Supplemental Supporting Statement for
Final Amendments to
Hart-Scott-Rodino (Premerger Notification) Rules and Report Form
16 C.F.R. Parts 801-803
(OMB Control No. 3084-0005)

The Federal Trade Commission ("FTC" or "Commission") seeks OMB clearance for revised information collection requirements under its Hart-Scott-Rodino Antitrust Improvements Act Rules ("HSR Rules") and corresponding Premerger Notification and Report Form for Certain Mergers and Acquisitions ("Notification and Report Form").

1. and 2. Necessity for and Use of the Information Collection

Section 7A of the Clayton Act ("Act"), 15 U.S.C. § 18a, as amended by the Hart-Scott-Rodino Antitrust Improvements Act of 1976, Pub. L. 94-435, 90 Stat. 1390, requires parties of a certain size contemplating large acquisitions to file notification with the FTC and the Assistant Attorney General in charge of the Antitrust Division of the Department of Justice ("Assistant Attorney General") (together, the "Agencies") and wait a specified time period before consummating the transaction. Section 7A(d) of the Act states that the Commission, with the concurrence of the Assistant Attorney General:

> shall require that the notification required under subsection (a) [of the Act] be in such form and contain such documentary material and information relevant to a proposed acquisition as is necessary and appropriate to enable the Federal Trade Commission and the Assistant Attorney General to determine whether such acquisitions may, if consummated, violate the antitrust laws; and . . . prescribe such other rules as may be necessary and appropriate to carry out the purposes of . . . [the Act].

The Commission is amending sections 801.1 and 801.2 of the HSR Rules to reflect the longstanding staff position that a transaction involving the transfer of exclusive rights to a patent in the pharmaceutical industry, which typically takes the form of an exclusive license, is potentially reportable under the Act. The rule amendments also clarify the treatment of retained manufacturing rights. The amended HSR Rules define and apply the concepts of "all commercially significant rights," "limited manufacturing rights," and "co-rights" in determining whether the rights transferred with regard to a patent in the pharmaceutical industry constitute a potentially reportable asset acquisition.

The HSR Act is intended to allow the Agencies to review significant transactions to determine, prior to consummation of a transaction, if it is anticompetitive. Like patent sales, exclusive patent licenses prevalent in the pharmaceutical industry are asset acquisitions that may produce anticompetitive effects. The rule amendments ensure that exclusive patent licensing transactions in the pharmaceutical industry are reported when they meet the requisite minimum thresholds, enabling the agencies to assess under the HSR Act the competitive impact of these transactions. Thus, the amended reporting requirements are necessary to effect the purposes of the HSR Act.

3. Use of Information Technology

Consistent with the Government Paperwork Elimination Act, 44 U.S.C. § 3504 note, the Notification and Report Form is available electronically and payment may be made by electronic funds transfer. Furthermore, electronic submission of the Notification and Report Form was introduced in 2006.[1] Due to technical reasons, however, electronic submission has been suspended.

4. Efforts to Identify Duplication

Most of the information required by the Notification and Report Form is not available from other government agencies or public sources. Prior to passage of the Act, efforts were made to obtain information that is necessary for a preliminary antitrust analysis from other sources but these sources proved to be inadequate for law enforcement purposes. The information that was available was not the type of information needed nor was it available on a timely basis. It was the lack of alternative sources of information and the need to receive information quickly that motivated Congress to enact Section 7A.

5. Efforts to Minimize Small Organization Burden

The Act and HSR Rules are designed to have minimal impact on small entities. First, for a transaction to trigger a reporting requirement under the Act, the transaction must be valued at more than $50 million (as adjusted).[2] Such a high transaction threshold will typically not catch most transactions involving small entities. In addition, the Act requires that in cases where the transaction is valued at greater than $50 million (as adjusted) but $200 million or less (as adjusted), one party to the transaction must have at least $10 million (as adjusted) in sales or assets in order to trigger reporting requirements. This size of person test also ensures that the Act does not regularly reach small entities.[3]

The FTC recognizes that some of the affected manufacturers subject to the rule amendments may qualify as small businesses under the relevant Small Business Administration ("SBA") thresholds, which for the pharmaceutical industry are based on number of employees and not on annual receipts. However, the FTC does not expect that the requirements specified in the rule amendments will have a significant impact on these businesses. A business falling within the

---

[1] 71 Fed. Reg. 35,995 (June 23, 2006).

