IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

FEDERAL TRADE COMMISSION, 600 Pennsylvania Ave., N.W., Washington, DC 20580, Petitioner, v. BOEHRINGER INGELHEIM PHARMACEUTICALS, INC., c/o Michael Sennet, Esq. Jones Day 77 West Wacker, Chicago, IL 60601-1692 Respondent.	)	Misc. No. _____

PETITION OF THE FEDERAL TRADE COMMISSION FOR AN ORDER ENFORCING SUBPOENA *DUCES TECUM* ISSUED IN FURTHERANCE OF A LAW ENFORCEMENT INVESTIGATION

Preamble and Request for Emergency Treatment

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 the course of a non-public investigation seeking to determine whether 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 patented pharmaceutical drugs, Aggrenox and Mirapex, or their generic equivalents.

Petition Allegations

To support this petition, the Commission alleges the following:

1. 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.

2. Section 3 of the FTC Act, 15 U.S.C. § 43, empowers the Commission to prosecute any inquiry necessary to its duties in any part of the United States. Section 6 of the Act, 15 U.S.C. § 46, 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, with certain exceptions not relevant here. Section 9 of the FTC Act, 15 U.S.C. § 49, authorizes the Commission to issue subpoenas to compel the testimony of witnesses and the production of all such documentary evidence relating to any matter under investigation.

3. This Court has jurisdiction to enforce the Commission's duly issued subpoenas, including the subpoena issue to Respondent, under Section 9 of the FTC Act, 15 U.S.C. § 49, which provides, in pertinent part:

> Any of the district courts of the United States within the jurisdiction of which such inquiry is carried on may, in case of contumacy or refusal to obey a subpoena issued to any person, partnership, or corporation, issue an order requiring such person, partnership, or corporation to appear before the Commission, or to produce documentary evidence if so ordered, or to give evidence touching the matter in question; and any failure to obey such order of the court may be punished by such court as a contempt thereof.

The Commission's investigation of Boehringer, Barr, and their affiliates is being carried on in this district. Pet. Exh. 1, ¶8.

4. The Declaration under penalty of perjury of Rebecca Egeland, which verifies the allegations of this Petition, is attached hereto as Petition Exhibit ("Pet. Exh.") 1.

5. On January 15, 2009, the Commission 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 all compulsory process available to the Commission to be used 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.

6. Boehringer is a privately held subsidiary of Boehringer Ingleheim GmbH of Ingelheim, Germany. Boehringer is in the business of developing, manufacturing and marketing pharmaceutical products in the United States, and is incorporated in the State of Delaware with its principal place of business at 900 Ridgebury Road, Ridgefield, Connecticut. 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. Pet. Exh. 1, ¶3.

7. Boehringer markets, inter alia, two branded pharmaceutical drugs: Aggrenox and Mirapex. Aggrenox is used to reduce the risk of stroke in patients who have had a "mini stroke" or completed stroke due to blood clots. Mirapex is used to treat Parkinson's disease and Restless Legs Syndrome. Aggrenox had U.S. sales of about $366 million in 2008, while Mirapex had sales of about $477 million in 2008. Boehringer claims that its two products are protected from infringement by valid U.S. patents, and has listed them, in accordance with the Food and Drug Administration

("FDA") regulations, in the FDA's "Orange Book" as covering its products Aggrenox and Mirapex. Pet. Exh. 1, ¶4.

8. Barr is a manufacturer of generic pharmaceuticals. It is now a part of Teva Pharmaceuticals, the world's largest generic drug company, following its acquisition by Teva in December 2008. Barr developed generic versions of both Aggrenox and Mirapex and was the first generic firm to file with the FDA Abbreviated New Drug Applications ("ANDAs") containing challenges to Boehringer patents covering the two drugs. In response, Boehringer filed separate patent infringement lawsuits against Barr in the United States District Court for the District of Delaware, first as to Mirapex (on September 26, 2005) and then as to Aggrenox (on July 11, 2007). The Mirapex patent litigation proceeded to trial and on June 26, 2008, the court held that Boehringer's patent was invalid under the doctrine of nonstatutory double patenting: The court found that an already-expired Boehringer patent covered largely the same material as the Boehringer patent at issue in the litigation with Barr. Pet. Exh. 1, ¶5.

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

10. On August 11, 2008, Boehringer and Barr entered into a series of settlement and related agreements covering both Aggrenox and Mirapex. Under the terms of 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. At the same time, Boehringer partnered with Barr to co-promote Aggrenox to women's health care professionals. Under that arrangement, Boehringer agreed to provide Barr with substantial compensation, including royalties based on net sales of Aggrenox. Pet. Exh. 1, ¶7. Boehringer's agreements with Barr might raise serious antitrust concerns. In particular, the Commission seeks to determine whether Boehringer and Barr and their

affiliates have engaged in unfair methods of competition with respect to the sale of Aggrenox or its generic equivalents and Mirapex or its generic equivalents. Pet. Exh. 1, ¶8.

11. As part of this investigation, on February 5, 2009, the Commission issued a subpoena *duces tecum* to Boehringer requiring it to produce certain documents relating to the subject matter of the investigation. Pet. Exh. 3. The subpoena contains 37 specifications. In particular, it seeks, *inter alia*, 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. By agreement, the subpoena was served on Boehringer's counsel, Jones Day. Boehringer did not challenge service. Pet. Exh. 1, ¶9.

12. Boehringer did not avail itself of the procedure set forth in Rule 2.7(d) of the Commission's Rules of Practice, 16 C.F.R. § 2.7(d), to petition the Commission to either quash or limit the subpoena. Pet. Exh. 1, ¶10.

13. On four occasions, pursuant to 16 C.F.R. § 2.7(c), Markus Meier, an Assistant Director in the Commission's Bureau of Competition, extended the deadline for Boehringer's response to the subpoena, finally to June 19, 2009. After June 19, 2009, no extensions to Boehringer's subpoena response date were requested or granted. Pet. Exh. 1, ¶11.

14. Boehringer has produced some responsive documents. But, despite the numerous extensions of time, it has failed to certify that it has complied in full with the subpoena. Pet. Exh. 1, ¶12.

