Working Party No. 3 on Co-operation and Enforcement

Methodologies for Conducting Market Studies - Note by the United States

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More documents related to this discussion can be found at www.oecd.org/daf/competition/market-study-methodologies-for-competition-authorities.htm.

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1. Introduction

1. Market studies are an important component of the policy efforts of the U.S. Federal Trade Commission (“FTC”) and the Department of Justice Antitrust Division (“Department”) (collectively, the “Antitrust Agencies”). While the Antitrust Agencies’ primary responsibility is enforcing the antitrust laws, they complement this work with a wide variety of additional activities designed to promote competition, including: empirical research; workshops; advocacy filings; *amicus curiae* briefs; public reports; and testimony before Congress. The Antitrust Agencies conduct market studies to support these efforts. These studies allow them to develop a deep understanding of sectors and business practices that forms the basis for policy recommendations. These studies also serve an additional independent function: they allow the Antitrust Agencies to develop a factual understanding of business practices that they can share with other federal government agencies, state and local governments, marketplace participants, and other stakeholders.

2. The Antitrust Agencies conduct hearings and workshops to educate themselves and the public on market conditions and will frequently use these workshops as the basis to issue reports. Often, they do so jointly. The FTC Act also explicitly provides the FTC with the authority to research “the organization, business, conduct, practices and management” of persons and of corporations, and to make public portions of the information it obtains where disclosure would serve the public interest.¹ In addition, the FTC has statutory authority to compel the production of information to conduct market studies.²

2. Information Gathering

3. The Antitrust Agencies have a variety of tools at their disposal to gather information for market studies. As mentioned above, the FTC has the authority to use compulsory process,³ and both Antitrust Agencies frequently hold hearings and workshops.⁴ In addition to these tools, the Antitrust Agencies may also use information

¹ 15 U.S.C. §§ 46(a), (f).
voluntarily supplied by firms. The Antitrust Agencies may also supplement these efforts with data obtained from commercial sources or from other government agencies.

4. The Antitrust Agencies use data collection techniques appropriate for the type of study they undertake. Most projects begin with an extensive literature review of academic, industry, and other publications to determine the scope of existing knowledge including the types of data available for analysis. When designing a study, the Antitrust Agencies take into account factors such as the types of questions they are attempting to answer and the time constraints for completing the study. In addition, when the needs of the study require the collection of confidential information, statutes and agency rules provide specific confidentiality protections. The Antitrust Agencies protect the confidentiality of the information by reporting it only on an aggregate or anonymous basis.

2.1. Workshops

5. Workshops are a useful tool for learning about a market from experts and stakeholders. The workshop record often includes both transcripts of live presentations and written comments submitted in response to a public call for comment. Workshops use a variety of formats that include panels, roundtable discussions, and presentations. The Antitrust Agencies frequently solicit diverse viewpoints on the subjects at issue and invite representatives of business, academics and policy-makers from other federal and state agencies. Often, interested parties from varied backgrounds also submit written comments.

6. The Antitrust Agencies often issue a public report summarizing the workshop record. One recent example is the FTC’s November 2016 report on the “Sharing


For example, for the Authorized Generic Drug study, FTC staff used the Food and Drug Administration’s National Drug Code database and its List of Authorized Generic Drugs in combination with other sources to identify drug products relevant to its study and then used that information to identify the firms which sold those drugs. AG REPORT, supra note 3, at H-3. In the Patent Assertion Entity study, FTC staff supplemented firm-supplied data regarding the patents that they held with bibliographic data from the U.S. Patent and Trademark Office. PAE REPORT, supra note 3, at 126. For the Authorized Generic Drug study, FTC staff also supplemented firm-supplied data with commercially available sales and pricing information. AG REPORT, supra note 3, at I-1.

See, e.g., 15 U.S.C. § 46(f) (trade secrets and confidential commercial or financial information obtained by the FTC); 15 U.S.C. § 57b-2(d)(1)(B) (same); 15 U.S.C. § 57b-2(c) (information marked as confidential by the person supplying it); 16 C.F.R. §§ 4.10(a)(2), (e), (g)(3).

See, supra note 4.
Economy,” based on a workshop held in June 2015. The FTC also received over 2,000 public comments. The FTC selected participants to provide varying viewpoints. For example, one panel included representatives from new entrants, such as Uber Technologies and Airbnb, as well as representatives from trade associations representing incumbents, such as the American Hotel and Lodging Association, and speakers who could provide the perspective of regulators, such as the former Chairman of the New York City Taxi and Limousine Commission. The workshop report summarized the contributions from these diverse sources of information and included chapters discussing the economics of sharing economy marketplaces, the use of trust mechanisms in the sharing economy, and the impact of regulation in the sharing economy. It also included a separate chapter focusing on regulation in the transport and lodging sectors.

