



# The Federal Trade Commission

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**Remarks of Deborah Platt Majoras  
Chairman of the Federal Trade Commission<sup>1</sup>  
Delivered at  
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**“Antitrust Enforcement in the Pharmaceutical Industry: Successes and Challenges”**

Thank you very much; it is a pleasure to be here to discuss antitrust issues in the pharmaceutical industry. Your discussions over these two days come at an important time in the development of the antitrust laws, intellectual property policy, and the pharmaceutical industry. A current primary focus for the FTC, and indeed the antitrust community, is the proper alignment and interaction of the antitrust and intellectual property laws. While IP and IP rights have always been important to the U.S. economy, today IP, like competition, plays a truly central role in promoting innovation, economic growth, and consumer welfare. And both, of course, play a crucial role in the pharmaceutical industry.

The Antitrust Modernization Commission, which Congress established three years ago, recently refuted those who tend to think of the antitrust laws as antiquated rules, finding that “the state of the U.S. antitrust laws [is] sound” and that “[t]here is no need to revise the antitrust laws

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<sup>1</sup> The views I express here are my own and do not necessarily reflect the views of the Federal Trade Commission or any other Commissioner.

to apply different rules to industries in which innovation, intellectual property, and technological change are central features.”<sup>2</sup> While we do not need to update the antitrust laws, this is nonetheless a critical time in the history of antitrust policy and enforcement. Over the past quarter of a century, in the United States and throughout the world, regulation and government ownership of assets have given way to free markets and competition. The result has been rapid rates of innovation and economic growth. The antitrust laws play a key role in keeping markets free from anticompetitive distortions: by ensuring that companies do not engage in anticompetitive conduct, and that consumers are protected not *from* competition, but instead *through* competition, the antitrust laws serve as a core component of U.S. economic policy.

This view of the importance of the antitrust laws is not limited to antitrust enforcers in the United States, the European Union, and a few other developed jurisdictions. Countries throughout the world have formed competition agencies to complement their deregulation and privatization policies. A quarter of a century ago, there were approximately 20 competition authorities around the world. Today, the International Competition Network, which later this month will hold its annual meeting in Moscow, has 100 member competition authorities. This represents an important milestone for the movement toward market-based economies, but it also presents tremendous challenges. After all, many who are assigned to protect competition in markets do not genuinely trust either; and the more ill-advised government intervention, the more crippled markets become – in a distorted self-fulfilling prophecy of those who distrust markets.

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<sup>2</sup> Antitrust Modernization Commission, Report and Recommendations (April 2007), available at [http://www.amc.gov/report\\_recommendation/amc\\_final\\_report.pdf](http://www.amc.gov/report_recommendation/amc_final_report.pdf), at i, 9 (quotations omitted).

Whereas many throughout the world believe that competition has no place in health care, we respectfully, but firmly, disagree. Sound competition policy is crucial to the health care industry in general, and the pharmaceutical sector in particular. Health care expenditures in the United States total almost \$2 trillion annually, accounting for approximately 16 percent of U.S. gross domestic product. Ten percent of that total is attributable to prescription drugs, meaning that prescription drugs make up approximately a \$200 billion market.<sup>3</sup> Given the amount of national resources that we expend on health care and pharmaceuticals, it is vitally important that consumers purchase these services in competitive markets.

And yet, the significance of competition in the industry obviously cannot be measured in dollars alone. Competition drives innovation, bringing, in the pharmaceutical sector, enormous non-pecuniary benefits to Americans, in the form of people living longer, healthier, and more productive lives. Consequently, protecting competition in the pharmaceutical industry continues to be one of the FTC's highest priorities, and I would like to describe our approach in these efforts for you today.

