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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

FEDERAL TRADE COMMISSION, Petitioner, v. BOEHRINGER INGELHEIM PHARMACEUTICALS, INC., Respondent.	)	Misc. No. 09-564

MEMORANDUM IN SUPPORT OF PETITION OF THE FEDERAL TRADE COMMISSION FOR AN ORDER ENFORCING A SUBPOENA *DUCES TECUM*

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, petitions this Court for an Order requiring Respondent, Boehringer Ingelheim Pharmaceuticals, Inc. ("Boehringer"), to comply with the subpoena *duces tecum* issued to it by the FTC on February 5, 2009. The subpoena seeks records relevant to an ongoing Commission law enforcement investigation. The Commission issued the subpoena in aid of its non-public investigation seeking to determine whether Respondent Boehringer, Barr Pharmaceuticals, Inc. ("Barr"), and their affiliates have engaged or are engaging in unfair methods of competition in or affecting commerce, in violation of Section 5 of the FTC Act, 15 U.S.C. § 45, with respect to the sale of two of Boehringer's pharmaceutical products, Aggrenox and Mirapex, or their generic equivalents. In particular, the Commission seeks to determine whether certain agreements entered into by Boehringer and Barr sought to delay the marketing of Barr's lower-cost generic substitutes to Aggrenox and Mirapex, in exchage for Barr receiving a share of Boehringer's monopoly profits

from the sale of those products. Aggrenox and Mirapex and Mirapex had combined sales of over $830 million in 2008, and generic entry typically results in significant savings to consumers (often on the order of 80% or higher). If the agreements are improper, any delay in the Commission's investigation costs consumers millions of dollars per month.

Nearly nine months after the supoena issued, and four months after the expiration of the last extension of production deadline granted to it by the Commission, Boehringer has yet to comply in full with the Commission's subpoena – with its counsel suggesting recently that the process could go on indefinitely. Boehringer has employed a number of tactics that not only have delayed the Commission's investigation, but that also resulted in the Commission *not* receiving all of the documents and data sought by the subpoena.

Because the subpoena was lawfully issued and the records sought are relevant to the Commission's investigation, the Court should order Boehringer to show cause why it should not fully comply, and thereafter enforce the subpoena. *See, e.g., 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. 81(a)(5); 26(b)(1).

JURISDICTION

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

Commission issued the subpoena duces tecum on February 5, 2009. Pet Exh. 3;[1] Pet. Exh. 1 (Declaration of Rebecca Egeland of October 22, 2009), ¶9. By agreement, it served the subpoena on Boehringer's counsel, and service is not in dispute here. Pet. Exh. 1, ¶9. The Commission's investigation is taking place within Washington, D.C. Pet. Exh. 1, ¶8. Because Boehringer has failed to comply with the subpoena, Section 9 of the FTC Act empowers this Court to issue its process (*e.g.*, a show cause order) to Boehringer in this proceeding. *See, e.g.*, *FTC v. Browning*, 435 F.2d 96, 100 (D.C. Cir. 1970); *FEC v. Committee to Elect Lyndon LaRouche*, 613 F.2d 849, 854-58 (D.C. Cir. 1979).

STATEMENT OF FACTS

The Parties

The Commission is an administrative agency of the United States government, 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. Section 3 of the FTC Act empowers the Commission to prosecute any inquiry necessary to its duties in any part of the United States. 15 U.S.C. § 43. Section 6 of the Act empowers the Commission "[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," with certain exceptions not relevant here. 15 U.S.C. § 46. As noted above, Section 9 of the Act empowers the Commission to demand, by subpoena, the production of all such documentary evidence relating to any matter under investigation.

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[1] Exhibits to the Commission's Petition are referred to as "Pet. Exh."

Respondent Boehringer is a Delaware corporation and a privately held subsidiary of Boehringer Ingelheim GmbH of Ingelheim, Germany. Boehringer is in the business of developing, manufacturing, and marketing pharmaceutical products in the United States. Pet. Exh. 1, ¶3. Boehringer is engaged in, and its business affects, "commerce," as that term is defined in Section 4 of the FTC Act, 15 U.S.C. § 44.

