PUBLIC VERSION

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

In the Matter of Schering-Plough Corporation, a corporation, Upsher-Smith Laboratories, a corporation, and American Home Products Corporation, a corporation	)	Docket No. 9297

RESPONDENT SCHERING-PLOUGH CORPORATION'S MOTION FOR IN CAMERA TREATMENT OF CONFIDENTIAL DOCUMENTS RELATING TO PRODUCTS THAT ARE CURRENTLY IN DEVELOPMENT

Respondent Schering-Plough Corporation ("Schering") moves pursuant to Rule 3.45(b) of the Federal Trade Commission Rules of Practice, 16 C.F.R. § 3.45(b), for an order directing *in camera* treatment of confidential documents relating to products that are currently in development by Schering, its affiliated joint ventures, or its division Warrick, which have been identified as Schering exhibits SPX-23 to SPX-25, SPX-41, SPX-99, SPX-111, SPX-144, SPX-219, SPX-221, SPX-231, SPX-345, SPX-346, SPX-348, SPX-349, SPX-351, SPX-353 to SPX-361, SPX-363, SPX-371 to SPX-375, SPX-406, SPX-408, SPX-410 to SPX-418, SPX-420, SPX-422 to SPX-433, SPX-435 to SPX-438, SPX-440, SPX-441, SPX-617, and SPX-625 to SPX-627.

Each of these documents describes sensitive and confidential information regarding products that Schering is currently developing. The documents reveal details regarding Schering's ongoing clinical development, marketing, pricing, distribution, sale

and profitability of these "pipeline" products. Moreover, many of the documents are forward-looking, discussing Schering's strategies to enter new markets or to expand its existing market presence.

The documents contain secret information that is material to Schering's business, competitiveness and profitability. The information contained in these documents can be used by Schering's competitors to view or extrapolate a model of Schering's development, marketing, pricing and/or sales plans. Accordingly, release of this information will cause the loss of business advantage and serious and irreparable injury to Schering. Therefore, the Court should grant an order directing *in camera* treatment for these documents for a period of five years.

For the foregoing reasons and those set forth in the accompanying memorandum, Schering respectfully requests that the Court grant the motion for an order directing *in camera* treatment for documents relating to products that are currently in development.

Respectfully submitted,

Laura S. Shores/LO

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Schering-Plough Corporation

Dated: December 27, 2001

PUBLIC VERSION

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

In the Matter of	)	
Schering-Plough Corporation, a corporation,	)	
Upsher-Smith Laboratories, a corporation,	)	Docket No. 9297
and	)	
American Home Products Corporation, a corporation	)	

MEMORANDUM OF LAW IN SUPPORT OF SCHERING-PLOUGH CORPORATION'S MOTION FOR IN CAMERA TREATMENT OF CONFIDENTIAL DOCUMENTS RELATING TO PRODUCTS THAT ARE CURRENTLY IN DEVELOPMENT

Respondent Schering-Plough Corporation ("Schering") moves pursuant to Rule 3.45(b) of the Federal Trade Commission Rules of Practice, 16 C.F.R. § 3.45(b), for a protective order directing *in camera* treatment of confidential documents relating to products that are currently in development by Schering, affiliated joint ventures, or its division Warrick. These documents have been identified as Schering proposed trial exhibits SPX-23 to SPX-25, SPX-41, SPX-99, SPX-111, SPX-144, SPX-219, SPX-221, SPX-231, SPX-345, SPX-346, SPX-348, SPX-349, SPX-351, SPX-353 to SPX-361, SPX-363, SPX-371 to SPX-375, SPX-406, SPX-408, SPX-410 to SPX-418, SPX-420, SPX-422 to SPX-433, SPX-435 to SPX-438, SPX-440, SPX-441, SPX-617, and SPX-625 to SPX-627.

I. INTRODUCTION

As set forth more fully below, each of the subject documents describes sensitive and confidential information regarding products that Schering is currently developing ("pipeline products"). These pipeline products, which are being developed at great expense, represent what Schering considers to be clinically significant, effective and profitable products. As described in more detail below, and in the declaration of Jonathan Wasserman (attached as Exhibit A to this memorandum), the documents relate to sensitive information regarding ongoing clinical development, marketing, pricing, distribution, sale and profitability. (Wasserman Decl. ¶¶ 6-9). The continued confidentiality of this information is of critical importance and its release will cause serious and irreparable damage to Schering's ability to compete with other companies to research, develop and market innovative pharmaceutical products. (*Id.* at ¶ 10).