### ***Mergers***

I will start with our merger review work. As you know, the FTC and the Department of Justice Antitrust Division are required by statute to review mergers of a certain size before they are consummated. Our merger work is crucial to preserving a dynamic competitive market for pharmaceuticals, and to preventing the inefficient and burdensome regulation that is often imposed by governments in markets where firms do not aggressively compete. The objectives of

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<sup>3</sup> See Aaron Catlin, et al., *National Health Spending in 2005*, 26 HEALTH AFFAIRS 142, Jan./Feb. 2007, available at <<http://content.healthaffairs.org/cgi/content/full/26/1/142>>.

our merger work are straightforward: to block only those mergers, or those portions of mergers, that will result in substantial reductions in competition; to ensure that we do not prevent firms from achieving efficiencies that benefit consumers; and to conduct our merger review process in an efficient manner that minimizes costs for the parties, the Commission, and, ultimately, the U.S. taxpayer.

We almost always begin our merger analysis of pharmaceutical transactions by identifying or estimating the relevant market, and then determining the number of actual and likely future competitors in that market. But this structural approach is only a starting point. We only conclude that a transaction presents competitive problems after also conducting a fact-specific assessment of the actual competitive dynamics of the market, assisted by sound economic theory.

Since the start of fiscal year 2004, the Commission has reviewed nearly 400 mergers involving pharmaceuticals and medical devices. For the overwhelming majority of these transactions, the Commission was able to determine during the initial 30-day Hart-Scott-Rodino waiting period that they presented no risk to competition. The Commission issued second requests for seventeen of these transactions that we determined warranted closer scrutiny. These second-request investigations have resulted to date in ten challenges, each of which we settled through enforcement orders collectively covering more than 55 different pharmaceutical products and seven medical devices, with combined annual sales of more than \$22 billion.

Through our merger work, we have protected different types of competition. Early in the pharmaceutical life cycle, competition among branded drugs is based on innovation – with firms competing at the product development stage to be the first to market with a product for treating a particular disease or condition. The winner of that race can (appropriately) earn significant

rewards – which provides economic incentives for firms to create new products and bring them to market faster, in turn providing consumers more choice. Non-price competition also produces incentives for firms to expand the use of their existing products by exploring new drug indications or to make other improvements.

The FTC has aggressively sought to protect these incentives to develop new drugs and new indications. For example, in its challenge to Sanofi’s acquisition of Aventis in 2004,<sup>4</sup> the FTC acted to protect potential competition for branded Factor Xa inhibitors, which are drugs that are used to treat excessive blood clot formation. Aventis’ Lovenox product had a 90% market share. Sanofi marketed the competing drug, Arixtra, but was also pursuing FDA approval for new indications, which were expected to increase the drug’s competitive significance. The Commission challenged the transaction and negotiated a remedy that required Sanofi to divest Arixtra to Glaxo Smith-Kline (“GSK”) and to assist GSK in completing key clinical trials in order to preserve the potential benefits of the new indications.

Protecting price competition is also a core component of our merger work in the pharmaceutical markets. The first generic competitor typically enters the market at a price that is 70 to 80 percent of its brand-name counterpart, and gains substantial share from the brand-name product in a short period of time.<sup>5</sup> Because this drop in price produces obvious and substantial benefits for consumers, we take action when a merger threatens to eliminate this

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<sup>4</sup> *In the Matter of Sanofi-Synthelabo and Aventis*, FTC Docket No. C-4112, Complaint (July 28, 2004) available at <http://www.ftc.gov/os/caselist/0410031/040728cmp0410031.pdf>

<sup>5</sup> See Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* (July 1998), available at <http://www.cbo.gov/showdoc.cfm?index=655&sequence=0> (hereinafter “CBO Study”); see generally David Reiffen & Michael R. Ward, *Generic Drug Industry Dynamics*, 87 REVIEW OF ECON. & STAT. 37-79 (2005).

competition. For example, the recent (2004) transaction between Cephalon and Cima<sup>6</sup> would have combined Cephalon, which had a monopoly in the market for treating cancer pain, and Cima, which was poised to enter that market with its own drug. Cephalon's ownership of both branded products could have allowed it to thwart generic entry by shifting patients from its product to Cima's, which had later expiring patents. The "switch" strategy would have deprived consumers of the full benefits of generic competition. The Commission remedied these potential anticompetitive effects by requiring Cephalon to license its patents, and to transfer all of its technological know-how to a third-party generic drug company, to expedite entry of a lower-priced generic version of Cephalon's drug.

