GILBERT'S LLP

June 5, 2006

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 Unites States. At the outset, we would like to thank the Federal Trade Commission for its interest in the anticompetitive effects of authorized generics and we welcome the opportunity to comment on the design of the FTC's study on this issue.

The practice of releasing authorized generics during a first ANDA filer's period of 180-day exclusivity is of major concern to the generic industry. Authorized generics plainly violate Congress' intent in enacting the *Hatch-Waxman Act* because they gut the value of the 180-day exclusivity, which was intended by Congress as a powerful incentive to generic companies to challenge or invent around ineffective, invalid or unenforceable brand patents. When the *Hatch-Waxman Act* was adopted in 1984, brand name companies did not make a practice of releasing their own products under a generic label. Congressman Waxman himself stated that had Congress anticipated this brand strategy, the loophole in the legislation that brand companies are now exploiting would have been closed.

Please find below our client's comments on the proposed FTC study design.

1. The FTC Should Hear Testimony on the Motives of Brand Name Companies

Our client's concern is not with all authorized generics, but with those which are released during the 180-day exclusivity promised to the first generic applicant to challenge a brand company's patents. The FTC should probe carefully the motives of brand companies in launching authorized generics during this period. Eli Lilly's CEO, Sidney Taurel, stated in 2003: "For this [strategy] to really work, you'd have to have the whole industry do that systematically each time a patent expires so that you truly eliminate the incentive in the calculation that generic companies would make. We cannot agree to do that as an industry [because of

antitrust concerns, but] it's a very interesting and intriguing idea. Food for thought" (*The Pink Sheet*, Dec. 8, 2003).

This sentiment was echoed by Jean-Pierre Garnier, the CEO of GlaxoSmithKline, in 2004: "The idea was somebody has a six month exclusivity, but we are king maker; we can make a generic company compete during a very profitable time… We are not a generic company, and do not wish to become one. If we acquired the most successful generic company in the world, it would barely move the needle on profit." (Q4 2003, Earnings Conference Call and Presentation, Feb. 13, 2004).

These statements reflect what generic companies have known for years: no brand name company launches an authorized generic during the 180-day exclusivity for the comparatively negligible profits associated with such licensing. Brand companies release authorized generics to undermine the incentives granted by Congress to generic companies to challenge and invent around patents. The ultimate goal of brand name companies in launching authorized generics is to neutralize the legislative scheme intended by Congress to nurture a vigorous generic industry capable of competing effectively with brand name companies over the long-term.

As a result, the only way to assess the genuine effect of authorized generics is to fully understand the motives of brand name companies – something unlikely to appear from document review – and to consider their long-term effects on generic drug innovation.

- Comment: The FTC should gather testimony, through interviews or hearings, about brand name motives in launching authorized generics.

2. The FTC Should Hear Testimony on Generic Company Decision-Making

A generic company's decision to develop a particular drug product is generally made between 3 to 7 years before the product is poised to enter the market. Thus, the market today reflects decisions made before the dramatic rise of authorized generics in or around 2003. The broad impact of this practice on access to generic drugs will not be felt fully for years.

In addition, only a limited number of courts have reviewed the legality of authorized generics under the *Hatch-Waxman Act*. While no court has yet prohibited authorized generics, it cannot be excluded that some will. As a result, documents may show that generic companies have continued developing certain products despite the threat of authorized generics in the hope that the practice is curtailed by the courts, regulation or legislation. A better insight into generic company decision-making would be gathered from interviews or hearings, rather than only from documents.

One of the main challenges in modeling generic company decision-making in the face of authorized generics is the great difficulty in predicting accurately the lifecycle of any drug product. Any calculation of the return on investment for a particular product must discount heavily expected revenues to account for drastic variations on projected lifecycle and returns. The threat of authorized generics, which guts the value of the 180-day exclusivity, adds considerable complexity to generic company decision-making because it delays, and even prevents, generic companies from recouping their investments over a shorter period of time, if at all.

As a result, it is essential for the FTC study to analyze the impact of authorized generics over the long-term. Moreover, only relying on documents is unlikely to allow the FTC to fully understand the additional layer of uncertainty introduced by authorized generics into the development of generic drugs. Documents are unlikely to set out fully the calculations and risk assessment of generic companies. For this reason also, we would urge the FTC to hold hearings or interview witnesses.

- Comment: The FTC should gather testimony, through interviews or hearings, about generic drug company decision-making.

3. The FTC Should Request Retail-Level Pricing Data

The FTC intends to ask for brand, authorized generic and generic pricing at the list price, average wholesale price, wholesale acquisition cost, price to Medicare, price to Medicaid, maximum allowable cost, and average manufacturer price. In addition, the FTC has asked for IMS data from companies that obtain IMS data in the regular course of business. We urge the FTC to specifically request information on the pricing of drugs at the *retail* level, as this data may not be captured by the request as currently stated.

While brand companies may be correct in pointing to the fact that the presence of an authorized generic on the market during the period of 180-day exclusivity lowers some prices for a drug, there is no evidence that lower wholesale prices translate into cost-savings for end consumers, namely, patients and third-party payors.

- Comment: The FTC should request documents and information about retail prices for all drugs considered in the study from brand name, authorized generic and generic companies.

4. The FTC Should Consider Authorized Generics in the Context of the Cumulative Impact of Brand Strategies

The impact of authorized generics on the generic industry is magnified by the other tactics used by brand companies to delay or undermine generic competition, including the filing of last-minute citizen petitions with the FDA and product switches. The consequences of releasing authorized generics during the 180-day exclusivity period can be wide-reaching.

For example, as FTC Commissioner Leibowitz recently observed, authorized generics have become a powerful weapon to force generic companies to settle cases. Authorized generics gut the returns to be earned during the 180-day exclusivity period, and skew a generic company's cost/benefit analysis towards settling the patent infringement case and obtaining a steady revenue stream from an authorized generic licence.

- Comment: The FTC should consider authorized generics in the context of the cumulative impact of other delay strategies by expanding the scope of the study to include understanding the impact of abusive citizen petitions, product switches, and the effect of authorized generics on incentives to settle patent disputes.

Conclusion

Brand name companies enjoy a number of statutorily-created exclusivities and incentives to innovate, including a 20-year patent term; 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.

By contrast, the 180-day exclusivity, which is now under attack, is the only incentive provided to generic companies to challenge or invent around patents. The 180-day exclusivity is crucial because it is the only opportunity for generic companies to recoup their considerable investments before the market for a generic drug becomes a commodity market. As a result, the 180-day exclusivity period is essential not only to the competitiveness of the generic industry, but also for long-term consumer welfare, even if it results in marginally-higher consumer prices for a period of 180 days.

An FTC study which focuses mainly on the price of generic substitutes during the 180-day exclusivity would fail to account for the long-term, chilling effects of authorized generics. Cutting the 20-year patent terms of brand name companies by half would no doubt lower consumer prices, but it might also have an impact on the ability of brands to develop new medicines. Similarly, it defies logic and common sense to pretend that cutting the incentive of the 180-day exclusivity by half, or more, does not impact generic drug innovation, to the greatest detriment of U.S. consumers over the long run.

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

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