[2] The 2000 amendments to the Clayton Act require the Commission to revise certain reportability thresholds annually, based on the change in the level of gross national product. The minimum size of transaction threshold as of February 11, 2013, is $70.9 million with one person having sales or assets of at least $141.8 million and the other person having sales or assets of at least $14.2 million.

[3] Of the 6,487 transactions filed over the last five years, only 66 of this total number were related to exclusive licenses, and all involved the pharmaceutical industry. Of these 66 transactions, only one involved an entity that did not have reportable sales or assets of $10 million or more (as adjusted).

SBA thresholds that is subject to a reporting obligation as a result of the rule would in most instances be filing under the Act as the acquired person in the context of an asset transaction and would therefore be submitting less information. For example, an acquired person in an asset acquisition is not required to complete Item 6 of the Form. In addition, the acquired person in the types of licensing transactions covered by the rule amendments would typically not report any revenues in Item 5 of the Form because the product has not yet generated any revenues, and this would mean no requirement to report overlaps in Item 7 of the Form. The acquired person would thus be required to submit only annual financial statements in Item 4(b) of the Form (assuming it is not publicly traded) and relevant transaction documents in Items 4(c) and 4(d) of the Form. Although there is some burden associated with gathering documents responsive to Items 4(c) and 4(d) of the Form, most of that burden will fall on the buyer with whom these kinds of documents typically reside. The buyer also typically pays the filing fee associated with the notification requirement.

6. Consequences to Program if Collection Done Less Frequently

The Act requires parties of a certain size who are contemplating proposed acquisitions of a specified minimum amount to file a notification report with the Commission and the Antitrust Division before consummating the transaction. Collection of information on a less frequent basis would be contrary to the Act since the enforcement agencies must review proposed acquisitions before they are consummated. Moreover, individual firms, not the enforcement agencies, control the frequency of filing.

7. Circumstances Requiring Collection Inconsistent with Guidelines

The collection of information in the HSR Rules and the Notification and Report Form is consistent with all applicable guidelines contained in 5 C.F.R. § 1320.5(d)(2).

8. Public Comments/Consultation outside the Agency

The HSR Rules and the Notification and Report Form are a product of public comments received in the rulemaking process and informal consultations with the affected public. The proposed amendments and the associated PRA burden analysis were published for public comment on August 20, 2012 (77 Fed. Reg. 50,057), pursuant to 5 C.F.R. §§ 1320.8(d)(3) and 1320.11.

The proposed rule recommended amendments to 16 C.F.R. §801.1 and §801.2 to clarify the longstanding staff position that a transaction involving the transfer of exclusive rights to a patent or a part of a patent in the pharmaceutical industry, which typically takes the form of an exclusive license, is potentially reportable under the Act. The proposed rule defined and applied the concepts of "all commercially significant rights," "limited manufacturing rights," and "co-rights" in determining whether the rights transferred with regard to a patent or a part of a patent in the pharmaceutical industry constitute a potentially reportable asset acquisition under the Act.

Under the proposed rule, the retention of limited manufacturing rights and co-rights does not affect whether the transfer of all commercially significant rights has occurred.

The final rule adopts the above-noted amendments.

The following submitted public comments on the cost burdens of the proposed amendments:

1. Pharmaceutical Research and Manufacturers of America ("PhRMA") (Baker Botts LLP, Stephen Weissman) (10/25/2012)[4]
2. Antonio Burrell (10/26/2012)

These communications and the FTC's responses are discussed below under items 12 and 13 of this document.

9. Payments of Gifts to Respondents

Not applicable.

10. and 11. Assurances of Confidentiality/Matters of a Sensitive Nature

The enforcement agencies are prohibited by Section 7A(h) of the Act from disclosing to the public information and documentary materials filed under the premerger notification program "except as may be relevant to an administrative or judicial action or proceeding." The Commission has implemented procedures to assure the confidentiality of the submitted information. Additionally, the Notification and Report Form does not request any information of a sensitive, personal nature that is commonly considered private.

12. Estimated Annual Hours Burden: 56,423 hours

PNO staff reviewed letters from outside counsel discussing non-reportable transactions that would be reportable under this proposal. The average annual number of letters over the past five years was 21. Consultations with several outside practitioners who are heavily involved in analyzing HSR reportability for patent licensing in the pharmaceutical industry indicate that there are an estimated 9 additional transactions per year that fall into this category and are not confirmed by letter with staff.

