutical products, will receive a license to utilize the HTF for the purpose of developing, manufacturing, warehousing, distributing, promoting, marketing and

---

1 For purposes of this letter, please assume that both the "size of persons" and "size of the transaction" criteria would be satisfied.

2 The description of the terms of the licensing agreement discussed herein are limited to use of U.S. intellectual property in the United States. The agreement also has provisions referring to the use of intellectual property outside of the United States.

[redacted]

12

selling an HTF-version of those two pharmaceutical products. Grantee currently manufactures and sells one of these products ("Product One") in a form not utilizing the HTF and is in the early stages of development with respect to the second of these products ("Product Two"). Under that license, Grantee will acquire the exclusive right to manufacture the end product, which will be a combination of the HTF and solely Product One and/or solely Product Two – products which are, to reiterate, Grantee's own drug products. Accordingly, the Grantor will not be able to manufacture or license the HTF for use in products containing the same sole active pharmaceutical ingredient ("API") as contained in Product One or Product Two. Significantly, however, Grantor will retain: (a) the right to manufacture any other products using the HTF; (b) the right to license the HTF to other pharmaceutical companies for use with an API other than that contained in Product One or Product Two; and (c) the right to manufacture or license to other pharmaceutical companies the right to manufacture products utilizing the HTF containing more than one API, even if one of those APIs is the same as the API used in Product One and/or Product Two.

We are aware that PNO Manual Interpretation No. 27 suggests that "a license [which] grants exclusive geographic territories or exclusivity for specific uses" may be reportable under the Act. Here, however, the license is substantively closer to "a co-exclusive license where the licensor retains rights to the intellectual property" -- specifically the right to license the patented HTF technology for use in other drugs. *See* PNO Manual Interpr. No. 27. Such a limited license is "not considered by the PNO to be [a reportable] exclusive license." *Id.*, citing HSR Informal Interpretation Letter No. 020300 (March 6, 2002).

In the instant transaction, as mentioned above, the Grantor would also retain the intellectual property rights to its HTF and may utilize or license such technology to third parties for developing, manufacturing, warehousing, distributing, promoting, marketing and selling any pharmaceutical product other than products containing the same sole API contained in either of Grantee's two patented products. These circumstances may be viewed as similar to those presented in Informal Staff Opinion 0612003 (December 4, 2006).

In the December 2006 informal staff opinion, the staff of the Premerger Notification Office held that a licensing transaction was not reportable when a grantee acquired the exclusive right to a delivery vehicle compound for the manufacture of an end product which was a combination of a grantor's delivery vehicle compound and grantee's own drugs. The grantor, as mentioned in the 2006 informal staff opinion, retained the manufacturing rights for the licensed compound.

We believe under the facts and circumstances as described above the filing of Premerger Notification Forms under the Act would not be necessary with respect to Grantee's anticipated utilization of the HTF as applied to Products One and Two. We would appreciate knowing if you concur or do not concur with our analysis.

[redacted]

[redacted]

Please do not hesitate to contact me at the above number if you have any questions regarding the foregoing or require additional information. On behalf of our client we thank you for your time and assistance.

Very truly yours,

[redacted]

cc: [redacted]

AGREE -
K. WALSH CONCURS
BM
3/20/09

[redacted]