15. Boehringer has employed several tactics that appear to be designed to promote delay, and to make it likely that Boehringer has failed, and will continue to fail, to supply the Commission with all responsive documents. First, Boehringer directly contravened Instruction 2 of the subpoena, which directs that "[e]xcept for privileged material, Boehringer will not redact * * * any responsive document." (Pet. Exh. 1, at 8). Boehringer's initial production of documents included numerous documents from which Boehringer had made substantial redactions. Boehringer did not base these redactions on any sort of claim of privilege. Not only were these redactions contrary to the subpoena's instructions, but they also made the documents impossible to understand. On at least five occasions, the Commission informed Boehringer that these redactions were inappropriate. And on at least five occasions, Boehringer's counsel represented to the Commission that the material that had been redacted from the responsive documents was beyond the scope of the Commission's investigation. These representations proved to be untrue. Pet. Exh. 1, ¶¶12-13.

16. Although those justifications were repeatedly rejected by the Commission, 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. Commission staff initially reached agreement with Boehringer's counsel that Boehringer would address the then-existing redactions in its production and would seek authorization before making any additional redactions on the basis of relevance. Boehringer continued to redact documents for reasons other than privilege, however, without first obtaining the Commission's authorization. On June 26, 2009, the Commission informed Boehringer that it would

initiate an enforcement action unless Boehringer provided the Commission with the documents in unredacted form. Faced with an imminent filing in federal court, Boehringer changed course and, beginning on July 29, 2009, re-produced those documents with substantially fewer redactions. Despite the assurances of Boehringer's counsel that the material it originally redacted concerned neither the Commission's investigation nor Aggrenox or Mirapex, in fact, this subsequent production revealed that some of the redactions did involve Aggrenox or Mirapex, and were highly relevant to the Commission's investigation, including material directly relating to the effects of the agreements which are the focus of the Commission's investigation. On August 26, 2009 (and again on September 15, 2009), the Commission requested that Boehringer's counsel submit a written certification stating that all remaining redacted material is either covered by a claim of legal privilege or relates solely to drugs other than Aggrenox or Mirapex. Boehringer has not done so. Pet. Exh. 1, ¶¶14-15.

17. The Commission is also concerned that Boehringer has failed to conduct its search for documents in compliance with Instruction 3 of the subpoena. That instruction explains that compliance with the 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." (Pet. Exh. 3, at 9). In response to compulsory process that the Commission issued to Boehringer on May 20, 2009, Boehringer identified eight employees who were involved in the negotiation or analysis of Boehringer's agreements with Barr. Boehringer produced documents responsive to the February 5 subpoena from only three of these eight employees, however, claiming that three other employees did not have any non-privileged responsive documents, while failing to search the records of the other two. Other employees with

seemingly relevant job responsibilities (but who had not been specifically identified by Boehringer as involved in the negotiations with Barr) initially did not have their files searched at all. Pet. Exh. 1, ¶16.

18. On August 28, 2009, the Commission issued a subpoena for an investigational hearing regarding Boehringer's compliance with the Commission's February 5 subpoena. The investigational hearing took place on October 1, 2009, and revealed that Boehringer had conducted its investigation of relevant documents in an unsystematic manner, and that Boehringer did not conduct the sort of complete and thorough search for documents that was required by the subpoena. For example, Boehringer apparently failed to conduct an independent search of the electronic documents it maintained on company databases, networks, and central archives, relying instead on the initiative of its individual employees. This has resulted in an incomplete document production. In particular, in connection with this investigation, the Commission has also served a subpoena on Barr. In response to that subpoena, the Commission has received from Barr copies of communications that were transmitted between Barr and Boehringer. These communications should have been in Boehringer's files, and they would have been responsive to the subpoena that Boehringer received. But Boehringer did not produce them to the Commission. The hearing also revealed that Boehringer has not yet completed its search and collection efforts in response to the subpoena, even though Boehringer's counsel represented to the Commission back in May 2009 that its production was nearly complete. Pet. Exh. 1, ¶¶16-19.

19. Boehringer's full response to the subpoena was due on June 19, 2009. Boehringer has not complied in full with the subpoena, and it has failed to provide the Commission with the certification indicating that its response is complete. 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. Pet. Exh. 1, ¶20.

20. Boehringer's failure to comply fully with the subpoena burdens the Commission's investigation, forces the Commission to expend additional public resources, and makes it impossible for the Commission to assess the legality of the subject agreements. It also prevents the Commission from completing its investigation in a timely manner, or from determining whether it wishes to challenge the conduct identified in the Commission resolution authorizing the investigation. Pet. Exh. 1, ¶21.

21. The subpoena directed to Boehringer is within the Commission's statutory authority, the information sought is reasonably related to the Commission's investigation, and the demand is not unreasonably burdensome. Further delays in the Commission's investigation caused by Boehringer's failure to comply are contrary to the public interest. Therefore, the subpoena should be enforced in full.

22. No previous application for the relief sought herein has been made to this Court or any other.

Prayer for Relief

WHEREFORE, the Commission invokes the aid of this Court and prays:

a. For the immediate issuance of an Order directing Boehringer to show cause why it should not comply in full with the subpoena;

b. For a prompt determination of this matter and an Order requiring Boehringer to fully comply with the subpoena;

c. For such other relief as the Court deems just and proper.

Respectfully submitted,

WILLARD K. TOM
General Counsel (D.C. Bar No. 297564)

DAVID C. SHONKA
Principal Deputy General Counsel
(D.C. Bar No. 224576)

JOHN F. DALY
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Dated: October 22, 2009

EXHIBIT 1

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

FEDERAL TRADE COMMISSION, Petitioner, v. BOEHRINGER INGELHEIM PHARMACEUTICALS, INC., Respondent.	)	Misc. No. _____

DECLARATION OF REBECCA EGELAND

Pursuant to 28 U.S.C. § 1746, I declare as follows:

1. I am an attorney employed by the U.S. Federal Trade Commission ("FTC" or "Commission"), in Washington, D.C. I am assigned to the FTC's investigation of patent litigation settlement and related agreements regarding the pharmaceutical products Aggrenox and Mirapex. These settlements were entered into between (1) the patent plaintiff, Boehringer Ingelheim Pharmaceuticals, Inc. ("Boehringer"); and (2) the patent defendant, Barr Laboratories, Inc. ("Barr").

