GILBERT'S LLP

June 4, 2007

By Electronic Mail

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

Dear Sir/Madam:

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

We are submitting this comment on FTC Project No. P062105 on behalf of one of the largest generic pharmaceutical companies in the United States. As we stated in our letter of June 5, 2006, we would like to thank the Federal Trade Commission for its interest in the anticompetitive effects of authorized generics, and for its responsiveness to our previously filed comments.

We commend the FTC for streamlining the scope of the study to focus on relevant documents and drug products, while recognizing the potential need for hearing testimony from both brand and generic companies. Further, we are encouraged by the FTC's specification that "retail-level sales and price data" will be considered in order to evaluate the effect of authorized generics on consumers. We are also pleased that the FTC has recognized the importance of considering documents evidencing future competitive strategies and prospective market analyses.

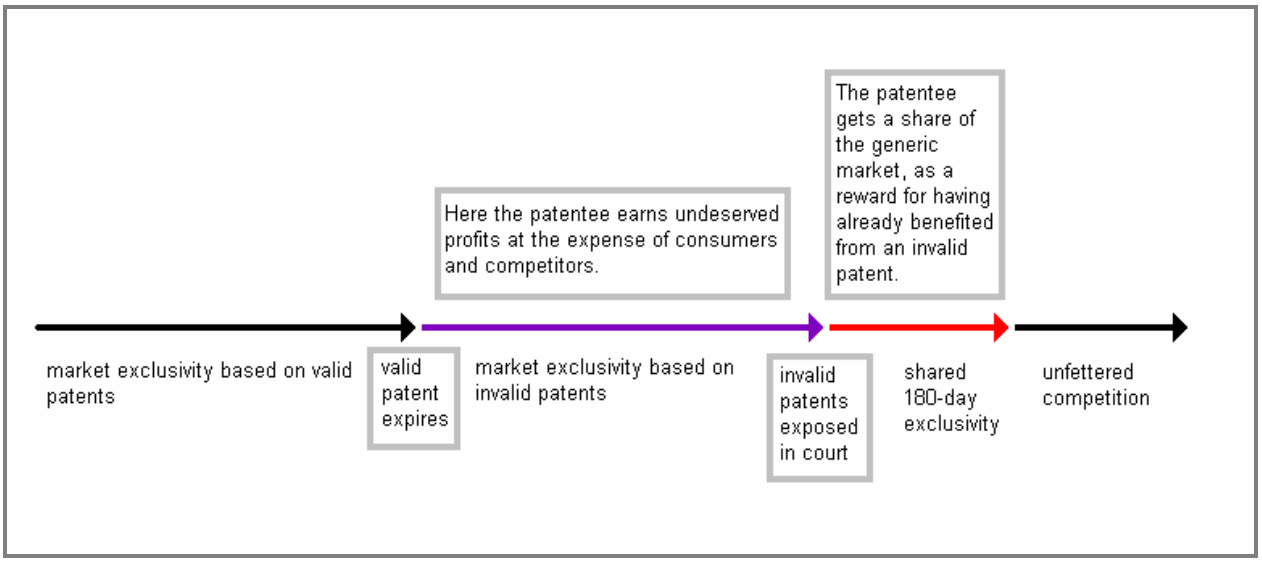
Though we believe that such modifications to the study design will assist the FTC in assessing some of the impact of authorized generics on consumers and generic decision-making, as well as brand companies' motivation for releasing authorized generics, we fear that FTC is "losing the forest for the trees." In specifically rejecting that authorized generics be evaluated in the context of the cumulative impact of brand strategies – including abusive citizen petitions, and the effect of authorized generics on incentives to settle patent disputes – the FTC is neglecting to recognize how these strategies are used in concert to delay generic drug entry, weaken the generic drug industry, and prolong brand monopolies.

1. The FTC Should Measure the Harm to Consumers of Brand Companies Benefiting from Invalid Patents – Both Through Monopoly Pricing and Extended Monopolies from Authorized Generics

The issue of protecting the 180-day exclusivity period is not merely a policy question. The practice of releasing authorized generics during the 180-day exclusivity period is *designed* to undercut the only incentive generic companies have to challenge brand patents. When brand companies are permitted to release authorized generics during the 180-day exclusivity period, they are essentially being rewarded for having invalid or non-infringed patents: (1) during the time-period when the invalid patent is relied upon, the brand company benefits by precluding rightful generi entry and competition and benefits from inappropriate monopoly prices and (2) in the following 180 days, the brand company then benefits from additional exclusivity rights following its wrongful monopoly while punishing the generic manufacturer that exposed the invalid patent.