Background – The Patent Litigations and Settlements

Boehringer markets two brand-name pharmaceutical drugs, "Aggrenox" and "Mirapex." Aggrenox, which had U.S. sales of about $366 million in 2008, is used to treat people who have had strokes caused by blood clots or "mini strokes." Mirapex, which had sales of about $477 million in 2008, is used to treat Parkinson's disease and moderate-to-severe Restless Legs Syndrome. Pet. Exh. 1, ¶4.

Barr is a manufacturer of generic pharmaceutical drugs. Pet. Exh. 5. Barr developed generic versions of both Aggrenox and Mirapex, and sought FDA approval to market the two generic drugs. *Id.* In response, Boehringer filed two patent infringement lawsuits against Barr, first as to Mirapex, *see Boehringer Ingelheim Int'l GmbH v. Barr Labs., Inc.*, No. 05-700 (D. Del. *Complaint filed* Sept. 26, 2005), and then as to Aggrenox, *see Boehringer Ingelheim Pharma GmbH & Co. KG v. Barr Labs., Inc.*, No. 07-432 (D. Del. *Complaint filed* July 11, 2007). *Id.* The court in the Mirapex patent litigation held that Boehringer's patent was invalid. *Boehringer Ingelheim Int'l GmbH v. Barr Labs., Inc.*, 562 F. Supp. 2d 619, 639 (D. Del. 2008), *appeal filed*, No. 2009-1032 (Fed. Cir.).[2] At

[2] Boehringer is pursuing the appeal only as to another party to that litigation, Mylan Pharmaceuticals Inc. *See Boehringer Ingelheim Int'l GmbH v. Barr Labs., Inc.*, No. 2009-1032 (Fed. Cir. *appeal docketed* Oct. 23, 2008).

the time of the Mirapex patent invalidity ruling, the Aggrenox patent litigation was in its early stages. Pet. Exh. 1, ¶6.

On August 11, 2008, Boehringer and Barr entered into a series of settlement and related agreements covering both the Aggrenox and Mirapex litigations. Pet. Exh. 1, ¶7. Under those agreements, Barr agreed not to compete with Boehringer by forgoing market entry with its generic versions of Aggrenox and Mirapex until 2015 and 2010, respectively. *Id.* At the same time, Boehringer partnered with Barr to co-promote Aggrenox to women's health care professionals. *Id.* Under that arrangement, Boehringer agreed to provide Barr with substantial compensation, including royalties based on net sales of Aggrenox. *Id.* As required by statute, Boehringer and Barr filed these agreements with the FTC and the U.S. Department of Justice for review. *Id.*

The Commission's Investigation and the Subpoena

On January 15, 2009, the Commission opened a formal investigation and issued a Resolution Authorizing Use of Compulsory Process in Nonpublic Investigation (FTC File No. 091-0023). Pet. Exh. 2; Pet. Exh. 1, ¶8. The Resolution authorized the use of all compulsory process in connection with the investigation, to determine "whether Boehringer Ingelheim Pharmaceuticals, Inc. and Barr Pharmaceuticals, Inc., and their affiliates, or any other person, has engaged or is engaging in unfair methods of competition in or affecting commerce, in violation of Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45, as amended, with respect to the sale of Aggrenox or its generic equivalents and Mirapex or its generic equivalents." Pet. Exh. 2, at 1.

As part of that investigation, on February 5, 2009, the Commission issued a subpoena *duces tecum* to Boehringer requiring Boehringer to produce documents and data relating to the investigation. Pet. Exh. 3. The subpoena contains 37 specifications. In particular, the subpoena seeks, *inter alia*, documents related to the patent litigation regarding Aggrenox and Mirapex