2. I am authorized to execute a declaration verifying the facts that are set forth in the Petition of the Federal Trade Commission for an Order Enforcing Subpoena *Duces Tecum* Issued in Furtherance of a Law Enforcement Investigation. I have read the petition and exhibits thereto (those exhibits are hereinafter referred to as "Pet. Exh."), and verify that Pet. Exh. 2 and Pet. Exh. 3 (this declaration is Pet. Exh. 1) are true and correct copies of the original documents.

3. Boehringer is 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 and is incorporated in the State of Delaware, with its

principal place of business at 900 Ridgebury Road, Ridgefield, Connecticut. Boehringer is represented in this investigation by the law firm of Jones Day, which has offices at 77 West Wacker, Chicago, IL 60601.

4. Boehringer markets, among other drugs, two branded pharmaceutical products, Aggrenox and Mirapex. Aggrenox is used to reduce the risk of stroke in patients who have had a "mini stroke" or a completed stroke due to blood clots. Mirapex is used to treat Parkinson's disease and Restless Legs Syndrome. Aggrenox had U.S. sales of about $366 million in 2008, while Mirapex had sales of about $477 million in 2008. Boehringer has listed several patents in which it claims interest in the Food and Drug Administration ("FDA") "Orange Book" as covering its products Aggrenox and Mirapex.

5. Barr is a manufacturer of generic pharmaceuticals. It is now a part of Teva Pharmaceuticals, the world's largest generic drug company, following its acquisition by Teva in December 2008. Barr developed generic versions of both Aggrenox and Mirapex and was the first generic firm to file with the FDA Abbreviated New Drug Applications ("ANDAs") containing challenges to Boehringer patents covering the two drugs. In response, Boehringer filed separate patent infringement lawsuits against Barr in the United States District Court for the District of Delaware, first as to Mirapex (on September 26, 2005) and then as to Aggrenox (on July 11, 2007). The Mirapex patent litigation proceeded to trial and on June 26, 2008, the court held that Boehringer's patent was invalid under the doctrine of nonstatutory double patenting: The court found that an already-expired Boehringer patent covered largely the same material as the Boehringer patent at issue in the litigation with Barr. *Boehringer Ingelheim Int'l GmbH v. Barr Labs., Inc.*, 562 F. Supp. 2d 619 (D. Del. 2008).

6. At the time of the Mirapex patent invalidity ruling, the Aggrenox patent litigation was in its early stages.

7. On August 11, 2008, Boehringer and Barr entered into a series of settlement and related agreements covering both Aggrenox and Mirapex. Under the terms of 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. At the same time, Boehringer partnered with Barr to co-promote Aggrenox to women's health care professionals. Under that arrangement, Boehringer agreed to provide Barr with substantial compensation, including royalties based on net sales of Aggrenox. As required by statute, Boehringer and Barr filed these agreements with the FTC and the U.S. Department of Justice for their review.

8. 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). The Commission seeks to determine whether Boehringer and Barr and their affiliates have engaged in unfair methods of competition with respect to the sale of Aggrenox or its generic equivalents and Mirapex or its generic equivalents. This investigation is being conducted from Washington, D.C.

9. As part of this investigation, on February 5, 2009, the Commission issued a subpoena *duces tecum* to Boehringer requiring it to produce certain documents and data relating to the subject matter of the investigation (Pet. Exh. 3). The subpoena contains 37 specifications. In particular, it seeks, *inter alia*, 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). By agreement, Boehringer's counsel, Jones Day, accepted service of the subpoena. Full compliance with the subpoena was required within 30 days.

10. Boehringer did not avail itself of the procedure set forth in Rule 2.7(d) of the Commission's Rules of Practice, 16 C.F.R. § 2.7(d), to petition the Commission to either quash or limit the subpoena.

11. On four occasions, pursuant to 16 C.F.R. § 2.7(c), Markus Meier, an Assistant Director in the Commission's Bureau of Competition, extended the deadline for Boehringer's response to the subpoena: to April 15, 2009; to May 13, 2009; to May 20, 2009; and finally to June 19, 2009. After June 19, 2009, no extensions to Boehringer's subpoena response date were requested or granted.

12. Boehringer has produced some responsive documents. But, despite the numerous extensions of time, it has failed to certify that it has complied in full with the subpoena. Moreover, in connection with its response, Boehringer has employed several tactics that appear to be designed to promote delay, and to make it likely that Boehringer has failed, and will continue to fail, to supply the Commission with all responsive documents.

13. Boehringer directly contravened Instruction 2 of the subpoena, which directs that "[e]xcept for privileged material, Boehringer will not redact * * * any responsive document." (Pet. Exh. 1, at 8). Boehringer's initial production of documents included numerous documents from which Boehringer had made substantial redactions. Boehringer did not base these redactions on any

sort of claim of privilege. Not only were these redactions contrary to the subpoena's instructions, but also they made the documents impossible to understand. On at least five occasions, the Commission informed Boehringer that these redactions were inappropriate. And on at least five occasions, Boehringer's counsel represented to the Commission that the material that had been redacted from the responsive documents was unrelated to the Commission's investigation. Boehringer claimed first that the redactions were of information unrelated to either Aggrenox or Mirapex. It also claimed that the redacted information was not necessary to understand or provide context for the unredacted portions. Finally, Boehringer claimed 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. These representations proved to be untrue.

14. Although those justifications were repeatedly rejected by the Commission, 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. Commission staff initially reached agreement with Boehringer's counsel that Boehringer would address the then-existing redactions in its production and would seek authorization before making any additional redactions on the basis of relevance. Boehringer continued to redact documents for reasons other than privilege, however, without first obtaining the Commission's authorization. On June 26, 2009, the Commission informed Boehringer that it would initiate an enforcement action unless Boehringer provided the Commission with the documents in unredacted form.

15. Faced with an imminent filing in federal court, Boehringer changed course and, beginning on July 29, 2009, re-produced those documents with substantially fewer redactions. Despite the assurances of Boehringer's counsel that the material it originally redacted concerned

neither the Commission's investigation nor Aggrenox or Mirapex, in fact, this subsequent production revealed that some of the redactions did involve Aggrenox or Mirapex, and were highly relevant to the Commission's investigation, including material directly relating to the effects of the agreements which are the focus of the Commission's investigation. On August 26, 2009 (and again on September 15, 2009), the Commission requested that Boehringer's counsel submit a written certification stating that all remaining redacted material is either covered by a claim of legal privilege or relates solely to drugs other than Aggrenox or Mirapex. Boehringer has not done so.