Consequently, PNO staff estimates that there will be an increase of 30 transactions per year requiring non-index HSR filings due to the rule change.[5] The outside practitioners who were

[4] PhRMA also provided additional information to the Commission in a letter dated June 7, 2013 ("PhRMA's Supplemental Letter").

[5] Clayton Act Sections 7A(c)(6) and (c)(8) exempt from the requirements of the premerger notification program certain transactions that are subject to the approval of other agencies, but only if copies of the information

contacted by staff agreed that this is a reasonable estimate.[6] As discussed in the analysis below, the estimated total burden hours under the amended HSR Rules would increase from 53,759 hours to 56,423 hours. Applying total burden hours, as revised (56,423) to an assumed hourly wage of $460 for executive and attorney compensation, yields $25,955,000 (rounded to the nearest thousand) in labor costs.

A. Filing Requirements, Including Form Preparation and Document Collection

PhRMA submitted two cost estimates. In its original submission, the commenter stated that the cost associated with preparation and completion of HSR forms for a "straightforward" transaction is at least $15,000 per party. Subsequently, however, the commenter submitted a Supplemental Letter stating that, on average, the cost associated with preparation of HSR forms, including collection and review of documents, is between $40,000 and $60,000 for each party to a transaction, with more straightforward transactions costing in the $15,000-$20,000 range. This assessment is higher than the Agencies' assessment, which is based on an hourly cost estimate derived after consultation with practitioners from the private bar. The FTC's estimate for a standard non-index filing is $16,650 (based on an assumed 37 hours per filing multiplied by $460/hour), and for filings requiring more precise valuation for fee determination purposes, it is $18,400 (based on an assumed 40 hours per filing, multiplied by $460/hour).

In the PNO's experience, PhRMA's Supplemental Letter substantially overestimates the costs of preparing an HSR filing. First, PhRMA's estimate suggests that the cost of preparing the HSR filing would depend in substantial part on the number of people involved in investigating, assessing, negotiating, and approving licensing transactions. In the PNO's experience, however, the competitive impact documents required by the HSR Rules usually reside with a core team of individuals, as not every person with some involvement in the transaction will have the specific documents that must be produced. Indeed, in the PNO's experience, HSR filings for exclusive licensing transactions typically contain fewer documents than company-wide acquisitions or mergers. Moreover, by not differentiating between the acquiring and acquired person, PhRMA's estimate suggests that both parties to a transaction would incur comparable costs. However, the acquired person's costs would be significantly lower, as that person does not have to supply as much information for the HSR form.

---

submitted to these other agencies are also submitted to the FTC and the Assistant Attorney General. Thus, parties must submit copies of these "index" filings, but completing the task requires significantly less time than non-exempt transactions which require "non-index" filings.

[6] The projection focuses on FY2012 to FY2014, a period closely coinciding with the Rule's existing clearance duration.

In addition, PhRMA's original estimate appears to include the costs of valuing the transactions.[7] Parties to an exclusive patent licensing agreement, however, are very likely to conduct a patent valuation as part of their due diligence for the transaction; accordingly, this is not an additional cost of rule compliance. While in some circumstances a more precise valuation would assist in determining whether a filing is required or the appropriate filing fee, such a more precise estimate would be needed only where the existing estimate is a range that straddles the minimum filing threshold or two filing fee categories.

While the FTC's per transaction estimate is lower than the estimates in PhRMA's Supplemental Letter, the FTC's estimate of the industry-wide incremental costs of filing due to the rule is roughly comparable to PhRMA's original estimate. PhRMA's original estimate stated that the proposed rule amendments would increase the costs of form preparation and document collection, cumulatively, by more than $1,000,000.[8] By comparison, in the NPRM, the FTC stated that, rounding upward the number of expected new filings, this rule would increase the cost burden of the existing Rules by a total of $1,225,000. Without such upward rounding, the estimated burden increase is smaller. Calculating the burden under the assumption that the rule will result in the filing of 30 additional transactions per year, or 60 additional filings, with 10 filings requiring a more precise valuation, the estimated increase in the industry-wide burden is 2,250 hours per year, [9] or $1,035,000 using a rate of $460 per hour.[10] Nevertheless, out of an abundance of caution and in light of the comments, the Commission retains its original, larger estimate that rounds up the projected effect of the rule and assumes more simply that the rule will increase the total number of non-index filings per year from the currently-cleared estimate of 1,428 to 1,500. This corresponds to an estimated 2,664 additional burden hours ((1,500 non-index filings - currently cleared 1,428 non-index filings per year) x 37 hours per filing = 2,664) with associated labor costs of approximately $1,225,000 (2,664 hours x $460/hour).