(Specifications 1-3); documents regarding the sales, profits, and marketing plans for Aggrenox and Mirapex (Specifications 7-18); documents relating to the agreements between Boehringer and Barr entered at the time of the settlement of their patent litigations (Specifications 19-21); documents relating to Boehringer's co-marketing of products (including Aggrenox) with other firms (Specifications 22-28); documents relating to the marketing of authorized generic versions of Boehringer's products (Specifications 29-32); and analyst reports relating to Aggrenox and Mirapex (Specification 33-34). *Id.* at 1-5. The subpoena also contains a number of instructions governing the timing, format, and manner of submission of responsive documents. *Id.* at 8-12. Of particular relevance here are Instructions 2, 3, and 13, which in relevant parts provide:

> 2. Except for privileged material, Boehringer will produce each responsive document in its entirety by including all attachments and all pages, regardless of whether they directly related to the specified subject matter. * * * Except for privileged material, Boehringer will not redact, mask, cut, expunge, edit, or delete any responsive document or portion thereof in any manner.
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> 3. Compliance with this subpoena requires a search of all documents in the possession, custody, or control of Boehringer including, without limitation, those documents held by any of Boehringer's officers, directors, employees, agents, representatives, or legal counsel, whether or not such documents are on the premises of Boehringer. * * * In addition to hard-copy documents, the search will include all of Boehringer's Electronically Stored Information.[3]
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> 13. Compliance with this subpoena requires Boehringer to submit to the Commission all responsive documents, data, information and the following:

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[3] Definition S of the Commission subpoena provides: "The term 'Electronically Stored Information' refers to any portion of data found on a computer or other device capable of storing electronic data, where such data is capable of being manipulated as an entry. 'Electronically Stored Information' includes, but is not limited to, e-mail, spreadsheets, databases, word processing documents, images, presentations, application files, executable files, log files, and all other files present on any type of device capable of storing electronic data. Devices capable of storing Electronically Stored Information include, but are not limited to: servers, desktop computers, portable computers, handheld computers, flash memory devices, wireless communication devices, pagers, workstations, minicomputers, mainframes, and any other forms of online or offline storage, whether on or off company premises." Pet. Exh. 3, at 7-8.

(a) Executed and notarized certification form, which is included herewith;

(b) Privilege Log according to Instruction 8, if any responsive documents are withheld or redacted; * * *.

Pet. Exh. 3, at 8-9, 12. Boehringer did not petition the Commission to limit or to quash the subpoena. Pet. Exh. 1, ¶10.

Boehringer's Failure to Comply with the Subpoena

The Commission's February 5, 2009, subpoena initially had a 30-day response time. Pet. Exh. 3. As Boehringer produced responsive materials on a rolling basis, the FTC granted four extensions to Boehringer's response date. Pet. Exh. 1, ¶11. The last of these extensions expired on June 19, 2009, after which no further extensions were requested or granted. *Id.* As of the date of this filing – four months after the last deadline extension, and over eight months after the subpoena issued – Boehringer has yet to certify that it has complied in full with the subpoena. Pet. Exh. 1, ¶12. Indeed, Commission staff learned only recently that Boehringer's document collection efforts were still ongoing, with *no* contemplated end date – despite earlier assurances by Boehringer's counsel that its rolling production was nearly complete. Pet Exh. 1, ¶¶18-20.

Boehringer has produced some documents in response to the subpoena, but review of Boehringer's document production, and two recent investigational hearings that focused on that response, have highlighted a number of deficiencies in Boehringer's production, and have pointed to a number of tactics employed by Boehringer that promote delay and unreliability in its subpoena compliance, and consequently undermine the Commission's investigation. *See* Pet Exh. 1, ¶¶12-20. These include:

Inappropriate Redaction. Directly contravening Instruction 2 of the subpoena, Boehringer initially produced numerous documents from which Boehringer had unilaterally made substantial

