IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

FILED

APR 2 7 2010

Clerk, U.S. District and

Bankruptcy Courts

FEDERAL TRADE COMMISSION

600 Pennsylvania Ave., N.W., Washington, DC 20580,

Petitioner,

v.

Misc. No.

PAUL M. BISARO,

President and CEO, Watson Pharmaceuticals, Inc. 360 Mt. Kemble Avenue, Morristown, NJ 07962

Respondent.

Case: 1:10-mc-00289

Assigned To: Kollar-Kotelly, Colleen

Assign. Date: 4/27/2010 Description: Miscellaneous

MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF PETITION OF FEDERAL TRADE COMMISSION FOR AN ORDER ENFORCING SUBPOENA AD TESTIFICANDUM

Preliminary Statement

Petitioner, the Federal Trade Commission ("FTC" or "Commission"), by its designated attorneys and pursuant to Sections 9 and 16 of the Federal Trade Commission Act (FTC Act), 15 U.S.C. §§ 49, 56, and Fed. R. Civ. P. 81(a)(5), petitions this Court for an Order requiring respondent, Paul M. Bisaro, President and Chief Executive Officer of Watson Pharmaceuticals, Inc. ("Watson"), to comply with the subpoena ad testificandum issued to him by the Commission on July 22, 2009. The Commission issued the subpoena in aid of an ongoing FTC investigation seeking to determine whether Watson has engaged or is engaging in unfair methods of competition in or affecting commerce, in violation of Section 5 of the FTC Act, 15 U.S.C. § 45, by entering into an agreement regarding any modafinil product.

Mr. Bisaro has persisted in refusing to comply with the subpoena, even after the full Commission considered his petition to quash, concluded that his arguments and contentions were lacking in merit, and issued an order directing him to appear and testify. Respondent's repeated refusals to provide the requested testimony has materially impeded the Commission's investigation. The Commission, accordingly, respectfully requests that the Court enter an order directing Mr. Bisaro to appear and show cause why he should not testify in accordance with the outstanding subpoena ad testificandum. See FTC v. Carter, 636 F.2d 781, 789 (D.C. Cir. 1980); FTC v. MacArthur, 532 F.2d 1135, 1141-42 (7th Cir. 1976); see also Fed. R. Civ. P. 26(a)(1)(E); Fed. R. Civ. P. 81(a)(5).

JURISDICTION

Section 9 of the FTC Act, 15 U.S.C. § 49, authorizes the Commission to issue subpoenas to require the production of documentary evidence and the testimony of witnesses relating to any matter under investigation. If the recipient fails to comply, the Commission may petition an appropriate district court for an order requiring compliance. *Id.* Section 9 confers jurisdiction on, and establishes venue in any district court in the United States in which the investigation is being carried on. *Id.*

The Commission issued a subpoena *ad testificandum* to Mr. Bisaro on July 22, 2009 and served it by overnight delivery to Watson's Corona, California corporate headquarters and his counsel in Washington, D.C. Petition Exhibit ("Pet. Exh.") 1 (Declaration of James Rhilinger)
¶ 12; Pet. Exh. 3.¹ The instant investigation is being carried on in Washington, D.C., where attorneys in the Health Care Division of the Commission's Bureau of Competition are located

Exhibits to the Commission's Petition are referred to herein as "Pet. Exh."

and are examining relevant documents and transcripts of testimony. Pet. Exh. 1 ¶ 5. Because Mr. Bisaro has failed to comply with the subpoena, this Court is empowered, pursuant to Section 9, to issue an order directing Mr. Bisaro to appear and show cause why this Court should not grant the instant petition and enter its own order enforcing the subpoena issued to respondent and requiring him to testify. See, e.g., FEC v. Comm. to Elect Lyndon LaRouche, 613 F.2d 849, 854-58 (D.C. Cir. 1979); FTC v. Browning, 435 F.2d 96, 100-01 (D.C. Cir. 1970).