II. THE PIPELINE PRODUCT DOCUMENTS AT ISSUE

A. Ezetimibe

Schering seeks confidential *in camera* treatment for materials that reveal sensitive and confidential information regarding Ezetimibe, a product that Schering is currently developing as part of a joint venture with Merck & Co. Exhibits SPX-23 to SPX-25, SPX-41, SPX-111, SPX-144, SPX-219, SPX-221, SPX-231, SPX-345, SPX-346, SPX-348, SPX-349, SPX-351, SPX-353 to SPX-361, SPX-363, SPX-371 to SPX-375, SPX-617, and SPX-625 to SPX-627, which contain detailed information about Ezetimibe, disclose some of the most sensitive and confidential material maintained by Schering.

Exhibit SPX-345-346, SPX 348, SPX-351, SPX-353, SPX-355, SPX-357, SPX-358, SPX-360, SPX-361, SPX-371, SPX-372, and SPX-375 contain assessments of the

clinical and economic feasibility of using Ezetimibe in combination with other drugs or in co-administration therapy. The materials reveal Schering's clinical and economic methods of analyzing prospective partnerships and disclose confidential clinical research, trial and study plans. Exhibits SPX-345 and SPX-346, for example, discuss terms, rationales and financial projections for a proposed deal with Merck. Similarly, SPX-351 reveals details of Schering's combination therapy project for Ezetimibe, including timelines and cost estimates for development.

Several exhibits contain executive summaries of confidential advisory board meetings regarding Ezetimibe's development. (SPX-25, SPX 111, SPX-144, SPX-219, SPX-231). These documents reveal details of Schering's plans for Ezetimibe, including clinical development information, clinical test results, marketing plans, and regulatory strategies.

Various other exhibits contain confidential financial information. (SPX-24, SPX-354, SPX-356, SPX-359, SPX-363). For example, Exhibit SPX-354 reveals Ezetimibe monotherapy and combination therapy sales and marketing cost forecasts to 2008 as well as marketing strategies and the anticipated launch date for Ezetimibe.

B. Enalapril

Schering seeks confidential *in camera* treatment for materials that reveal sensitive and confidential information regarding the drug Enalapril, a product also currently under development. Exhibits SPX-408 to SPX-411, SPX-417, SPX-434, and SPX-439, similarly disclose virtually every detail of Schering's plans to develop and market Enalapril. For example, SPX-408 and SPX-410 are January 2001 clinical documents that reveal Schering's confidential methods for researching, testing and studying

pharmaceutical products and contain sensitive clinical strategies for gaining regulatory approval for Enalapril.

Similarly, SPX-417, minutes from a March 2001 confidential meeting, reveals Schering's progress and future potential in developing Enalapril. Specifically, the document contains details of the clinical protocol, clinical manufacturing and material requirements, as well as potential material suppliers.

Like the foregoing documents, Schering correspondence also contains sensitive information regarding development plans for Enalapril. Exhibit SPX-409 reveals clinical protocol and biostudy details, European regulatory strategies, clinical budget information and both meeting schedules and topics for future development requirements for Enalapril. This information, like that discussed with respect to Ezetimibe, will provide competitors with confidential information regarding products currently in development, and will similarly disclose details that will enable competitors to see or extrapolate Schering's future marketing and sales plans.

C. Buspirone

Schering also seeks confidential *in camera* treatment for confidential information regarding the drug Buspirone, a product that is also currently under development. (SPX-412 to SPX-416, SPX-418, SPX-420, SPX-422 to SPX-426, SPX-428, SPX-430, SPX-433, SPX-437, SPX-440, and SPX-441).

For example, SPX-416 and SPX-420 are 2001 clinical documents that reveal sensitive clinical strategies for gaining regulatory approval for Buspirone. SPX-415, a March 2001 clinical research agreement "to determine the relative bioavailabilities of two formulations of Buspirone," likewise details Schering's strategies and methods of clinical

development. The document also contains sensitive research funding and payment information. Finally, the agreement contains a confidentiality provision restricting disclosure of its terms.