redactions. Pet. Exh. 1, ¶13. Not only were those redactions unrelated to any claim of privilege, but they were so extensive as to make it, in many instances, impossible to understand the subject documents. For example, multiple-page documents were produced with only one or two lines unredacted. Boehringer claimed first that the redactions were of information unrelated to either Aggrenox or Mirapex and, more broadly, unrelated to the Commission's investigation. *Id.* It also claimed that the redacted information was not necessary to understand or provide context for the unredacted portions. *Id.* These justifications were repeatedly rejected by the Commission, although Boehringer was told that the Commission was willing to consider some proposed redactions, on a case-by-case basis, and only if the Commission's consent to the redaction was secured in advance of production. *Id.*, ¶14. Boehringer continued to redact some documents unilaterally, however, and, over time, it modified its position to claim that it was entitled to make relevance-based redactions because the redacted material was beyond the scope of the Commission's subpoena and its authorizing resolution. *Id.*, ¶13. After months of delay, and on the eve of a Commission-planned court filing of an enforcement action focused on the redactions issue, Boehringer changed course and re-produced those same documents with substantially fewer redactions. *Id.*, ¶15. This subsequent production revealed that – contrary to Boehringer's repeated earlier representations – many of those redactions were in fact responsive to the subpoena, including some that were highly relevant to the Commission's investigation. *Id.* In fact, Boehringer redacted not only specific mentions of the drugs at issue but also redacted material directly relating to the effects of an agreement which is the focus of the Commission's investigation. *Id.*

Inadequate Document Collection Procedures. Boehringer has failed to conduct an adequate search for, and collection of, responsive material, in contravention of Instruction 3 of the Commission subpoena. Pet Exh. 1, ¶16. Boehringer identified eight employees that were directly

involved in the negotiation or analysis of Boehringer's agreements with Barr, but produced responsive documents from only three of these eight employees (claiming that three did not have any non-privileged responsive documents, while failing to search the records of the other two). *Id.* Other employees with seemingly relevant job responsibilities initially did not have their files searched at all. *Id.* And Boehringer apparently failed to conduct an independent search of the electronic documents it maintained on company databases, networks, and central archives, as mandated by Instruction 3, relying instead on the initiative of its individual employees. *Id.*

Failure to Certify Compliance. In May 2009, Boehringer's counsel represented that its production in response to the subpoena was nearly complete. Pet. Exh. 1, ¶19. Since then, on a number of occasions, the Commission staff have requested that Boehringer execute the certification of compliance required by Instruction 13 of the subpoena. Boehringer not only has failed to do so, but its counsel has now declined to give even a general time frame for when full compliance, including execution of the certification, will take place, suggesting that the process may go on indefinitely. Pet. Exh. 1, ¶¶12, 20.

The Commission's repeated efforts to address the shortcomings in Boehringer's subpoena response, and to obtain a time commitment on its full compliance, have all failed, necessitating the filing of this action.

LEGAL STANDARD FOR ENFORCEMENT

The standards for the judicial enforcement of administrative compulsory process have long been settled in this Circuit: "the court's role in a proceeding to enforce an administrative subpoena is a strictly limited one." *FTC v. Texaco*, 555 F.2d 862, 872 (D.C. Cir. 1977) (*en banc*) (citing *Endicott Johnson v. Perkins*, 317 U.S. 501 (1943); *Oklahoma Press Publ'g Co. v. Walling*, 327 U.S. 186 (1946); *United States v. Morton Salt Co.*, 338 U.S. 632 (1950)). And "while 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.* (citing *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). A court must enforce an agency's investigative subpoena "'if the inquiry is within the authority of the agency, the demand is not too indefinite and the information sought is reasonably relevant,'" *FTC v. Texaco*, 555 F.2d at 872 (quoting *Morton Salt*, 338 U.S. at 652).

Proceedings to enforce administrative investigative subpoenas are entitled to summary disposition. 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), (b). And they are summary in nature: discovery or evidentiary hearings may be granted only upon a showing of "extraordinary circumstances" – which are not present here; otherwise, "discovery is improper in a summary subpoena enforcement proceeding." *FTC v. Carter*, 636 F.2d 781, 789 (D.C. Cir. 1980) (quoting *United States v. Exxon Corp.*, 628 F.2d 70, 77 n.7 (D.C. Cir. 1980)); *see also, e.g., Appeal of FTC Line of Business Report Litig.*, 595 F.2d 685, 704-05 (D.C. Cir. 1978); *FTC v. MacArthur*, 532 F.2d 1135, 1141-42 (7th Cir. 1976); *FTC v. Browning*, 435 F.2d 96, 104 (D.C. Cir. 1970).