STATEMENT OF FACTS

1. The Parties

The Commission is an administrative agency of the United States, organized and existing pursuant to the FTC Act, 15 U.S.C. § 41 et seq. The Commission is authorized and directed by Section 5(a) of the FTC Act, 15 U.S.C. § 45(a), to prevent the use of "unfair methods of competition" and "unfair or deceptive acts or practices in or affecting commerce." To carry out those responsibilities, the Commission is empowered to prosecute any inquiry necessary to its duties in any part of the United States (15 U.S.C. § 43), and "[t]o gather and compile information concerning, and to investigate from time to time the organization, business, conduct, practices, and management of any person, partnership, or corporation engaged in or whose business affects commerce." 15 U.S.C. § 46. Specifically, Section 9 of the Act empowers the Commission to require, by subpoena, the attendance and testimony of witnesses and the production of documentary evidence relating to any matter under investigation. 15 U.S.C. § 49.2

Respondent Paul M. Bisaro is President and Chief Executive Officer of Watson

In addition, Section 20 of the FTC Act empowers the Commission to require by Civil Investigative Demand ("CID") the production of documents or other information relating to any Commission law enforcement investigation. 15 U.S.C. § 57b-1(e).

Pharmaceuticals, Inc., a publicly held company. Pet. Exh. 1 ¶ 3. Watson develops, manufactures and markets a broad range of bioequivalent generic versions of pharmaceutical products throughout the United States. *Id.* The company is incorporated in the State of Nevada, headquartered in Corona, California, and has offices in Morristown, New Jersey, where respondent Bisaro's office is located. *Id.* Watson and Bisaro transact business throughout the United States, including Washington, D.C. *Id.* Watson and Bisaro are engaged in, and their business affects, "commerce," as that term is defined in Section 4 of the FTC Act, 15 U.S.C. § 44. *Id.*

2. Background

A. Provigil Patent Settlements and Initial Commission Investigation

The instant subpoena relates to an ongoing Commission investigation

To determine whether Cephalon, Inc., Teva Pharmaceuticals, Inc. (and its affiliate Teva Pharmaceuticals USA, Inc.), Barr Laboratories, Inc., Ranbaxy Laboratories, Inc., Mylan Pharmaceuticals, Inc., Carlsbad Technology, Inc., Watson Pharmaceuticals, Inc., or others have engaged in any unfair methods of competition that violate Section 5 of the Federal Trade Commission Act, 15 U.S.C. Sec. 45, as amended, by entering into agreements regarding any modafinil products.³

Modafinil is a wakefulness-enhancing drug that Cephalon, Inc. ("Cephalon") markets under the brand name Provigil – a drug with annual sales in excess of \$800 million. Pet. Exh. 1 ¶ 4. Cephalon had sued each of the generic companies identified in the process resolution, alleging that the generic manufacturers were infringing Cephalon's U.S. Reissued Patent No. 37,516 ("516 Patent") by filing abbreviated new drug applications ("ANDAs") with the Food

Resolution Authorizing Use of Compulsory Process in a Nonpublic Investigation, File No. 06110182 (August 30, 2006). Pet. Exh. 2.

and Drug Administration ("FDA").⁴ Pet. Exh. 1 ¶ 6. Cephalon settled each of these patent infringement suits between late 2005 and 2006, including a settlement reached with Watson and its development partner Carlsbad Technologies, Inc. ("Carlsbad") on August 2, 2006.⁵ Pet. Exh. 1 ¶ 7. Under the settlement agreements, Watson and the other generic manufacturers agreed they would not market generic modafinil until 2012.⁶ *Id*.

In 2006, the Commission opened an investigation, and authorized the use of compulsory process, to determine whether there were any agreements that would unlawfully delay the introduction of generic Provigil. Pet. Exh. 1 ¶ 5. The initial Commission investigation focused on the agreements settling the '516 patent litigation. Pet. Exh. 1 ¶ 5-8.

B. New Concerns about Watson's Ability to Block Generic Entry

In December 2007, Cephalon listed a new patent with the FDA relating to Provigil: U.S. Patent No. 7,297,346 ("'346 Patent'). Pet. Exh. 1 ¶ 9. On the same day, Watson/Carlsbad filed a certification with the FDA that its generic version of modafinil did not infringe the '346 patent,

⁴ ANDAs reflect a streamlined FDA approval process that enables manufacturers of generic drugs (*i.e.*, drugs that are "bioequivalent" to branded drugs) to rely on safety and efficacy studies relating to the branded drug.

