The Federal Trade Commission

Remarks of Deborah Platt Majoras
Chairman of the Federal Trade Commission[1]
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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

[1] 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."[2] 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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[2] Antitrust Modernization Commission, Report and Recommendations (April 2007), *available at* 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.[3] 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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[3] *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>.

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,[4] 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 po8tin.9(a)3n3lFf the ypm

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[4] *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

[5] *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).

[6] *Cephalon, Inc./Cima Labs, Inc.*, FTC

transactions involving Novartis and Eon,[7] Teva and Ivax,[8] Barr and Pliva,[9] Watson and Andrx,[10] Hospira and Mayne,[11] and, most recently, Actavis and Arbika.[12] 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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[7] *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.

[8] *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

[9] *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

[10] *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.

[11] *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.

[12] *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.

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[20] Agreements Filed with the Federal Trade Commission under the Medicare Prescription

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.[23]

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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[23] *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.