ARGUMENT

I. THE SUBPOENA IS LAWFUL AND SEEKS RELEVANT DOCUMENTS

Because the Commission lawfully issued the subpoena to Respondent Boehringer, and because the information being sought is relevant to the Commission's investigation, the Court should order Boehringer to show cause why it should not fully comply.

A. The Boehringer Subpoena Is Lawful

The Commission properly issued the Boehringer subpoena as part of an investigation concerning possible violations of Section 5 of the FTC Act, 15 U.S.C. § 45.[4] To initiate the investigation, the Commission on January 15, 2009, and pursuant to the FTC Act and its rules and procedures,[5] issued a duly authorized "Resolution Authorizing Use of Compulsory Process in Nonpublic Investigation" setting out the nature and scope of the investigation. *See* Pet. Exh. 2. In particular, the Commission sought to determine whether Boehringer, along with Barr or any of their affiliates, "has engaged or is engaging in unfair methods of competition * * * with respect to the sale of Aggrenox or its generic equivalents and Mirapex or its generic equivalents." *Id.* It also resolved that "all compulsory process available to it be used in connection with this investigation." *Id.*

There is no question that the Commission is authorized to initiate such an investigation. Section 6 of the FTC Act, for example, empowers the Commission to "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(a); *see also FTC v. Carter*, 636 F.2d at 787-88 (an investigation

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[4] Section 5 provides, in relevant parts:

> (a)(1) Unfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce, are hereby declared unlawful.
>
> (2) The Commission is hereby empowered and directed to prevent persons, partnerships, or corporations * * * from using unfair methods of competition in or affecting commerce and unfair or deceptive acts or practices in or affecting commerce.

[5] Specifically, the Resolution listed as the Commission's authority to conduct the investigation Sections 6, 9, 10, and 20 of the FTC Act, 15 U.S.C. §§ 46, 49, 50, and 57b-1, as amended; and FTC Procedures and Rules of Practice, 16 C.F.R. §§ 1.1 *et seq.*, and supplements thereto. Pet. Exh. 2.

is properly authorized when adequate notice of its purposes is given). Nor is there any question that the subpoena was properly authorized, and duly issued. Section 9 of the FTC Act provides, in part, that "the Commission shall have power to require by subpoena the attendance and testimony of witnesses and the production of all such documentary evidence relating to any matter under investigation. Any member of the Commission may sign subpoenas." 15 U.S.C. § 49; *see also* 15 C.F.R. § 2.7(a).[6] The Boehringer subpoena seeks documents (described in detailed specifications) that are indisputably "relating to" the subject matter of the investigation, and it was duly signed by a member of the Commission. Pet. Exh. 2. Although the Commission's rules and procedures afford respondents the opportunity to petition the Commission to limit or quash any investigative subpoena, *see* 15 C.F.R. § 2.7(d), and although the subpoena itself provides clear notice of such opportunity, *see* Pet. Exh. 2, at 1, Boehringer chose not to do so within the required time period, and cannot do so now.[7]

B. The Subpoena Seeks Documents That Are Reasonably Relevant to the Commission's Investigation

The judicial standard for ascertaining "relevance" in an investigatory proceeding is deferential to the administrative agency, and is more relaxed than in an adjudicatory proceeding.

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[6] 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 or a civil investigative demand directing the person named therein to appear before a designated representative at a designated time and place to testify or to produce documentary evidence, or both, or, in the case of a civil investigative demand, to provide a written report or answers to questions relating to any matter under investigation by the Commission." The subpoena issued to Boehringer was signed by Commissioner Pamela Jones Harbour. Pet. Exh. 3, at 1.

[7] Arguments not first raised before the Commission in a petition to quash are waived here. *See, e.g.*, *FTC v. Invention Submission Corp.*, Misc. No. 89-272-RCL, 1991 WL 47104, at *2 n.12 (D.D.C. Feb. 14, 1991), *aff'd*, 965 F.2d 1086 (D.C. Cir. 1992); *see also FTC v. O'Connell*, 828 F. Supp. 165, 168 (E.D. N.Y. 1993); *EEOC v. City of Milwaukee*, 919 F. Supp. 1247 (E.D. Wis. 1996).