On February 13, 2008, the Commission filed a complaint against Cephalon, alleging that its settlement agreements, which provided compensation to the generic firms for foregoing generic entry, were anticompetitive, an abuse of monopoly power, and unlawful under Section 5 of the FTC Act. FTC v. Cephalon, Inc., 08-cv-2141-MSG (E.D. Pa.). On March 29, 2010, the district court denied Cephalon's motion to dismiss the Commission's complaint.

Unlike the other generics identified in the process resolution, Watson was not a "first filer" for the '516 patent. Each of the generic firms listed in the process resolution, other than Watson/Carlsbad, filed their ANDAs on the same day, before any other parties. As "first filers," these entities were eligible under applicable law for 180 days of joint marketing exclusivity at such time that the FDA approved their ANDAs. This marketing exclusivity, together with the patent settlements, functions as a bottleneck to generic competition that barred any subsequent generic filer from marketing modafinil until 2012.

or that the patent was invalid. *Id.* This event created the possibility – one that did not exist for the '516 patent – that Watson could be a "first filer" for the '346 patent, and therefore could block market entry for later-filing generics. *Id.*

In May 2009, as part of its investigation into "agreements regarding any modafinil products," the Commission issued CIDs to Watson and Carlsbad and subpoenas *ad testificandum* to executives of each company to enable it to determine, *inter alia*, whether Watson was a party to any agreement limiting its ability to relinquish any eligibility for marketing exclusivity it may have with respect to modafinil. Such an agreement, if one exists, could delay generic entry and may constitute an "unfair method of competition" in violation of the FTC Act. Pet. Exh. 1 ¶¶ 10-11.

The Commission issued a CID to Watson on May 19, 2009. Pet. Exh. 1 ¶ 10. Watson provided only partial responses to the CID. *Id.* Accordingly, Commission staff asked Watson to supplement its initial responses. *Id.* Watson's counsel denied that the initial responses were deficient and, again, failed to provide the requested information, in part, on the basis of attorney-client privilege. *Id.* On June 25, 2009, pursuant to a subpoena *ad testificandum*, David A. Buchen, Watson's Senior Vice President, General Counsel, and Secretary, appeared and testified at an investigational hearing. Pet. Exh. 1 ¶ 11. Mr. Buchen did not fully respond to the Commission's questions. However, he identified Mr. Bisaro as the only person at Watson with whom he had spoken regarding discussions he had with a third party about a possible deal for generic Provigil. *Id.*

C. Bisaro Subpoena and Proceedings Before the Commission

Accordingly on July 22, 2009, the Commission issued a subpoena *ad testificandum* to Mr. Bisaro. Pet. Exh. 3. On July 30, 2009, Mr. Bisaro petitioned the Commission to quash the

subpoena.⁷ Pet. Exh. 4. In his petition, Mr. Bisaro contended that the subpoena should be quashed, asserting that it: 1) demanded information that the Commission already had; 2) improperly sought testimony from the "apex" of Watson's organization; 3) was issued for an improper purpose; and 4) imposed an undue burden by requiring travel to Washington, D.C. Additionally, he contended that the resolution authorizing the investigatory resolution had already been used in connection with an investigation that culminated in a civil action against Cephalon and, therefore, that the resolution could not be "resurrect[ed]" to burden Watson with more process. Pet. Exh. 4. On November 13, 2009, FTC Commissioner Pamela Jones Harbour, pursuant to authority delegated by the full Commission, denied the petition. Pet. Exh. 5. Mr. Bisaro then filed a petition for review by the full Commission. Pet. Exh. 6.

On April 2, 2010, the full Commission denied Mr. Bisaro's petition and directed him to appear for an investigational hearing in Washington, D.C., on April 15, 2010. Pet. Exh. 7. By letter dated April 13, 2010, Mr. Bisaro's counsel informed Commission staff attorneys that Watson would not produce Mr. Bisaro. Pet. Exh. 8. On April 19, 2010, Commission attorneys met with counsel for Mr. Bisaro, at counsel's request, to discuss Mr. Bisaro's testimony. At the meeting, counsel reiterated that Mr. Bisaro would not appear for an investigational hearing as required by the Commission's subpoena. Pet. Exh. 1 ¶ 15.

