Federal Trade Commission

FTC INITIATIVES TO PROMOTE COMPETITION IN THE PHARMACEUTICAL INDUSTRY

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I. Introduction

Good afternoon. I am pleased to be here today to talk about some of the Commission's initiatives in promoting competition in the pharmaceutical industry.

Advances in the bio-pharmaceutical industry continue to bring enormous benefits to Americans. Through biological and pharmaceutical innovations, a growing number of medical conditions can be treated more effectively with drugs and drug therapy than with alternative means. Yet the development of new drugs is risky and costly. Out of the scores of chemical compounds that are identified, only a few result in the creation of new therapeutically successful drugs. Thus, it is vital to our healthcare system that pharmaceutical companies continue to have strong incentives to takes these risks and incur these costs.

At the same time, the health care industry plays a crucial role in the U.S. economy in terms of its impact on spending and on consumer welfare. Health care expenditures in the United States total almost $2 trillion annually, reaching 16 percent of GDP in 2005, and those costs have been increasing steadily for the last 30 years. Notably, ten percent of that total can be attributed to prescription drugs.[1] Within this context, reductions in competition through mergers or other agreements may lead to further price increases, and fewer competing drugs and drug candidates in the marketplace.

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[1] *See* http://www.cms.hhs.gov/NationalHealthExpendData/02_NationalHealthAccountsHistorical.asp#TopOfPage.

Recognizing each of these important interests, the Federal Trade Commission is at the forefront of the effort to protect competition in the bio-pharmaceutical industry. That effort has been, and continues to be, among the FTC's highest priorities. Appropriate agency action can preserve both the necessary financial incentives to continue to produce and develop new drugs, as well as the benefits to consumers of competition on price, quality, quantity, and innovation.

Today, I plan to highlight several of the Commission's initiatives in the bio-pharma area. These include: (1) merger review; (2) patent settlement cases with exclusionary payments; (3) non-patent-related restraints on trade; and (4) our pending study of authorized generic drugs.

II. Merger Review

One important area of ongoing Commission involvement in the pharmaceutical industry is merger review. Since the start of fiscal year 2004, the Commission has reviewed close to 400 mergers relating to pharmaceuticals and medical devices. In most of these cases, the Commission was able to determine that the mergers raised no significant competitive issues without the issuance of a second request. Out of these 400 mergers, the FTC issued second requests in thirteen pharmaceutical transactions. These investigations resulted in ten consent decrees with remedies designed to protect competition without unnecessarily interfering with competition in the market. Theses consents covered more than 55 different pharmaceuticals products, with combined sales of more than $16 billion.

The Commission's review of mergers within the pharmaceutical industry spans competition in all its forms, including current and future competition. For current competition, we look at three primary areas: (1) competition between different formulations of branded drugs; (2) competition between branded and generic formulations of the same drug; and (3) competition

in a market that contains multiple generic products of the same drug. How the FTC evaluates the loss of competition resulting from the merger of two pharmaceutical products will depend in large part on where these products are in their particular life cycles. Often times, the competitive constraints or interactions that a drug faces early in its life cycle will differ from those it faces later in its life cycle.

At the beginning of its life cycle, the most significant competition or competitive constraint a branded pharmaceutical product will likely face will be that from another branded product with a similar mechanism of action or that treats the same condition. Thus, a transaction may create competitive concern if it combines two branded products that are significant competitors. Later in its life cycle, however, the branded product will likely face direct competition from the first generic equivalent on the market and less competitive interaction with other branded products. In those situations, the FTC will look closely at a merger eliminating the only generic competition with a branded product. Finally, at the latest stages of a drug's life cycle, it is likely that the closest competition will not include the branded product, which often sells at a premium, but the multiple generics that have entered the market. There is abundant evidence that drug pricing is heavily influenced by the number of generic competitors that participate in a given market. In fact, the price of a generic drug product can decrease with the entry of each additional competitor. Thus, the FTC has taken enforcement action with mergers that have a significant impact on generic-generic competition.

One example where the Commission required a divestiture in a deal eliminating competition between two branded drugs was the Pfizer/Pharmacia deal. After its review of Pfizer's $60 billion dollar acquisition of Pharmacia in 2003, the Commission alleged that the market for combination hormone replacement therapies, or HRT, had only three significant

branded competitors, two of which were Pfizer and Pharmacia. The Commission's consent agreement with the parties preserved competition that otherwise would have been lost by requiring Pfizer to divest all of its rights and assets related to its branded HRT product, including its intellectual property.[2] Thus, the Commission preserved competition by maintaining three independent HRT competitors in the market.

