The FTC: A Framework for Promoting Competition and Protecting Consumers

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Introduction

Over the course of the last 100 years, the Federal Trade Commission (“FTC” or “Commission”) has successfully tackled complex and often politically charged economic issues by elevating reason over rhetoric and consensus over contention. It has a history of bipartisan and effective action that promotes competition and protects consumers. In my view, much of its success is a product of the way the agency was designed by its Progressive Era founders.

North Carolina State Board of Dental Examiners v. FTC1 is a good recent illustration. In that case, the Commission defended its view that professional licensing bodies comprised of market participants cannot shield their activities from antitrust scrutiny using the state-action doctrine in the absence of active state supervision.2

The editorial boards of the New York Times and Wall Street Journal, which typically agree on little, both supported the FTC’s position while the matter was pending before the Supreme Court. The Times

* Chairwoman of the Federal Trade Commission. This Essay is adapted from the opening address Chairwoman Ramirez delivered at The George Washington Law Review Symposium, The FTC at 100, held on November 8, 2014. The views expressed here are her own and do not necessarily reflect the views of the Federal Trade Commission or any other Commissioner. Chairwoman Ramirez is grateful to Jon Nathan, Liz Hilder, and Kelly Signs for their assistance in preparing this Essay.

2 Id. at 1108–09.
concluded that, while “[s]tates have the right to regulate competition in the public interest . . . they cannot blindly outsource that responsibility to professionals who stand to benefit from such restrictions.”

The Wall Street Journal credited the FTC with being on “the right side” and urged the Supreme Court “to pull the dentists’ rules against competition.” Ultimately, the Supreme Court also sided with the FTC, noting that, without neutral supervision, there is always a risk that market participants serving on state licensing boards will confuse their own interests with the policy goals of the state.

The two newspapers also endorsed the FTC’s decision in 2012 not to challenge Express Script, Inc.’s acquisition of Medco Health Solutions, a transaction that combined two of the country’s largest pharmacy benefit managers. The Wall Street Journal hailed the FTC’s approval of the deal as “a win for competition and consumer choice,” while the New York Times declared that it was “persuaded that the commissioners made the right choice.”

Matters like North Carolina Dental and Express Scripts/Medco show the FTC at its best: an agency engaging in thorough, fact-intensive antitrust investigations and making decisions backed by sound factual, legal, and economic analysis that benefit competition and consumers. At the FTC, results like these are the rule, not the exception.

This Essay focuses on certain core features of the FTC that have contributed significantly to its consistent and successful pursuit of the agency’s dual mission to promote competition and protect consumers: the FTC’s institutional structure and the variety of tools it has at its disposal. In particular, I will highlight the agency’s role as an expert administrative body and the importance of the agency’s combination of enforcement, research, and advocacy work. To illustrate how these attributes have helped the FTC achieve its mission, I present as a case study one of the agency’s longest-running campaigns—its fight against unlawful reverse payment patent settlements.

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5 North Carolina Dental, 135 S. Ct. at 1114.


I. Core FTC Strengths

A. Institutional Design

The FTC was the product of a distinct moment in our nation’s history. At the turn of the twentieth century, the United States was struggling to overcome major financial shocks and the impact of rapid industrialization. The public was losing faith in government’s ability to respond to the economic and social challenges of the time.

By 1914, however, Progressive movement leaders had begun to develop and put in place a public policy framework based on the dispassionate decisions of experts in the new social sciences. The FTC’s founders, very much a part of this movement, sought to create an independent agency that could rise above the political fray by applying its expertise to economic markets to ensure they worked for the benefit of consumers. As Justice Sutherland wrote in Humphrey’s Executor v. United States, the aim was for the FTC to “exercise the trained judgment of a body of experts” when “dealing with these special questions concerning industry that comes from experience.”

To do this, the FTC was vested with both administrative and prosecutorial functions. President Wilson, Justice Brandeis, and Congress shared a vision of an expert administrative agency capable of both investigating and analyzing markets, and adjudicating cases in order to shape antitrust doctrine and policy. At the same time, however, they sought to imbue the product of the agency’s administrative process with the credibility and precedential effect of judicial oversight by the federal appellate courts.