A generic company is only entitled to the 180-day exclusivity after the patent having been challenged is found to be invalid or not infringed by the generic's product (Paragraph IV Certification). Brand companies are mainly interested in launching an authorized generic during this critical time - when they can benefit from the exclusivity intended for the generic challenger and undercut the incentive for generic company challenge or innovate around patents. The fact that brand companies release authorized generics primarily, if not exclusively, during the 180-day exclusivity period means that the only cases where there is an authorized generic on the market is when the brand has benefited from a patent ultimately found invalid or not infringed.

Consider the following example. The brand company has one valid patent, which expires on day X. However, the brand also files an invalid patent, expiring 10 years after X. The brand company knows the invalid patient will likely not survive the generic company's challenge in court, but the generic company must still address it. Assume that the generic company expends the necessary resources to successfully challenge the invalid patent under a Paragraph IV certification. The generic company plans to introduce its generic product the next day, and is entitled to 180-days of market exclusivity. The brand company introduces an authorized generic the same day.



The consequence is that, first, the brand company profited from a period of unwarranted monopoly pricing (the time after the expiry of the valid patent and before the invalid patent was found invalid), which is reliant upon the filing of an invalid patent. Second, beyond this period of inappropriate monopoly pricing, the brand company then also gets to share in the exclusivity profits of the generic company who exposed the brand's invalid patent. By filing an invalid patent and then introducing an authorized generic, the brand company shares the 180-day exclusivity, making the filing of the invalid patent that much more lucrative. Finally, at the same time, by filing the invalid patent and severely undercutting the generic company's profits during the exclusivity period using an authorized generic, the brand company concomitantly reduces the generic company's incentive to challenge the brand company's invalid patent.

From a competition perspective, the results are highly problematic. Authorized generics magnify the value of invalid patents. They also reward and encourage anti-competitive behavior by brand companies (filing and relying upon invalid patents to obtain joint exclusivity) and discourage pro-competitive behavior by generics (challenging invalid patents or inventing around them).

- Comment: The FT should measure the impact of wrongfully extended monopolies and harm to competition based on invalid or not infringed patents by determining:

(i) the number of AGs launched during the 180-day exclusivity period in the last 3 years and determine which of these AG products were subject to a successful paragraph IV certification;

(ii) in these cases, determine the earliest date of possible generic entry, i.e. the date a generic would have entered, had the patent(s) that was the subject of a successful paragraph IV certification(s) not been asserted; and

(iii) the brand's earnings (on both the brand and AG product) during the period between the earliest date of possible generic entry and expiry of the 180-day exclusivity (i.e. during which its AG was sold).

- Comment: The FTC should determine whether authorized generics are released in the absence of a 180-day exclusivity period and if so, what percentage.

2. The FTC Should Examine How Prices for Brand Products are Affected by the Release of Authorized Generics During the 180-day Exclusivity Period

There is compelling evidence that prices for brand products *increase more* when an authorized generic is released[1]. The anti-competitive effects of authorized generics are not

[1] *See* David Reiffen & Michael Ward, *"Branded Generics" as a Strategy to Limit Cannibilization of Pharmaceutical Markets*, May 2005, available at

limited to just independent generic companies, and users of generic drugs, but also to patients and third-party payors who pay elevated prices for the brand drug. The FTC should examine how authorized generics impact brand pricing, and how this affects consumer welfare.

- Comment: The FTC should examine how prices for brand products are affected by the release of an authorized generic during the 180-day exclusivity period as compared to markets where no authorized generic was released.

3. The FTC Should Compare and Contrast Incentives Provided to Brand Companies and Economic Evidence in Support of Them as Compared to the 180-day Exclusivity Period

The FTC has itself recognized that the strategy of releasing authorized generics during the 180-day exclusivity period is intimately related to other practices which have raised antitrust concerns. For example, FTC Commissioner Leibowitz commented on the impact of authorized generics on brand-generic patent settlements at last year's Second Annual In-House Counsel's Forum on Pharmaceutical Antitrust:

> "The growing threat of authorized generics may diminish a generic's incentive to fight. If a first-filer believes that the brand will sponsor an authorized generic – something that many expect today on any significant drug – the profits to be made in the 180-day exclusivity period are reduced substantially, perhaps even cut in half. So the generic firm's calculus in the fight-versus-settle equation may now be more heavily weighted towards settling. Rather than gamble on winning in court, a generic may decide that a fixed entry date and guaranteed revenue stream is a better value than rolling the dice."