There are also numerous recent examples of where the Commission took enforcement action to preserve competition between two merging generic competitors. In fact, over the past two years the Commission has entered into six consents with merging generic firms, including Novartis and Eon,[3] Teva and Ivax,[4] Barr and Pliva,[5] Watson and Andrx,[6] Hospira and Mayne,[7] and, most recently, Actavis and Abrika.[8]

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[2] *Pfizer, Inc., and Pharmacia Corp*., No. C-4075 (Apr. 14, 2003), Analysis to Aid Public Comment at 3, *available at* http://www.ftc.gov/os/caselist/c4075.htm.

[3] *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.

[4] *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

[5] *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

[6] *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.

[7] *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.

[8] *In the Matter of Actavis Group hf. a corporation; and Abrika Pharmaceuticals, Inc. a corporation,* File No. 071-0063, FTC Docket No. C-4190, Complaint (April 16, 2007), *available*

In the Barr/Pliva transaction last fall, one of the drugs implicated was the antidepressant trazodone. A branded version was sold on the market, as well as five generics that were priced at around 20% below the branded product. (This is an example of a branded product in the latter stages of its life cycle, where there is limited competitive interaction between the brand and its multiple generic versions). After concluding its investigation, the Commission found that the merger would have a negative impact on the market for generic trazodone by eliminating the competition between Barr's and Pliva's generic products and reducing the number of generic competitors from five to four. As a result, the Commission required the parties to divest Barr's generic trazodone product to a third party, thereby maintaining competition in that market.

Mergers that appear to limit future competition between branded and generic drugs also can raise competitive concerns. 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.[9] Delays in generic entry resulting from a merger can therefore have a substantial effect on consumer pricing.

In this regard, the FTC in 2004 entered a consent order to resolve a merger that combined Cephalon, which had a monopoly in the market for treating break-through cancer pain, and Cima, which was poised to enter that market with its own drug.[10] Cephalon's ownership of both

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at http://www.ftc.gov/os/caselist/0710063/0710063cmp.pdf.

[9] *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).

[10] *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

products appeared likely to give it the ability to delay generic entry by shifting patients from its product to Cima's, which had many more years of patent protection. The Commission remedied the potential anticompetitive effects of the transaction by requiring Cephalon to license its patents and 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.

Price competition and future price competition are not the only forms of competition with which the Commission is concerned in merger review. Initially, competition occurs during the product development stage when companies compete in the race to innovate. The winner of that race can earn significant rewards. Other forms of non-price competition may include competition on product quality, quantity, advertising, or post-marketing clinical trials to expand the indications for the drug.

For example, the Commission sought to protect potential competition and innovation that could increase the availability of new treatments through the remedy it established in response to Sanofi's acquisition of Aventis in 2004.[11] Factor Xa inhibitors are anticoagulant products that are used to break up blood clots in the body. Aventis' Factor Xa inhibitor product (Lovenox) had around a 90% market share. Sanofi marketed Factor Xa inhibitor Arixtra, but was also pursuing FDA approval for new indications. Arixtra's competitive significance was expected to expand as it received FDA approval for the new indications. Thus, the acquisition would have caused consumers to lose not only the independent presence of Arixtra in the market for Factor

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Order (Sept. 20, 2004), *available at* http://www.ftc.gov/os/caselist/0410025/040924do0410025.pdf.

[11] *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

Xa inhibitors, but also the innovations that Sanofi had been pursuing in seeking approval for new indications. This was because the Commission found that a combined Sanofi-Aventis may have less incentive to develop new indications than an independent Sanofi would have had. The Commission's remedy addressed both harms. The consent order required Sanofi to divest Arixtra to Glaxo Smith-Kline. It also required that Sanofi assist GSK in completing key clinical trials in order to preserve the potential benefits of that innovation.