The Commission's Rules of Practice and Procedure allow subpoena recipients to petition the Commission to limit or quash any investigative subpoena, and to subsequently request review of an adverse ruling to the full Commission. See 16 C.F.R. § 2.7(d).

ARGUMENT

THE SUBPOENA AD TESTIFICANDUM IS LAWFUL, SEEKS RELEVANT TESTIMONY, AND IS NOT UNDULY BURDENSOME

A. Standards for Enforcement of Agency Process

The standards for judicial enforcement of administrative investigative process have long been settled in this Circuit. "[T]he court's role in a proceeding to enforce an administrative subpoena is a strictly limited one." FTC v. Texaco, Inc., 555 F.2d 862, 871-72 (D.C. Cir. 1977) (en banc) (citing Endicott Johnson Corp. v. Perkins, 317 U.S. 501, 509 (1943); accord, Oklahoma Press Publ'g Co. v. Walling, 327 U.S. 186, 209 (1946); United States v. Morton Salt Co., 338 U.S. 632, 643 (1950)). "[W]hile the court's function is 'neither minor nor ministerial,' the scope of issues which may be litigated in an enforcement proceeding must be narrow, because of the important governmental interest in the expeditious investigation of possible unlawful activity." Id. (quoting Oklahoma Press Publ'g, 327 U.S. at 217 n.57); accord, FTC v. Anderson, 631 F.2d 741, 744-45 (D.C. Cir. 1979).

Thus, a district court must enforce agency process so long as the information sought is not "unduly burdensome" to produce (*Texaco*, 555 F.2d at 881), and is "reasonably relevant" (*id.* at 872-73 n.23 (quoting *Morton Salt*, 338 U.S. at 652), or, putting it differently, "not plainly incompetent or irrelevant to any lawful purpose" of the agency. *Texaco*, 555 F.2d at 872 (quoting *Endicott Johnson*, 317 U.S. at 509). In making this determination, the agency's own appraisal of relevancy must be accepted so long as it is not "obviously wrong." *FTC v. Invention Submission Corp.*, 965 F.2d 1086, 1089 (D.C. Cir. 1992) (citing *Carter*, 636 F.2d at 787-88 (quoting *Texaco*, 555 F.2d at 877 n.32)); *Appeal of FTC Line of Business Report Litigation*, 595 F.2d 685, 702-03 (D.C. Cir. 1978) (per curiam); *see also* Fed. R. Civ. P.

26(a)(1)(E). Mr. Bisaro carries a heavy burden to show that the subpoena should not be enforced.

Proceedings to enforce administrative investigative subpoenas are special statutory matters cognizable under Fed. R. Civ. P. 81(a)(5), and are entitled to summary disposition.

Carter, 636 F.2d at 789; FTC Line of Business Report Litig., 595 F.2d at 704-05. They are properly instituted by a petition and order to show cause (rather than by complaint and summons). See Fed. R. Civ. P. 81(a)(5); MacArthur, 532 F.2d at 1141-42. Furthermore, even limited discovery or evidentiary hearings are improper except upon a showing of "extraordinary circumstances." See, e.g. Invention Submission Corp., 965 F.2d at 1091; SEC v. Knopfler, 658 F.2d 25, 26 (2d Cir. 1981); Carter, 636 F.2d at 789 (quoting United States v. Exxon Corp., 628 F.2d 70, 77 n.7 (D.C. Cir. 1980); MacArthur, 532 F.2d at 1141-42; FTC v. Browning, 435 F.2d 96, 104 (D.C. 1970); see also Fed. R. Civ. P. 26(a)(1)(B)(v).

As shown below, all the standards governing enforcement of Commission compulsory process have been satisfied. The Commission plainly has the authority to issue the subpoenas, the information required by the subpoenas is reasonably relevant to the subject matter of the inquiry, and respondent has not shown that compliance would be unduly burdensome. Because respondent has not provided any valid objections to the subpoena, it must be enforced.