Exhibit SPX-422, an April 2001 memorandum, is representative of several documents revealing the material requirements for Buspirone tablets. The memorandum also reveals sensitive information about Buspirone's clinical manufacturing and information regarding future strategies including the identification of potential material suppliers. Exhibit SPX-440 similarly reveals future development efforts for Buspirone. It charts the stages of the product's development and describes regulatory strategies, clinical research and testing and clinical manufacturing.

Further, various communications between Schering and Shandon employees working on the clinical development of Buspirone, such as Exhibit SPX-413, contain sensitive information regarding Schering's clinical development plans and timelines, clinical strategies and payment information. Like the foregoing documents, the Buspirone documents reveal current confidential information regarding Schering's development methods as well as a blueprint for the future marketing and sale of this pipeline product.

D. Additional Documents Relating To Products Currently Under Development

Exhibits SPX-406, SPX-427, SPX-431, SPX-432, SPX-435, SPX-436 and SPX-438 contain confidential information regarding multiple products currently under development by Schering. Schering also seeks *in camera* treatment for these sensitive documents.

Exhibit SPX-99 is the June 1998 license agreement with ESI Lederle, Inc., which remains in effect today. It sets forth the details of the parties' business relationship, including royalties due for the licensed products – Enalapril and Buspirone – both of which Schering is actively developing today.

Similarly, SPX-427 is a consultant agreement with Regulatory Resources Group Ltd. to file marketing applications for buspirone, enalapril, pentoxifylline and other products. This agreement, effective until 2004, contains sensitive regulatory strategies as well as business and marketing methods information. The agreement also reveals sensitive funding, pricing and payment information. Finally, the agreement contains a confidentiality provision limiting disclosure of terms.

Exhibit SPX-406 is a facsimile that reveals Schering research regarding two clinical research organizations. The document discloses Schering's methods and plans for selecting prospective clinics to perform its bioequivalence research, tests and studies for product development.

Exhibit SPX-435 is a July 2001 memorandum planning for the introduction of Vasomax, Buspirone and Enalapril tablets, all pipeline products. This document contains clinical regulatory timelines and identifies Schering's clinical development strategies and procedures.

Exhibit SPX-429 contains a June and July 2001 correspondence with Shandon employees working on the clinical development of several products. The communications reveal clinical and bioanalytical regulatory strategies, clinical manufacturing and production information, clinical protocol strategies, and product development progress. The exhibit also contains sensitive clinical budget information.

III. ARGUMENT

A. Legal Standard For *In Camera* Treatment

Pursuant to Rule 3.45, a party may obtain *in camera* treatment for materials offered into evidence if their public disclosure "will likely result in a clearly defined, serious injury to the . . . corporation requesting *in camera* treatment." 16 C.F.R. § 3.45(b). Demonstrating "serious injury" requires the moving party to establish that the documents are both secret and material to the movant's business. *See Bristol-Myers Co.*, 90 F.T.C. 455 (1977); *General Foods Corp.*, 95 F.T.C. 352 (1980); *see also Hoechst Marion Russel, Inc.*, 2000 F.T.C. LEXIS 138 (2000). The Commission has articulated six factors that are relevant to a determination of secrecy and materiality: (1) the extent to which the information is known outside of the movant's business; (2) the extent to which it is known by employees and others involved in the business; (3) the extent of measures taken to guard the secrecy of the information; (4) the value of the information to the movant and competitors; (5) the amount of effort or money expended in developing the information; (6) the ease or difficulty with which the information could be properly acquired or duplicated by others. *See Bristol-Myers*, 90 F.T.C. at 456; *Hoechst*, 2000 F.T.C. LEXIS at *6. Finally, "[t]he likely loss of business advantages is a good example of a 'clearly defined, serious injury.'" *Hoechst*, 2000 F.T.C. LEXIS at *6 (citing *General Foods*, 95 F.T.C. at 355).

B. The Documents At Issue Relating To Schering's Pipeline Products Qualify For *In Camera* Treatment Because Disclosure Of These Highly Confidential Documents Would Result In Likely Loss Of Business Advantage To Schering

As described above and in the accompanying declaration of Jonathan Wasserman, the subject exhibits relate to the ongoing development, marketing, distribution, sale, pricing and profitability of Schering's current pipeline products. Given their value to Schering's ongoing business operations, these documents merit *in camera* status.

