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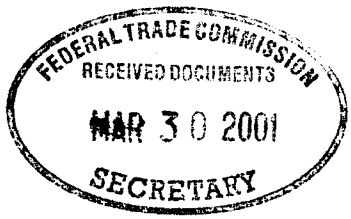

Direct Line: (416) 865-3093

March 30, 2001

VIA FACSIMILE AND E-MAIL

Desk Officer for the Federal Trade Commission
Office of Information and Regulatory Affairs
Office of Management and Budget
New Executive Office Building
Room 10202
Washington, D.C.
20503

Secretary
Federal Trade Commission
Room H-159
600 Pennsylvania Ave. NW
Washington, D.C.
20580

Dear Sir or Madam:

Re: Generic Drug Study - FTC File No. V000014

Apotex Corporation ("Apotex") welcomes this opportunity to respond to the proposed Information Requests of the Federal Trade Commission ("FTC") relating to the FTC's study on the development of generic drug competition.

Apotex is a generic pharmaceutical manufacturer with offices in Weston, Florida and Chicago, Illinois. At present, it sells approximately 20 products in the United States and has numerous applications in the pipeline at the Food and Drug Administration ("FDA"). Apotex is a subsidiary of Apotex Inc., Canada's largest manufacturer of generic drug products. As such, Apotex is very familiar with the anticompetitive practices employed by innovator drug companies in the United States.

The stated purpose of the FTC's proposed study is: "to examine the extent to which the 180-day marketing exclusivity and 30-month stay provisions of the Act have encouraged generic competition or facilitated the use of anticompetitive strategies."[1]

Apotex proposes to limit its comments: (1) to the issue of 180-day exclusivity; and (2) the interplay between Information Request #2 for innovator companies and Information Request #4 for generic companies.

[1] Federal Trade Commission, "*Agency Information Collection Activities; Submission for OMB Review; Comment Request*" Federal Register, Vol. 66, No. 39 (February 27, 2001) at 12514. Hereafter cited as "FTC Comment Request".

With respect to 180-day exclusivity, Apotex is concerned that the information proposed to be gathered by the FTC is insufficient for a considered analysis of this statutory provision. Specifically, such analysis should be undertaken in light of the economic environment in which generic companies must operate.

Apotex submits that, in addition to the information proposed to be gathered, the FTC should also request information about existing costs and barriers to generic competition, including whether there are sufficient economic incentives to generic competition, without the reward of 180-day exclusivity.

Information Request #2 for innovator companies requests, *inter alia,* that these companies identify all patents that the company has filed in the Orange Book "and the date of listing (regardless of whether currently listed in the Orange Book) relating to each Drug Product for which the company has been notified of the filing of an ANDA by another person". The request also asks innovator companies to indicate "if the patent(s) was (were) filed in the Orange Book after the company received approval of the New Drug Application, as defined under 21 U.S.C. 355(b) *et seq.* for the Drug Product."[2]

Information Request #4 for generic companies requests that these companies identify "each instance in which the company has asserted before a court or before the FDA that a patent was improperly or untimely listed in the Orange Book as defined in 21 U.S.C. 355(b) or (c)." The request includes, for each such assertion, the submission of "the pleading(s) in which such assertion was made and any responsive pleading(s)."[3]

The stated purpose of these requests is to provide "factual evidence about innovator companies' patent listings in the Orange Book and how frequently challenges are made to these listings by generic companies"[4] (*emphasis added*). This appears to be in contrast to the FTC's stated purpose of collecting agreements between innovator and generic companies, which is to provide a discussion, and presumably to reach conclusions, as to whether such agreements may have operated to delay generic drug competition.[5]

Apotex proposes that the results of these Information Requests relating to patent listings in the Orange Book, in addition to providing factual evidence, should form the basis of a discussion of whether it appears that listing of patents by innovator companies, after generic companies have submitted ANDA's (thus triggering the need for additional certifications, the possibility of additional lawsuits and automatic additional 30-month stays) constitutes an anticompetitive practice.