The FTC also recognizes that a merger will sometimes generate important efficiencies and procompetitive benefits related to innovation. For instance, the merger may increase the likelihood that a new drug will reach the market or reach the market sooner. One of the merging firms may have superior 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 FTC's 2004 review of the *Genzyme/Ilex* merger demonstrates the agency's appreciation of efficiencies that benefit innovation. The drugs at issue in that matter provided acute therapy for solid organ transplants by suppressing the immune system during initial organ transplant and during episodes of acute rejection.[12] 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 price of Campath was significantly lower than the price of Genzyme's drug. In addition to the Genetech and Ilex drugs, there were four other solid organ transplant acute therapy products used in the United States. However, due to similar mechanisms of action,

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[12] *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

Campath and Thymoglobulin were especially close competitors. The Commission found that the merger would have lessened competition in the market for acute therapy drugs used in solid organ transplant by eliminating the actual competition between Genzyme and Ilex.

At the same time, however, the merging parties argued that the merger would have significant efficiencies because Genzyme had expertise that would facilitate the development of Campath for additional leukemia and oncology indications. Recognizing both the potential anticompetitive and procompetitive effects from the deal as it related to Campath, the Commission sought to fashion a remedy that would prevent the anticompetitive effects without interfering with the potential efficiencies. Thus, instead of requiring the merged firm to divest all of its interests in Campath, the FTC approved 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 and ensured that the price of Campath would continue to be determined through competition with drugs in the category of its approved use, oncology. Just as importantly, however, this remedy also allowed Genzyme to continue its relationship with Schering, the distributor of Campath, regarding uses of Campath outside solid organ transplant. In this way, the remedy preserved the likely efficiencies in innovation that the merger brings to Campath's development.

III. Exclusion Payments

Beyond merger matters, the Commission also vigorously investigates, and when necessary litigates, conduct-related competition matters in the pharmaceutical industry. One of the highest priorities for the agency in this area antitrust challenges to "exclusion payment

settlements." That term describes settlements of patent litigation in which the brand-name firm pays its potential generic competitor to abandon a patent challenge and delay entering the market.[13] Such settlements restrict competition at the expense of consumers, whose access to lower-priced generic drugs is delayed, often for many years.

Most settlements of litigation include some form of consideration flowing between the parties. But it is the type of consideration that matters in the antitrust analysis. Some types of consideration, such as an early entry date, a royalty to the patent-holder, or compromising on a damage claim, do not generally involve sharing the benefits that come from eliminating potential competition. The sharing of profits achieved by eliminating competition, however, is at the core of the what Section 1 of the Sherman Act proscribes.

The Commission's initial enforcement efforts in this area appeared be a significant deterrent to anticompetitive behavior. In the late 1990s, the Commission learned of exclusion payments arising in Hatch-Waxman patent litigation,[14] and the Commission brought a number of

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[13] *Abbott Labs.*, Dkt. No. C-3945 (May 22, 2000) (consent order), complaint *available at* <http://www.ftc.gov/os/2000/05/c3945complaint.htm>; *Geneva Pharms., Inc.*, Dkt. No. C-3946 (May 22, 2000) (consent order), complaint *available at* <http://www.ftc.gov/os/2000/05/c3946complaint.htm>. The consent order in *Abbott Laboratories* is *available at* <http://www.ftc.gov/os/2000/03/abbot.do.htm>. The consent order in *Geneva Pharmaceuticals* is *available at* <http://www.ftc.gov/os/2000/03/genevad&o.htm>. The consent order in *Hoechst/Andrx* is *available at* <http://www.ftc.gov/os/2001/05/hoechstdo.htm>. *Hoechst Marion Roussel, Inc.*, Dkt. No. 9293 (May 8, 2001) (consent order), complaint *available at* http://www.ftc.gov/os/2000/03/hoechstandrxcomplaint.htm. *Bristol-Myers Squibb Co.*, Dkt. No. C-4076, *available at* <http://www.ftc.gov/os/caselist/c4076.htm>.

[14] The Commission ultimately determined that, in the seven years between 1992 and 1999, there were fourteen final settlements between brand-name manufacturers and the generic first-filer, and that eight of those settlements included a payment from the brand name drug company to the generic drug applicant in exchange for the generic company's agreement not to market its product. Bureau of Competition Report, Federal Trade Commission, *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and*

enforcement actions beginning in 2000. To facilitate antitrust enforcement, in 2003 Congress enacted a requirement that all such settlements be filed with the FTC and the Department of Justice. Thanks to this filing requirement, the FTC staff is able to review all settlements of patent cases brought under the Act.