Some of the documents reveal clinical and technical information about the various products. (SPX-408, SPX-409, SPX-410, SPX-416, SPX-417, SPX-420). The information contained in these documents falls under the definition of "trade secrets" as defined in Commission precedent. *See H. P. Hood & Sons, Inc.*, 58 F.T.C. 1184, 1188 (1961) (defining "trade secret" as "secret formulas, research or processes," the disclosure of which "will almost invariably result in injury..."). The Commission has stated that "[m]otions to place documents of this nature '*in camera*' should be sympathetically considered" and "injury sufficient to establish 'good cause' for sealing the documents can be inferred from the nature of the 'trade secret' itself." *Hood*, 58 F.T.C. at 1189.

Similarly, the Commission has granted *in camera* protection for documents that reveal manufacturing or materials specifications for particular products. *In re Kaiser Aluminum & Chemical Corp.*, 103 F.T.C. 500, 1977 FTC LEXIS 1, at *10-*11 (1984) (granting *in camera* protection for documents revealing specifications of Kaiser's production process and type of equipment used at Kaiser plants). Several of the exhibits at issue here fall into that category, and thus merit confidential treatment. (*See* SPX-412 to SPX-416, SPX-418, SPX-420, SPX-422 to SPX-426, SPX-428, SPX-430, SPX-433, SPX-437, SPX-440 to SPX-441(disclosing information about the development and

manufacturing of Buspirone); SPX-422 (April 2001 revealing the material requirements for Buspirone tablets)).

A number of the documents at issue in this motion contain assessments of the clinical and economic feasibility of various therapeutic uses of these products. (SPX-355, SPX-357, SPX-358, SPX-360, SPX-361, SPX-371, SPX-372, SPX-375). In addition, some documents contain confidential information evaluating proposed agreements and setting forth the terms and operation of current agreements between Schering and third parties for the development and/or marketing of the pipeline products. (SPX-99, SPX-345, SPX-346, SPX-348, SPX-351, SPX-353, SPX-413, SPX-415, SPX-427). *In camera* protection is likewise justified for these documents that reveal details of Schering's strategic alliances and agreements with third parties as well as its ongoing and future plans for product development. *See, e.g., Kaiser Aluminum*, 103 F.T.C. 500, FTC LEXIS 1, at *5-*6 (1984) (granting *in camera* status to documents that revealed Kaiser's future marketing strategy); *International Assoc. of Conference Interpreters*, 1996 FTC LEXIS 298, *10 (June 26, 1996) (applicants made a sufficient showing of clearly defined injury to warrant *in camera* protection for contract proposals and contract terms where access to this information "could allow competitors in the future to mimic the applicants' technical presentations and to price just below the applicants").

Other documents for which Schering seeks *in camera* status contain recent financial forecasts (SPX-354, SPX-356, SPX-359, SPX-363) or specific information concerning the timelines and costs of development of these products. (SPX-351, SPX-413). The Commission has frequently recognized the justification for protecting the confidentiality of these types of documents. *E.g., Kaiser Aluminum*, 103 F.T.C. 500

(1984) (*in camera* treatment for product sales information); *In re E.I. DuPont de Nemours & Co.*, 97 F.T.C. 116 (1981) (profit, earnings, sales and cost information given *in camera* treatment); *General Foods Corp.*, 96 F.T.C. 168 (1980) (profit data given *in camera* treatment).

The information within all of these documents relating to pipeline products is known only to those third parties with whom communications or agreements were made, and within Schering, is distributed only among senior management and those parties working directly on the products' development. Pursuant to its confidentiality policies, Schering maintains strict controls to prevent both internal and external dissemination of this material and highly confidential information. Furthermore, the documents reflect Schering's great effort and expense in researching, developing, manufacturing and marketing pharmaceutical products. The information is extremely valuable both to Schering and competitors and could not be reproduced by any other means.

