UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

Office of Commissioner Ohlhausen

To: Don Clark
From: Alexander Okuliar
Date: February 26, 2013
Re: HSR IP Rulemaking (No. P989316): Meeting to be placed on the public record

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On February 26, 2013, representatives from the Pharmaceutical Research and Manufacturers of America (PhRMA) met with Commissioner Maureen K. Ohlhausen and her attorney advisors to discuss the Commission's proposed modifications to the pre-notification rules applicable to certain intellectual property licensing agreements under the Hart-Scott-Rodino Antitrust Improvements Act, 15 U.S.C. § 18a (HSR Rules).[1]

The representatives expressed concern about the proposal to clarify the premerger notification rules to require filings for certain intellectual property licensing agreements in the pharmaceutical industry that involve the patentee retaining either manufacturing rights or co-rights. They argued that the rule change would expand filing requirements for the pharmaceutical industry unfairly and had concerns about the rule's legality and its policy implications.

The representatives expressed concerns that the proposed rule would single out pharmaceutical companies, which would exceed the FTC's statutory authority; constitute unfair discrimination against those companies without any reasoned justification; contradict the government's international advocacy that the law should be administered equally; and create a unique burden on this industry despite the fact that other industries also use similar license agreements for similar reasons.

On the issue of unfair discrimination, the representatives expressed concern that the Commission offered only its expertise as a basis for this rule. The representatives stated the Commission should present some form of empirical evidence that these licensing agreements occur more frequently or are more problematic in the pharmaceutical industry. They did not find this industry to be unique in its licensing practices or in the impact of those practices, as indicated in the expert report submitted with their written comment and in academic research. They considered this proposed rule to potentially set bad precedent and to contradict the

[1] The following representatives from PhRMA attended the meeting: James M. "Mit" Spears, Executive Vice President and General Counsel of PhRMA, Melissa Kimmel, Assistant General Counsel of PhRMA; and outside counsel James Rill, Steve Weissman, and Bill Henry of Baker Botts L.L.P. Alexander Okuliar and Greg Luib, attorney advisors to Commissioner Ohlhausen, also attended.

government's general position, espoused abroad, against such overly-targeted application of the law. In addition, although the goal of transparency is admirable, it should be applied uniformly and as written the rule potentially creates confusion in non-pharmaceutical industries.