For several years, agreements with exclusion payments essentially stopped. The Commission is not aware of any pharmaceutical settlement between a brand-name manufacturer and a generic filer that included both a payment to the generic company and an agreement by the generic company to defer marketing its product between 2000 and the end of 2004. During the same period, however, patent settlements did not disappear. To the contrary, in less than five years, there were at least as many settlements as there were in the seven years in which pharmaceutical companies were settling litigation with payments and restrictions on generic entry.[15] Parties simply found different ways to resolve their disputes, presumably on the basis of the relative strength of their cases.

Recent court decisions, however, have made it more difficult to bring antitrust cases to stop exclusion payment settlements, and the impact of those court rulings is becoming evident in the marketplace. In 2005, two appellate courts adopted a permissive – and, respectfully, in our

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Modernization Act of 2003: Summary of Agreements Filed in FY 2005: A Report by the Bureau of Competition (Apr. 2006), *available at* <http://www.ftc.gov/os/2006/04/fy2005drugsettlementsrpt.pdf>.

[15] We lack data for the approximately three year period between the end of the Generic Drug Study and the beginning of the MMA reporting period. It is quite likely that there are additional settlements that occurred during this period for which we do not have information.

view, incorrect – position on certain exclusion payment settlements.[16] In the *Schering* case,[17] the Eleventh Circuit vacated a decision in which the Commission found that two patent settlements violated the FTC Act. The court purported to assess whether the agreement exceeded the exclusionary potential of Schering's patent. In so doing, the court relied on the incorrect supposition that the patent provided Schering with "the legal right to exclude . . . [generics] from the market until they proved either that the . . . patent was invalid or that their products . . . did not infringe Schering's patent,"[18] and noted that there was no allegation that the patent claim was a "sham."[19]

The impact of the Eleventh Circuit's decision – in the courts and in the pharmaceutical industry – has been evident. Other courts have read that decision to require only an inquiry into the nominal reach of the patent, and not (as some have suggested) a direct assessment of the likelihood that the patent holder could successfully effect exclusion through patent litigation.[20] A divided panel of the Second Circuit, ruling on an antitrust challenge to a patent settlement

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[16] *Schering-Plough Corp. v. F.T.C.,* 403 F.3d 1056 (11th Cir. 2005); *In re Tamoxifen Citrate Antitrust Litig.*, 429 F.3d 370 (2d Cir. 2005) (Pooler, J., dissenting).

[17] *Schering-Plough Corp.,* 2003 FTC LEXIS 187 (FTC Dec. 8, 2003), *vacated*, 402 F.3d 1056 (11 Cir. 2005), *cert. denied,* 126 S. Ct. 2929 (2006); *Schering-Plough Corp., Upsher-Smith Labs., and American Home Products Corp*., Dkt. No. 9297 (Apr. 2, 2002) (consent order as American Home Products).

[18] *Id.* at 1066-67.

[19] *Id.* at 1068.

[20] *See, e.g., In re Ciprofloxacin Hydrochloride Antitrust Litig*., 363 F. Supp. 2d 514, 539 (E.D.N.Y. 2005), *appeal docketed*, No. 05-2851 (2d Cir. June 7, 2005) ("Cipro") (stating that the ruling below "is more fairly read as requiring an evaluation of the scope of the patent's claims, and not a post hoc analysis of the patent's validity").

involving the anti-cancer drug Tamoxifen, followed the Eleventh Circuit's holding.[21] The plaintiffs in the *Tamoxifen* case have asked the Supreme Court to review the Second Circuit's ruling, and their petition for certiorari is pending.[22] After years of active antitrust enforcement,[23] these two rulings prompted a resurgence of settlements in which the parties settle with compensation to the generic company and restrictions on generic market entry.

Where a patent holder makes a payment to a challenger to induce it to agree to a later entry date than it would otherwise agree to, consumers are harmed – *either* because a settlement with an earlier entry date might have been reached, *or* because continuation of the litigation without settlement would yield a greater prospect of competition. Through the payment, the patent holder has purchased insurance against the prospect of competition. Some who disagree with the Commission's position argue that, rather than treat the outcome of the patent suit as uncertain (as it certainly is), antitrust analysis must presume the patent is valid and infringed unless patent litigation proves otherwise. This argument, however, ignores both the law and the facts.