Moreover, due to the ongoing development of these drugs, the fact that some of the documents at issue were created in 1996 or 1997 does not diminish their current and future sensitivity or confidentiality. First, many of the documents, even if created in 1997, make projections well into the future and reveal static strategy positions to enter a new market or to expand existing market presence. Second, the information contained in these documents can be used by Schering's competitors to extrapolate an accurate model of Schering's development, marketing, pricing, distribution and/or sales plans. *See E.I. DuPont de Nemours & Co.*, 97 F.T.C. 116 (1981) (extending *in camera* treatment for 6 year old documents enabling competitors to extrapolate business plans from profit, earnings, cost and sales information). As such, these documents, if made public, will

seriously and irreparably injure Schering's product development efforts and competitiveness, and disclosure could compromise Schering's incentives to bring innovative new drugs to market.

C. The Value Of These Pipeline Product Documents To Schering's Current And Future Business Efforts Justifies Schering's Request For *In Camera* Protection For A Period Of Five Years

Schering seeks *in camera* protection for the foregoing documents for a period of five years. As demonstrated here and in the accompanying declaration of Jonathan Wasserman, these documents represent Schering's innovative research and development as well as its prospective business profitability. Forward looking documents of this nature are frequently given protection for five years. *See International Assoc. of Conference Interpreters*, 1996 F.T.C. LEXIS 298, *13-*14 (1996) (granting five year *in camera* protection for "forward looking" documents, including internal documents containing "market, product, and sales strategies") (citing cases); *see also Hoechst Marion Roussel, Inc.* 2000 F.T.C. LEXIS 157, *7 (2000) (protection of up to five years appropriate for sales business and marketing plans). Thus, based on the unique forward looking nature of the subject documents, Schering respectfully requests *in camera* protection for a period of five years, with the option to move for extended *in camera* protection at the end of that period if necessary to protect ongoing development efforts.

IV. CONCLUSION

For the foregoing reasons, Schering respectfully requests that the Court grant the motion directing *in camera* treatment for the documents discussed herein.

Respectfully submitted,

Laura S. Shores /DEB

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Dated: December 27, 2001

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

In the Matter of Schering-Plough Corporation, a corporation, Upsher-Smith Laboratories, a corporation, and American Home Products Corporation, a corporation	)	Docket No. 9297

DECLARATION OF JONATHAN WASSERMAN

I, Jonathan Wasserman, do solemnly and sincerely declare as follows:

1. I am over the age of eighteen and competent to give testimony. The information set forth below is based on my own personal knowledge, information and/or belief.

2. I am the Senior Antitrust Counsel for Schering-Plough Corporation ("Schering").

3. I make this declaration in support of Schering's motion for *in camera* treatment of confidential documents relating to products that are currently in development by Schering, affiliated joint ventures, or its division Warrick, which have been identified as Schering exhibits SPX-23 to SPX-25, SPX-41, SPX-111, SPX-144, SPX-219, SPX-221, SPX-231, SPX-345, SPX-346, SPX-348, SPX-349, SPX-351, SPX-353 to SPX-361, SPX-363, SPX-371 to SPX-375, SPX-406, SPX-408, SPX-410 to SPX-

418, SPX-420, SPX-422 to SPX-428, SPX-430 to SPX-433, SPX-435 to SPX-438, SPX-441, SPX-617, and SPX-625 to SPX-627.

4. Each of these documents has been designated "Confidential" internally within Schering and/or has been marked "Confidential" or "Restricted Confidential" pursuant to the protective order.

5. No objection has ever been made by any party to Schering's designation of these documents as "Confidential" or "Restricted Confidential."

6. Schering seeks confidential *in camera* treatment for materials that reveal sensitive and confidential information regarding Ezetimibe, a product currently under development pursuant to a joint venture agreement between Schering and Merck & Co., Inc.. Exhibits SPX-23 to SPX-25, SPX-41, SPX-111, SPX-144, SPX-219, SPX-221, SPX-231, SPX-345, SPX-346, SPX-348, SPX-349, SPX-351, SPX-353 to SPX-361, SPX-363, SPX-371 to SPX-375, SPX-617, and SPX-625 to SPX-627, which contain detailed information about Ezetimibe, disclose sensitive and confidential material maintained by Schering.

a. For example, Exhibit SPX-355, SPX-357, SPX-358, SPX-360, SPX-361, SPX-371, SPX-372, and SPX-375 contain assessments of the clinical and economic feasibility of using Ezetimibe in combination with other lipid-lowering drugs or co-administration therapy. The materials reveal Schering's clinical and economic methods of analyzing prospective partnerships. Further, the documents disclose Schering's clinical research, trial and study plans.