Indeed, "a court must respect the agency's 'power of inquisition' and interpret relevance broadly." *Invention Submission Corp.*, 1991 WL 47104, at *2 (quoting *Morton Salt*, 338 U.S. at 642). In elucidating the relevance standard, the D.C. Circuit "recognize[d] that in the pre-complaint stage, an investigating agency is under no obligation to propound a narrowly focused theory of a possible future case," and cautioned that a "court must not lose sight of the fact that the agency is merely exercising its legitimate right to determine the facts, and that a complaint may not, and need not, ever issue." *FTC v. Texaco*, 555 F.2d at 874 & n.23. Thus, "an investigative subpoena of a federal agency will be enforced if the 'evidence sought * * * [is] not plainly incompetent or irrelevant to any lawful purpose' of the agency." *United States v. Aero Mayflower Transit Co.*, 831 F.2d 1142, 1145 (D.C. Cir. 1987) (alteration original) (quoting *Endicott Johnson*, 317 U.S. at 509); *see also FTC v. Invention Submission Corp.*, 965 F.2d 1086, 1089 (D.C. Cir. 1992); *FTC v. Carter*, 636 F.2d at 788; *FTC v. Texaco*, 555 F.2d at 871-73. In petitions for enforcement by the Commission, "[t]he relevance of the material sought by the FTC must be measured against the scope and purpose of the FTC's investigation, as set forth in the Commission's resolution." *FTC v. Texaco*, 555 F.2d at 874. But, "the agency's own appraisal of relevancy must be accepted so long as it is not 'obviously wrong'." *Invention Submission Corp.*, 965 F.2d at 1089 (quoting *FTC v. Carter*, 636 F.2d at 788; *FTC v. Texaco*, 555 F.2d at 877 n.32).

In an investigation such as the one here, the Commission does not seek the information necessary to prove any specific charges; it merely seeks to learn if the law is being violated and *whether* to file a complaint. "An agency can inquire 'merely on suspicion that the law is being violated, or even just because it wants assurance that it is not'." *Invention Submission Corp.*, 1991 WL 47104, at *2 (quoting *Morton Salt*, 338 U.S. at 642-43). Under such circumstances, "the law requires that courts give agencies leeway when considering relevance objections." *Id.; see Texaco*,

55 F.2d at 872. The requested documents, therefore, need only be relevant to the investigation – the boundary of which may be defined quite broadly. *See Carter*, 636 F.2d at 787-88; *Texaco*, 555 F.2d at 874 & n. 26.

The present investigation seeks to determine, among other things, whether Boehringer's payments to Barr were made to delay the latter's marketing of competitive generic versions of Aggrenox and Mirapex. Pet. Exh. 1, ¶¶8-9. As part of this investigation, the FTC seeks to know the details surrounding the parties' agreements to settle their patent litigations and to exchange licensing, co-promotion, and other benefits made attendant thereto, and other relevant conduct. *Id.* The information sought by the Commission's subpoena, as detailed in the specifications, is relevant to these issues. The subpoena seeks, for example, documents related to the patent litigation that Boehringer initiated against Barr regarding Aggrenox and Mirapex (Specifications 1-3); documents regarding Boehringer's sales, profits, and marketing plans for Aggrenox and Mirapex (Specifications 7-18); documents relating to all the agreements that Boehringer entered into with Barr at the time of the settlement of their patent litigations (Specifications 19-21); documents relating to Boehringer's co-marketing of products (including Aggrenox) with other firms, including Barr (Specifications 22-28); documents relating to plans or agreements for the marketing of "authorized" generic versions of Aggrenox and Mirapex (Specifications 29-32); and analyst reports relating to Aggrenox and Mirapex (Specification 33-34). Pet. Exh. 3, at 1-5; Pet. Exh. 1, ¶9.

Boehringer has not sought to limit the scope of the information requested by the subpoena's specifications. Pet. Exh. 1, ¶10. Accordingly, the Commission's subpoena should be enforced by this Court. *See FTC v. Texaco*, 555 F.2d at 874-76.