The antitrust laws prohibit paying a potential competitor to stay out of the market, even if its entry is uncertain. Indeed, the position that antitrust law would bar a brand name drug firm from paying a generic filer to withdraw its application for FDA approval should be uncontroversial, even though the potential generic competitor's application might not be

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[21] *In re Tamoxifen Citrate Antitrust Litig*., 429 F.3d 370 (2d Cir. 2005), *amended*, 466 F.3d 187 (Aug 10, 2006), *petition for cert. filed*, http://www.supremecourtus.gov/docket/06-830.htm (Dec. 13, 2006) (No. 06-830).

[22] The Court has invited the Solicitor General to submit a brief expressing the views of the United States.

[23] *In re Cardizem Antitrust Litigation*, 332 F.3d 896 (6th Cir. 2003).

approved. The suggestion that generic entry before the end of a patent term is too uncertain to be of competitive concern is likewise untenable. The empirical evidence shows that generic applicants have enjoyed a nearly 75 percent success rate in patent litigation. Finally, the argument that prohibiting exclusion payments will prevent legitimate settlements is contradicted by experience during the period from 2000 through 2004. Patent settlements – using means other than exclusion payments – continued to occur.

These developments threaten substantial harm to consumers and others who pay for prescription drugs. For that reason, the Commission remains vigilant in its monitoring of these settlements and will pursue an appropriate case. In light of the difficulties we have encountered in the courts, however, the Commission also supports legislation to prohibit these anticompetitive settlements. In working with Congress to craft new legislation, we have adhered to certain principles regarding the best form and scope of any such legislative remedy.

The fundamental concern underlying exclusion 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.

We believe a recent bill introduced in the House of Representatives by Chairman Rush and other members of the Committee on Energy and Commerce, H.R. 1902, represents a sound approach to addressing the exclusion payment problem.[24] H.R. 1902 provides a general

[24] Protecting Consumer Access to Generic Drugs Act of 2007, H.R. 1902, 110th Cong. (2007).

prohibition on settlements in which the generic firm receives something of value and agrees to refrain from selling its product – but it also contains express exclusions from this prohibition to try to ensure that settlement avenues are not unduly limited. When the value received by the generic applicant amounts to nothing more than the right to sell a generic version of the branded drug the innovator firm is seeking to protect – whether it be the right to sell the generic drug product before patent expiration, a waiver of the brand's market exclusivity based on testing of a drug for pediatric use, or a waiver of patent infringement damages against a generic for entry that has already occurred – the settlement is unlikely to involve a sharing of profits preserved by avoiding competition. The bill properly exempts such settlements. The Commission is also willing to work with the Congress to ensure that, if other exemptions are warranted, that they are included in the legislation. It may be appropriate, for example, to include an exemption for payments of the generic companies' reasonable attorneys fees.

In addition, the bill provides flexibility by authorizing the FTC to adopt rules to exempt certain agreements from the general prohibition. With this authority, the Commission can ensure that the law remains flexible and keeps pace with changes in patent settlement terms – by continuing to review the diverse ways in which value is being transferred, the Commission can identify those exchanges that are not harmful to competition and consumers, and exempt them from the prohibition.[25]

IV. Non-Patent Agreements in Restraint of Trade: Warner Chilcott/Barr

[25] The bill also provides a legislative solution to another strategy that brand-name drug firms can use to effectively block generic entry – by settling with the first generic applicant and declining to sue subsequent applicant. H.R. 1902, 110th Cong. § 4 (2007).

Although the Commission's exclusion payment patent settlement cases attract much of the attention in the pharmaceutical arena, we continue to be active in other pharmaceutical conduct matters. For example, in November 2005, the Commission filed a complaint seeking to permanently enjoin an agreement in which Warner Chilcott – manufacturer of the branded oral contraceptive Ovcon 35, which is off patent – and Barr Labs, the only potential generic competitor, agreed that Barr would stay out of the market for five years in exchange for a $20 million payment from Warner.[26] The Commission alleged that Warner entered into this agreement because generic entry by Barr would interfere with Warner's strategy of switching customers away from the tablet version of Ovcon to a new chewable form that would be patent-protected. By delaying generic entry, Warner could then convert customers without interference and effectively foreclose future generic competition after doctors stopped writing prescriptions for the tablet version.