Judicial supervision cabins the FTC’s lawmaking and policymaking within the bounds of our common-law tradition. But it also leaves room for the FTC to bring its expertise to bear on novel issues of antitrust and consumer protection law. The sheer number of FTC cases taken up by the Supreme Court over the last twenty-five years, including three in the last three terms alone, shows that the agency regularly addresses significant and often unsettled questions of law.

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10 Cf. Walter Lippmann, Drift and Mastery: An Attempt to Diagnose the Current Unrest 42 (1914).
13 Id. at 624 (quoting Ill. Cent. R.R. v. Interstate Commerce Comm’n., 206 U.S. 441, 454 (1907); S. Rep. No. 63-597, at 10–11 (1914)).
14 See generally Winerman, supra note 11, at 32–92.
15 See id. at 90–91.
meriting the Court’s time and attention. We have often seen the FTC incorporate into its decisions new ideas and modes of analysis that have yet to be accepted widely by courts.

Examples include the novel merger policy issues addressed by the Commission in *Chicago Bridge & Iron*, *Polypore*, and *ProMedica*, as well as the application of the truncated or “quick look” rule of reason analysis in *Polygram*, *North Texas Specialty Physicians*, and *RealComp*, in which the Commission concluded that the conduct at issue was “inherently suspect.” Although the courts of appeal in each of these cases affirmed and adopted the FTC’s analysis, federal district courts might well have been reluctant to apply novel approaches had the courts ruled in the first instance given their institutional preference for precedent. As an expert body, the FTC is well positioned to advance antitrust doctrine provided its reasoning and conclusions are backed by rigorous analysis and grounded in the administrative record.

Another institutional feature that has proven important to the agency’s success is the FTC’s governing structure—a five-member bipartisan commission serving seven-year staggered terms. The FTC’s architects believed that decisions made by consensus through a collective body, rather than by a single agency head, would make for better

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policy. Significant social science research today supports the view that collective decisionmaking has certain important benefits, especially when it comes to resolving complex matters requiring predictive analysis.24

Five independent decisionmakers, with a diversity of views and experiences, help ensure that the main issues in FTC matters are fully explored and weaknesses fully debated. It reduces the likelihood that key questions are overlooked, or that action is taken or avoided for any reason other than the public interest. It also imposes analytical discipline on the agency as whole. Staff recommendations to the Commission require thorough, rational arguments based on compelling facts and strong legal analysis that will withstand deliberative scrutiny from a variety of angles. The Commission in turn must reach a consensus decision of at least a majority of commissioners to authorize, or forbear from, action.

This process forces the agency to grapple with a wide spectrum of arguments and develop responses during the investigation phase rather than confronting them for the first time in litigation. In addition to preparing the agency for the rigors of litigation, this iterative process also produces well-informed decisions.

Further, the staggered, seven-year terms for commissioners provide institutional stability that leads to continuity of policy and the tempering of swings in priorities across administrations. This structure fosters consistency and allows the agency to make investments in research and analysis with respect to specific issues and industries over time. That in turn contributes to the development and implementation of long-term strategies for confronting anticompetitive harms.25


25 For example, the Commission has focused on the proper application of the state action doctrine for years, including issuing a report on the subject in 2003. See Fed. Trade Comm’n, Office of Policy Planning, Report of the State Action Task Force (2003), http://www.ftc.gov/sites/default/files/documents/advocacy_documents/report-state-action-task-force/stateactionreport.pdf. On the enforcement front, in addition to the recently decided North Carolina Dental case, the Commission also prevailed before the Supreme Court in FTC v. Phoebe Putney Health Sys., Inc., 133 S. Ct. 1003 (2013). In that case, a unanimous Court ruled that the granting of general corporate powers to government entities under state law does not provide blanket immunity from the antitrust laws. Id. at 1011–12.
Perhaps the strongest evidence of the benefits of the agency’s expertise and intensive deliberative process is the agency’s administrative appellate record. Over the last two decades, appellate courts have affirmed ten out of thirteen Commission administrative competition decisions. That number increases to eleven wins out of thirteen cases once one considers that the Commission’s 2003 ruling in Schering-Plough, reversed by the Eleventh Circuit in 2005, was ultimately vindicated by the Supreme Court’s 2013 decision in FTC v. Actavis. In Actavis, the Supreme Court agreed with the principles set forth by the Commission in Schering-Plough, holding that reverse payment patent settlements are subject to antitrust scrutiny even if they fall within the scope of the patent.