7. Another example is the Department’s May 2012 report on competition and agriculture, based on a series of five public workshops the Department held jointly with the Department of Agriculture in 2010. Workshop panels focused on different segments of the agriculture industry, such as dairy, poultry, and livestock, and one workshop examined margins at various levels of the supply chain across several agricultural industries. These workshops were held in cities across the United States in an effort to maximize participation and the diversity of perspectives. Both agencies sought to learn from the real-world experiences of farmers, processors, members of cooperatives, academics, and others who work in agriculture, as well as to advance the dialogue on legal and economic learning on issues in agriculture. The workshops attracted as many as 1,700 attendees and 18,000 public comments. Participants raised a range of concerns, including, but not limited to, threatened harm from anticompetitive mergers, high market concentration, monopsony power, market transparency and captive supply, and market manipulation. The report highlighted these concerns, and it addressed how certain specific practices in agriculture markets can harm producers and consumers in ways that violate the antitrust laws, but it also recognized that some concerns expressed by commenters about these industries are beyond the scope of the antitrust laws.


10. Id; THE “SHARING” ECONOMY, supra note 4, at 2.

11. Id.


14. Id.

15. See AGRICULTURE REPORT, supra note 4.


17. See AGRICULTURE REPORT, supra note 4, at 3.

18. Id. at 4-15.

19. Id. at 15-23.
8. Sometimes, the Antitrust Agencies prepare a public report based upon both the workshop record as well as new empirical research. The FTC’s 2005 report on potential barriers to Internet commerce in contact lenses is one example.20 The FTC conducted its own survey of contact lens prices and availability, comparing online contact lens sellers with retailers near Washington D.C.21 The report presented the findings of that survey as well as a summary of the workshop record and included chapters providing a description of the contact lens industry, discussion of relationships between manufacturers and distributors, and discussion of the impact of regulations and licensing requirements on competition.22

9. In addition, workshop presentations sometimes uncover areas where further empirical research is needed, and the Antitrust Agencies will conduct a separate market study in response. This was the case with the FTC’s 2016 Patent Assertion Entity report, which summarized a market study conducted between 2013 and 2016.23 That market study followed two workshops investigating patent assertion entity (PAE) activity. The Antitrust Agencies held the first workshop over several days in 2008 and 2010, and the FTC summarized the record in its 2011 Evolving IP Marketplace report.24 The workshop considered a broad set of issues regarding the secondary market for patents and patent policy. At the workshop, panelists spoke about how PAEs were a new class of firms trading in the secondary market for patents.25 In December 2012, the Antitrust Agencies conducted a second joint workshop focusing solely on PAE behavior.26 They received presentations and submissions from academics, patent lawyers, trade associations, and representatives of firms involved in patent licensing.27 Participants identified that a lack of empirical data frustrated the analysis of the impact of PAE behavior on competition and innovation.28 They indicated that this was due in large part to the fact that most PAE transactions were non-public and confidential. This observation motivated the FTC’s use of compulsory process to obtain non-public data by conducting a market study.

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21 Id. at 2, 36.
22 Id. at 3-4.
23 The Patent Assertion Entity study is described in greater detail in the Case Studies section. See infra § 4.1.
25 Id. at 60-62.
27 Id.
28 PAE REPORT, supra note 3, at 36.
2.2. Compulsory Process

2.2.1. Orders Pursuant to Section 6(b) of the FTC Act

10. Many of the FTC’s market studies that include original empirical research make use of the Commission’s statutory authority to use compulsory process. This authority, set out in Section 6(b) of the FTC Act, allows the FTC to use compulsory process for research purposes that are independent of law enforcement.²⁹

11. When the public interest warrants, the Commission may issue a resolution authorizing the use of a 6(b) Order.³⁰ Upon receipt, a recipient of a 6(b) Order has a set period of time in which to submit its response or file a petition to the Commission to quash or limit the 6(b) Order.³¹ If a party receiving a 6(b) Order fails to respond, the Commission may issue a Notice of Default that it can enforce in federal court.³²

12. If the FTC intends to send 6(b) Orders to ten or more persons, the Paperwork Reduction Act typically also requires that the White House Office of Management and Budget (OMB) approve the orders.³³ As part of the process to obtain OMB approval, the FTC must provide public notice of its intended study and solicit public comment. Commenters are invited to “evaluate whether the proposed collection of information … shall have practical utility,” “enhance the quality, utility, and clarity of the information to be collected,” and “minimize the burden of the collection of information on those who are to respond.”³⁴ The Paperwork Reduction Act requires that the FTC solicit public comment twice prior to seeking OMB approval. Sometimes, the FTC will publish a draft of the specific questions that it intends to include in the 6(b) Order in the public notice and revise its questions in response to public comment.³⁵ This enables the FTC to incorporate feedback from a wide variety of stakeholders.