16. The Commission is also concerned that Boehringer has failed to conduct its search for documents in compliance with Instruction 3 of the subpoena. That instruction explains that compliance with the 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." (Pet. Exh. 3, at 9). In response to compulsory process that the Commission issued to Boehringer on May 20, 2009, Boehringer identified eight employees who were involved in the negotiation or analysis of Boehringer's agreements with Barr. Boehringer produced documents responsive to the February 5 subpoena from only three of these eight employees, however, claiming that three other employees did not have any non-privileged responsive documents, while failing to search the records of the other two. Other employees with seemingly relevant job responsibilities (but who had not been specifically identified by Boehringer as involved in the negotiations with Barr) initially did not have their files searched at all.

17. After reviewing Boehringer's production, I raised these and other concerns with Boehringer's counsel. Although Boehringer's counsel responded as to some of those concerns, it failed to provide adequate response as to others. For example, Boehringer provided information

regarding the files of three relevant employees only after the Commission threatened court enforcement. We did not receive information regarding the files of other employees who had seemingly relevant job titles. Boehringer produced adequate organizational charts in response to subpoena Specification 6 (*i.e.* sufficient to identify the employees who had submitted responsive documents) but only after being threatened with additional compulsory process.

18. Because the Commission was concerned that Boehringer had not conducted its document search in accordance with subpoena Instruction 3, on August 28, 2009, the Commission issued a subpoena for an investigational hearing regarding Boehringer's compliance with the Commission's February 5 subpoena.

19. The investigational hearing that the Commission noticed on August 28 took place on October 1, 2009. That hearing revealed that Boehringer had conducted its investigation of relevant documents in an unsystematic manner, and that Boehringer did not conduct the sort of complete and thorough search for documents that was required by the subpoena. For example, Boehringer apparently failed to conduct an independent search of the electronic documents it maintained on company databases, networks, and central archives, relying instead on the initiative of its individual employees. This has resulted in an incomplete document production. In particular, in connection with this investigation, the Commission has also served a subpoena on Barr. In response to that subpoena, the Commission has received from Barr copies of communications that were transmitted between Barr and Boehringer. These communications should have been in Boehringer's files, and they would have been responsive to the subpoena that Boehringer received. But Boehringer did not produce them to the Commission. The hearing also revealed that Boehringer has not yet completed its search and collection efforts in response to the subpoena, even though Boehringer's counsel represented to the Commission back in May 2009 that its production was nearly complete.

20. Boehringer's full response to the subpoena was due on June 19, 2009. Boehringer has not complied in full with the subpoena, and it has failed to provide the Commission with the certification indicating that its response is complete. 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.

21. Boehringer's failure to comply fully with the subpoena burdens the Commission's investigation, forces the Commission to expend additional public resources, and makes it impossible for the Commission to assess the legality of the subject agreements. It also prevents the Commission from completing its investigation in a timely manner, or from determining whether it wishes to challenge the conduct identified in the Commission resolution authorizing the investigation.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on October 22, 2009.

Rebecca Egeland

EXHIBIT 2

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: William E. Kovacic, Chairman
Pamela Jones Harbour
Jon Leibowitz
J. Thomas Rosch

RESOLUTION AUTHORIZING USE OF COMPULSORY PROCESS IN NONPUBLIC INVESTIGATION

File No. 091-0023

Nature and Scope of 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.

The Federal Trade Commission hereby resolves and directs that any and all compulsory processes available to it be used in connection with this investigation.

Authority to Conduct Investigation:

Sections 6, 9, 10, and 20 of the Federal Trade Commission Act, 15 U.S.C. §§ 46, 49, 50, and 57b-1, as amended; FTC Procedures and Rules of Practice, 16 C.F.R. § 1.1 *et seq.*, and supplements thereto.

By direction of the Commission.

Donald S. Clark
Secretary

Issued: January 15, 2009

EXHIBIT 3

SUBPOENA DUCES TECUM

1. TO	2. FROM
Boehringer Ingelheim Pharmaceuticals, Inc. c/o Michael Sennett Jones Day 77 West Wacker Chicago, IL 60601-1692	UNITED STATES OF AMERICA FEDERAL TRADE COMMISSION

This subpoena requires you to appear and testify at the request of the Federal Trade Commission at a hearing [or deposition] in the proceeding described in Item 6.

3. LOCATION OF HEARING	4. YOUR APPEARANCE WILL BE BEFORE
	No appearance required
	5. DATE AND TIME OF HEARING OR DEPOSITION
	Return date is 30 days from date of subpoena

6. SUBJECT OF INVESTIGATION

See attached resolution, FTC File No. 091-0023

7. RECORDS YOU MUST BRING WITH YOU

See attached Specifications, Definitions, and Instructions

8. RECORDS CUSTODIAN/DEPUTY RECORDS CUSTODIAN	9. COMMISSION COUNSEL
Bradley S. Albert, Records Custodian Mark J. Woodward, Deputy Records Custodian	Mark J. Woodward, Jonathan R. Lutinski

DATE ISSUED	COMMISSIONER'S SIGNATURE
2/5/09	

GENERAL INSTRUCTIONS

The delivery of this subpoena to you by any method prescribed by the Commission's Rules of Practice is legal service and may subject you to a penalty imposed by law for failure to comply.

PETITION TO LIMIT OR QUASH

The Commission's Rules of Practice require that any petition to limit or quash this subpoena be filed within 20 days after service or, if the return date is less than 20 days after service, prior to the return date. The original and ten copies of the petition must be filed with the Secretary of the Federal Trade Commission. Send one copy to the Commission Counsel named in Item 9.

TRAVEL EXPENSES

Use the enclosed travel voucher to claim compensation to which you are entitled as a witness for the Commission. The completed travel voucher and this subpoena should be presented to Commission Counsel for payment. If you are permanently or temporarily living somewhere other than the address on this subpoena and it would require excessive travel for you to appear, you must get prior approval from Commission Counsel.

This subpoena does not require approval by OMB under the Paperwork Reduction Act of 1980.