It is an impressive record, particularly given that many of those opinions have involved novel questions of law on which the Commission is given no deference, as well as the fact that respondents have the ability to choose the most favorable appellate forum. This record affirms the virtues of the FTC’s role as an expert arbiter of anticompetitive mergers and business practices in an administrative setting.

B. Agency Tools

The advantages of the FTC’s institutional structure are complemented by the unique combination of tools the agency employs.

As shown by the cases addressed above, law enforcement functions as the core of the FTC’s dual mission to protect consumers and maintain competition. The agency has two enforcement bureaus dedi-
cated to carrying out this mission. In 2014, for instance, the agency brought 130 consumer protection and 25 competition enforcement actions.33

But while they may garner fewer headlines, the FTC’s other tools also play a crucial role in cementing the agency’s continuing relevance and impact on the daily lives of consumers. The agency’s research efforts include more formal studies facilitated by its ability to compel the production of information under Section 6(b) of the FTC Act as well as workshops.34 These efforts help ensure that the Commission has the data and information needed to track market developments and chart future priorities. They also allow the agency to play an active role in the development of relevant legal standards and policies.

To give a recent example, in 2014, the FTC conducted a workshop examining emerging competition issues involving the introduction of biosimilars and interchangeable biologic drugs.35 We convened relevant experts and interested parties, including consumer groups, academics, pharmacists, health insurers, and biosimilar and biologics companies, to explore various issues, among them how naming conventions may affect the development of biosimilar competition.36 Based in part on the information obtained through this workshop, the FTC has urged the development of policies that protect patient health and safety, but without unnecessarily chilling competition and deterring investment in follow-on biologics.37

Another example is the FTC’s 2003 report on balancing competition policy and patent law and policy.38 This report resulted from a

series of hearings that the agency held in 2002 and 2003 to study patent quality and its impact on competition in our knowledge-based economy. Although the report’s recommendations focused on suggested changes to patent law, rather than antitrust law, it has been widely influential. More recently, in 2011, the FTC issued a report examining patent notice and remedies.

Research has also improved the agency’s own performance. In 1999, the FTC conducted a remedy study to evaluate the effectiveness of Commission-ordered divestitures and understand why certain divestitures had not achieved their remedial objectives. Drawing on information gathered during the study, the FTC adopted a number of changes to its divestiture policies that have proven effective in maintaining competition in affected markets. The agency is currently engaged in a follow-up and more expanded remedy study.

Another example of the role of research in improving agency outcomes is the FTC’s hospital merger retrospective project, announced in 2002, which made significant contributions to the agency’s enforcement efforts in healthcare provider markets. Those efforts, which included retrospective studies of several hospital mergers as well as a series of workshops focusing on healthcare markets, led to a shift in the FTC’s litigation approach to hospital mergers. The new approach led to a winning streak that now includes four successfully litigated merger challenges and a growing number of transactions.

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39 See id. at 3–4.
40 See id. at 7–18.
44 Id. at iv–v.
46 For a general discussion of the FTC’s hospital merger retrospective efforts, see Joseph Farrell et. al., Economics at the FTC: Retrospective Merger Analysis with a Focus on Hospitals, 35 REV. INDUS. ORG. 369 (2009).
47 See id. at 373–76.
abandoned after the FTC raised competitive concerns and had either
decided to challenge or was close to doing so.\textsuperscript{49} In light of the signifi-
cant costs of health care and strong evidence that hospital consolida-
tion can lead to higher prices without corresponding quality
improvements,\textsuperscript{50} the FTC’s recent success in blocking anticompetitive
hospital mergers has provided significant benefits to consumers.

The FTC’s advocacy efforts—aimed at Congress, state legisla-
tures, state and federal policymakers, and courts—also complement
our law enforcement and other policy work.\textsuperscript{51} Advocacy can be espe-
cially effective in helping to address government restraints, which are
often imposed for reasons unrelated to competition and without due
consideration for their impact on consumers. For instance, the FTC
has been active in encouraging the removal of unnecessary scope of
practice restrictions that prevent healthcare professionals from being
able to take full advantage of their training and expertise.\textsuperscript{52} Through
these efforts, the FTC seeks to enhance competition, expand access to
qualified providers, and encourage new, innovative models of care.

