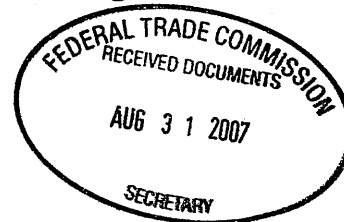




GENERIC PHARMACEUTICAL ASSOCIATION

ORIGINAL



August 22, 2007

Federal Trade Commission
Office of the Secretary
Room H-135 (Annex J)
600 Pennsylvania Avenue, N.W.
Washington, D.C. 20580

Re: Authorized Generic Drug Study: FTC Project No. P062105

Dear Secretary Clark:

The Generic Pharmaceutical Association ("GPhA")<sup>1</sup> submits these comments on the FTC's proposed study of authorized generics (Project No. P062105 ("the Study")). We commend the FTC's decision to issue the Study and suggest specific refinements to enable the Study to clarify the competitive impact of authorized generics. As the Commission noted in its request for comments, the Hatch-Waxman Act is intended to encourage generic entry as soon as is warranted. As the chief antitrust enforcer in the pharmaceutical market, the FTC is readily aware that the vibrant presence of generic drugs leads to enhanced competition and lower prices.

The proposed Study is a step in the right direction. But the Study, as proposed, will gather a limited range of information that is unlikely to fully illuminate the long-term consequences of authorized generics, especially when combined with the other anticompetitive practices in which brand-name manufacturers engage. The study focuses primarily on pricing data which—at best—can provide a snapshot of the immediate impact of these practices. But because authorized generics are a relatively recent practice, limited pricing data will not be entirely informative. To overcome these limitations we suggest that the Commission should institute hearings as a supplement to its proposed analysis. Such hearings could be used to query the real incentives and rationales by which brand-name manufacturers and generic manufacturers operate. It could also bring together industry and economic experts to provide more detailed guidance. Only when the FTC gathers this information will a full picture of the impact of authorized generics in the pharmaceutical market become clear.

<sup>1</sup> The Generic Pharmaceutical Association (GPhA) represents 98% of generic manufacturers, whose products are dispensed for the majority of prescriptions in the United States. GPhA is committed to producing safe, low-cost products; the efforts of GPhA members save consumers billions of dollars every year.

### **The Proposed Study is Important and Timely**

GPhA commends the FTC for taking initiative on this important issue. The Study will be crucial to a proper understanding of authorized generics, and is a prudent use of the Commission's resources. This Study no less crucial than the FTC's earlier efforts on the generic drug front, such as the 2002 FTC study of generic pharmaceuticals that led to a broad and nuanced perspective at a critical time in the industry. As the Commission is aware from those previous efforts, brand name pharmaceutical manufacturers frequently act strategically to delay the entry of lower priced-generic drugs. The opportunities for such conduct are abundant given the web of regulatory conditions that brand-name manufacturers have a hand in gaming.

As the FTC and others have documented, the competition that generic drugs bring to the market, and the consequent savings that they offer to consumers, are substantial. Generic pharmaceuticals currently save consumers over \$10 billion annually: the average price of generic prescription drug was \$28.71, compared to \$95.54 for the branded version.<sup>2</sup> Generic drugs account for over 56% of all prescriptions, yet they less than 10% of drug all expenditures. With an estimated \$78 billion in sales are expected to go off-patent in the next three years,<sup>3</sup> the potential future savings from generics can have a significant impact on our nation's health care costs. Given the critical nature of both competitive markets and affordable healthcare, the FTC should be applauded for engaging in this essential and timely study of a practice that harms pharmaceutical consumers.

### **Background on Authorized Generics**

In order to reward generic firms for the risky and costly conduct of challenging or attempting to invent around brand-name firm patents, Congress provided for a 180-day exclusivity period. That period has played a critical role in the development of the generic drug industry. Patent challenges and creating noninfringing drugs is an expensive and time-consuming process. With the potential for that short period of exclusivity generic firms are spurred to attempt to open markets for vital drugs. The vast majority of potential profits for a generic drug manufacturer are from that 180-day exclusivity period. As FTC and other economic studies have demonstrated once that period expires price quickly is competed down to cost.

The 180-day exclusivity provision provides the first generic company to challenge a brand patent with statutory protection from generic competition. By providing this exclusivity, Congress gave generic drug manufacturers the incentive that they needed to expend the significant resources necessary to challenge or design or invent around suspect patents that otherwise might go unchallenged and to pave the way for eventual full generic competition.

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<sup>2</sup> Id.

<sup>3</sup> Generic Pharmaceutical Association, Statistics, <http://www.gphaonline.org/Content/Navigational/Menu/AboutGenerics/Statistics/Statistics.htm> (Accessed May 18, 2006).