RETURN OF SERVICE

I hereby certify that a duplicate original of the within subpoena was duly served: (check the method used)

○ *in person.*

○ *by registered mail.*

○ *by leaving copy at principal office or place of business, to wit:*

---

on the person named herein on:

(Month, day, and year)

(Name of person making service)

(Official title)

SUBPOENA DUCES TECUM TO BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.

SPECIFICATIONS

SPECIFICATION 1: From the '086/'812 Patent Litigation, submit all (1) trial exhibits and any other material admitted into evidence at trial; (2) trial transcripts; (3) post-trial briefs filed by Boehringer or Mylan; and (4) orders, memoranda, or other written communication from the court to the parties after December 1, 2007.

SPECIFICATION 2: Submit all materials filed by any party with the United States Court of Appeals for the Federal Circuit in *Boehringer Ingelheim v. Barr Labs*, Fed. Cir. Docket No. 2009-1032, or any related case before the Federal Circuit.

SPECIFICATION 3: From the '577 Patent Litigation, submit all (1) complaints and answers to counterclaims; (2) interrogatories, requests for admission, interrogatory responses, and responses to requests for admission; (3) court hearing or conference transcripts, including both hearings and conferences conducted in person and by telephone; (4) deposition transcripts (with exhibits); (5) expert reports (with exhibits) prepared by experts retained by Boehringer; and (6) claim construction filings.

SPECIFICATION 4: Submit patent prosecution histories for all Licensed Intellectual Property, as that term is used in the Aggrenox Supply and License Agreement and the Mirapex License Agreement.

SPECIFICATION 5: Submit all paragraph IV certifications, and accompanying statements, received by Boehringer with respect to patents listed in the FDA's Orange Book for Aggrenox or Mirapex.

SPECIFICATION 6: Submit one copy of Boehringer's organization chart and personnel directory for (1) top-level worldwide and U.S. management; (2) each of the company's facilities or divisions involved in any activity relating to Aggrenox or any Generic Aggrenox product; and (3) each of the company's facilities or divisions involved in any activity relating to Mirapex or any Generic Mirapex product.

SPECIFICATION 7: Submit all annual business or brand plans for Aggrenox, Mirapex, and Mirapex ER.

SPECIFICATION 8: Submit all profit & loss or contribution statements for (1) Aggrenox; and (2) Mirapex, or, if such statements are not prepared, for the smallest applicable unit or division responsible

for U.S. Aggrenox and/or Mirapex sales for which profit & loss or contribution statements are prepared.

SPECIFICATION 9: Submit, on a monthly basis since January 1, 2007 through the present, all forecasts for sales of Aggrenox or Aggrenox Authorized Generic Product.

SPECIFICATION 10: Submit, on a monthly basis since January 1, 2007 through the present, all forecasts for sales of Mirapex, Mirapex ER, or Mirapex Authorized Generic Product.

SPECIFICATION 11: Submit all documents presented to management committees, executive committees, and/or boards of directors relating to the marketing or sale of Aggrenox or Mirapex.

SPECIFICATION 12: Submit all documents relating to Generic Aggrenox.

SPECIFICATION 13: Submit all documents relating to Generic Mirapex.

SPECIFICATION 14: For each of Aggrenox and Mirapex, submit data sufficient to show each Wholesale Acquisition Cost ("WAC") at which the drug was listed and the corresponding range of dates for which it was listed at that value.

SPECIFICATION 15: Submit all documents prepared for any committee or individual responsible for (1) Aggrenox pricing, relating to each change in Aggrenox WAC; and (2) Mirapex pricing, relating to each change in Mirapex WAC.

SPECIFICATION 16: For the ten largest non-governmental Purchasers of (1) Aggrenox; and (2) Mirapex (each based on 2008 sales) who have active contracts in 2009, submit the current contract in place that provides for the terms of Aggrenox or Mirapex sales (including pricing, rebates, discounts, or other incentives).

SPECIFICATION 17: Submit data sufficient to show, on a monthly basis, in dollars and units and separately for each dosage form and strength, gross and net sales of (1) Aggrenox; and (2) Mirapex.

SPECIFICATION 18: For (1) Aggrenox, (2) any drug which has competed, competes and/or may compete with Aggrenox in the next year, (3) Mirapex, and (4) any drug which has competed, competes and/or may compete with Mirapex in the next year, submit on a monthly basis:

A. IMS National Sales Perspective (Retail and Non-Retail) data, or the equivalent thereof, by product form and by strength, and by doctor specialty, for total sales in dollars and units;

B. IMS National Prescription Audit data, or the equivalent thereof, by product form and strength, and by doctor specialty, for newly dispensed prescriptions, refill dispensed prescriptions, and total dispensed prescriptions.

SPECIFICATION 19: Submit all documents relating to the Aggrenox Agreements, including but not limited to documents related to the negotiations of such agreement(s); internal or external discussions, communications, analyses, evaluations and notes regarding such agreements; drafts of the agreements (whether or not incorporated in the executed agreement); and any communications between Boehringer and Barr regarding the agreements, settlement of the '577 Patent Litigation and actual or potential business arrangements among the parties related to Aggrenox or other products.

SPECIFICATION 20: Submit all documents relating to the Mirapex Agreements, including but not limited to documents related to the negotiations of such agreement(s); internal or external discussions, communications, analyses, evaluations and notes regarding such agreements; drafts of the agreements (whether or not incorporated in the executed agreement); and any communications among Boehringer, Barr and/or Mylan regarding the agreements, settlement of the '086/'812 Patent Litigation and actual or potential business arrangements among the parties related to Mirapex or other products.

SPECIFICATION 21: Submit all documents relating to the projected or anticipated profitability of the Aggrenox Co-Promotion Agreement, the Aggrenox Supply and License Agreement, or the Mirapex License Agreement.

SPECIFICATION 22: Submit one copy of each agreement under which Boehringer uses another company's sales force to promote or help promote a Boehringer product.