Filing amicus briefs in private litigation is another common route
for the Commission to share its experience and expertise where it may
prove helpful.\textsuperscript{53} One notable example of this form of advocacy is the amicus
brief the FTC submitted in \emph{Leegin Creative Leather Products v.}
Faced with the weighty decision about whether to overturn *Dr. Miles* and the per se rule against vertical price restraints, the Court took comfort in the fact that both the FTC and the Department of Justice (“DOJ”)—“the antitrust enforcement agencies with the ability to assess the long-term impacts of resale price maintenance—ha[d] recommended that [it] replace the per se rule with the traditional rule of reason.”

II. The FTC’s Efforts to Combat Unlawful Reverse-Payment Patent Settlements

An FTC effort in which the institutional design and tools I have just discussed have proven key is the Commission’s long-running fight against unlawful reverse payment patent settlements in the pharmaceutical industry (referred to colloquially as “pay-for-delay” agreements).

The Supreme Court’s *Actavis* ruling, in which the Court overturned the so-called “scope-of-the-patent” test and held that pay-for-delay patent settlements are subject to antitrust scrutiny, was a significant victory for consumers and a vindication of basic antitrust principles. But the road to *Actavis* began decades ago for the FTC. It involved a long-term effort consisting not only of enforcement, but also of extensive research, advocacy, interagency collaboration, and engagement from the Bureaus of Competition, Consumer Protection, and Economics. *Actavis* is a story that showcases the many strengths of the FTC and its ability to use its broad expertise and unique authority to drive real change for the benefit of competition and consumers.

The FTC’s efforts to address concerns about impediments to generic competition began the way that many important FTC initiatives do—with research. In the mid-1970s, the Commission tasked the staff of the Bureau of Consumer Protection with a series of industry-wide studies of emerging issues in the distribution of pharmaceuticals. One of the studies examined state “anti-substitution” laws, which prevented pharmacists from dispensing a lower-cost generic drug unless a physician specifically prescribed the drug by its nonproprietary

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55 *Leegin*, 551 U.S. at 900.


name.58 Another study led to a model state law, developed by the FTC in cooperation with the FDA, to help states reform their regulations to promote competition and facilitate consumer access to lower-cost generic drugs.59 Today, laws permitting pharmacists to substitute generics, many of which were modeled on the FTC template, exist in every state and help consumers save millions on their medications.60

In 1984, Congress passed the Hatch-Waxman Act,61 which established an abbreviated regulatory pathway for generic drugs to enter the market.62 By the late 1990s, however, there were indications that aspects of this regulatory framework—the promise of 180 days of market exclusivity for the first patent challenger,63 for example—could also be used to prevent or impede generic competition.64

At that time, the FTC began to observe that brand-name drug firms, guided by judicial interpretations of the Hatch-Waxman market exclusivity provisions, were paying generic competitors to settle their patent challenges and defer generic entry.65 Supported by staff research showing the clear benefits of generic competition, the FTC responded by opening a number of law enforcement investigations.

Using its authority under Section 6(b), the FTC also completed another industry-wide study to examine whether certain features of the Hatch-Waxman framework facilitated strategies to delay generic

64 In April 1998, two federal appellate courts invalidated an FDA regulation that limited the award of 180-day exclusivity to first filers that successfully defended a patent infringement suit. Mova Pharm. Corp. v. Shalala, 140 F.3d 1060, 1066–74 (D.C. Cir. 1998); Granutech, Inc. v. Shalala, Nos. 97-1873, 97-1874, 1998 WL 153410, at *6–7 (4th Cir. Apr. 3, 1998). In defending its rule, the FDA noted the risk under the statute that “the first applicant colludes with the pioneer drug company to eliminate generic competition.” Mova Pharm., 140 F.3d at 1067.
competition. It would be hard to overstate the impact of the FTC’s empirical findings and the recommendations contained in the resulting report. Perhaps most significantly, Congress adopted reforms to the Hatch-Waxman framework in 2003 with the Medicare Modernization Act based on FTC recommendations. One central reform was the requirement that drug companies file various types of agreements, including settlements between brands and generics, with the FTC and DOJ, thereby enabling the examination of agreements that might otherwise escape review. This notification program provides the FTC with a unique source of data on the nature and extent of brand-generic patent settlements, which has proven to be instrumental in monitoring the evolution of reverse payment patent settlement agreements.