13. In addition to gathering stakeholder feedback through the Paperwork Reduction Act process, the FTC often performs other research to draft well-designed 6(b) Orders. For example, in the FTC’s study of pharmacy benefits managers, the FTC used a two-stage process whereby it first used a 6(b) Order to collect high-level business documents and aggregate data from a group of firms, and then followed up with a second 6(b) Order

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²⁹ 15 U.S.C. § 46(b). Section 6(b) of the FTC Act allows the Commission “to require, by … special orders, persons, partnerships, and corporations, engaged in or whose business affects commerce… to file with the Commission in such form as the Commission may prescribe … reports or answers in writing to specific questions.”

³⁰ Id.; 16 C.F.R. § 2.7(a), (d).

³¹ 16 C.F.R. § 2.10.

³² 16 C.F.R. § 2.13.


requesting transactions-level data from a smaller group of firms.\textsuperscript{36} In other studies, the FTC had to perform significant research and analysis to identify the recipients of the 6(b) Order. In various studies, the FTC has requested information from either all firms active in a market during a specified time\textsuperscript{37} or a selection of firms representing different firm sizes.\textsuperscript{38}

14. The FTC often streamlines questions in the 6(b) Order as it receives stakeholder feedback and refines its understanding of the information necessary to achieve its research objective. For example, after receiving public comment on a draft 6(b) Order for the Patent Assertion Entity study, the FTC revised a request for “all documents Relating to the Firm’s Acquisitions” to the more focused request for “agreements … relating to any Acquisitions” as well as “studies, analyses, and reports which were prepared by or for any officer(s) or director(s) of a corporate entity … or presented to any Person outside the Firm.”\textsuperscript{39} Such streamlining helps the FTC to limit the burden that responding to 6(b) Orders places on recipients, while balancing the need for detailed information with the likelihood that a question will be understood and provide consistent responses from across firms. This also helps to minimize incentives for 6(b) Order recipients to petition to limit the order.

15. Although the FTC can compel the production of confidential information using 6(b) Orders, the FTC follows specific legal protections for confidential information collected.\textsuperscript{40} Section 6(f) of the FTC Act provides that, with certain exceptions, “the Commission shall not have any authority to make public any trade secret or any commercial or financial information which is obtained from any person and which is privileged or confidential.”\textsuperscript{41} If a party submitting material in response to a 6(b) Order identifies specific material as confidential, the material is protected from disclosure, subject to limited statutory exceptions.\textsuperscript{42} If an exception applies, the submitter generally is provided notice before disclosure.

\section*{2.2.2. Types of Information Obtained}

16. 6(b) Orders typically require that recipients answer questions in writing.\textsuperscript{43} 6(b) Orders also typically require that recipients produce relevant documents and business records. The FTC typically does not compel the production of testimony using 6(b)

\textsuperscript{36} FED. TRADE COMM’N, PHARMACY BENEFIT MANAGERS: OWNERSHIP OF MAIL-ORDER PHARMACIES iii-iv (2005), \url{https://www.ftc.gov/reports/pharmacy-benefit-managers-ownership-mail-order-pharmacies-federal-trade-commission-report}.

\textsuperscript{37} See AG REPORT, supra note 3, at 36-37, H-4-6.

\textsuperscript{38} PAE REPORT, supra note 3, at 39.


\textsuperscript{41} See 15 U.S.C. § 46(f).

\textsuperscript{42} See 15 U.S.C. § 57b-2(c), (d); 16 C.F.R. §§ 4.10(a)(2), (e), (g)(3). Trade secrets and confidential commercial information are exempt from public disclosure under the Freedom of Information Act 5 U.S.C. 552(b)(4).

\textsuperscript{43} 16 C.F.R. § 2.7(d).
Orders, although recipients frequently voluntarily discuss their responses with FTC staff to clarify the questions and their answers.

17. Sometimes, the FTC will request that recipients provide their responses in two parts: a document containing narrative responses and an electronic spreadsheet containing quantitative data in a structured format. The spreadsheet generates responses in uniform format to facilitate comparison across responding firms. The spreadsheet also reduces the effort required to comply by requesting short answers. For example, in the Patent Assertion Entity study, “wherever practical, the FTC [asked] for short responses that can be provided as spreadsheet entries, such as dates, dollar amounts, and ‘yes’ or ‘no’ responses.”