II. RESPONDENT BOEHRINGER HAS FAILED TO COMPLY WITH THE COMMISSION'S SUBPOENA

As discussed above, Respondent Boehringer has failed to certify its full compliance with the Commission's subpoena, and has in fact indicated that it has yet to complete its search and production of responsive documents – despite the passage of four months after the last of four deadline extensions the Commission afforded it. Boehringer has not proffered any justification for its failure to comply fully with the Commission subpoena. To the contrary, in initially producing responsive documents with substantial redactions that are unrelated to any legitimate claim of privilege, in resisting Commission demands to remove these illegitimate redactions and reneging on an agreement with Commission staff to do so (all the while misrepresenting the import of those redactions to the ongoing investigation), and in employing unsystematic methods to search for responsive material, Boehringer not only has contravened the clear instructions of the Commission's subpoena, but it also has appears to have deliberately delayed its full compliance and hindered the Commission's investigation. If, as explained above, Boehringer's agreements with Barr have, in fact, illegally delayed the marketing of Barr's lower-cost generic substitutes to Aggrenox and Mirapex, then Boehringer's hinderance of the Commission's investigation is highly profitable to it (and to Barr), and is harming consumers.

There is no dispute that Boehringer has not complied with the Commission subpoena. The subpoena was issued on February 5, 2009, and initially had a return date of 30 days thereafter. That deadline was extended by the Commission four times, the last of which extended the return date to June 19, 2009. Pet. Exh. 1, ¶11. Boehringer made no further requests for extension of time for its compliance, and none was granted by the Commission. Nonetheless, Boehringer is still not in full compliance. It has not executed its certification of compliance, as required by Instruction 13 (*see*

Pet. Exh. 3, at 12), and it has indicated in an investigational hearing that took place on October 1, 2009, that even its document collection efforts have not been completed. Pet. Exh. 1, ¶19. Indeed, Boehringer's counsel has refused to give the Commission even a general time frame for Boehringer's full compliance, suggesting that the process could go on indefinitely. Pet. Exh. 1, ¶20.

III. THE COURT SHOULD ORDER BOEHRINGER TO COMPLY WITH THE COMMISSION'S SUBPOENA IMMEDIATELY, FULLY, AND WITHOUT UNAUTHORIZED REDACTIONS

Boehringer's failure to comply, moreover, should be viewed in the context of its ongoing pattern of delay and obstruction, which necessitates an enforcement order that mandates Boehringer's response to the Commission's subpoena be immediate and in strict compliance with its instructions. Boehringer's delay tactics stretch back to its initial production of documents with substantial but unwarranted redactions. *See* Pet. Exh. 1, ¶¶13-15. Not only were those redactions contrary to the subpoena instructions, but, on many occasions, they made it impossible to discern the meaning and context of the redacted documents (*e.g.*, board of directors presentations where all but a few lines of multiple-page documents were redacted). As noted above, Instruction 2 of the subpoena explicitly directs that, except for privileged material, " Boehringer will not redact, mask, cut, expunge, edit, or delete any responsive document or portion thereof in any manner." Pet. Exh. 3, at 8. Boehringer did not petition the Commission to modify Instruction 2. Pet. Exh. 1, ¶10; *see* 16 C.F.R. § 2.7(d). Nor did Boehringer claim that the redacted information is protected by any cognizable privilege. Pet. Exh. 1, ¶13. Boehringer's only basis for the redaction, instead,[8] is its

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[8] Boehringer's redactions were made despite the extensive statutory and regulatory safeguards of confidentiality accorded to records produced in response to Commission compulsory process. *See, e.g.*, 15 U.S.C. §§ 46, 46(f), 50, 57b-1(d), 57b-2; 16 C.F.R. §§ 2.16, 4.10(a)(2), 4.10(a)(8), 4.10(a)(9), 4.10(c), 4.10(d), 4.10(e). Boehringer's failure to comply fully with the Commission's subpoena cannot, therefore, be excused as merely the product of justifiable caution.

