Appendix C

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

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[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.

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

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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

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[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.

TO: Don Clark
FROM: Darren Tucker
DATE: April 30, 2013
SUBJECT: Summary of Oral Communications Regarding Notice of Proposed Rulemaking

On April 3, 2013, counsel for the Pharmaceutical Research and Manufacturers of America (PhRMA) met with FTC Commissioner Joshua D. Wright and his advisors Darren Tucker, Jan Rybnicek, and Joanna Tsai regarding a Notice of Proposed Rulemaking regarding certain licensing transactions in the pharmaceutical industry. Appearing on behalf of PhRMA were Mit Spears and Melissa Kimmel, as well as Stephen Weissman and Jim Rill of the Baker Botts LLP law firm, which serves as outside counsel to PhRMA. Also attending the meeting were Lisa Harrison from the Office of General Counsel and Bob Jones and Mike Verne from the Premerger Notification Office.

The Notice of Proposed Rulemaking at issue was published in the Federal Register on August 20, 2012 in Volume 77 of the Federal Register at page 50,057. This memorandum is to be placed on the public record pursuant to 16 C.F.R. § 1.26(b)(5) and the Notice of Proposed Rulemaking, under which summaries or transcripts of oral communications respecting the merits of the proposed rulemaking from any outside party to any Commissioner or Commissioner advisor are to be placed in the public record.

At the April 3, 2013 meeting, PhRMA's counsel asserted that the Notice of Proposed Rulemaking would expand the reach of the Hart-Scott-Rodino Act, 15 U.S.C. § 18a, and that the FTC lacks authority to do so. Counsel also asserted that the Commission did not provide a reasoned explanation in the Notice for expanding HSR requirements or for singling out the pharmaceutical industry for these increased burdens. In addition, counsel asserted that the proposed rulemaking conflicted with international antitrust enforcement principles, which espouse nondiscrimination. Counsel also stated that transactions subject to the proposed rulemaking would be easy to unwind and would not involve assets that would be eliminated by an acquiring party. Finally, counsel asserted that the Notice understated the costs to the private sector of complying with the proposed rules. PhRMA requested that the FTC not proceed with the rulemaking.

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

To: Don Clark, Secretary
From: Alyssa O'Connor
Date: May 23, 2013
Re: Proposed Changes to the HSR Rules: Comments to be Placed on the Public Record

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On April 18, 2013, Chairwoman Edith Ramirez and FTC staff met with counsel for the Pharmaceutical Research and Manufacturers of America ("PhRMA") to discuss proposed amendments to the Hart-Scott-Rodino ("HSR") premerger notification rules that address patent licensing transactions in the pharmaceutical industry.[1]

During the meeting, PhRMA counsel provided an overview of the organization's legal and policy concerns with the Notice of Proposed Rulemaking ("NPRM"). Counsel argued that the HSR Act is a law of general application that permits statutory exceptions but not affirmative targeting of a specific industry. Counsel stated the HSR Act's legislative history reinforces this assessment of the Act's scope. Counsel also asserted that the NPRM does not comply with Section 553 of the Administrative Procedure Act because the NPRM (1) does not include a reasonable explanation or factual basis of harm for why the transactions in question are anticompetitive; and (2) inappropriately discriminates against the pharmaceutical industry without justification or explanation.

PhRMA's counsel also raised policy concerns with the NPRM. First, counsel argued that the Commission should not enact what PhRMA views as discriminatory antitrust policy when the agency promotes nondiscrimination internationally. Next, counsel again asserted the NPRM lacks a factual record. Counsel mentioned that there was no investigation or study justifying the NPRM's proposed changes and opined that the agency's statement of subject matter expertise is an inadequate substitute. Third, counsel returned to the legislative history of the HSR Act and argued that different HSR rules for different industries are inconsistent and confusing. Finally, counsel expressed the view that the rulemaking proceedings were not transparent. Given their concerns, PhRMA counsel requested that the Commission refrain from adopting the proposed changes.

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[1] In attendance were James M. Spears, Executive Vice President & General Counsel, PhRMA; Melissa Kimmel, Assistant General Counsel, PhRMA; and James Rill and Stephen Weissman of Baker Botts, LLP (outside counsel to PhRMA). In addition to Chairwoman Ramirez, Lisa Kimmel, Attorney Advisor, and Alyssa O'Connor, Honors Paralegal, participated on behalf of the FTC.

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June 7, 2013

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BY HAND DELIVERY & REGULAR MAIL

Honorable Joshua D. Wright
Commissioner
Federal Trade Commission
600 Pennsylvania Avenue, NW
Washington, DC 20580

Re: HSR IP Rulemaking Project No. P989316 – Response to Commissioner Wright's Request for Information About Costs

Dear Commissioner Wright:

Thank you for meeting with us recently regarding the above-referenced Notice of Proposed Rulemaking, which singles out the pharmaceutical industry for increased burdens under the Hart-Scott-Rodino Antitrust Improvements Act ("HSR Act"). As we explained both at the meeting and in our earlier written comments, the principal objections of our client, the Pharmaceutical Research and Manufacturers of America ("PhRMA"), to the proposed rulemaking are that the HSR Act does not authorize the FTC to increase the Act's coverage and burden to only a single industry to the exclusion of all others, nor does the proposed rulemaking comply with the Administrative Procedures Act ("APA"). During our meeting, we raised the additional concern that the proposed rulemaking, if adopted, would inflict a number of substantial and unnecessary costs on the pharmaceutical industry, especially when viewed against the absence of any articulated and demonstrated need for the proposed rule. You asked us to provide you with additional information about these projected costs.