In March 2000, the FTC filed its first two pay-for-delay cases: a proposed administrative consent agreement involving Abbott’s brand name hypertension and prostate drug, Hytrin, and an administrative complaint involving Cardizem CD. The proposed settlement provided immediate guidance to the drug industry and the antitrust bar, as well as an opportunity for public comment. Meanwhile, the administrative action afforded the Commission an opportunity to consider the relevant competition issues in the context of an extensive factual record developed during an administrative proceeding. This action was ultimately resolved with a consent order.

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66 See Genetic Drug Entry, supra, note 65, at 1–3.


68 See id.


In 2001, the FTC filed an administrative complaint against brand manufacturer Schering-Plough and two generics. Following an administrative hearing, the Commission concluded Schering-Plough had entered into an unlawful reverse payment settlement agreement. That determination, which was appealed by Schering-Plough to the Eleventh Circuit, became the first FTC pay-for-delay case to be considered by a federal court.

In 2005, the Eleventh Circuit reversed the Commission decision, dealing the FTC the first of several setbacks on the pay-for-delay battlefront. The Eleventh Circuit adopted the so-called scope-of-the-patent test, effectively immunizing pay-for-delay deals from antitrust scrutiny. The Second Circuit and the Federal Circuit followed suit soon after. All told, the Supreme Court denied certiorari three times in the late 2000s leaving in place appellate rulings that disfavored the FTC position. As the defeats mounted, internally, senior Commission officials took to quoting the classic rallying cry often cited when facing near impossible odds—the St. Crispin’s Day speech from Shakespeare’s *Henry V*.

Following the Eleventh Circuit’s ruling in *Schering-Plough*, reverse payment patent settlements increased dramatically. The FTC, with the unanimous support of all Commissioners—Republicans, Democrats, and Independents alike—redoubled its efforts on three fronts. The agency first went back to the data. Drawing from the pool of patent settlement agreements filed with the antitrust agencies, the FTC published details about the proliferation of reverse payment pat-

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75 Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1076–77 (11th Cir. 2005).

76 Id. at 1066.


80 WILLIAM SHAKESPEARE, *H ENRY V * act 4, sc. 3 (“We few, we happy few, we band of brothers . . . .”).

ent deals. In addition, FTC economists examined a range of data and calculated that these payments led to billions of dollars a year in higher prescription drug costs.

The FTC also identified other relevant agreements for investigation and potential enforcement action. In 2008, the FTC filed a federal lawsuit against Cephalon alleging that it had entered into agreements to prevent generic competition to its leading product, Provigil. In 2009, the FTC challenged two patent settlements involving the testosterone replacement drug AndroGel in the federal district court lawsuit that eventually went up to the Supreme Court.

Finally, the FTC turned to advocacy. It publicized its findings about the extent of the pay-for-delay problem. The agency testified before Congress about its research and enforcement efforts, advocating for federal legislation to protect consumers from anticompetitive reverse payment patent settlements. The FTC also continued to file amicus briefs in private actions to explain to courts why pay-for-delay settlements are anticompetitive, urging the application of traditional antitrust standards. This effort eventually bore fruit in 2012 when the Third Circuit rejected the scope-of-the-patent test in In re K-Dur

82 Id.
86 See, e.g., supra notes 69, 83.
Antitrust Litigation. That ruling, which interestingly involved the same agreements that the Commission had unsuccessfully challenged in 2001 in Schering-Plough, set the stage for Supreme Court review and eventual FTC victory in Actavis.

Despite the success in Actavis, the FTC’s effort to combat illegal reverse payments is not over. The agency continues to litigate on multiple fronts. In fact, the Commission filed its most recent pay-for-delay case in September 2014. But this long-term effort highlights how the agency can use its expertise and unique authority effectively, sometimes over the course of decades, in an effort to stop anticompetitive conduct that causes substantial consumer harm. It is an important example to revisit as one examines the agency’s accomplishments and the role it can play in the future.

Conclusion

The FTC’s founders wisely designed an agency that would operate in accordance with principles of bipartisan consensus, rational analysis, careful research, and thoughtful enforcement and advocacy. The FTC has adhered to those principles, remaining useful and relevant for 100 years—even as the U.S. economy has undergone successive and dramatic transformations. I believe continued adherence to these principles will keep the FTC useful and relevant in its next century.