Consumers have saved billions of dollars through the willingness of generic firms to challenge patents or develop noninfringing drugs. To provide just one example, several years ago Barr challenged Lilly's patent on the brand-name drug Prozac. Their success in the litigation expedited the marketing of a generic version of Prozac by two and a half years and saved consumers over \$2.5 billion. The FTC's own generic drug study found that generic patent challenges succeeded in 73 percent of cases, resulting in substantial consumer savings.<sup>4</sup>

As the FTC has documented through its generic drug study and countless enforcement actions, brand name firms frequently act strategically to manipulate the regulatory system or engage in other anticompetitive conduct to delay generic entry. Brand name companies recognize that the 180-day exclusivity period is the only incentive that Congress created to encourage prompt patent challenges, and thus earlier generic market entry. Thus, in the past 2 or 3 years brand name companies have entered into alliances with generic manufacturers to license so-called "authorized generics" at the onset of this 180-day exclusivity period.

The proponents of authorized generics may suggest that they are another aggressive rival in the market. Nothing could be further from the truth. Authorized generic licensing agreements generally provide that the "generic" product not be marketed until after a generic product has been approved. This is not surprising, since to do so earlier would only diminish the profits received by the brand company by allowing a lower-priced generic to compete with the brand name product. Instead, entry by the authorized generic only occurs if the brand-name firm faces the threat of a legitimate generic entry, with the authorized generic's sole purpose to undercut and devalue legitimate generic entry. The sale of authorized generics during the generic exclusivity period reduces the value of the 180-day exclusivity and, consequently, reduces the incentive for generic drug companies to challenge questionable patents.

Authorized generics are also inconsistent with another fundamental goal of the Hatch-Waxman Act: facilitating timely and affordable consumer access to pharmaceuticals sold under questionable brand-name patents. By authorizing a particular generic to compete in the post-patent 180-day ANDA period, the brand-name firms are intentionally diminishing the incentive of any generic to engage in litigation. The result will be that more brand-name patents will go unchallenged (because the value of the diluted exclusivity makes patent challenges less cost-effective), generic competition will be diminished, and consumers will be denied lower-cost generic drugs.

We strongly concur with the need for the FTC study. But for the study to truly inform Congress and regulators we suggest three important changes. The study should focus on both qualitative and quantitative data; the FTC should consider the broad range of ongoing anticompetitive conduct in its study; and the FTC should hold hearings to fully address the subject.

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<sup>4</sup> See Federal Trade Commission, "Generic Drug Entry Prior to Patent Expiration" (July 2002), at 16.

### **Data Collection Must Include Both Quantitative and Qualitative Data**

When the FTC collects data for this study, it must consider that different types of data will be useful for different analytical purposes. The Study as proposed will collect a modest range of quantitative data from drug manufacturers focusing almost entirely on pricing data. Pricing data can provide some information about the immediate effects of the practices, but it by no means will tell the whole story. Quantitative data will be most useful in determining the short-term effects of authorized generics on generic drug prices. But because authorized generics are a recent strategic practice, quantitative data will not accurately present the long-term consequences of these practices. Moreover, pricing data will not provide useful information on the impact of authorized generics on future entry decisions.

Generic pharmaceutical companies interested in Paragraph IV filings evaluate the profitability of entering the market with a 180-day exclusivity period in determining whether the ANDA process is worth their while. The decision to bring a generic to market is typically a three-to-seven year proposition, so the current landscape for authorized generics reflects entry decisions made well before the authorized generic agreements became so prevalent (circa 2003). Thus, the short-term quantitative data that the Study proposes collecting will be helpful, but will not present a complete picture of the true incentives and/or barriers that a generic entrant will consider. The short-term quantitative snapshot will not account for this delayed lead-up time, or for the fact that the current state of the market reflects generic firms' entry decisions made without knowledge of authorized generics.

Qualitative measures are necessary because likely presence of authorized generics will reduce the entrant's perceived profitability during the 180-day exclusivity period at the time that they must commit to entering. If the practice continues, a generic entrant in 2006 will consider it less profitable to enter the market sometime in 2009 to 2013, and the reduced profitability will reduce its overall incentive to enter the market at all. At the margin, this will force some generics to conclude that—because of the presence of authorized generics—it is not worthwhile to enter the market. This will lead to less competition and harm consumers. Of course this rational-decision-maker analysis cannot readily be quantified.<sup>5</sup> Therefore, evidence regarding the decision-making process is necessary to develop a complete understanding of how the authorized generic practice will impact the market—and therefore consumers—in the long term.