---

[7] Mr. Burrell also expressed concern that the Rule would add administrative costs to pharmaceutical deals, including the costs of analyzing whether the transaction is reportable and the costs of conducting a valuation of the acquisition.

[8] PhRMA comment at 14.

[9] Based on a review of valuations for prior licensing transactions, the FTC estimates that about one third of the 30 added transactions will require a more precise valuation, with one party per transaction conducting such valuation. [(50 filings x 37 burden hours) + (10 filings requiring a more precise valuation x 40 burden hours) = 2,250 burden hours]. Even assuming, however, that two thirds of the transactions would require a more precise valuation, the total estimated burden hours are not significantly higher. [(40 filings x 37 burden hours) + (20 filings requiring a more precise valuation x 40 burden hours) = 2,280].

[10] As noted above, because the acquired person (or licensor) would be submitting less information for the HSR form than the acquiring person (or licensee), it would have a smaller burden than the acquiring person. Nevertheless, for purposes of this rulemaking, the FTC will assume that, like the acquiring person, the acquired person will incur a burden of 37 hours per filing.

B. Second Requests

PhRMA also asserts that the costs of responding to additional information requests ("second requests") should also be included in the PRA estimates.[11] "Second requests," however, are not a "collection of information" subject to the PRA because they are issued "during the conduct of an . . . investigation . . . involving an agency against specific individuals or entities." *See* 44 U.S.C. 3518(c)(1)(B)(ii); 5 C.F.R. 1320.4(a)(2).

13. Estimated Capital/Other Non-Labor Costs Burden

PhRMA asserts further that filing fees associated with reporting a transaction covered by the HSR Act should be included in the PRA cost estimates.[12] Filing fees, however, are not part of a respondent's burden of a PRA "collection of information" as they are not resources expended "to generate, maintain, or provide information" regarding the transactions to the Agencies, *see* 44 U.S.C. 3502(2), but rather are paid pursuant to an accompanying, additional statutory requirement in order to offset the Agencies' expenses. *See* Pub. L. 106–553, 114 Stat. 2762.

PNO staff believes that the final amendments will impose minimal or no additional capital or other non-labor costs, as businesses subject to the HSR Rules generally have or obtain necessary equipment for other business purposes. Staff believes that the above-noted requirements necessitate ongoing, regular training so that covered entities stay current and have a clear understanding of federal mandates, but that this would be a small portion of and subsumed within the ordinary training that employees receive apart from that associated with the information collected under the HSR Rules and the corresponding Notification and Report Form.

14. Estimated Cost to Federal Government

The total cost to the Commission for the premerger notification program for fiscal year 2012 was approximately $3.4 million. This includes the cost of administering the overall program, a responsibility with which the Commission is charged under the Act. The costs cover professional and clerical salaries and expenses for the performance of an initial antitrust review of the filings submitted to the Commission.

In fiscal year 2012, the Antitrust Division of the U.S. Department of Justice expended approximately $323,000 in salary and overhead costs in support of the initial processing of premerger notifications by its Premerger Office. The Department of Justice does not allocate costs of initial substantive review to the program.

Thus, the total cost to the federal government is approximately $3,723,000.

---

[11] *Id.* at 14 – 15.

[12] *Id.* at 14.

15. Program Changes or Adjustments

As discussed above, the Commission assumes that the rule will increase the number of non-index filings from 1,428 to 1,500 per year, which at 37 hours each would yield an incremental burden of 2,664 hours ((1,500 - 1,428) x 37 hours per non-index filing). Thus, added to the existing base of 53,759 hours, cumulative burden under the final amended HSR Rules totals 56,423 hours.

16. Statistical Use of Information

Collection of information under the Act is for law enforcement purposes. There are no plans to use complex analytical techniques on information collected from the Notification and Report Form. The FTC does include the total number of filings in an annual report describing the premerger notification program. This report also indicates the number of filings by value of the transaction, the sales and assets of the parties, and industry sector, but no other information from the Notification and Report Form is included in the report.

17. Requesting Permission Not to Display Expiration Date for OMB Approval

Not applicable; the OMB control number and expiration date appears in the upper right-hand corner of page 1 of the Notification and Report Form.

18. Exceptions to Certification

Not applicable.