18. Documents (including copies of agreements), narrative responses and discussions with recipients are sources of qualitative information. Qualitative information is often useful to provide context and general background for firms’ business practices. This is useful in market studies exploring industries that are not well understood as it provides context for quantitative data. In addition, qualitative data often can shed light on the motivations and intent of firms. The Authorized Generic (AG) Drug study is an example of how this can augment quantitative data: the FTC used quantitative data to determine that branded pharmaceutical manufacturers’ sale of AG drugs had the effect of lowering prices for generic drugs and the FTC used qualitative data to study whether the anticipated price effect factored into generic manufacturers’ decision making regarding whether to enter the market.

19. Qualitative data often provides analytical flexibility. It can provide answers to questions that the FTC may not have anticipated when drafting the 6(b) Order. For example, the Patent Assertion Entity study asked responding firms both to provide copies of all of their patent license agreements and to submit a spreadsheet answering many questions regarding each license agreement. Recipients populated the spreadsheet with data regarding whether each agreement contained certain contract terms such as a field-of-use restriction and a cross-license. In addition, FTC staff reviewed the actual agreements and learned that PAEs used other contract terms that were not the subject of the questions posed in the 6(b) Order.


The Authorized Generic Drug study is described in greater detail in the Case Studies section. See infra §4.4.

See AG REPORT, supra note 3, at 79-80.

PAE REPORT, supra note 3, at 82.

Id. at 86-87.

Id. at 85-86.
20. Spreadsheet responses and documents provide quantitative information. Quantitative information can often serve as a basis for detailed analysis of firm behavior. Lists of products, contracts or transactions allow the FTC to recreate the recipients’ conduct. For example, the Patent Assertion Entity Study requested a list of each patent infringement lawsuit that recipients filed during the study period.\textsuperscript{51} Asking respondents to provide answers to specific questions also provides uniform responses that can be aggregated or compared across firms. For example, the Patent Assertion Entity study asked recipients to describe the technology at issue in each lawsuit that they identified by choosing from a list of sectors such as “Chemical” and “Mechanical.”\textsuperscript{52} Such questions can also be used to gather price and revenue information.

21. There are tradeoffs in requesting quantitative data using a spreadsheet with defined fields as opposed to requesting it in the native format kept by recipients. Using a common format makes comparison across firms easier but may raise challenges when record keeping practices at recipients differ from the format used in the spreadsheet. If possible, exploratory research may be beneficial to understand the record-keeping practices of firms in the market under study, prior to sending the final requests for information. The use of third-party data in uniform formats may be less resource intensive than comparing quantitative data obtained from different firms, but it is often not available in new or changing markets. The data collected also may not be in the format or depth necessary for the Antitrust Agencies.

3. Information Analysis

22. The Antitrust Agencies do not use a particular set of analytical tools in their market studies, but rather perform analyses as appropriate to meet the needs of each particular study. As a result, the Antitrust Agencies have used a variety of analytical approaches. Nevertheless, they frequently employ a case study approach, focusing on understanding the business practices of the specific firms under study.

23. When reporting the results of their analysis, the Antitrust Agencies take care not to divulge confidential business information received from firms under study. Often, the Antitrust Agencies report only aggregate data across all recipients for this purpose. In some cases, they may provide more granular data in their public reports, but only when it can be revealed in a manner that does not allow the reader to divine the confidential information provided by a single study recipient.

24. Some market studies rely heavily on the holistic assessment of qualitative and quantitative information to create a descriptive report of industry practices. This was the case with the Department of Justice’s 2008 \textit{Voice, Video, and Broadband} report, which was based on a November 2007 workshop.\textsuperscript{53} The report relied on a combination of sources: the perspectives of workshop participants such as industry executives, economists, analysts, and local government officials;\textsuperscript{54} submissions and comments;\textsuperscript{55}

\textsuperscript{51} \textit{Id.} at 67-68.

\textsuperscript{52} \textit{Id.} at C-12.

\textsuperscript{53} \textit{See} \textit{VOICE, VIDEO, AND BROADBAND REPORT, supra} note 4.

\textsuperscript{54} \textit{Id.} at 2-3; \textit{see also Public Workshop: Telecommunications Symposium, U.S. DEP’T OF JUSTICE,} \url{https://www.justice.gov/atr/events/public-workshop-telecommunications-symposium}.  

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25. Some market studies gather information on the impact of a specific law or regulation on a market. In addition to soliciting the views of market participants and other stakeholders, the Antitrust Agencies may conduct empirical comparisons of markets subject to restrictive regulation to those that are not. For example, the FTC’s 2003 report on anticompetitive barriers to Internet commerce in wine considered the impact of state regulations prohibiting the direct shipment of wine to consumers. The report included an FTC study comparing the prices and variety of wine offered in a locale that prohibited the interstate direct shipping of wine with the options that would otherwise be available to consumers online. Similarly, the FTC’s 2005 report on potential barriers to Internet commerce in contact lenses considered the impact of state licensing requirements and state restrictions on advertising of Internet contact lens sales. That report included a comparison of prices between bricks-and-mortar retailers in one locale and on-line sellers in order to compare the two retail channels.