SPECIFICATION 23:	For each agreement responsive to Specification 22, submit all documents relating to the projected or anticipated impact of the agreement on the revenues, costs, and/or profitability of the product co-promoted.
SPECIFICATION 24:	Submit all communications with Barr relating to co-promotion of Aggrenox, including but not limited to minutes of any meetings between Boehringer and Barr.
SPECIFICATION 25:	Submit (1) documents sufficient to show the size, structure, and organization of Boehringer's branded sales force as of (a) July 1, 2008; and (b) the present; and (2) documents relating to changes to the size, structure, and organization of Boehringer's branded sales force between July 1, 2008 and the present.
SPECIFICATION 26:	Submit all (1) company-wide marketing plans relating to Boehringer's U.S. marketing or sales strategies for its branded sales force; and (2) documents prepared by outside consultants relating to Boehringer's U.S. marketing or sales strategies for its branded sales force.
SPECIFICATION 27:	Submit all documents relating to the promotion or sale, or possible promotion or sale, of Aggrenox to healthcare professionals working in the obstetric/gynecological or women's healthcare field.
SPECIFICATION 28:	Submit all (1) communications with any other company regarding a possible or actual partnership or agreement with respect to the promotion of Aggrenox; and (2) all documents relating to Boehringer's consideration of any other company as a possible or actual partner in the promotion of Aggrenox.
SPECIFICATION 29:	Submit one copy of each agreement under which Boehringer licenses another company to market a generic product under a Boehringer New Drug Application (NDA) (an "authorized generic" product).
SPECIFICATION 30 :	For each agreement responsive to Specification 29, submit all documents sufficient to show Boehringer's projected or anticipated revenues, costs, and/or profitability under the agreement.
SPECIFICATION 31:	Submit all documents relating to possible sale, marketing, licensing, or distribution of (1) an Authorized Generic Aggrenox Product; and (2) an Authorized Generic Mirapex Product.

SPECIFICATION 32: Submit all communications with Barr relating to Mirapex ER, including but not limited to communications relating to Article 5.3 of the Mirapex License Agreement.

SPECIFICATION 33: Submit all analyst reports from 2007 through the present covering Boehringer or Barr and relating to Aggrenox and/or Generic Aggrenox.

SPECIFICATION 34: Submit all analyst reports from 2005 through the present covering Boehringer, Barr, or Mylan and relating to Mirapex, Mirapex ER, and/or Generic Mirapex.

SPECIFICATION 35: Submit data or documents sufficient to show Boehringer's litigation costs on a monthly basis in (1) the '086/'812 Patent Litigation; and (2) the '577 Patent Litigation.

SPECIFICATION 36: Submit one copy of each agreement providing for the supply to Boehringer of active pharmaceutical ingredient or finished pharmaceutical product, as applicable, for Aggrenox, Mirapex, or Mirapex ER.

SPECIFICATION 37: Submit one copy of Boehringer's document retention policy.

DEFINITIONS

A. The term "'577 Patent Litigation" means *Boehringer Ingelheim Pharma GmbH et al. v. Barr Laboratories, Inc. et al.*, Civil Action No. 07-432 (GMS) (D. Del.), and any related actions.

B. The term "'086/'812 Patent Litigation" means (1) *Boehringer Ingelheim International GmbH et al. v. Barr Laboratories, Inc.*, Civil Action No. 05-700 (JJF) (D. Del.); and/or (2) *Boehringer Ingelheim International GmbH et al. v. Mylan Pharmaceuticals, Inc.*, Civil Action No. 05-854 (JJF) (D. Del.), and any related actions.

C. The term "Aggrenox" means the branded dipyridamole/aspirin product marketed in the United States under NDA No. 020-884.

D. The term "Mirapex" means the branded pramipexole dihydrochloride product marketed in the United States under NDA No. 020-667.

E. The term "Mirapex ER" means Boehringer's extended release version of Mirapex.

F. The term "Aggrenox Authorized Generic Product" means a dipyridamole/aspirin product to be sold, licensed, distributed, or marketed (directly or indirectly) under NDA No. 020-884 but not under the Aggrenox brand name.

G. The term "Mirapex Authorized Generic Product" means a dipyridamole/aspirin product to be sold, licensed, distributed, or marketed (directly or indirectly) under NDA No. 020-884 but not under the Mirapex brand name.

H. The term "Generic Aggrenox" means any product sold or projected to be sold pursuant to an ANDA which references NDA No. 020-884.

I. The term "Generic Mirapex" means any product sold or projected to be sold pursuant to an ANDA which references NDA No. 020-667.

J. The terms "Boehringer," "You," "Your," or "the Company" mean Boehringer Ingelheim Pharmaceuticals, Inc., Boehringer Ingelheim International GmbH, Dr. Karl Thomae GmbH, Boehringer Ingelheim Pharma GmbH & Co. KG, Roxane Laboratories, Inc., their successors, predecessors, divisions, wholly or partially owned subsidiaries, domestic or foreign parents, affiliates, partnerships, and joint ventures; and all the directors, officers, employees, consultants, agents, and representatives of the foregoing.

K. The term "Barr" means Barr Pharmaceuticals, Inc., Barr Laboratories, Inc., Duramed Pharmaceuticals, Inc., and, after December 22, 2008, Teva Pharmaceutical Industries Ltd., together with their successors, predecessors, divisions, wholly or partially owned subsidiaries, domestic or foreign parents, affiliates, partnerships, and joint ventures; and all the directors, officers, employees, consultants, agents, and representatives of the foregoing.

L. The term "Mylan" means Mylan Inc., Mylan Pharmaceuticals, Inc., their successors, predecessors, divisions, wholly or partially owned subsidiaries, domestic or foreign parents, affiliates, partnerships, and joint ventures; and all the directors, officers, employees, consultants, agents, and representatives of the foregoing.

M. The term "Aggrenox Agreements" means (1) the August 11, 2008 Settlement Agreement and Mutual Release between Boehringer and Barr concerning the '577 Patent Litigation ("Aggrenox Settlement Agreement"); (2) the August 11, 2008 Supply and License Agreement between Boehringer and Barr concerning a dipyridamole/aspirin product ("Aggrenox Supply and License Agreement"); (3) the August 11, 2008 Co-Promotion Agreement between Boehringer and Barr concerning Aggrenox ("Aggrenox Co-Promotion Agreement"), and all amendments to the foregoing.