Over the last two years, a large percentage of our challenges in the pharmaceutical market have been directed at protecting the aggressive price competition that occurs among generic pharmaceutical manufacturers. As I said, generic competition can drive prices as low as 80 percent or more below the price of the brand name drug, and our work has shown that, up to a point, pricing is heavily influenced by the number of generic firms in the market for a particular drug. Since 2005, the Commission has challenged six transactions between generic manufacturers, all of which were resolved by divestitures. These challenges were directed at

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<sup>6</sup> *Cephalon, Inc./Cima Labs, Inc.*, FTC Docket No. C-4121, Complaint (Sept. 20, 2004), available at <http://www.ftc.gov/os/caselist/0410025/040924comp0410025.pdf>; Decision and Order (Sept. 20, 2004), available at <http://www.ftc.gov/os/caselist/0410025/040924do0410025.pdf>.

transactions involving Novartis and Eon,<sup>7</sup> Teva and Ivax,<sup>8</sup> Barr and Pliva,<sup>9</sup> Watson and Andrx,<sup>10</sup> Hospira and Mayne,<sup>11</sup> and, most recently, Actavis and Arbika.<sup>12</sup> In each case, the Commission identified several markets in which the proposed merger would cause significant anticompetitive harm to consumers by eliminating a current or future generic product.

We also focus our merger enforcement work on ensuring that we do not prevent efficient mergers, such as those that will increase the likelihood that a new drug will get to market or get to market sooner. One merging firm may have expertise in bringing products to market quickly or gaining market acceptance that will increase the use of a product that the other firm has in development. The Commission credits these efficiencies. The FTC's review of the Genzyme/Ilex merger demonstrates the agency's appreciation of efficiencies that benefit

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<sup>7</sup> *In the Matter of Novartis AG*, File No. 051-0106, FTC Docket No. C-4150, Complaint (September 21, 2005), *available at* <http://www.ftc.gov/os/caselist/0510106/0509236comp0510106.pdf>.

<sup>8</sup> *In the Matter of Teva Pharmaceutical Industries Ltd., and IVAX Corporation*, File No. 051-0214, FTC Docket No. C-4155, Complaint (January 20, 2006), *available at* <http://www.ftc.gov/os/caselist/0510214/0510214complaint.pdf>

<sup>9</sup> *In the Matter of Barr Pharmaceuticals, Inc.*, File No. 061 0217, FTC Docket No. C-4171, Complaint (October 19, 2006), *available at* <http://www.ftc.gov/os/caselist/0610217/0610217barrcomplaint.pdf>

<sup>10</sup> *In the Matter of Watson Pharmaceuticals, Inc. and Andrx Corporation*, File No. 061-0139, FTC Docket No. C-4172, Complaint (October 21, 2006), *available at* <http://www.ftc.gov/os/caselist/0610139/0610139complaint.pdf>.

<sup>11</sup> *In the Matter of Hospira, Inc. and Mayne Pharma Limited*, File No. 071-0002, FTC Docket No. C-4182, Complaint (January 18, 2007), *available at* <http://www.ftc.gov/os/caselist/0710002/070118cmp0710002.pdf>.