26. In addition, the Antitrust Agencies conduct many market studies to answer specific questions about the impact of particular industry practices. Often, Congress requests that the FTC use its compulsory process authority to do so. For example, the FTC’s 2005 report on pharmacy benefit managers was made in response to a

E.g., VOICE, VIDEO, AND BROADBAND REPORT, supra note 4, at 24.
E.g., id. at 13-14, 16, 20 (presenting FCC data and analysis).
E.g., id. at 72-73 (describing DOJ ex parte letter to FCC on entry by telephone companies into the MVPD market).
Id. at 5-30.
Id.
Id. at 31-35.
E.g., id. at 35-48.
Id. at 69-85.
Id. at 87, 90.
Id. at 16.
THE STRENGTH OF COMPETITION IN THE SALE OF RX CONTACT LENSES, supra note 20, at 1-4.
Id. at 36-37.
Congressional request that the FTC investigate the impact that potential conflicts of interest regarding the managers’ ownership of mail-order pharmacies would have on competition and prescription drug prices. When performing such studies, the FTC frequently develops testable questions that illuminate the impact or extent of the conduct under study and collect quantitative data that allows it to observe the conduct of the recipients of the 6(b) Order.

4. Case Studies

27. As noted above, the Antitrust Agencies have conducted market studies in a variety of contexts. This section provides a detailed description of several examples from the Antitrust Agencies’ recent work intended to illustrate the variety of studies they undertake. For simplicity, the remainder of this section will focus on the data collection and analysis in each study as opposed to its conclusions or recommendations.

4.1. Patent Assertion Entity Activity: An FTC Study (October 2016)

28. In October 2016, the FTC released a report on its Patent Assertion Entity study based upon a market study that the FTC started in 2013. PAEs are businesses that acquire patents from third parties and seek to generate revenue by asserting them against alleged infringers. When PAEs assert patents, they tend to do so by either sending a request for royalties to prospective licensees in an attempt to negotiate a patent license (frequently called a “demand letter”) or by filing a patent infringement lawsuit against potential infringers in an attempt to obtain damages or a negotiated settlement. Because PAE activity involves filing lawsuits and/or making unsolicited demands for payment, it has garnered the attention of policymakers. Commentators have provided alternative views on PAEs: that PAEs impose an unnecessary tax upon industry or, alternatively, that PAEs provide needed assistance to innovators licensing or otherwise monetizing their patents.

29. The Antitrust Agencies held a workshop in 2012 to examine PAE behavior. Workshop participants included PAEs, private practitioners, academics, and representatives from businesses in high technology industries. The participants generally agreed that the opaque nature of PAE activity frustrated attempts at empirical research in the sector. In particular, the only publicly available information regarding

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PHARMACY BENEFIT MANAGERS, supra note 36, at i-iii.

See PAE REPORT, supra note 3.

Id. at 15.

Id.

Id. at 28.

THE EVOLVING IP MARKETPLACE, supra note 24, at 7–9.


Id.

See PAE REPORT, supra note 3, at 36.
PAE assertion conduct were the court records when PAEs filed lawsuits.\textsuperscript{76} There was little data on other aspects of PAE behavior or corporate structures. In light of this background, the FTC conducted a market study of PAEs with the goal of taking advantage of its compulsory process authority to obtain a clearer understanding of PAE practices.

30. The FTC identified study subjects using a methodology designed to observe the spectrum of PAE behavior. To do so, it identified a representative group of different sizes of PAEs.\textsuperscript{77} There was no publicly available registry that identified all PAEs and their size or revenues, so the FTC constructed a measure to serve as a proxy for firm size.\textsuperscript{78} The FTC based the measure upon the number of patents that each PAE held and the number of patent infringement lawsuits that each PAE filed.\textsuperscript{79} The FTC acquired this data from two commercial databases that maintained information on PAEs.\textsuperscript{80} After using this data to identify a set of small, medium, and large PAEs for study, the FTC engaged in its own review of public records to confirm that each subject met its definition of a PAE.\textsuperscript{81} Ultimately, the FTC included twenty-two PAEs in the study.

31. The FTC studied the business practices and internal organization of PAEs.\textsuperscript{82} Its 6(b) Orders requested information regarding each recipient’s affiliated companies, including parents, subsidiaries, and other related entities, and asked each recipient to respond on behalf of all of its affiliated companies.\textsuperscript{83} The twenty-two firms included in the study identified over 2,500 affiliated entities.\textsuperscript{84} The 6(b) Orders requested a variety of information regarding how the PAEs acquired and transferred patents, how they organized their patent holdings, and their economic relationships with third parties.\textsuperscript{85} The orders also requested copies of patent acquisition and license agreements.\textsuperscript{86} The FTC prepared a qualitative description based upon this data.

