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

Office of Commissioner
Julie Brill

To: Don Clark
From: Samuel Comi
Date: March 21, 2013
Re: HSR IP Rulemaking: Comments to be Placed on the Public Record

---

On March 13, 2013, Commissioner Julie Brill, her Attorney Advisors, and other agency staff met with representatives from the trade group Pharmaceutical Research and Manufacturers of America ("PhRMA") to discuss the FTC's proposed modifications to the HSR premerger notification rules.[1]

PhRMA expressed concern that the proposed rulemaking is discriminatory against the pharmaceutical industry. PhRMA asserted that the Commission lacks statutory authority to issue this rule and that the rule contradicts the Commission's established policy of non-discrimination.

PhRMA stated that the HSR is a statute of general application, applicable to all persons, and that while the Commission has the ability to exempt a class of persons, it does not have the ability to increase the burden of a class. PhRMA stated that the factual basis for this rule is opaque, and that the Commission must articulate a factually supported reason why these transactions should be reviewed *ex ante*.

PhRMA stated that the proposed rule is not just a clarification of existing practice, but expands notification requirements to include licenses where the licensor retains limited manufacturing rights. PhRMA stated that the proposed rulemaking addresses a hypothetical concern, and asserted that if retention of manufacturing rights created actual anticompetitive concerns, there would have been investigations into such licenses in the past. PhRMA also stated that if anticompetitive issues arise, the licenses could easily be unwound post-consummation.

PhRMA stated that its expert, in the attachment to its public comment, had identified many essentially equivalent transactions in other industries. PhRMA stated that if a legitimate competitive concern exists with exclusive licenses in the pharmaceutical industry, that concern

---

[1] In attendance on behalf of PhRMA were James (Mitt) Spears and Melissa Kimmel and from Baker Botts LLP representing PhRMA were Stephen Weissman, Paul Cuomo, and James Rill. In attendance from the FTC were Commissioner Julie Brill, Abigail Slater, Holly Vedova, Robert Jones, Kathryn Walsh, Olga Vaytsman, and Samuel Comi.

should apply to all industries, and would apply to exclusive distribution agreements as well. PhRMA stated that restricting application to the pharmaceutical industry would create confusion with respect to similar transactions in other industries.

PhRMA stated that the Commission could avoid the legal and policy issues of a discriminatory rule by issuing a policy statement or an industry-neutral rule. PhRMA also stated that the Commission should refrain from using NAICS codes or industry specific language to restrict the application of a rule, and that that the difficulty of drafting an industry-neutral rule cannot be used as justification for a discriminatory rule.