<sup>12</sup> *In the Matter of Actavis Group, HF.*, File No. 071-0063, FTC Docket No. C-4182, Complaint (Apr. 16, 2007), *available at* <http://www.ftc.gov/os/caselist/0710063/0710063cmp.pdf>.

innovation. That case also demonstrates the flexibility that can emerge from an analysis focused on the particular facts rather than rigid structural rules. The drugs at issue provide acute therapy for solid organ transplants by suppressing the immune system during initial organ transplant and during episodes of acute rejection.<sup>13</sup> Genzyme was the leading supplier of such drugs with its product, Thymoglobulin. Ilex sold Campath, which the FDA had approved for the treatment of chronic lymphocytic leukemia, but which doctors also prescribed off-label for transplants. The merger would have lessened competition in the market for acute therapy drugs used in solid organ transplant by eliminating this competition between Genzyme and Ilex. Instead of requiring that the merged firm divest all of its interests in Campath, however, and eliminating efficiencies that would have been produced from the acquisition of Campath by Genzyme, the FTC negotiated a consent decree that required the divestiture to Schering of the firm's contractual rights, including earnings, involving Campath's use for solid organ transplant only. This unique remedy maintained competition in the market for solid organ transplant drugs, while preserving the efficiencies of the transaction.

Finally, it is important to emphasize the success of the process that we use to conduct our merger work. The FTC staff, the private antitrust bar, and the industry, have consistently worked well together to identify and remedy competitive concerns. Like most areas of law enforcement, antitrust enforcement is often, and understandably characterized as an adversarial process, and some of our investigations are resolved through litigation. I think that it is fair to say, however, that the bulk of our merger review work in this industry is characterized by

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<sup>13</sup> *In the matter of Genzyme Corp. and Ilex Oncology, Inc.*, FTC Docket No. C-4128, Complaint (December 21, 2004) available at <http://www.ftc.gov/os/caselist/0410083/041220comp0410083.pdf>



constructive cooperation between our staff and the industry. I have often said, and, indeed it was one of the central underpinnings of the merger process reforms that I announced last year, that for the merger review process to work well, the enforcement agencies and the parties need to work together. If one side acts strategically, or even fails to make the effort to act efficiently, the system breaks down.

The FTC's Mergers I Division, which is responsible for the merger work in the pharmaceutical sector, does a terrific job at crafting targeted requests for information that minimize the burdens on the parties, and, in the large majority of matters, private counsel and the industry have been equally proficient at providing the responsive information quickly. The result is an antitrust process that identifies and quickly resolves competitive concerns with transactions, while minimizing the costs to the FTC, the parties, and, ultimately, consumers.

### ***Non-Merger Enforcement***

In addition to merger review, of course, the Commission also vigorously investigates, and when necessary litigates, conduct-related competition matters in the pharmaceutical industry. You have heard at this conference about the FTC's successful challenge in the federal district court in Washington, DC, to a supply agreement between Warner Chilcott and Barr Laboratories. In November 2005, the Commission filed a complaint in federal district court that alleged that Warner Chilcott and Barr had entered into an agreement in which Barr had agreed not to market a lower-priced generic version of Warner Chilcott's Ovcon 35, an oral contraceptive drug, in exchange for \$20 million.<sup>14</sup> In September 2006, under the threat of a

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<sup>14</sup> Complaint, Federal Trade Comm'n v. Warner Chilcott Holdings Co., Ltd. (D.D.C.) (No 05-CV02179), *available at* <http://www.ftc.gov/os/caselist/0410034/051107comp0410034%20.pdf>.

preliminary injunction sought by the Commission, Warner Chilcott waived the exclusionary provision in its agreement, and the next day Barr announced its intention to start selling generic Ovcon in the U.S.<sup>15</sup> Under the terms of the October 2006 order settling the Commission's charges, Warner Chilcott agreed to certain terms to protect generic entry into the market. Though Warner Chilcott settled, the FTC's case against Barr continues.