32. The FTC’s qualitative assessment of PAE business models yielded one particularly significant finding, which was that PAE business models fell into two distinct categories: Portfolio PAEs and Litigation PAEs.\textsuperscript{87} Portfolio PAEs negotiated licenses covering large portfolios, often containing hundreds or thousands of patents, frequently without first suing the alleged infringer.\textsuperscript{88} Litigation PAEs typically sued potential licensees and settled shortly afterward by entering into license agreements with

\textsuperscript{76} Id. at 38.
\textsuperscript{77} Id.
\textsuperscript{78} Id.
\textsuperscript{79} Id.
\textsuperscript{80} Id. at 38-39.
\textsuperscript{81} Id. at B-10 – 14.
\textsuperscript{82} Id. at Ch. 2.
\textsuperscript{83} Id. at C -2.
\textsuperscript{84} Id. at 40.
\textsuperscript{85} Id. at App. C.
\textsuperscript{86} Id. at App. C.
\textsuperscript{87} Id. at 3-4.
\textsuperscript{88} Id.
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89 The FTC did not anticipate this finding when it initiated the study; rather, it observed that the responding firms fell into two categories based upon two quantitative measures: the volume of patent licenses that they granted and their licensing revenues. Of the twenty-two responding firms, the four Portfolio PAEs accounted for only 9% of the reported licenses in the study but 80% of the reported revenue. The FTC’s subsequent review of qualitative data showed that the two groups had very different business models and the FTC used these two categories when presenting the remainder of the findings in its report.

90 The FTC’s review of existing literature showed that there had been considerable research into PAE patent litigation activity relying on publicly-available court filings. However, the prior literature was unable to tell how often PAEs sent demand letters or negotiated licenses when those activities took place without litigation. The FTC’s study addressed this deficiency by asking each responding firm to identify each instance where it performed one of these acts. The FTC did not observe PAEs successfully generating low-revenue licenses by sending demands without suing the target. The FTC also found that most licenses in the sample, reflecting the activity of Litigation PAEs, followed a patent infringement suit against the alleged infringer.

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34. One policy concern was that PAEs asserted their patents differently from other firms that held patents such as manufacturers (that produce final goods) or non-practicing entities that engage in original research and then license their patents to manufacturers. For this reason, the FTC also conducted a case study comparing PAE patent assertion to non-PAE patent assertion in one industry: the wireless chipset industry. The FTC sent 6(b) Orders to fifteen non-PAEs that asserted patents related to wireless chipsets, including manufacturing firms as well as other non-practicing entities that did not meet the definition of a PAE. The FTC presented a comparison of patent assertion behavior between these firms and the PAEs in its study, which had also asserted patents related to wireless chipsets. Among the firms in the case study, the FTC found that manufacturing firms very rarely made use of litigation in licensing their patents, while Litigation PAEs, in particular, almost always sued before licensing their patents.

35. The FTC also studied PAEs’ patent holdings. It requested that each PAE identify each patent that it held. The FTC combined this information with data

89 Id.
90 Id.
91 Id.
92 Id. at 20-27.
93 Id. at 54.
94 Id. at 5.
95 Id.
96 Id. at Ch. 4.
97 Id. at 103.
98 Id. at 123.
99 Id. at Ch. 5.
100 Id. at 125.
available from the U.S. Patent and Trademark Office. The FTC presented the technology classifications of the patents held by responding firms. The FTC also presented a distribution of patent age and citation frequency, comparing the citation of study patents to a cohort of patents with the same technology classification and grant year. The FTC found that the PAEs primarily held patents related to information and communication technologies, and that the patents PAEs asserted in litigation generally were cited more frequently than the population of patents overall.

36. The FTC concluded its study with a series of recommendations for legislative and judicial reform intended to address PAE litigation asymmetries through procedural and substantive reform.

4.2. Reports to Congress on Ethanol Market Concentration (Annual)

37. The FTC prepares an annual report regarding market concentration of the ethanol production industry. Each year, the FTC presents the public report to both Congress and to the Administrator of the Environmental Protection Agency. The Energy Policy Act of 2005 requires the FTC to perform this annual analysis. The act requires that the FTC perform a market concentration analysis using the Herfindahl-Hirschman Index (HHI). The 2016 report presents four different HHIs. The report presents HHIs calculated using two different measures of market share: production capacity and actual production. The report presents market shares calculated for both producers and ethanol marketers using these measures. FTC staff reported that the HHIs indicate that the ethanol production industry is unconcentrated.

