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Verne, B. Michael

From: [redacted]
Sent: Friday, January 13, 2006 10:22 AM
To: Verne, B. Michael
Subject: HSR question

Dear Mike:

I have a question about the possible application of the Hart-Scott-Rodino ("HSR") Act and Rules to a proposed collaboration and licensing agreement for development and commercialization of biotechnology-based medicines and treatments. Based on your prior advice on similar agreements, the proposed agreement should not trigger HSR notification obligations because the only exclusive rights acquired under the agreement are marketing and distribution rights, and the licensor will retain co-manufacturing rights for the licensed products in the United States. I thought it would be most helpful to outline the basic facts briefly in this email, and then follow up with a telephone call to confirm that you concur with that conclusion.

1. Proposed Agreement

A U.S. biotechnology company that is focused on research and development of biotechnology medical therapies ("US Company") proposes to enter a Collaboration Agreement with the U.S. subsidiary of a foreign pharmaceutical company (collectively, "Foreign Company") to cooperate and jointly fund the development of certain biotechnology therapies, and to grant one another licenses to commercialize the resulting products. The two companies will cooperate to develop a plan and budget for joint development of the products, and to develop a global strategy for commercialization.

Under the proposed agreement, US Company grants Foreign Company licenses under its technology for exclusive commercialization rights outside the United States and Canada (collectively, "North America") for up to ten products (as well as certain related "follow-on" products) to be selected later by Foreign Company from candidates developed by US Company. US Company also grants Foreign Company non-exclusive rights for development and manufacture of the licensed products anywhere in the world. Foreign Company will have no rights to market, sell, or otherwise commercialize the licensed products in North America, however.

In exchange, Foreign Company will provide substantial support for US Company's research and development efforts starting with an initial cash payment at the time of signing, but with the bulk of its commitment in the form of additional payments each quarter over a number of years and possible additional milestone payments in amounts that vary depending on when or if certain development milestones are hit. The total of these payments is therefore not certain, but may be more than $250 million over the full life of the agreement. Foreign Company will also purchase US Company common stock valued at well under $53 million, and provide a credit facility to US Company at commercial rates and terms. Finally, Foreign Company will make additional payments when it selects a product, with the amounts depending upon the stage of product development at the time of selection, and, if any selected product is successfully commercialized, it will also pay a royalty based on a percentage of its net sales.

US Company retains for itself the rights to market, sell and otherwise commercialize the licensed products in North America. To support US Company's retained North America commercialization rights, Foreign Company also grants reciprocal licenses under its technology to US Company for exclusive rights to market, distribute or otherwise commercialize the licensed products in North

America, and US Company will pay a royalty based on its net sales in the event any of the products is successfully commercialized in North America. But Foreign Company grants only non-exclusive manufacturing and development rights, and retains the right to use its own technology for development and for manufacture of the licensed products anywhere in the world, including the United States (and it will have a non-exclusive license to use US Company technology for such development and manufacturing as well). Thus the only exclusive rights granted under the Collaboration Agreement are marketing and distribution rights, and both Foreign Company and US Company will have co-manufacturing rights as well as co-development rights in the United States ai elsewhere.

2. No HSR filing is necessary for the proposed license grants, because the licensor retains U.S. manufacturing rights.

My question focuses specifically on the grant of license rights to US Company. Under PNO interpretations, a grant of an exclusive license to intellectual property is deemed an acquisition of ar asset that may be subject to HSR filing requirements. But as you know, a license grant limited to exclusive marketing and distribution rights is not deemed an asset acquisition, and is not subject to HSR reporting. (See, e.g., Interpretation 29, ABA Premerger Notification Practice Manual (3d).) Under the proposed agreement, US Company will receive license rights from Foreign Company to support commercialization of the licensed products in the United States (and Canada), but the only exclusive rights that US Company will receive are marketing and distribution rights. Foreign Company only grants non-exclusive manufacturing rights and development rights to US Company, and will retain co-manufacturing rights as well as co-development rights in the United States and everywhere else. Because the exclusive rights under the license granted to US Company are limite to marketing and distribution only, under PNO interpretations the license grant to US Company should not be deemed an exclusive license that creates an acquisition of assets that is subject to HSR reporting.

You recently advised other parties, for instance, that no HSR notification was required for closely similar arrangements under a pharmaceutical "co-promotion" agreement with the following relevant features: (1) Licensor and Licensee would have co-promotion rights outside the United States, and Licensee would have exclusive U.S. sales rights (except for a limited option for Licensor to co-promote the product to certain specialists only); (2) Licensor and Licensee would each have non-exclusive co-manufacturing rights in the U.S. and elsewhere; and (3) both parties would have "full engagement in strategy and planning" for global sales. (Letter to Michael Verne, Information Staff Opinion 0507007 (July 17, 2005).) Likewise, in the proposed Collaboration Agreement, the only exclusive rights granted to US Company will be marketing and distribution rights, both parties will have non-exclusive co-manufacturing and co-development rights, and both parties will be engaged strategy and planning for global sales.

I will call you shortly to discuss the issue and confirm that you concur with these conclusions, but please feel free to reply by email or telephone me at [redacted]. Many thanks for your help with this question.

Best regards.

[redacted]

Agree -
B Mueller
11/13/06