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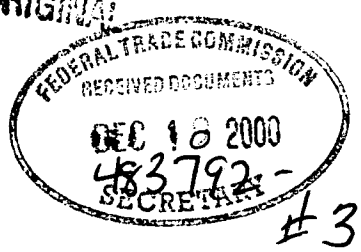
ORIGINAL



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WAYNE A. CROSS
212 259-6850

December 15, 2000

The Federal Trade Commission
Room H-159
600 Pennsylvania Avenue, N.W.
Washington, D.C. 20580

Re: Generic Drug Study - FTC File No. V000014

Ladies and Gentlemen:

As counsel for Geneva Pharmaceuticals, Inc. ("Geneva"), I respectfully submit the following comments to the draft information requests published by the Commission in connection with its proposed "Generic Drug Study." As the discussion below illustrates, as drafted, certain of the requests would sweep in materials that seem of little relevance to the Commission's stated goal (namely "to examine whether brand-name and generic drug manufacturers have entered into agreements, or have used other strategies, to delay competition from generic versions of patent-protected drugs") and would be very burdensome for Geneva to identify and collect. Geneva's comments provide suggestions for narrowing the draft requests (thus reducing the burdens of compliance) in ways that should not compromise the Commission's objectives.

GENERAL COMMENTS

Date Range. The requests call for the production of information back to January 1, 1991, a period of approximately ten years. As an initial matter, it seems highly unlikely that an agreement between an innovator and a generic drug company entered into in the early 1990s relating to the onset of generic entry would continue to be in effect. Geneva is aware of no major innovator drug product that went off patent prior to 1995 that does not now face vigorous generic competition. Moreover, searching for such older material will add an extra dimension of burden for Geneva and many other companies in that it will require searches of archived records. Archived records, often maintained in off-site storage facilities, often are not well indexed and thus are very difficult to search. In addition, given the substantial consolidation that has occurred in the pharmaceutical industry starting in the early 1990s, many companies would be required to search the archived files of *predecessor* entities.

Accordingly, Geneva suggests that the Commission modify the date cutoff to January 1, 1995, except for *still-active* agreements between innovator and generic drug companies in which the generic company has committed to refrain from launching a generic version of the innovator's patented product in return for consideration. To the extent such earlier dated agreements remain active they appear to fall within the Commission's concerns. And, documents relating to active agreements are likely to remain in active file areas.

Duplication. It should be made clear that the Commission will not require collection and production of material already provided to it by innovator and generic companies pursuant to earlier Commission investigations of such brand-generic agreements. As the Commission is aware, Geneva was subject to an investigation (FTC File No. 981-0395) with respect to terazosin hydrochloride and produced to the Commission massive amounts of documents relating to terazosin and other products in the context of that investigation. Geneva does not believe that there would be any justification for requiring it (and similarly-situated companies) to duplicate such an effort.

Burden. Geneva believes that the "Estimated Burden Hours" and "Estimated Cost Burden" set forth in the draft information requests materially understate the likely burdens that will be imposed on companies responding to the requests. Based on Geneva's prior extensive experience in responding to information requests from the Commission (particularly FTC File No. 981-0395), Geneva estimates that if it is required to respond to the information requests as proposed, it will spend in excess of $300,000 including company personnel costs and substantial expenditure for outside counsel.

GENERIC COMPANY REQUESTS

Generic Request No. 1. Request No. 1 calls for all agreements between the generic company and "any other person ... relating to any ANDA involving any Drug Product." Since the very business of a generic company is to develop and market drugs by way of ANDAs, almost every agreement such a company makes in some sense "relates to" an ANDA. For example, the request as drafted arguably would sweep in all agreements with active ingredient suppliers, licensing and co-development agreements with other generic companies, employment agreements, agreements with consultants to provide technical advice, and the like. Geneva suggests that the request be limited to agreements with innovator companies relating to ANDAs, where the innovator company holds the NDA corresponding to the ANDA that is the subject of the agreement.

Generic Request No. 2. Request No. 2 seeks a description of "how litigation expenses are or have been distributed among the parties" in connection with certain lawsuits. It is not immediately apparent why such information is relevant to the Commission's study, and the production of such information could constitute a waiver of legitimate joint defense and/or work product privileges. Litigation over the applicability

of such privileges would materially increase the burden on responding companies. Geneva believes this aspect of the request should be stricken.

Generic Request No. 3. Request No. 3 seeks information concerning generic drugs marketed by the generic company, *inter alia*, where (1) the generic company was itself sued for patent infringement by the innovator with respect to the product in question and (2) another ANDA applicant (not the responding generic company), was sued by the innovator company with respect to the product. As to the second prong, to require a generic company to review its entire portfolio (which could include hundreds of products) for antecedent litigation between the innovator and other parties would be unduly burdensome, and does not seem calculated to obtain information central to the Commission's study. Moreover, given the number of companies to whom the request will be submitted, it seems highly probable that such litigation documents would be revealed by the parties to the litigation. Geneva therefore suggests that the second prong of the request be stricken.

Generic Request No 5. Request No. 5 seeks information relating to all products as to which the generic company has made a Paragraph IV certification. Given the concerns underlying the FTC's study, Geneva suggests that the request be limited to products subject to Paragraph IV certifications that actually resulted in patent litigation between the generic company and the innovator.

Very truly yours,

/Wayne A. Cross/Edl.

Wayne A. Cross