
IN THE MATTER OF
WARNER-LAMBERT COMPANY

Docket 8850. Interlocutory Order, Oct. 5, 1973.

Order granting appeal of complaint counsel; instructing the law judge that on question of whether a firm should be considered a potential entrant into a market because of research activity, he should limit the evidence and discovery to companies where research activity has at least reached the stage for filing of New Drug Application; and remanding case to law judge for further proceedings consistent with order.

Appearances

For the Commission: *Paul R. Teetor, Thomas P. Athridge, Robert R. Jacobs and Donald A. Lofty.*

For the respondent: *Mudge, Rose, Guthrie & Alexander, New York, N.Y. and Bergson, Borkland, Margolis & Adler, Wash., D.C.*

ORDER RULING ON INTERLOCUTORY APPEAL

Before the Commission is an application filed by complaint counsel under Rule 3.23 (a) requesting the Commission to entertain an interlocutory appeal from a ruling by the administrative law judge directing complaint counsel to turn over to respondent's counsel, as part of a prehearing discovery order, a copy of a 527-page Food and Drug Administration (FDA) computer print-out entitled "Alphabetic List of IND Generics."

The FDA computer print-out lists all Investigational New Drug notices (IND's) filed with the agency.¹ The print-out was given to

¹ Under FDA procedures, prior to marketing most new drugs, the manufacturer must complete a series of tests demonstrating safety and efficacy. After substantial completion of laboratory and animal testing, an IND notice must be filed and accepted by the FDA. An IND is

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complaint counsel during the pre-complaint stage of this matter by the FDA. The FDA claims the print-out was given only on a confidential basis and it objects to the turnover of the document to respondent's counsel.

The law judge ruled that the list is discoverable because it may contain exculpatory material that would aid respondent in defending against the "potential competition" part of complaint counsel's case. In this connection, complaint counsel contends that the merger violated Section 7, not only because it eliminated existing competition between the two companies in an overall "drug" market and "ethical drugs" segment thereof (as well as some seven product submarkets), but also because potential competition was eliminated in numerous other submarkets. As a result of "Complaint Counsel's Limitation of Proof" dated March 8, 1973, and earlier concessions, the merger remains subject to challenge in the two broad markets and in 23 products listed in Appendix A to complaint counsel's Limitation of Proof.

In addition, there are 22 "Appendix B" submarkets as to which complaint counsel intend to offer proof as to the existence of competition or potential competition "to show the breadth of competition between the merging parties in the complaint's two major markets (all drug and all ethical drugs), as bearing on the issue of violation and on the issue of relief." However, complaint counsel do not intend to argue that a violation occurred in any Appendix B market standing alone.

It appears that complaint counsel intends to offer evidence of potential competition between the merging firms as to 16 "Appendix A" submarkets. They have indicated that they would rely on pre-NDA research by one or the other of the merging firms to show the existence of potential competition in some of these submarkets. In addition, they intend to show violation of Section 7 in a total of nine markets because of elimination of actual competition between the two firms.

Although respondent denied that pre-clinical or IND-level research was sufficient to establish Warner-Lambert or Parke, Davis as likely potential entrants into a drug product line, it argued that it should have access to the list in question since it may show, or lead it to evidence that will show that there were

a prerequisite to the clinical use of the drug on humans in tests designed to demonstrate efficacy and safety in order to support a New Drug Application ("NDA"). Frequently, supplemental testing is required by the FDA after the filing of an NDA. Many drugs given IND clearance never receive approval for marketing and may never even be the subject of an NDA filing by the company.

numerous other firms engaged in pre-NDA research. If so, respondent contended this would support an argument that any loss of potential competition resulting from the merger was not significant.²

Prehearing conferences were held to consider the claim of confidentiality of the list in question as well as some other computer print-outs which complaint counsel had obtained from FDA. As a result of these conferences, at which the FDA was represented by counsel, the administrative law judge ordered that the "Alphabetic List of IND Generics" be produced subject to a protective order which would limit access to respondent's outside counsel and independent medical or scientific experts.³ The law judge indicated that if the print-out was not produced, he would have to dismiss all of the submarkets in the complaint in which elimination of potential competition is alleged. Both aspects of his ruling are challenged in complaint counsel's petition which was filed with the Commission on June 22, 1973.

In their appeal complaint counsel state in part that:

[NDA's] are infinitely more significant to the question of potential competition, since many drugs that are the subject of Investigational New Drugs [IND] testing never mature into the stage of New Drug Applications, approval of which is *sine qua non* for marketing. It is for this reason that complaint counsel nowhere allege that the mere fact that one of the parties to the acquisition had an IND on file by itself signifies that serious potential competition has been eliminated in any particular submarket.

² It appears that if respondent's counsel were given the "Alphabetic List of IND Generics" they could, through some effort, tell who the sponsoring manufacturer is. This would involve comparing the entries on the Alphabetic List with manufacturer entries on another FDA print-out in complaint counsel's possession (which FDA is willing to have disclosed). Respondent's counsel further assert that they believe a knowledgeable pharmacologist could ascertain from the generic names the probable therapeutic uses for which many of the drugs were tested. Although complaint counsel question that respondent's counsel and expert could glean pertinent information from the list, respondent's argument is supported by FDA objections to disclosure on the grounds, *inter alia*, that information on the list "is a matter of great secrecy and value in the drug industry because it indicates those chemical compounds that have been successfully tested at the preclinical stage * * * * * "Disclosure of such information would enable a person to assemble a picture and assessment of the research activities of drug investigators * * * " Affidavit of Mr. Sam D. Fine, Associate Commissioner for Compliance, FDA, p. 5, attached as Exhibit 2 to complaint counsel's petition.