B. The Inquiry is Within the Commission's Authority

The Commission issued the instant subpoena *ad testificandum* in aid of an investigation into possible violations of Section 5 of the FTC Act, 15 U.S.C. § 45. The Commission initiated the investigation by issuing a Resolution Authorizing Use of Compulsory Process in a Nonpublic Investigation on August 30, 2006. Pet. Exh. 2. According to the Resolution, the Commission seeks to determine whether Watson and Carlsbad, along with Cephalon, and other generic

manufacturers, have engaged in "unfair methods of competition" in violation of Section 5 of the FTC Act, 15 U.S.C. § 45, "by entering into agreements regarding any modafinil products." *Id.*The Commission also resolved that "all compulsory process available to it be used in connection with this investigation." *Id.*

As explained above, Sections 6 and 9 of the FTC Act give the Commission ample authority to conduct the investigation and to issue subpoenas in furtherance of such investigation. See 15 U.S.C. §§ 46, 49; see also 16 C.F.R. § 2.7(a).8 The subpoena seeks the appearance of Mr. Bisaro, who has information that is indisputably "relating to" the subject matter of the investigation, and, as required by 15 U.S.C. § 49, was duly signed by a member of the Commission. Pet. Exh. 3. Respondent, in refusing to comply with the subpoena, has advanced the novel proposition that the Commission's investigatory resolution has already been used in connection with the Commission's investigation of, and ensuing litigation against, Cephalon. Pet. Exh. 4 at 3. As the Commission explained, however, a Commission resolution authorizing compulsory process for an investigation does not expire upon the filing of an enforcement action, or because litigation related to a similar subject may have begun. Pet, Exh. 7 at 5 (citing Linde Thomson Langworthy Kohn & Van Dyke, P.C. v. Resolution Trust Corp., 5 F.3d 1508 (D.C. Cir. 1993)). As for respondent's further contention that the subpoena was issued for the purpose of pressuring Watson into relinquishing any exclusivity rights it may have in effort to "engineer[] generic entry into the modafinil market," (Pet. Exh. 4 at 19), the full Commission, in its April 2, 2010 denial of respondent's petition to quash reaffirmed that

Section 2.7(a) of the Commission's Rules of Practice provides, in relevant part: "The Commission or any member thereof may, pursuant to a Commission resolution, issue a subpoena * * * directing the person named therein to appear before a designated representative at a designated time and place to testify * * *."

"issuing a subpoena for the testimony of the President and CEO of Watson about any company agreements and discussions with third parties with regard to relinquishment – after first issuing CIDs to the company and receiving the testimony of another of its executives – is clearly a proper purpose." Pet. Exh. 7 at 8. Respondent's speculative concerns and groundless allegations are no basis for questioning the Commission's good faith, or otherwise disturbing the presumption of regularity to which the Commission is entitled under governing law. See FCC v. Schreiber, 381 U.S. 279, 296 (1965); see also Invention Submission Corp., 965 F.2d at 1091-92 ("validity of Commission subpoenas is to be measured against the purposes stated in the resolution, and not by reference to extraneous evidence") (quoting Carter, 636 F.2d at 789); United States v. Aero Mayflower Transit Co., 831 F.2d 1142 (D.C. Cir. 1987) (rejecting allegations of agency misconduct where subpoenas "seek information relevant to the discharge of [agency's Inspector General's] duties"); see also SEC v. Dresser Industries, Inc., 628 F.2d 1368 (D.C. Cir. 1980) (rejecting allegations of agency bad faith to justify discovery); CFTC v. Harker, 615 F. Supp. 420, 423-425 (D.D.C. 1985) (same).

C. The Subpoena Seeks Testimony That Is Reasonably Relevant to the Commission's Investigation

The standard for judging relevancy in an investigatory proceeding is more relaxed than in an adjudication. In an investigation, the Commission is not limited to seeking information that is necessary to prove specific charges. It merely seeks to learn whether there is reason to believe that the law is being violated and, if so, whether issuance of a complaint would be in the public interest. *See Texaco*, 555 F.2d at 872. The requested testimony, therefore, need only be relevant to the investigation – the boundary of which may be defined by the agency quite generally. *See Carter*, 636 F.2d at 787-88; *Texaco*, 555 F.2d at 874 & n.26.

In the present investigation, the Commission is seeking to determine whether Watson is a party to any agreement regarding modafinil products that may unlawfully delay consumer access to generic modafinil. Mr. Buchen identified Mr. Bisaro as having personal knowledge of events relevant to the investigation, and even testified that Mr. Bisaro was the only person at Watson with whom he spoke about certain conversations regarding relinquishment. Pet. Exh. 1 ¶ 11. The Commission, however, has been stymied in its efforts to ask Mr. Bisaro about his knowledge of the existence of such an agreement or discussions relating to such an agreement. See e.g., Pet. Exh. 1 ¶ 10, 13, 14, 15.