The FTC has also actively challenged what we believe are anticompetitive settlements of Hatch-Waxman patent litigation, in which the brand-name drug firm pays its potential generic competitor to abandon a patent challenge and delay entering the market. The FTC's position, of course, has not garnered universal support. From industry, we have heard that we are not accounting appropriately for innovation incentives. We disagree. We recognize, as the FTC's 2003 report on the patent system explains,<sup>16</sup> that patent protection is critical to promoting innovation for new drug products. The discovery, development, and testing of new medicines is time-consuming, uncertain, and expensive. The temporary exclusivity that the patent system provides prompts brand name drug companies to undertake that risk and expense. In the absence of patent protection, other firms could, with small cost and no risk, sell the same new drug, now identified by the innovator. Those sales can erode the innovator's profits and incentives to innovate. By preventing rival firms from free riding on the innovating firms' discoveries,

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<sup>15</sup> Final Order and Stipulated Permanent Injunction, Federal Trade Comm'n v. Warner Chilcott Holdings Co., Ltd. (D.D.C.) (No 05-CV02179), *available at* .

<sup>16</sup> *To Promote Innovation: The Proper Balance of Competition and Intellectual Property Law and Policy*, *available at* <http://www.ftc.gov/opa/2003/10/ipreport.htm>, [hereinafter IP Rpt.].

patents can enable pharmaceutical firms to cover their fixed costs and regain the high levels of capital that they invest in risky research and development efforts.<sup>17</sup>

Patents are also important because they facilitate inter-firm relationships, such as licensing and joint ventures. This is important because many biotechnology companies conduct basic research to identify promising products, and then partner with a pharmaceutical company to test and commercialize them. Patent protection provides a helpful platform for those relationships.<sup>18</sup>

The grant of a patent, however, is not a grant of immunity from the antitrust laws. Firms and individuals can use patent rights, like real property rights, to engage in anticompetitive conduct. Settlement of patent litigation cases between brand and generic manufacturers can result in substantial anticompetitive effects. The Hatch-Waxman legislation altered the competitive landscape in a manner that has a significant impact on the antitrust analysis of these settlements. By increasing the potential economic value of generic entry, the statute also increased the incentive for brand and generic manufacturers to conspire to share rather than compete for the expected profits generated by sales of both brand and generic drugs. For example, a brand manufacturer and generic pharmaceutical company now have an incentive to divide up the profits from the Hatch-Waxman 180-day generic exclusivity period -- a period that did not exist prior to the passage of the Act. In nearly any case in which generic entry is contemplated, the profit that the generic anticipates will be much less than the profit that the brand-drug company would make from the same sales. Consequently, it will often be more

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<sup>17</sup> IP Rpt., Ch. 3 at 11-12.

<sup>18</sup> IP Rpt., Ch. 3 at 15, 17-18.

profitable for the branded manufacturer to buy off generics. Indeed, Congress expressly recognized the risk that the Act might promote such market allocation agreements, and implicitly directed the enforcement agencies to prosecute such agreements by amending the Hatch-Waxman Act in 2003 to require brand pharmaceutical companies and generic applicants to file patent settlement agreements with the FTC and the Antitrust Division.

From Courts of Appeals, we have heard that the FTC is not giving enough weight to the importance of settlement. We also disagree with this criticism. Undoubtedly, there can be significant procompetitive benefits of settling patent litigation between brand and generic manufacturers. Further, we recognize the importance of settlements generally to the judicial system. The benefits achieved from settlements, however, do not trump the antitrust laws.

Of course, the FTC did not prevail in the *Schering* case, and the *Schering* and *Tamoxifen* appellate decisions prompted a resurgence of settlements in which the parties agree to compensation to the generic company and restrictions on generic market entry. In fiscal year 2003, the first year following Congress's requirement that pharmaceutical patent settlements be filed with the antitrust agencies, the Commission reported that *fourteen* agreements that resolved patent infringement actions by brand-name manufacturers against a generic rival were filed, but *none* involved a reverse payment.<sup>19</sup> In contrast, in the following reporting year, during which the Eleventh Circuit handed down its decision in *Schering*, there were *eleven* final settlements of brand-generic patent litigation, of which *three* (27%) included both compensation to the generic

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<sup>19</sup> Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2004: Summary of Agreements Filed in FY 2005: A Report by The Bureau of Competition 1-2, *available at* <<http://www.ftc.gov/os/2005/01/050107medicareactrpt.pdf>>.