39. FTC staff relied on publicly available information and interviews with industry participants to determine the production capacity and to calculate the market shares based on marketing arrangements. To measure actual production, FTC staff relied upon

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101. Id. at 125-26.
102. Id. at 128.
103. Id. at 137.
104. Id. at 124-25.
105. Id. at 8-14.
107. Id.
108. Id.
109. Id.
110. Id. at 7-8.
111. Id.
112. Id.
113. Id. at 2.
114. Id. at 7-8.
confidential information that the U.S. Energy Information Administration (EIA) collected. Due to the confidential nature of the data, FTC staff provided the information necessary to allocate market shares to the EIA staff, who performed the HHI calculations and provided the resulting HHIs to FTC staff.115

4.3. Examining Health Care Competition (February 2015)

40. The Antitrust Agencies conducted a series of workshops on “Examining Health Care Competition” over four days in 2014 and 2015.116 The workshops examined changes in the health care industry and the potential implications for competition and consumer protection.117 The Antitrust Agencies did not prepare a formal public report on these workshops. Workshop-related material that the Antitrust Agencies received or generated – including speaker presentations, written comments, video recordings, and an event transcript – are available to the public on the event webpage.118

41. The 2015 workshop focused on five main themes: accountable care organizations; alternatives to traditional fee-for-service payment models; trends in provider consolidation; trends in provider network and benefit design strategies; and health insurance exchanges. The 2014 workshop focused on professional regulation of health care providers, innovations in health care delivery, technological advancements such as health information technology, measuring and assessing quality of care, and price transparency of health care services.119

42. The workshop series featured presentations by over 75 experts. In addition, the Antitrust Agencies received over 250 written comments. Stakeholders who shared their views included academics, industry representatives, health care practitioners, policy experts, and others.

4.4. Authorized Generic Drugs: Short-Term Effects and Long-Term Impact (August 2011)

43. In August 2011, the FTC released a report on its Authorized Generic Drug study, presenting the results of a study it began in 2006.120 An authorized generic, or AG, is a generic drug marketed under the same regulatory approval used by the branded drug. The incremental competition provided by the introduction of an AG can decrease the revenues of other generic entrants.121 This impact on other generic entrants may be particularly significant when the number of competitors is small. For instance, the Hatch-Waxman

115 Id.


117 Id.

118 Id.


121 See id. at iii.
Amendments encourage generic firms to pursue entry as soon as warranted by challenging questionable patents covering brand-name drugs and seeking Food and Drug Administration (FDA) approval to market a generic prior to patent expiration.\textsuperscript{122} When a generic entrant obtains this approval, the FDA will not approve additional generics to enter for at least 180 days after the first generic (or “first-filer”) launches, which provides strong incentives for generic firms to be the first to challenge questionable patent protection.\textsuperscript{123} Since the brand company already has approval to market the drug, it requires no further approval to introduce an AG. Consequently, an AG launched during this 180-day period would cause the generic firm that successfully challenged the brand’s patent protection to face one generic competitor rather than having no generic competitors. Given the potential impact this could have on the incentives to challenge patents built into the Hatch-Waxman Amendments, the study thoroughly analyzed this particular scenario.\textsuperscript{124}

44. The FTC undertook the study following requests from legislators to study the “short term and long term effect on competition of the practice.”\textsuperscript{125} In particular, the report focused on two effects: (1) whether AGs offer consumers a short-term benefit by lowering prices during the 180-day period and (2) whether AGs deter future generic patent challenges, having the long-term harm of reducing the availability of lower-priced generic products.\textsuperscript{126}

45. The FTC used three separate 6(b) Orders sent to (1) branded drug companies; (2) generic drug companies; and (3) authorized generic drug companies.\textsuperscript{127} The FTC identified recipients based upon whether they held regulatory approval for a particular drug.\textsuperscript{128} FTC staff relied primarily upon databases provided by the FDA, supplemented by the Thompson Healthcare “Red Book” directory to identify these firms.\textsuperscript{129} The FTC also asked questions in the 6(b) Order to identify additional AG drugs relevant to branded drugs.\textsuperscript{130} The FTC sent 6(b) Orders to approximately 120 firms.\textsuperscript{131}

46. The FTC studied the effect of AG drug competition during the 180-day exclusivity period on price and revenue.\textsuperscript{132} The FTC identified all AGs sold between 2003 and 2008 using drug information provided by the FDA supplemented with information