N. The term "Mirapex Agreements" means (1) the August 11, 2008 Settlement Agreement and Mutual Release between Boehringer and Barr concerning the '086/'812 Patent Litigation ("Mirapex Settlement Agreement"); (2) the August 11, 2008 License

Agreement between Boehringer and Barr concerning a pramipexole dihydrochloride product ("Mirapex License Agreement"); and all amendments to the foregoing.

O. The term "Agreement" means any oral or written contract, arrangement, or understanding, whether formal or informal, between two or more persons, together with all modifications or amendments thereto.

P. The term "Communication" means any exchange, transfer, or dissemination of information, regardless of the means by which it is accomplished.

Q. The terms "Discuss" and "Discussing" mean in whole or in part constituting, containing, describing, or addressing the designated subject matter, regardless of the length of the treatment or detail of analysis of the subject matter, but not merely referring to the designated subject matter without elaboration. In addition, a document that "discusses" another document includes the other document itself (*e.g.*, a document that "discusses" an agreement or contract includes the agreement or contract itself). Further, these terms include any operating or financial data about the designated subject matter where such data are separately set out as in a chart, listing, table, or graph.

R. The term "Document" means all written, recorded, or graphic material of every kind, prepared by any person, that is in the possession, custody, or control of Boehringer. It includes all Electronically Stored Information. The term "document" includes the complete original document (or a copy thereof if the original is not available), all drafts, whether or not they resulted in a final document, and all copies that differ in any respect from the original, including any notation, underlining, marking, or information not on the original. Documents covered by this subpoena include, but are not limited to, the following: letters; memoranda; reports; contracts and other agreements; studies; plans; entries in notebooks, calendars and diaries; minutes, records, and transcripts of conferences, meetings, telephone calls or other communications; publications and unpublished speeches or articles; typed and handwritten notes; electronic mail; facsimiles (including the header showing the receipt date and time); tabulations; statements, ledgers, and other records of financial matters or commercial transactions; diagrams, graphs, charts, blueprints, and other drawings; technical plans and specifications; advertising, product labels, and packaging materials; photographs, photocopies, slides, microfilm, microfiche, and other copies or reproductions; film, audio and video tapes; tape, disk, and other electronic recordings; and computer printouts.

S. 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.

T. The terms "Each," "Any," and "All" mean "each and every." The terms "and" and "or" have both conjunctive and disjunctive meanings as necessary to bring within the scope of this Subpoena anything that might otherwise be outside its scope. The singular form of a noun or pronoun includes its plural form, and vice versa; and the present tense of any word includes the past tense, and vice versa.

U. The term "Person" includes Boehringer and means any natural person, corporate entity, sole proprietorship, partnership, association, governmental entity, or trust.

V. The term "Plan" means a proposal, recommendation, or consideration, whether or not precisely formulated, finalized, authorized, or adopted.

W. The term "Purchaser" means an entity with whom Boehringer has a contract in place that sets the price for Aggrenox or Mirapex sales, including but not limited to pharmacy benefit managers and health plans

X. The terms "Relate" and "Relating to" mean, in whole or in part, addressing, analyzing, concerning, constituting, containing, commenting on, discussing, describing, identifying, referring to, reflecting, reporting on, stating, or dealing with.

INSTRUCTIONS

1. Unless otherwise indicated, each specification in this subpoena covers documents and information dated, generated, received or in effect from January 1, 2003 to thirty days before the day when Boehringer provides the Commission with its final document submission, the executed certification form, and other compliance-related documents described in Instruction 13 ("Request Period"). Boehringer shall preserve documents responsive to the subpoena created or received after the Request Period until a Commission representative notifies Boehringer that the investigation has ended.

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 relate to the specified subject matter. Boehringer should submit any appendix, table, or other attachment by either physically attaching it to the responsive document or clearly marking it to indicate the responsive document to which it corresponds. Except for privileged material, Boehringer will not redact, mask, cut, expunge, edit, or delete any responsive document or portion thereof in any manner.

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. If any person is unwilling to have his or her files searched, or is unwilling to produce responsive documents, Boehringer must provide the Commission with the following information as to each such person: his or her name, address, telephone number, and relationship to Boehringer. In addition to hard-copy documents, the search will include all of Boehringer's Electronically Stored Information.

4. Electronically Stored Information. Documents, information or data stored in an electronic format in the ordinary course of business must be submitted in electronic format. Metadata associated with Electronically Stored Information must be produced. Boehringer may produce Electronically Stored Information in the following forms and formats, provided that such copies are true, correct and complete copies of the original documents:

   a. Microsoft Excel and Access files must be submitted in native format.

   b. TIFF files. Submit files as single-page, 300 DPI - Group IV TIFF files, with a corresponding file containing the extracted text from the document. Name each file, comprised of both images and text, for the Bates number of the document. Include a Concordance/Opticon load file preserves all document breaks (document delimitation). Include metadata and other information about the documents in delimited ASCII format. Produce Microsoft PowerPoint presentations in "Notes Pages" format. "Notes Pages" includes a small version of the slide that appears at the top of the page with any notes appearing directly below.

      i. Include the following metadata fields for electronic files other than email: creation date/time; modified date/time; last accessed date/time; size; location or path file name; and custodian.

      ii. Include the following metadata fields for emails: to; from; CC; BCC; subject; date and time sent; attachment (range or begin attach, end attach); file name of attachments; and custodian.

   c. Native format. Electronically stored documents, excluding e-mail other than Microsoft Outlook, may be produced natively. Please discuss logistics of native production with the Commission representative identified below.

      i. Data productions as ASCII text files. Boehringer may submit database files, with prior approval, as delimited ASCII text files, with field names as the first record, or as fixed-length flat files with appropriate record layout. For ASCII text files, provide field-level documentation and ensure that delimiters and quote characters

do not appear in the data. All database files should include or be accompanied with the definitions of the field names, codes, and abbreviations used in the database and, upon request from the FTC, the instructions for using the database. The FTC may require that a sample of the data be sent for testing. File and record structures must conform to the following requirements:

ii. File structures. The FTC will accept sequential files only. Convert all other file structures into sequential format.

iii. Record structures. The FTC will accept fixed-length records only. Include all data in the record as it would appear in printed format: viz, numbers unpacked, and decimal points and signs printed.

d. Submit electronic files and images in any combination of the following forms:

i. For any production over 10 gigabytes, use IDE and EIDE hard disk drives, formatted in Microsoft Windows-compatible, uncompressed data.

ii. For productions under 10 gigabytes, CD-R CD-ROMs formatted to ISO 9660 specifications, DVD-ROM for Windows-compatible personal computers, and USB 2.0 Flash Drives are also acceptable storage formats.

e. All documents produced in electronic format shall be scanned for and free of viruses. The FTC will return any infected media for replacement.

