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**From:** [REDACTED]  
**To:** FTC.SERIOUS(mverne@ftc.gov)  
**Date:** 5/21/02 11:16AM  
**Subject:** HSR Licensing Issue

CONFIDENTIAL

Mr. Verne:

I would like to confirm that the following licensing arrangement does not constitute the transfer of beneficial ownership of an asset under applicable HSR rules and regulations.

For present purposes, please assume that the requisite size-of-person and size-of-transaction tests are satisfied.

I have a client that is in the process of negotiating a license agreement for a new compound to treat certain diseases. My client, Company A, does not currently have any products on the market or in development for this indication. The facts are set out in the numbered paragraphs below:

- (1) Under the proposed agreement, Company A would obtain an exclusive license under the IP of the third party for use with any product that contains this compound (or any prodrugs or metabolites of this compound). The license would be for the entire world, excluding certain markets in Asia.
- (2) With one exception, noted in Paragraph (4) below, Company A will not have the right to manufacture the compound itself. Indeed, the licensor will retain the right to manufacture the compound.
- (3) The parties envision that the compound will be manufactured by the licensor, who will then ship it to Company A in bulk. Company A would then manufacture finished product and develop, market and sell the product on an exclusive basis in its territory. The "manufacturing" that is being undertaken by the licensee will be to take the powdered compound supplied by the licensor and press it into tablets.
- (4) Although not determined at this time, Company A may ultimately get a "back-up" manufacturing right for the compound that would apply only in the event that the licensor breached its supply obligations.
- (5) As noted above, Company A will not actually make the compound (absent supply disruption). Company A will use the compound to make a finished product -- a tablet -- that it will then market and sell. With respect to the tabletization process, Company A will seek an exclusive license for intellectual property rights that pertain to the broader patents covering the formula and manufacture of the compound that might pertain to the "tabletization" of the compound, i.e., Company A will seek an exclusive license from the licensor so that it (Company A) does not infringe the broader patent rights associated with the compound that might be infringed by Company A's tabletization efforts. Again, absent breach by the supplier of the compound, Company A will not have the right to manufacture the compound.

Based on our discussions, I would appreciate confirmation that the

situation outlined above would not constitute a reportable event for HSR purposes.

Please feel free to contact me at your earliest convenience if you need further information about this matter.

Best regards,

[Redacted signature and name]

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BENEFICIAL OWNERSHIP OF THE UNDERLYING IP DOES NOT APPEAR TO PASS TO THE LICENSEE UNDER THIS ARRANGEMENT. ADVISED THAT NO FILING IS REQUIRED. N. OVURA CONCURS.

B. Michel  
5/29/02