b. Several exhibits are executive summaries of Ezetimibe advisory board meetings. (SPX-25, SPX 111, SPX-144, SPX-219, SPX-231, SPX 625). For example,

Exhibit SPX-25 is a summary of a February 1997 meeting held in New York; SPX-231 summarizes a meeting conducted in Paris in May 1997. These meetings were conducted at considerable expense to Schering, so that Schering could benefit from the advice of leading medical experts as it developed this new cholosterol lowering drug. The documents reveal clinical development information, clinical test results and recommendations, marketing plans, and clinical regulatory strategies.

c. A number of exhibits reveal details of the investigation and negotiations regarding potential agreements between Schering and a third party. (SPX-345, SPX-346, SPX-348, SPX-351, SPX-353). For, example, SPX-345 and SPX-346 discuss potential terms, rationales and financial projections for a proposed deal with Merck concerning Ezetimibe and other products. Similarly, SPX-351 is a March 1998 memorandum revealing details of the Ezetimibe combination project. Specifically, the document contains sensitive timelines and estimated costs for Ezetimibe's development.

d. Exhibit SPX-24 is comprised of various memoranda exchanged between Schering employees in February 1999. The materials reveal sensitive pricing information and European regulatory compliance plans. The documents also contain confidential combination and single therapy marketing suggestions and strategies. Further, the exhibit discloses clinical development recommendations and plans.

e. Various exhibits contain confidential Ezetimibe financial information. (SPX-354, SPX-356, SPX-359, SPX-363). For example, Exhibit SPX-354 reveals Ezetimibe monotherapy and combination therapy sales and marketing costs forecasts. The forecasts project sales and marketing costs from 2001 to 2008. In addition, the

document reveals Schering's marketing strategies and anticipated launch date for Ezetimibe.

f. Exhibit SPX-41 is a memorandum containing early stage plans for Ezetimibe. The memorandum reveals details about the product's preliminary development timeline. The document also discloses potential marketing and clinical strategies.

7. Schering seeks confidential *in camera* treatment for materials that reveal sensitive and confidential information regarding Enalapril, a product currently under development by Schering. Exhibits SPX-408 to SPX-411, SPX-417, SPX-434, and SPX-439, which contain detailed information about Enalapril, disclose sensitive and confidential business development information maintained by Schering.

a. For example, Exhibit SPX-410 is a January 2001 draft of the Clinical Research Protocol for Enalapril. Exhibit SPX-408 is a January 2001 Review of Bioequivalence Data for Enalapril. Both clinical documents reveal Schering's confidential methods for researching, testing and studying pharmaceutical products for clinical development. The documents also contain sensitive clinical strategies for gaining regulatory approval for Enalapril.

b. Exhibit SPX-417, minutes from a March 2001 meeting, reveals Schering's progress in developing Enalapril. Specifically, the document contains details of the clinical protocol, clinical manufacturing and material requirements, and potential material suppliers.

c. Correspondence between Schering and clinic employees also contains sensitive information regarding Schering's Enalapril development plans. Exhibit SPX-

409, for example, reveals clinical protocol and biostudy details, European regulatory strategies, clinical budget information and meeting schedules.

8. Schering also seeks confidential *in camera* treatment for materials that reveal sensitive and confidential information regarding Buspirone, a product currently under development by Schering. Exhibits SPX-412 to SPX-416, SPX-418, SPX-420, SPX-422 to SPX-426, SPX-428, SPX-430, SPX-433, SPX-437, SPX-440, and SPX-441, disclose detailed, confidential information maintained by Schering about the development and manufacturing of Buspirone.

a. For example, Exhibit SPX-416 is a July 2001 draft of the Clinical Research Protocol for Buspirone. Exhibit SPX-420 is an April 2001 Draft Outline of Proposed Stability Study for Buspirone. Both clinical documents reveal Schering's confidential methods for researching, testing and studying pharmaceutical products for clinical development. Further, the documents contain sensitive clinical strategies for gaining regulatory approval for Buspirone.

b. Exhibit SPX-415 is a clinical research agreement between Shandon Clinic Limited ("Shandon"). This March 2001 agreement "to determine the relative bioavailabilities of two formulations of Buspirone" reveals Schering's strategies and methods of clinical development. The document also contains sensitive funding and payment information. Finally, the agreement contains a confidentiality provision strictly prohibiting disclosure of terms and requiring the parties to seek confidential treatment of the terms.