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[2] FTC Comment Request at 12520.
[3] FTC Comment Request at 12521.
[4] FTC Comment Request at 12521.
[5] FTC Comment Request at 12521.

It is the position of Apotex that innovator drug companies are in fact submitting improper patent listings to the FDA, after generic companies have submitted an ANDA, in order to create significant additional barriers to generic entry. These improperly listed patents include patents that do not claim the drug or a method of using the drug as originally approved by the FDA, and as such do not meet the test for listing set out in the *Hatch-Waxman Act*.[6] These innovator companies are taking advantage of the FDA's current policy not to conduct an independent assessment of whether such patents should be listed on the Orange Book, and its policy requiring generic companies to certify to new patents appearing on the Orange Book after a completed ANDA has been submitted to the FDA.

A discussion of this practice is timely, given the recent grant of a preliminary injunction against Bristol-Myers Squibb Co. by the United States District Court for the District of Columbia in *Mylan v. Thompson and Bristol-Myers Squibb Co.*[7] In that case, the Court noted that by causing its later patent to be listed in the Orange Book, the defendant Bristol-Myers Squibb had effectively blocked FDA approval of the generic alternative and that "by creating new – and probably impermissible – ways to extend its monopoly, Bristol not only limits the public's access to low-cost drugs but impedes the very innovation that *Hatch-Waxman* is designed to promote."[8]

The widely-prescribed anti-depressant medication Paxil® is another case in point. In 1999, consumers spent in excess $1.3 billion on Paxil®. At that time, the average cost per tablet of Paxil® was $2.39. Apotex has applied for approval of its safe and effective generic alternative to Paxil®. The original 30-month stay was associated with the lawsuit commenced by SmithKline Beecham, now called Glaxo SmithKline ("GSK"), which related to the pioneer patent. This original stay expired on November 18, 2000. Despite the fact that the FDA has advised Apotex that there are no outstanding concerns with respect to its generic product, the FDA has not been able to issue Apotex' final approval to sell generic Paxil®.

Since Apotex originally submitted its ANDS application, GSK has filed numerous additional patents purporting to "claim" the original Paxil® drug as approved by the FDA. GSK has commenced three additional lawsuits against Apotex (apart from the lawsuit associated with the pioneer patent), each of which has triggered successive automatic 30-month stays. As a result of this deliberately anticompetitive conduct by GSK, Americans may not receive the benefit of a safe, effective and low cost alternative to this important medication until July, 2003. This delay represents a loss to American consumers in 1999 of approximately $2.7 million every day.

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[6] Where a patent issues after a drug product has been approved, 21 U.S.C. § 355(c)(2) provides that the holder of an approved application shall file with the Secretary the patent number and the expiration date of any patent which claims the drug *for which the application was submitted* or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug. (Emphasis added).

[7] Released March 13, 2001.

[8] *Mylan v. Thompson and Bristol-Myers Squibb Co.*, Memorandum Opinion of Judge Urbina at p. 50.

This loss is based on the unchecked assurances by GSK that its proposed patents do indeed "claim" the original FDA approved drug and the manipulation of the FDA policy requiring certification to patents appearing on the Orange Book after submission of a complete ANDA.

There is no doubt that innovator companies have economic incentives to delay the entry of generic competitors. By manipulating the certification process in order to trigger successive 30-month stays, they have found a way to do so.

Apotex therefore strongly urges the FTC to go beyond collecting factual evidence under Information Request #2 for innovator companies and Information Request #4 for generic companies, and to use this evidence to engage in a discussion and analysis of the anticompetitive purpose and effects of innovator practices.

In addition, Apotex urges the FTC to examine whether, in the absence of a 180-day exclusivity period, sufficient economic incentives would remain to create generic competition.

We trust that the above submission will assist the FTC in its final formulation of the study. We would be pleased to answer any questions that the FTC might have regarding this submission.

Yours very truly,

LENCZNER SLAGHT ROYCE SMITH GRIFFIN

Per:

Tim Gilbert

TG/lb