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Federal Trade Commission
Office of the Secretary, Room H-135 (Annex J)
600 Pennsylvania Avenue, NW
Washington, DC 20580

Re: Authorized Generic Drug Study: FTC Project No. P062105; Request for Comments;

Dear Sir or Madam:

Eli Lilly and Company (Lilly) appreciates the opportunity to submit comments on the Federal Trade Commission's proposed collection of information to analyze the economic effects of authorized generic drugs. The Commission invited comments on, among other points,

> [w]hether the proposed collections of information are necessary for the proper performance of the functions of the FTC, including whether the information will have practical utility.

71 Fed. Reg. 16779 (April 4, 2006).

Lilly's comments focus on the necessity and utility of the information to be collected in light of the stated goals of this study. In summary, Lilly believes that a narrow or isolated look at the issue of authorized generics would be a meaningless exercise unless coupled with a broader analysis of the context in which the 180-day exclusivity provisions of Hatch-Waxman operate. Indeed, any information related to the 180-day exclusivity provisions should be utilized only to assess the impact of authorized generics as part of the mosaic of the impact of the 180-day generic exclusivity provisions on competition and consumers.

The Commission also invited comments on the scope and extent of information being requested. On these points Lilly supports the comments filed by the Pharmaceutical Research and Manufacturers of America as to the need for the Commission to more closely tailor its information requests to the objectives of the study.

Background on 180-Day Generic Exclusivity

The first generic company to file an ANDA containing a paragraph IV certification may be eligible for 180-day exclusivity. This "exclusivity" has been described as the incentive and the reward to a generic company that exposes itself to the risk of patent litigation. FDA's Response to Citizen Petition Docket Nos. 2005P-0008/CP1 and 2005P-0046/CP1 at 6. The Hatch-Waxman Act, as amended by the Medicare Modernization Act of 2003 (MMA), provides:

> Subject to subparagraph (D), if the application contains a certification described in paragraph (2)(A)(vii)(IV) and is for a drug for which a first applicant has submitted an application containing such a certification, the application shall be made effective on the date that is 180 days after the date of the first commercial marketing of the drug (including the commercial marketing of the listed drug) by any first applicant.

21 U.S.C. § 355(j)(5)(B)(iv)(I). This provision only prevents the FDA from approving a subsequent ANDA containing a paragraph IV certification during the 180-day period.

However, the first company to submit an ANDA containing a paragraph IV certification may lose its eligibility if one of the new forfeiture events occurs. *See* 21 U.S.C. § 355(j)(5)(D). For example, if the first generic company to file an ANDA containing a paragraph IV certification fails to market the drug within 75 days after the occurrence of certain events or 30 months after the date of submission of its application, the 180-day exclusivity period is forfeited. The 180-day exclusivity period also is forfeited if the first applicant is not able to lawfully maintain its paragraph IV certification.

In addition, the 180-day exclusivity is not completely exclusive because it may be shared with other first filers. More than one company may be considered a first applicant where multiple applications are submitted on the first day which are substantially complete and contain paragraph IV certifications. 21 U.S.C. § 355(j)(5)(B)(iv)(II)(bb). For ANDAs that were submitted prior to the MMA, the FDA has on occasion recognized more than one company as eligible for 180-day exclusivity. This occurs because the FDA has applied a patent-based approach to determining eligibility. Where more than one patent is listed in the FDA's Orange Book for a reference drug, multiple generic companies may be the first to file a paragraph IV certification for at least one of the listed patents. In those instances, the FDA has determined that multiple first filers may share any 180-day exclusivity. *See Apotex Inc. v. Food and Drug Administration*, 414 F.Supp 2d. 61 (D.D.C. 2006).

Utilizing the Data To Be Collected To Assess the Impact of the 180-Day Generic Exclusivity Period on Competition and Consumers

The Commission's stated objectives for this data collection and study are to analyze the short-term and long-term competitive effects of authorized generics. The short-term effects of authorized generics on consumers should be sufficiently clear (*i.e.*, additional and potentially accelerated competition that results in lower generic prices) that an FTC analysis may not be needed.

Questions about the long-term effects of authorized generics are sometimes stated as whether authorized generics might decrease the profitability of the 180-day exclusivity for the first-filing generic. There are at least three assumptions implicit in this question that the Commission should scrutinize with the information it is collecting:

1. There exist at least some scenarios in which the 180-day exclusivity provisions provide an overall benefit to consumers that outweighs the negatives arising from paragraph IV patent challenges;
2. One potential benefit is that the 180-day exclusivity operates to either accelerate generic drug entry in a manner that provides a net benefit to consumers or increases competition among generics that otherwise would be delayed; and
3. The 180-day exclusivity is necessary to provide a sufficient incentive for paragraph IV challenges that are needed to produce these net consumer benefits.