While the FTC permanent injunction proceeding was pending, the Commission learned that Warner intended to move forward on its switch strategy by launching chewable Ovcon in September 2006. Because a successful switch by Warner would substantially interfere with the Commission's ability to preserve generic Ovcon competition, on September 25, 2006, the Commission filed a motion for a preliminary inunction, not to stop Warner from launching chewable Ovcon, but from taking steps to remove the tablet version from the market.

The very same day the FTC filed the motion for preliminary injunction, Warner waived the exclusionary provision in its agreement with Barr that prevented Barr from entering with its

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[26] FTC v. Warner Chilcott Holdings Co. III, No. 1:05-cv-02179-CKK (D.D.C. filed Nov. 7, 2005) (complaint filed), *available at* http://www.ftc.gov/os/caselist/0410034/051107comp0410034%20.pdf.

generic version of Ovcon. The next day, Barr announced its intention to start selling a generic version of the product, and it now has done so, over 2 ½ years earlier than possible under the anticompetitive agreement with Barr.[27]

In October 2006, the district court entered a final order that settled the FTC's charges against Warner Chilcott. As a result of the settlement, Warner Chilcott: (1) must refrain from entering into agreements with generic pharmaceutical companies in which the generic agrees not to compete with Warner Chilcott and there is either a supply agreement between the parties or Warner Chilcott provides the generic with anything of value and the agreement adversely affects competition; (2) must notify the FTC whenever it enters into supply or other agreements with generic pharmaceutical companies; and (3) for three months, had to take interim steps to preserve the market for the tablet form of Ovcon in order to provide Barr the opportunity to compete with its generic version.[28] The FTC's case against Barr is ongoing.

What is remarkable about the FTC's action in this case is that instead of a single competitor on the market – chewable Ovcon – we now have three competitors, including Warner with both a chewable and tablet version of Ovcon; Barr with its generic tablet; and now a new authorized generic from Watson. The evidence indicates that the generic versions are selling at about half the price of the original Warner Ovcon tablet.

V. Advocacy: Authorized Generic Drug Study

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[27] FTC News Release, Consumers Win as FTC Action Results in Generic Ovcon Launch (Oct. 23, 2006), *available at* http://www.ftc.gov/opa/2006/10/chilcott.htm.

[28] *FTC v. Warner Chilcott Holdings Co. III*, No. 1:05-cv-02179-CKK (D.D.C. filed Oct. 23, 2006) (stipulated permanent injunction and final order), *available at* http://www.ftc.gov/os/caselist/0410034/finalorder.pdf.

The Commission complements its merger and nonmerger law enforcement through a broad series of activities, including research and reports, workshops, advocacy filings, and amicus briefs. Some of those activities relate to the workings of the Hatch-Waxman Act and the relationship of brand and generic drugs. The Commission's 2002 Generic Drug Study,[29] which led to the MMA's 2003 amendments to Hatch-Waxman, was ground-breaking in this regard.

One of the Commission's current initiatives is a study of the short- and long-term competitive effects of authorized generic drugs in the prescription drug marketplace.[30] An authorized generic is chemically identical to a particular brand-name drug, which the brand-name manufacturer authorizes to be marketed as a generic version under the approval that the FDA granted for the brand-name drug. The brand-name manufacturer either sells the authorized generic itself through a subsidiary or licenses a generic firm to sell the authorized generic.

Issues have been raised regarding the impact of authorized generics and the 180-day exclusivity period. In recent years and with increasing frequency, brand-name drug manufacturers have begun to market authorized generic drugs at precisely the same time that a paragraph IV generic is beginning its period of 180-day marketing exclusivity.

The likely effects of this practice on generic competition have been subject to a good deal of debate. In the short run, the entry of an authorized generic drug may benefit consumers by creating additional competition that lowers generic prices further than if only the paragraph IV

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[29] Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration: An FTC Study* (July 2002), *available at* http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf.

[30] *FTC Proposes Study of Competitive Impacts of Authorized Generic Drugs* (News Release March 29, 2006), *available at* http://www.ftc.gov/opa/2006/03/authgenerics.shtm; Notice, 71 Fed. Reg. 16779-02 (April 4, 2006).

generic were marketed. Many generic manufacturers assert, however, that in the long run consumers will be harmed because an expectation of competition from authorized generics will significantly decrease the incentives of generic manufacturers to pursue entry prior to patent expiration, especially for "non-blockbuster" drugs. For a generic manufacturer, the additional competition from an authorized generic may result in significantly less profit during the period of 180-day exclusivity than if the generic manufacturer had no authorized-generic competition during that time. Another potential concern is that, in the context of settlement, the brand-name manufacturer will promise to forego introducing an authorized generic in exchange for the first-filer agreeing to push back its entry date.