rival and a restriction on its ability to market its product.<sup>20</sup> In the most recent reporting year, the number of brand-generic patent litigation settlements more than doubled, to 28 agreements.<sup>21</sup> Of those, *fourteen* (50%) included both compensation to the generic and a restriction on the generic's ability to enter the market with a rival generic product.<sup>22</sup>

Congress has required the FTC to continue to review Hatch-Waxman settlements, and the Commission will remain vigilant in monitoring these settlements, and will bring enforcement actions in appropriate cases. Moreover, going forward, the Commission will work to change the prevailing legal standards for evaluating the antitrust implications of reverse-payment settlements because they have tipped too far in favor of settlement payments to holders of even the "weakest" of patents. It simply cannot be correct, as at least one court ruling implies, that, in the absence of a sham or a fraud, any patent holder that walks into a federal courthouse, and files a court complaint that alleges that a generic manufacturer has infringed its patent, is then entitled to pay the generic manufacturer any amount of money not to compete with the brand manufacturer for as long as the nominal term of the patent. Put more bluntly, there is no reason

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<sup>20</sup> Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2005: A Report by The Bureau of Competition ("FY2005 Settlements Report"), *available at* <<http://www.ftc.gov/os/2006/04/fy2005drugsettlementsrpt.pdf>>.

<sup>21</sup> Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2006: A Report by The Bureau of Competition ("FY2006 Settlements Report"), *available at* <<http://www.ftc.gov/reports/mmact/MMAreport2006.pdf>>.

<sup>22</sup> It is also worth noting that of the fourteen agreements that included compensation to the generic rival, ten "included some type of side-deal involving elements not directly related to the resolution of the patent dispute between the brand and generic." FY2006 Settlements Report, at 3. That was the factual scenario in the *Schering* case. In contrast, of the eight settlement agreements that included no restriction on generic entry, only two had "side deals," and neither of those two agreements has resulted in competition between the brand and the generic. *Id.*

to believe that every time that patent holder alleges infringement of its patent in a complaint, that the infringement has in fact occurred. Indeed, the empirical evidence is to the contrary. Data show that generic applicants have had nearly a 75 percent success rate in pharmaceutical patent litigation.<sup>23</sup>

The challenge for the antitrust enforcement agencies, the courts, and the pharmaceutical industry at large is to devise a workable rule, or set of rules, to distinguish those patent settlements that restrain competition from those that do not. By workable, I mean rules that provide clear standards, promote innovation and efficiency, and can be applied in a cost-effective manner.

I had preferred that we do so through the development of case law within the antitrust laws. But with courts finding no place for antitrust in this critical area, we have agreed to work with Congress on new legislation to prohibit anticompetitive reverse-payment settlements. Policymakers need to consider certain principles in crafting the precise form and scope of a legislative remedy. The fundamental concern underlying reverse-payment settlements is the sharing of profits preserved by an agreement not to compete, whatever form the compensation to the generic takes. Thus, legislation must be sufficiently broad to encompass the various ways that a branded firm may share its profits with the generic, including not only the ways we have seen to date, but also those that may arise in the future. At the same time, legislation should be designed to avoid unwarranted deterrence of settlements.

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<sup>23</sup> See Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration: An FTC Study 19-20* (July 2002), available at <<http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf>>.

Legislation that bans most reverse-payment settlements represents a sound approach to addressing the problem because, far more often than not, reverse payments in settlements will result in a generic entry date that is later than the parties' expectations about the strength of the underlying patent. As I stated, however, there may be circumstances where reverse-payment settlements do not result in anticompetitive delays in generic entry. The Commission is willing to work with the industry and Congress to ensure that appropriate exemptions are included in any legislation. To this end, I strongly urge members of the industry to work with me and the Commission to identify such exceptions.

***Conclusion***

As I stated at the outset of my remarks, vigorous competition in the pharmaceutical industry is essential for our economy and for the health of American consumers. Thank you for allowing me to share with you some insights into how the FTC tries to protect such competition at this important time in the industry's history.