No analysis of any aspect of the 180-day exclusivity provisions of Hatch-Waxman, including the issue of authorized generics, can produce any practically useful results unless it challenges and attempts to validate and repudiate one or more of these assumptions. Given the numerous situations in which the 180-day exclusivity period is overtly anti-consumer because it delays or diminishes competition among generic drugs that would otherwise occur or because it chills the ability to develop certain types of medical breakthroughs that might otherwise improve health or save lives, it is inherently insufficient to study authorized generics without developing a predicate understanding of whether and to what extent an overall benefit to consumers exists and, if so, the materiality of authorized generics to the net consumer benefit.

In terms of the impact on generic competition, the evidence may show that in fact the 180-day exclusivity retards, rather than enhances, competition among generics. In many cases the paragraph IV challenge does not result in any acceleration of generic entry whatsoever, and yet the first filer benefits from the 180-day windfall while other generics who are ready to enter the market must wait and consumers bear the higher generic drug prices during that time. Two generic companies are currently claiming that they are entitled to 180-day exclusivity upon the expiration of Merck's exclusivity for Zocor®. *See Ranbaxy Laboratories Ltd., et al. v. Michael O. Leavitt, et al.*, No. 05-1838 (D.D.C. April 30, 2006). In this case, neither company

was successful in invalidating Merck's patent because neither was involved in patent litigation. Both companies filed a paragraph III certification for Merck's compound patent, and filed paragraph IV certifications for two patents that have been withdrawn from the Orange Book. If those two companies are provided a 180-day period of exclusivity, two other generic companies with tentative approval – companies that stand ready to bring their product to market – will be blocked from entering the market.

During the process that led to the enactment of the MMA amendments to the Hatch-Waxman law, Congress considered, but rejected, an additional forfeiture provision, the so-called "failure to sue" forfeiture that would apply in the event a patent listed in the Orange Book was not the subject of a patent infringement action brought within the 45-day period after the first-filer's paragraph IV certification. With a "failure to sue" forfeiture in place such a patent could not be a basis for a 180-day exclusivity period. In situations where the Hatch-Waxman law requires the listing of multiple patents, there will be listed patents that, although completely valid, will not necessarily be infringed by any generic manufacturer. The FTC should assess whether there are any circumstances in which paragraph IV challenges to such patents ought to afford the first-filer the opportunity for a 180-day exclusivity period. If it is not sued under the patent or is sued and demonstrates non-infringement of the patent, neither of these two outcomes may afford later-filing generic drug applicants any advantage in gaining generic drug approval.

Regarding the assumption that the 180-day exclusivity is essential to encourage paragraph IV challenges, the Commission should analyze the data to determine whether sufficient incentives would exist to file appropriate patent challenges in the absence of the 180-day exclusivity. This should include assessment of the many paragraph IV challenges that are filed with full knowledge that the ANDA applicant will not achieve first-filer status. The Commission also should seek to understand the advantages to being a first or early paragraph IV filer other than the 180-day exclusivity and whether the risk of legal expenses (fees that may be largely contingent on success) associated with a paragraph IV challenge are truly prohibitive without the 180-day incentive.

Finally, any FTC analysis would not be complete without a thorough look at the issue of early and speculative patent challenges, especially those in which the listed patent appears on its face to be valid and will necessarily be infringed by any generic drug manufacturer seeking ANDA approval. Such challenges appear to be brought with only the hope that the inherent uncertainty in any litigation will either result in a fortuitous court decision and/or the ability to coerce a settlement with the innovator to avoid such an unfavorable outcome. Suits of this type can have a chilling effect on innovation – forcing innovators away from development of highly promising drugs simply because a patent on the drug may not appear to be categorically strong enough to withstand an early challenge. Similarly, even where a patent is fully valid and has been infringed, perverse litigation outcomes can have devastating effects on innovation. The recent Federal Circuit decisions in the *Purdue Pharma* and *Ferring* appeals demonstrate that nearly frivolous attacks on strong patents can disrupt the innovator's expectations for marketing exclusivity that formed the basis for the ability to invest in developing the innovative medicine in the first place. In the case of *Purdue Pharma*, the Federal Circuit eventually retracted its original holding, but not before huge damage had been done to the company itself. Thus, it would appear that any FTC analysis of the impact of authorized generics should not be undertaken in isolation from the larger policy context in which such practices are taking place, especially in light of the quite profound anti-competitive and anti-innovation features that form the backdrop before which such practices occur.

In conclusion, while it is important to know whether authorized generics impact the attractiveness of the 180-day exclusivity, understanding that issue does not provide a basis for the Commission to carry out its function unless there is also an understanding of how the 180-day generic exclusivity impacts competition and consumers. The Commission appropriately makes reference to this point in its Notice:

> These data will enable the proposed study to make new contributions to the economic literature on the effects of generic drug entry on prescription drug prices and, in particular, the role of the 180-day period of exclusivity in generic competition prior to the patent expiration.

71 Fed. Reg. 16779, 780 (April 4, 2006).

Lilly believes this broader aspect of the Commission's study will be of overarching importance and fundamental to reaching any meaningful conclusions regarding authorized generics.

Lilly very much appreciates Commission's willingness to take these comments into account as it prepares its information requests and study.

Sincerely,

ELI LILLY AND COMPANY

Robert A. Armitage
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