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Methodologies for Conducting Market Studies - Note by the United States

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United States

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

requesting transactions-level data fs3f9a f f eev(f)72( )-(3f9a)9(1(e)9p( )-3(Ud)]a)9(f)11((f)7fi)-5()7(a)9a

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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.[68] 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.[69] PAEs are businesses that acquire patents from third parties and seek to generate revenue by asserting them against alleged infringers.[70] 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.[71] Because PAE activity involves filing lawsuits and/or making unsolicited demands for payment, it has garnered the attention of policymakers.[72] 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.[73]

29. The Antitrust Agencies held a workshop in 2012 to examine PAE behavior.[74] Workshop participants included PAEs, private thei1 0 1 269.20999145(i1o(n)] 0 1 490.05999755 411.2(

PAE assertion conduct were the court records when PAEs filed lawsuits.[76] There was little data on other aspects of PAE behavior or corporate structures. In light of this

defendants covering small portfolios, often containing fewer than ten patents.[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.[90] 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.[91]

33. 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.[92] However, the prior literature was unable to tell how often PAEs sent demand letters or negotiated licenses when those activities took place without litigation.[93] 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.[94] 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.[95]

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.[96] 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.[97] 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,

available from the U.S. Patent and Trademark Office.[101] Using a classification scheme used by the National Bureau of Economic Research, the FTC presented the technology classifications of the patents held by responding firms.[102] 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.[103] 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.[104]

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.[105]

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.[106]

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 –

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.[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.[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.[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."[125] In particular, the

the 6(b) Orders requested from brand and generic firms.[133] The FTC acquired a license for both retail and wholesale monthly dispensing and sales data from IMS Health Services.[134] 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.[135] 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.[136]

47. 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.[137] 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.[138] 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.[139]

48. 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."[140] 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.[141] 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.[142]

49. 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.[143] 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.[144] The FTC prepared a descriptive summary based upon its review of the documents. It

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*.