5. Boehringer may submit copies of original hard copy documents as either hard copies or electronic copies in lieu of original documents, provided that such copies are accompanied by an affidavit stating that the copies are true, correct and complete copies of the original documents. However, if the coloring of any document communicates any substantive information, or if black-and-white photocopying of any document (*e.g.*, a chart or graph) makes any substantive information contained in the document unintelligible, Boehringer must submit the original document or a like-colored photocopy.

a. Hard copies. Submit copies in sturdy cartons not larger than 1.5 cubic feet. Number and mark each box with corporate identification. Produce all documents as they are kept in the ordinary course of business (*e.g.*, produce documents that in their original condition were stapled, clipped, or otherwise fastened in the same form).

b. Electronic copies. Boehringer may submit original hard-copy documents as single-page TIFF images, named for the Bates number of the document, and accompanied by OCR and a Concordance/Opticon load file denoting the appropriate document breaks (document delimitation), OCR may be produced in

corresponding files, either by page or by document, or can be produced in ASCII format suitable for loading into Concordance.

6. Each submitted page, sheet or image will include an identification acronym for Boehringer and a consecutive control number.

7. Identification of document custodian must accompany each electronically produced document. Information sufficient to identify document custodian must also accompany documents produced in paper format.

8. If Boehringer withholds any responsive document or masks or redacts any portion of any responsive document based on a claim of privilege or work-product immunity, Boehringer must provide the Commission with a log describing the privilege claim and all facts supporting the claim sufficient to comply with Federal Trade Commission Rule of Practice § 2.8A. 16 C.F.R. § 2.8A. For each document withheld, masked, or redacted, the log shall list the following: (a) specific grounds for claim of privilege or immunity, (b) type of document, (c) title, (d) author(s), (e) date, (f) addressees and recipients of the original document or any copy thereof (including persons "cc'd" or "blind cc'd"), (g) a description of the subject matter, with sufficient detail to assess the claim of privilege, (h) a description identifying each attachment to the document, (i) the page length of the document, (j) the relevant specification(s), and (k) for redacted documents, the document control number (as described in Instruction 6). Additionally, for each document withheld under a claim of attorney work-product immunity, the log will list: (l) whether the document was prepared in anticipation of litigation or for trial, (m) the other parties or expected other parties to the litigation and whether that party is adverse, (n) case number, (o) complaint filing date, and (p) court name. For each person listed, the log will include the person's full name, address, job title, and employer or firm; for each non-company recipient, include such additional description sufficient to show that individual's need to know the information contained in the document. Please denote all attorneys with an asterisk ("*").

   An attachment to a document must be entitled to privilege in its own right. If an attachment is responsive and not entitled to privilege in its own right, it must be provided. Boehringer must provide all non-privileged portions of any responsive document for which a claim of privilege is asserted, noting where redactions in the document have been made. With respect to documents withheld on grounds of privilege that discuss or describe any U.S. or foreign patent, each individual patent identified in the withheld document must be specified by its patent number.

9. Documents written in a language other than English shall be translated into English, with the English translation attached to the foreign language document.

10. Do not destroy or dispose of documents responsive to this subpoena, or any other documents relating to the subject matter of this subpoena. The destruction or disposal of such documents during the pendency of this investigation might constitute a felony in violation of 18 U.S.C. § 1505 and/or 18 U.S.C. § 1512.

11. Boehringer will provide the Commission with the following: (a) a statement identifying the procedures used to search for electronically stored documents; and (b) a statement identifying the procedures used to search for documents stored in paper format, including for each document custodian identification of individuals who provided information on the location of responsive documents.

12. Boehringer must comply with this subpoena by submitting all documents and information responsive to it on or before the date identified in the subpoena. In addition, when it has completed production, Boehringer should also submit the executed and notarized certification form (attached). Boehringer should submit responsive documents to Jonathan Lutinski, Federal Trade Commission, Room NJ-7202, 601 New Jersey Ave., NW, Washington, DC 20580.

13. Compliance with this subpoena requires Boehringer to submit to the Commission all responsive documents, data, information and the following:

    (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;

    (c) List of any persons (by name, address, telephone number, and relationship to Boehringer) whose files have not been searched according to Instruction 3.

    (d) For each document submitted, information sufficient to identify the name of the person from whose files the document was obtained (document custodian), according to Instruction 7; and

    (e) Statement of the procedures used by Boehringer to comply with this subpoena, according to Instruction 11.

14. If Boehringer believes that this subpoena's specifications can be narrowed consistent with the Commission's need for information, we encourage it to discuss possible modifications with a Commission representative at the earliest possible date. Note that an authorized Commission representative, generally the Bureau's Assistant Directors, must agree in writing to any modifications to this subpoena. All inquiries about this subpoena and modification requests should be directed to Mark Woodward at (202) 326-2754 or Jonathan Lutinski at (202) 326-2679.

SUBPOENA DUCES TECUM TO BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.

CERTIFICATION

This response to the Subpoena issued by the Federal Trade Commission, together with any and all appendices and attachments thereto, was prepared and assembled under my supervision in accordance with instructions issued by the Federal Trade Commission.

All of the documents and information required by the Subpoena which are in the possession, custody, or control of Boehringer Ingelheim Pharmaceuticals, Inc. have been submitted to a designated Federal Trade Commission custodian. If a document responsive to this Subpoena has not been submitted, the objections to its submission and the reasons for the objection have been stated.

The information is, to the best of my knowledge, true, correct and complete. Where copies rather than original documents have been submitted, the copies are true, correct and complete. If the Commission uses such copies in any court or administrative proceeding, the Company will not object based on the Commission not offering the original document.

I declare under penalty of perjury that the foregoing is true and correct.

_____

TYPE OR PRINT NAME AND TITLE

_____

(Signature)

Subscribed and sworn to before me at the City of _____,

State of _____, this _____ day of _____, 2009.

_____

(Notary Public)

My Commission expires: _____