While respondent argued in his petition to quash that the subpoena is unnecessary (Pet. Exh. 4 at 16), that is a judgment that the Commission, not respondent, is entitled to make. Mr. Bisaro might very well have personal knowledge of highly relevant information concerning any agreements limiting Watson's ability to relinquish any exclusivity it might possess relating to the sale of modafinil, as well as discussions with third parties concerning relinquishment, that the Commission does not already possess. As the Commission properly concluded in rejecting respondent's objection, "[w]hile Watson has provided the Commission information relating to the '346 Patent, [respondent] has not shown that his testimony will shed no additional light on matters that fall within the scope of the Commission's investigatory concerns." Pet. Exh. 7 at 7.

D. Compliance with the Subpoena is Not Unduly Burdensome

As for respondent's contention that it would be "unduly burdensome" for him to appear at Commission offices in Washington, D.C. (Pet. Exh. 4 at 19; Pet. Exh. 6 at 3), he has not offered any evidence to support that assertion. Pet. Exh. 7 at 9. It is well established that it is respondent's burden to demonstrate that compliance with investigatory process is unduly burdensome. See, e.g., Invention Submission Corp., 965 F.2d at 1090; FTC v. Rockefeller, 591

F.2d 182, 190 (2d Cir. 1979); Texaco, 555 F.2d at 882.

Nor has respondent shown that the subpoena is "unreasonable" because, under the so-called "apex doctrine," the Commission must demonstrate that it cannot obtain the relevant information elsewhere. Pet. Exh. 4 at 17-19; Pet. Exh. 6 at 3. As the Commission concluded, however, respondent had provided no support for the proposition that this doctrine limits the investigatory powers of an enforcement agency. In any event, even in the very different context of civil discovery, this doctrine has limited application and high-level corporate executives have discovery obligations. As the Commission stated, respondent "is another logical, possible source of relevant information" based on his discussions with Mr. Buchen, as well as other non-privileged information he may possess. See Pet. Exh. 5 at 6-7; Pet. Exh. 7 at 7-8.

The Commission has met all of the requirements necessary for enforcement of the subpoena. The Commission is investigating possible "unfair methods of competition" and marketing practices in violation of Section 5 of the FTC Act regarding agreements involving modafinil products. Mr. Bisaro's testimony is clearly relevant to the investigation. As the Commission concluded in its April 2, 2010 denial of respondent's petition to quash, Pet. Exh. 7, the Commission does not yet possess the information sought in the subpoena and, to date, has been unable to obtain the information by other means. Mr. Bisaro also has failed to articulate how attending the investigational hearing in Washington, D.C. is unduly burdensome. Finally, the Commission has made numerous attempts to gain Mr. Bisaro's cooperation in the investigation short of judicial intervention. Based on the foregoing, the subpoena should be enforced.

CONCLUSION

For all the foregoing reasons, the Commission respectfully requests that this Court issue its own order directing Mr. Bisaro to comply in full with the July 22, 2009 subpoena ad testificandum by providing testimony within 10 days of the date of the Court's Order, or at such later date as may be established by the Commission.

Respectfully submitted,

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Dated: April 23, 2010

CERTIFICATE OF SERVICE

I hereby certify that I will cause to be served true and correct public copies of:

Petition of Federal Trade Commission for an Order Enforcing Administrative Subpoena Ad Testificandum (and supporting exhibits); and

Memorandum of Points and Authorities in Support of Petition of Federal Trade Commission for an Order Enforcing Subpoena Ad Testificandum; and

Proposed Order to Show Cause;

Proposed Final Order;

upon:

Paul M. Bisaro President and CEO Watson Pharmaceuticals, Inc. 360 Mt. Kemble Avenue, Morristown, NJ 07962

and

c/o Steven C. Sunshine, Esq. Skadden, Arps, Slate, Meagher & Flom LLP 1440 New York Avenue, N.W. Washington, D.C. 20005

upon the Court's issuance of an Order to Show Cause by personal service, or by certified mail with return receipt requested, or by overnight express delivery service.

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