³ Some six other FDA print-outs (which include print-outs of lists of NDA manufacturers and generic names)—not directly involved in this appeal—were also given to complaint counsel by the FDA during the early stages of the investigation and were ordered to be turned over to respondent's counsel. Although originally confidential in FDA's eyes, pursuant to a new policy on disclosure of information proposed in the Federal Register (37 Fed. Reg. 9128), FDA informed the law judge and complaint counsel that the entire contents of these print-outs may be disclosed publicly except for a small portion of one concerning inactive ingredients which should be the subject of the law judge's proposed protective order. However, it maintains its objection to turnover of the IND Generics print-out even under a protective order, citing long-standing policy and statutory provisions.

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In view of this statement, the Commission on July 26, 1973, directed the parties to brief the Commission on whether the Commission, "in the interest of keeping the scope of the record within reasonable bounds and confined to evidence clearly probative," should limit both parties' evidence and discovery to research activity that has at least reached the stage of the filing of a New Drug Application.⁴

Although complaint counsel state that such a limitation would be undesirable, we are not persuaded from their submission that this is so. They describe only 4 submarkets out of the 23 "Appendix A" submarkets that would be affected or eliminated by such limitation.⁵ Our purpose in suggesting such limitation of proof in this case was not, as complaint counsel seem to assume, based on the view that pre-NDA research could never be "relevant" as to the question of whether a firm is a potential entrant, but out of concern that inquiry into facets of research at the pre-NDA stage—usually regarded as highly confidential by drug houses—might not be essential in this case given the fact that complaint counsel have indicated that post-NDA activity and other evidence will be shown to establish potential competition in many submarkets and that they acknowledge that NDA's "are infinitely more significant to the question of potential competition."

Respondent in its brief in response to our order reiterates its position that pre-NDA research activity is "too remote from ultimate competitive entry to be significant for Section 7 purposes," but argues that the proposed limitation would nevertheless unduly restrict its ability to rebut the possibility that complaint counsel might rely solely on expressions of "marketing interest" to demonstrate likely potential entry by Warner-Lambert or Parke, Davis. Assuming such a bare bones approach was made by complaint counsel, we fail to see how evidence, which respondent itself argues is not probative on the question of potential entry, would be necessary for effective rebuttal in such eventuality.

⁴ The order also directed complaint counsel to submit an affidavit showing to what extent, if any, they have used the print-out in preparing their case-in-chief. Complaint counsel's affidavit makes it clear that although they retained the print-out in question, along with other print-outs, "on the basis of a general feeling that such information might prove useful in the course of the pending investigation," they have not used nor intend to use the IND list for preparing their own case.

⁵ Complaint counsel state that these four are not the only ones that would be affected, but fail to spell out what other markets would be affected. The purpose of our order directing further briefing was to find out the probable impact on the case by such limitation of proof. We cannot be left to speculate as to how many additional unnamed markets might be affected or to what extent.

The Commission in the past has recognized its responsibility in seeing that hearings in Section 7 cases do not reach unnecessarily large proportions with detailed inquiry into every possible economic ramification of a merger:

[T]he danger is acute that if proceedings under Section 7 are allowed to become top-heavy with masses of economic and business data which are not strictly probative, the statute will become useless as an enforcement tool. * * * Clear and relatively simple rules, and the rigorous exclusion of evidence which bears only remotely upon the central concerns of the statute, are essential if Section 7 is not to become a judicial and administrative nullity. *Procter & Gamble*, 63 F.T.C. 1465, 1559 (1963).

See also, *United States v. Philadelphia National Bank*, 374 U.S. 321, 362 (1963): "[W]e must be alert to the danger of subverting Congressional intent by permitting a too-broad economic investigation."

It is apparent to us that pre-NDA research is not crucial to complaint counsel's case and lacks the probative force of evidence that complaint counsel intend to rely on with respect to other markets. We note this case has been in the pre-hearing stage for two years, and it would appear that access to the IND listing might in turn lead to further attempts to inquire into highly-guarded research by drug firms and needlessly threaten further delay in the proceeding. Accordingly, we grant the appeal and instruct the administrative law judge that on the question of whether a firm should be considered a potential entrant into a market because of research activity, he should limit the evidence and discovery to companies where research activity has at least reached the stage of the filing of a New Drug Application.⁶

The matter is remanded to the law judge for further proceedings consistent with this order.

It is so ordered.

IN THE MATTER OF

LOVE TELEVISION & STEREO RENTAL, INC., ET AL.

Docket C-2245. Order, Oct. 9, 1973.

Order denying respondent's petition for modification of consent order in lieu

⁶ In the case of certain products such as biologicals, where the regulatory mechanisms do not include "NDA" filings, the law judge should endeavor to limit the evidence in an equivalent fashion. Also, our disposition of this interlocutory appeal should not be regarded as removing from him authority to deal fully with other questions that may arise that bear on the subject to research evidence or other motions directed to simplification of issues.