There is no publicly available, comprehensive economic study that assesses the likely short- and long-run effects of entry by authorized generics on generic competition. Given the importance of generic drugs in lowering health care costs, Senators Grassley, Leahy, and Rockefeller have requested that the Commission conduct such a study.[31] Thus, Commission has proposed to examine both the likely short-term competitive effects of authorized generic drug entry and, to the extent possible, the likely long-term impact of entry by authorized generic drugs on competition by generic manufacturers. Among other things, the study will examine actual wholesale prices (including rebates, discounts, etc.) for brand-name and generic drugs, both with and without competition from authorized generics; business reasons that support authorized generic entry; factors relevant to the decisions of generic firms about whether and under what

[31] *See* Letter to Chairman Deborah Platt Majoras, from Senators Grassley, Leahy, and Rockefeller (May 9, 2005).

circumstances to seek entry prior to patent expiration; and licensing agreements with authorized generics.

The Commission intends to rely on data and information from the FDA, brand manufacturers, independent generic manufacturers, and authorized generic companies. In March 2006, the Commission issued a notice in the Federal Register describing the study and the types of information it would be seeking from the industry.[32] The FTC received 13 comments on the proposed information collection requests.[33] All of the public interest organizations that submitted comments, which included a nonprofit group dedicated to the use of antitrust as a component of competition policy, strongly endorsed the study – as did generic companies and their trade organization, GPhA.[34] Comments from the brand-name pharmaceutical industry,

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[32] *FTC Proposes Study of Competitive Impacts of Authorized Generic Drugs* (News Release March 29, 2006), *available at* http://www.ftc.gov/opa/2006/03/authgenerics.shtm; Notice, 71 Fed. Reg. 16779-02 (April 4, 2006).

[33] The comments are available at http:// www.ftc.gov/os/comments/genericdrugstudy3/. The 13 submissions are from AARP (nongovernmental organization for Americans age 50 and older); Actavis Group (Actavis) (generic pharmaceutical company); American Antitrust Institute, Consumer Federation of America, Families USA, and U.S. Public Interest Research Groups (AAI/CFA/FUSA/USPIRG) (nongovernmental public interest organizations); Consumers Union (nonprofit organization representing consumers); Ronald W. Davis (Davis) (attorney submitting comments "on behalf of an undisclosed client"); Generic Pharmaceutical Association (GPhA) (trade association representing generic pharmaceutical manufacturers); Gilbert's LLP (Gilbert's) (law firm representing "one of the largest generic pharmaceutical companies in the United States"); IMS Health Inc. (IMS) (provider of information and research to the health care industry); Eli Lilly and Co. (Lilly) (an innovation-driven pharmaceutical company); Ohio Public Employees Retirement System (OPERS) (Ohio pension system); Pharmaceutical Research and Manufacturers of America (PhRMA) (trade association representing research-based pharmaceutical and biotechnology companies); Prasco, LLC (Prasco) (privately held, independent pharmaceutical company that makes AGs); and Prescription Access Litigation (PAL) (coalition of "consumer, healthcare, labor, senior, legal services, and women's health organizations").

[34] Notice, 72 Fed. Reg. 25304, n.8, n.11 (May 4, 2007), *available at* http://www.ftc.gov/os/2007/04/P062105Authorized_Genericsfrn.pdf.

which markets or authorizes the marketing of authorized generics, generally accepted the core concepts of the study, but expressed concerns primarily focused on the breadth of the originally proposed document requests.[35]

In May of this year, the Commission published a Federal Register notice discussing the comments, and revising the previously published information requests in light of the comments received.[36] The FTC has narrowed a number of the information requests in light of the industry comments, and has given consideration to various suggestions to limit or expand the scope of the study. The public again has an opportunity to comment on the Commission's revised notice, while the FTC requests that OMB grant clearance for the proposed information requests.

VI. Conclusion

In conclusion, I would like to thank you for allowing me to share some insights into the varied and important work that the FTC undertakes in this critical industry. I would be happy to take any questions. Thank you.

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[35] Notice, 72 Fed. Reg. 25304 at n.13.

[36] *Id.*