This link was identified again when the FTC testified before the Senate Aging Committee Testimony in July 2006:

> "Another 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."

We encourage the FTC to seize this opportunity to assess the impact of authorized generics in a comprehensive fashion, and not to ignore the purpose for which the 180-day exclusivity period was created.

This exclusivity period was created by Congress for a very specific purpose: to encourage generic companies to challenge brand patents and enter the market early. This was based on the premise that brand companies may benefit from monopolies based on invalid

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http://www.ftc.gov/be/healthcare/wp/12_Reiffen_BrandedGenericsAsAStrategy.pdf; J. Johnson & D. Myatt, *Multiproduct Quality Competition: Fighting Brands and Product Line Pruning*, 93(3) AMER. ECON. REV. 748 (2003); Hollis, Aidan, and Bryan A. Liang, "Assessing the Effects of Authorized Generics on Consumer Prices." *Journal of Biolaw & Business*, January 2007, 10(1): 10-18.

patents, to the detriment of competition, and the American public. In other words, the 180-exclusivity period was designed to foster greater competition between *brands* and *generics*.

Generic-generic competition was intended to commence only after the "heavy-lifter" had recouped its extensive litigation costs and been rewarded for challenging the brand and potentially opening the market. In contrast to the 180-day period provided to the first generic to challenge the brand's patents or innovate around them, brand companies enjoy a number of statutorily-created exclusivities, including a 20-year patent term; a 6-month pediatric exclusivity, a 5-year data exclusivity for new chemical entities, a 3-year data exclusivity supplement for clinical trials; a 30-month automatic stay, and up to 5 years of patent term extension.

The FTC has never investigated what the "short- and long-run competitive effects" of competition during any of these periods of exclusivities would be on the prescription drug market. There is absolutely no justification for overlooking such an analysis given that the *only* exclusivity enjoyed by generic companies is under attack by brands and review by the FTC.

- Comment: The FTC should compare and contrast the exclusivities provided to brand companies and the economic evidence in support of them with the 180-day exclusivity period. The FTC should compare how increased competition during the brand's exclusivity periods would impact both consumers and the industry as a whole.

Conclusion

The practice of releasing authorized generics during the 180-day exclusivity period is a targeted attack on the only incentive provided to generic companies to challenge or innovate around brand patents, as well as to extend a monopoly on a drug which relies on a potentially invalid patent. Brand companies have succeeded in finding a way to benefit from invalid patents, extend their monopolies and decrease the incentive for those patents to be challenged at all.

This brand strategy is also closely linked to other brand tactics designed to delay generic entry. The FTC has already acknowledged the link between authorized generics and questionable patent settlements. Further, in this study the FTC has recognized that the passage of the *Medicare Modernization Act* in 2003 is relevant:

> "The FTC agrees that generic company documents dated after Jan. 1, 2003 are likely to be the most useful for understanding the effects of AGs on generic companies' incentives to file ANDAs and to challenge patents via paragraph IV certification."

The date of passage of the MMA is relevant precisely this Act closed a loophole which had allowed brand companies to indefinitely extend their monopolies through "evergreening" automatic stays. In 2003, brand companies began to release authorized generics in earnest, as part of a concerted strategy to extend patent life and to weaken the generic industry. The core value of the authorized generic tactic comes from releasing the authorized generic during an

exclusivity period – when the brand can undercut prices, capture valuable market share, and diminish generic incentives to challenge its patents.

We also point out that brand companies are taking advantage of a unique feature in regulations affecting how and when generic drugs come on the market. Generic companies are obliged to notify their brand competitor when they intend to launch a competing product. This provides brand companies with knowledge of when they can release an authorized generic at the critical point where they can undermine the true generic's market share and revenue, while minimizing the impact on the brand product. Brand companies are misusing this information in order to further extend the benefits of their monopolies.

As we stated in our earlier comments, an FTC study which focuses mainly on the price of generic substitutes during the 180-day exclusivity period would overlook the long-term, chilling effects of authorized generics. Further, such an analysis would fail to assess the consumer harm caused by brand companies benefiting from invalid patents through monopoly prices initially and subsequently though extended monopolies with authorized generics. While the choice to create exclusivities as incentives for companies lies within the jurisdiction of Congress, measuring the competitive impact of these choices is the responsibility of the FTC.

Again, we thank the Commission for the opportunity to provide comments on its authorized generic drug study.

Yours very truly,

GILBERT'S LLP

Tim Gilbert