unilateral determination that the redacted information is not related to the Commission's investigation. But this is not the correct standard. The Commission's subpoena – which Boehringer neither challenged nor sought to modify – explicitly prohibits relevance-based redactions from responsive documents. Pet. Exh. 3, at 8. While Commission staff were originally willing to make some accommodation to Boehringer on this issue, Boehringer's repeated representations about the nature of those redactions – that the redacted information was unrelated to the Commission investigation – proved untrue. When faced with the prospect of a court enforcement action, Boehringer re-produced those documents with substantially fewer redactions, revealing that many of the redactions were not only within the scope of the subpoena, but in fact highly relevant to the investigation. A number of documents mention Aggrenox and Mirapex by name, and in one example, the redacted material relates directly to the effects of the agreements which are the focus of the Commission's investigation. Pet. Exh. 1, ¶15.

These redactions appear to be part of a deliberate pattern of delay and obstruction. Boehringer's non-compliance takes on added significance in the context of the Commission's investigation. At the heart of the Commission's antitrust concerns is a possible quid pro quo: Barr delays the marketing of its generic substitutes to Aggrenox and Mirapex, and thus Boehringer continues to reap monopoly profits from the sale of those products, and Boehringer pays Barr off with a share of those monopoly profits. If those agreements are illegal, every day they remain in effect and Barr's competitive products remain off the market provides Boehringer with an extra day of monopoly profits. Thus, every day of delay in the Commission's investigation of those agreements represents more money for Boehringer. At the rate of annual sales of nearly $850 million for the two Boehringer products at issue here, the delay in Boehringer's compliance with

the subpoena, and thus in the Commission's conclusion of its investigation, could be worth millions of dollars each month to Boehringer.

Boehringer's apparent delay tactics are also evidenced by its failure to search adequately for responsive information. Instruction 3 of the subpoena makes clear that compliance requires "a search of all documents * * * held by any of Boehringer's officers, directors, employees, agents, representatives, or legal counsel, whether or not such documents are on the premises of Boehringer," and that "the search will include all of Boehringer's Electronically Stored Information." Pet. Exh. 3, at 9. Boehringer's search efforts fall far short of satisfying those instructions. For example, Boehringer identified eight key employees who were involved in the negotiation or analysis of Boehringer's agreements with Barr, but produced documents from only three of them. Its counsel indicated that for another three of those employees, no responsive documents existed that were not privileged (although Boehringer has never certified this to be true). The files of the remaining two key personnel were never even searched. Accordingly, relatively few documents were produced from the files of the persons whom Boehringer itself identified as the key knowledgeable personnel. Moreover, other employees whom Boehringer's organizational charts identify as likely having relevant information initially did not have their files searched at all. Finally, there is no indication that Boehringer has done any reasonable search for its relevant electronically stored information. Pet. Exh. 1, ¶19.

These shortcomings in Boehringer's compliance were made clear in the October 1, 2009, investigational hearing, which focused on its compliance efforts. Boehringer made no systematic effort to determine which employees' files should be searched. Moreover, Boehringer's search of electronically stored information was left to the initiative of Boehringer's individual employees, even though Boehringer had the capacity to conduct a more thorough and reliable – and, indeed, a

more efficient – search of its centrally maintained network servers and archives. Pet. Exh. 1, ¶19. Boehringer's unsystematic search methods not only contravene the subpoena's instructions – which require the search of *all* available sources of electroniclly stored information – but are clearly designed to produce an inadequate response to the Commission's subpoena. *See, e.g., Peskoff v. Faber*, 240 F.R.D. 26, , 31 (D.D.C. 2007) (Facciola, Mag. J.) (compliance with request for discovery of electronically stored information requires that the producing party "conduct a search of all depositories of electronic information in which one may reasonably expect to find" the requested information). Boehringer should not be allowed to use such tactics to stonewall the Commission's investigation of its conduct.

CONCLUSION

For the foregoing reasons, this Court should order Boehringer to comply fully with the Commission subpoena within ten (10) days of the Court's Order, and, going forward, to produce all responsive materials without any redactions.

Respectfully submitted,

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