\textsuperscript{122} Id. at 2-4.
\textsuperscript{123} Id.
\textsuperscript{124} Id. at 4-6.
\textsuperscript{125} Id. at 1; App. A (quoting Letter from Senators Charles Grassley, Patrick Leahy, and John Rockefeller to Deborah Platt Majoras, Chairman, Fed. Trade Comm’n (May 9, 2005).
\textsuperscript{126} Id. at 4.
\textsuperscript{127} Id. at H-5
\textsuperscript{128} Id. at H-4. The FTC identified recipients based upon whether they held either new drug applications (NDAs) or abbreviated new drug applications (ANDAs) for a particular drug. The FTC also identified a small number of AG manufacturers that did not themselves hold an NDA.
\textsuperscript{129} Id.
\textsuperscript{130} Id.
\textsuperscript{131} Id. at 7.
\textsuperscript{132} Id. at Ch. 3.
the 6(b) Orders requested from brand and generic firms. The FTC acquired a license for both retail and wholesale monthly dispensing and sales data from IMS Health Services. The FTC performed a series of regression analyses to determine the effect of the introduction of an AG on price and revenues for both the brand and generic products. The FTC observed that the introduction of an AG into a market was associated with lower prices for generic versions of that product and that first-filer generics make considerably less revenue when an AG enters the market.

The FTC also studied the long-term effect of AGs by performing additional analysis on the data that it collected for time periods outside the 180-day exclusivity period. The FTC performed a series of regression analyses to determine the effect of the introduction of an AG on the price of a brand product relative to a generic product and on wholesale revenues. The FTC found that, to the extent that AG presence in a market had an impact on prices, it tended to be associated with lower prices in markets where an exclusivity period had expired.

The FTC studied the motivations of brand manufacturers to test the allegation raised by several commenters that “brand-name companies market AGs primarily to deter generic firms’ challenges to patents.” The 6(b) Orders sent to brand manufacturers requested both “documents … prepared by or for any officer(s) or director(s)” of each responding firm as well as “planning, decisional [and] strategy documents” that “evaluated, considered, or analyzed” the possible marketing of an AG including discussing the reasons for doing so. The FTC prepared a descriptive summary based upon its review of the documents. It concluded that the brand-name firms’ documents and marketing practices provided a mixed picture of their motivations, one consistent with both revenue-generating and entry-deterring objectives.

The FTC also studied generic companies’ reactions to AGs and the impact of AGs on generic companies’ incentives to file patent challenges against branded pharmaceutical firms. The 6(b) Orders sent to generic manufacturers requested both “documents … prepared by or for any officer(s) or director(s)” of each responding firm as well as “planning, decisional [and] strategy documents” that “evaluated, considered, or analyzed” the how the possibility of an AG would influence its decision to file a patent challenge. The FTC prepared a descriptive summary based upon its review of the documents.

133 Id. at 36-37.
134 Id. at 36.
135 Id. at 38.
136 Id. at 63.
137 Id. at Ch. 6.
138 Id. at 100-08.
139 Id. at 118.
140 Id. at Ch. 4; 160.
141 Id. at D – 5-6.
142 Id. at 78.
143 Id. at Ch. 5.
144 Id. at E – 4-5.
concluded that the generic company documents confirmed that competition from an AG substantially reduced the revenue of non-AG generics during 180-day exclusivity and spoke to the importance some generic companies place on first-to-file opportunities.145

50. To provide context for the issue of whether AGs influenced incentives to file patent challenges, the FTC studied the relationship between patent challenges and the sales levels of brand name drugs, as well as trends in the prevalence of such challenges.146 The FTC relied upon data from the FDA to identify when generic manufacturers filed patent challenges.147 The FTC observed an increase in the number of challenges filed in the years preceding the report.148

51. The report concluded that competition from an AG had the short-term effect of lowering retail prices for generic drugs during the 180-day exclusivity period and lowered generic manufacturer revenues during the period.149 With regard to long-term incentive effects, the report concluded that the reduced revenue stemming from AG competition during 180-day exclusivity has not affected the generic’s incentives in a way that has measurably reduced the number of patent challenges by generic firms.150

5. Conclusion

52. Market studies are an important component of the Antitrust Agencies’ research and advocacy activities. The Antitrust Agencies use market studies to perform empirical research in support of policy recommendations. They also use studies as a means of educating stakeholders and policymakers. The Antitrust Agencies make use of a variety of tools to conduct market studies. In many instances, workshops and hearings serve as a cost-effective means of learning about an industry, business practice, or the impact of a regulation. In other cases, the Antitrust Agencies perform independent empirical research. The FTC frequently uses its compulsory process authority when engaging in empirical research. The Antitrust Agencies employ a variety of analytical techniques when conducting empirical research, reflecting the various purposes for which they conduct studies.

145 Id. at 92.
146 Id. at Ch. 7.
147 Id. at 122.
148 Id. at 137.
149 Id. at iii.
150 Id.