Since the meeting, we have undertaken to further quantify the costs based on information from PhRMA members as well as on a review of our firm's own experience in preparing and filing HSR forms, particularly for pharmaceutical companies. The costs that businesses face when required to file HSR forms with the FTC and DoJ include filing fees, costs associated with collection of information and documents necessary for completion of the HSR form (including attachments such as so-called "Item 4(c)" and "Item 4(d)" documents), and costs associated with responding to requests by the agency for additional information.

- **Filing Fees**: As summarized in our earlier comments, the current HSR filing fee per transaction ranges from $45,000 to $280,000, depending on the value of the transaction. Based upon the Commission's estimate of an annual increase of 30 HSR reportable

transactions as a result of the proposed rulemaking,[1] companies subject to the proposed HSR rule amendments each year would be forced to expend between $ 1,350,000 to $ 8,400,000 in increased filing fees alone.

- **Costs Associated with Preparation of HSR Forms, Including Document Collection and Review.** Based on information we obtained in responding to your question, we estimate that, on average, the costs associated with preparation of the HSR forms, including collection and review of so-called Item 4 documents, amount to $40,000 - $60,000 in legal fees and direct costs for each party to the transaction. This amount does not include the substantial costs incurred as a result of management time and effort involved in document collection and review, which are difficult to quantify but can be a significant burden and distraction for companies.

  The $40,000 - $60,000 per party, per transaction estimate can be lower (≈ $15,000 - $20,000) in straightforward transactions; *e.g.*, where the number of Item 4 custodians and potential documents is very small and where license valuation for HSR purposes is not an issue. But those situations are relatively rare. In our experience and based upon feedback from PhRMA members, the significant costs associated with the preparation and submission of HSR forms in the pharmaceutical industry is a function of various factors. These factors include the number of individuals frequently considered "officers" for purposes of Item 4; the often large, multi-function teams that are involved in investigating, assessing, negotiating and approving licensing transactions; the difficulty of determining fair market valuation for HSR purposes based upon the often uncertain nature of future milestone payments, royalty streams, and other financial elements typical of pharmaceutical licensing transactions; and the thoroughness and care expended by pharmaceutical companies to search for, review, and collect Item 4(c) and Item 4(d) documentation.

- **Responding to Additional Information Requests.** It is common for the Commission staff reviewing a proposed HSR filing to ask for additional information and materials from parties before the end of the initial 30-day waiting period. Such requests can range widely based on, among other factors, staff's familiarity with the businesses or business segments of the transacting parties. Similarly, costs associated with responding to staff's inquiries can vary significantly based upon the scope and extent of the information requested, as well as whether such information is readily available. While it is difficult to quantify an average cost figure, it is not uncommon in our experience for filing parties to expend many thousands of dollars responding to requests for information during the 30-day waiting period after the forms are filed.

  Furthermore, when an antitrust agency issues a Request for Additional Information (a "Second Request") pursuant to 15 U.S.C. 18a(e), the costs associated with an HSR filing increase exponentially. According to estimates compiled by the Antitrust Section of the

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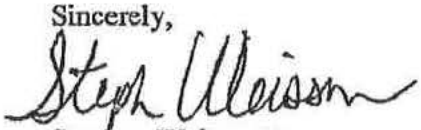
[1] *See* PhRMA Comments, dated October 25, 2012, at 2-3 n. 3 (citing Notice of Proposed Rulemaking, 77 FED. REG. 50,060).

American Bar Association in 2006, compliance with a Second Request on average costs about $5 million per transaction and up to $20 million in very complex cases.[2] According to a recent HSR Annual Report, in FY 2011 the agencies issued Second Requests in 8% of HSR-reportable transactions involving the chemical, including pharmaceutical, manufacturing industries.[3] While the Notice of Proposed Rulemaking provides no basis to conclude that any of the pharmaceutical licensing transactions at issue would raise competitive concerns so as to trigger a Second Request, simply applying this 8% to the 30 additional HSR-reportable transactions estimated by the FTC yields between 2 and 3 additional Second Requests. An additional two to three Second Requests per year would result in approximately $10 million to $15 million in increased annual costs to businesses, on average.

Moreover, the above costs do not account for the potential distortion to the marketplace that would result from the proposed rulemaking. The proposed rule not only would incent companies to structure their transactions less efficiently to avoid licensing transactions that might most effectively allocate the investment, risk, and shared benefits of development and commercialization of intellectual property. As we mentioned during our meeting, it also proposes to impose added regulatory cost and delay on early stage pharmaceutical research and development so as to further discourage the already diminishing funding of such projects. *See "Vital Signs: The Crisis in Investment in the U.S. Medical Innovation and the Imperative of FDA Reform,"* NVCA and MedIC, Oct. 2011, http://www.nvca.org/vital_signs_data_slides.pdf .

We hope this responds to your request for additional information. Please do not hesitate to contact us if you have any questions or would like additional information. Thank you your consideration.

Sincerely,



Stephen Weissman

cc: Chairwoman Edith Ramirez
Commissioner Judith Brill ✓
Commissioner Maureen K. Ohlhausen
James F. Rill
James M. Spears
Melissa B. Kimmel

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[2] Comments of the Section of Antitrust Law, ABA, in Response to the Antitrust Modernization Commission's Request for Public Comment Regarding the HSR Second Request Process (2006), at 4.

[3] *See* Hart-Scott-Rodino Annual Report, Fiscal Year 2011, at 6 *available at* http://www.ftc.gov/os/2012/06/2011hsrreport.pdf.