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<sup>5</sup> The FTC study does request certain studies and other internal documents about generic entry. This request is appropriate but the type of information available may be very limited.

### **Authorized Generics Must Be Analyzed as one of Several Tools used to Delay Generic Entry**

As is always the case at the intersection of intellectual property and antitrust, there is a delicate balance to be struck in order to fully incentivize innovation and competition. As the Commission is aware, the Hatch-Waxman Act provides generics with the incentive to enter the market by granting them a 180-day exclusivity period. The period provides enhanced revenue to compensate generics for patent challenges,<sup>6</sup> innovating non-infringing alternatives, and navigating the Paragraph IV morass. A mechanical evaluation that queries only the raw number of ANDA applicants, or short-term effects on price, will not adequately illustrate the potential long-term effects on the market, especially considering that the authorized generics exist in a market with a rich history of anticompetitive behavior.

As the FTC is aware, branded pharmaceutical companies frequently engage in anticompetitive conduct to delay generic entry. Authorized generics are only the latest of several strategies used by branded companies to punish, delay, or hinder generic entry. For example, branded pharmaceuticals continue to “product hop,” shifting demand from drugs with questionable or nearly expired patents to practically identical drugs with new patents.<sup>7</sup> The declaratory judgment system has thus far failed to provide an alternative to drawn-out litigation battles. The FTC’s own brief in the *Teva v. Pfizer* case (03-cv-10167) provides an excellent analysis of how the declaratory judgment system has been misused by the branded pharmaceuticals in order to advance their own interests.<sup>8</sup> These same companies have also abused the citizen petition system in an attempt to create roadblocks to the timely approval of generic drugs.

Each of these practices, like authorized generics serve a very important goal of the brand name firms—to manipulate the regulatory system, raise roadblocks and increase uncertainty about the ability of generic firms to enter. None of these practices are efficiency-enhancing. Each is intended to dampen the incentive and ability of generic firms to challenge patents or develop noninfringing drugs. Each practice clouds the ability to enter by creating uncertainty about likely potential for the market. With the added uncertainty it is not surprising, as FTC Commissioner Liebowitz has observed that authorized generics may have led to an increase in the settlement of patent litigation.

Any analysis of the impact of authorized generics on the incentive and ability of generic firms to compete must look at this full range of anticompetitive practices. Thus, we suggest that the FTC expand its study to include decisions by brand name firms to engage

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<sup>6</sup> Patent litigation is extremely expensive and time-consuming. Cases may take a decade or longer to complete and cost millions of dollars.

<sup>7</sup> Cite Tricor case

<sup>8</sup> 2005 “Brief of Amicus Curiae Federal Trade Commission Supporting Appellant’s Combined Petition for Rehearing and Rehearing En Banc”: *Teva Pharmaceuticals USA, Inc. v. Pfizer, Inc.*, 04-1186 (Fed. Cir.)

in product hopping and the filing of citizens petitions. In this fashion the FTC can inform Congress as it did in the 2002 Study of the full range of practices and how they impact generic entry.

### **The FTC Should Hold Hearings on Authorized Generics**

In order to develop a complete picture of the long-term market effects of authorized generics, the FTC should hold hearings on the subject. The FTC should inquire about:

- the role of the 180-day exclusivity period in a generic firm's cost-benefit analysis;
- how generic pharmaceutical companies plan to deal with their reduced profits when they foresee an authorized generic on the horizon;
- how best to ensure open competition while encouraging innovation.

As is described above, the answers to these questions cannot be provided through quantitative data. In addition, a request for documents to assess the decision-making process will not provide a sufficient basis for a rigorous study as these are issues not always reliably documented. Hearings will therefore provide a broader base for a careful analysis of the incentives that influence this market.

The FTC has effectively used hearings in several settings to illuminate both the short and long-term effects of different competitive practices. For example, the 2002 FTC/DOJ Hearings on the Intersection of Intellectual Property and Antitrust Law addressed many complex issues including standard setting, patent pools, and licensing. By bringing together business persons, industry experts, lawyers and economists the hearings were able to illuminate the type of qualitative and long-term competition issues the FTC should address in this study. The FTC hearings on Health Care Competition took a similar approach. We believe hearings may provide the most effective forum to gather the full range of information on these and other anticompetitive practices.

Protecting generic entry is critical to controlling health care costs in America. The proposed study of authorized generics has the potential to examine an important issue in this delicately balanced market. GPhA appreciates the opportunity to comment, and looks forward to working with the FTC in this matter.

Sincerely,

Kathleen Jaeger  
President & CEO  
Generic Pharmaceutical Association