c. Exhibit SPX-422, an April 2001 memorandum, is representative of several documents that reveal the material requirements for Buspirone tablets. The memorandum

reveals sensitive information about the clinical manufacturing of Buspirone, its material requirements and potential material suppliers.

d. Exhibit SPX-440 charts the stages of the product's development, revealing details about Schering's clinical regulatory strategies, clinical research and testing, and clinical manufacturing.

e. Further, various correspondences between Schering and Shandon employees working on the clinical development of Buspirone, such as Exhibit SPX-413, contain sensitive information regarding Schering's clinical development plans and timelines, clinical strategies and payment information. The documents also reveal Schering's clinical regulatory strategies.

9. Exhibits SPX-406, SPX-427, SPX-431, SPX-432, SPX-435, SPX-436 and SPX-438 contain confidential information regarding more than one product that is currently under development by Schering. Schering also seeks *In camera* treatment for these sensitive documents.

a. For example, SPX-99 is the license agreement between Schering and ESI Lederle, Inc. This licensing agreement, executed in June 1998, remains in effect today. It sets forth the details of the parties' business relationship, including the royalties due to ESI for the licensed products enalapril and buspirone, both of which Schering is actively developing today.

b. SPX-427 is a consultant agreement with Regulatory Resources Group Ltd. to file "marketing application[s] for buspirone, enalapril, pentoxifylline and other products." This agreement, which will remain in effect until 2004, contains sensitive regulatory strategies, business and marketing methods information. The agreement also

reveals sensitive funding, pricing and payment information. Finally, the agreement contains a confidentiality provision strictly prohibiting disclosure of terms and requiring parties to seek confidential treatment of deal terms.

c. Exhibit SPX-406 is a facsimile that reveals Schering research on two clinical research organizations. The document discloses Schering's methods and plans for selecting prospective clinics to perform its bioequivalence research, tests and studies for product development.

d. Exhibit SPX-435 is a July 2001 memorandum planning for the introduction of Vasomax, Buspirone and Enalapril tablets. The document contains clinical regulatory timelines and identifies Schering's clinical development strategies and procedures.

e. Exhibit SPX-429 is June and July 2001 correspondence between Schering and Shandon employees working on the clinical development of several products. The communications reveal clinical and bioanalytical regulatory strategies, clinical manufacturing and production information, clinical protocol strategies, and product development progress. The exhibit also contains clinical budget information.

10. Release of the information contained in the foregoing product development documents will have serious and adverse competitive impacts on Schering. The documents provide detailed information regarding Schering's clinical development of products, regulatory submissions, research and development expenses, sales forecasts, and ongoing marketing activity.

11. The information within these product development documents is known only to those parties with whom communications or agreements were made, and within

Schering, only by top management and those parties working directly on the products' development. Pursuant to its confidentiality policies, Schering maintains strict controls to prevent both internal and external dissemination of confidential information. Furthermore, the documents reflect Schering's great effort and expense to research, develop, manufacture and sell pharmaceutical products. The information is extremely valuable both to Schering and competitors and could not be reproduced by any other means. Moreover, since efforts to develop Ezetimibe, enalapril and buspirone are ongoing, disclosure of commercial information dating back as far as 1996 and 1997 could permit competitors to extrapolate and make determinations concerning Schering's current business plans and strategies with regard to these products.

12. As such, the documents contain secret information that is material to Schering business, competitiveness and profitability. Release of this information will cause the loss of business advantage and serious and irreparable injury to Schering.

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

Dated: December 26, 2001

Jonathan Wasserman

CERTIFICATE OF SERVICE

I hereby certify that this 27th day of December, 2001, I caused an original, one paper copy and an electronic copy of the foregoing Respondent Schering-Plough Corporation's Motion for *In Camera* Treatment of Documents Relating to Products That Are Currently in Development, supporting Memorandum and Declaration to be filed with the Secretary of the Commission, and that two paper copies were served by hand upon:

Honorable D. Michael Chappell
Administrative Law Judge
Federal Trade Commission
Room 104
600 Pennsylvania Avenue, N.W.
Washington, D.C. 20580

and one paper copy was hand delivered upon:

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