PUBLIC VERSION

UNITED STATES OF AMERICA
BEFORE 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.	)	

RESPONDENT SCHERING-PLOUGH CORPORATION'S
MOTION FOR *IN CAMERA* TREATMENT OF CERTAIN DOCUMENTS

Respondent Schering-Plough Corporation ("Schering") respectfully requests that the Commission enter a protective order directing indefinite *in camera* treatment, pursuant to Rule 3.45(b) of the Federal Trade Commission Rules of Practice, 16 C.F.R. § 3.45(b), of certain documents containing confidential and technical information produced in this adjudicatory proceeding.

1. The documents at issue are the New Drug Application ("NDA") for K-Dur® (SPX-771), and pages of a laboratory notebook issued to Mr. Richard Traitz and excerpts from his deposition transcript relating to the laboratory notebook that were attached as exhibits to Schering's Trial Exhibits SPX-684, 685 and 691 (collectively, "the Lab Notebook").

2. The K-Dur® NDA and Lab Notebook are proprietary in nature, revealing Schering's technical data and secret product development processes.

3. Public disclosure of such information would divulge Schering's most sensitive and confidential information to its competitors and result in irreparable harm to Schering.

The grounds for this motion are set forth in full in the accompanying memorandum of law, and the motion is supported by the declaration of James Nelson, Staff Vice President and Associate General Counsel for Patents and Trademarks at Schering. (Declaration of James Nelson is attached as Exhibit A to the memorandum of law).

Respectfully submitted,

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Dated: December 27, 2001

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MEMORANDUM OF LAW IN SUPPORT OF RESPONDENT SCHERING-PLOUGH CORPORATION'S MOTION FOR *IN CAMERA* TREATMENT OF CERTAIN DOCUMENTS

Respondent Schering-Plough Corporation ("Schering") respectfully submits this memorandum of law in support of its motion for an order directing *in camera* treatment, pursuant to Rule 3.45(b) of the Federal Trade Commission Rules of Practice, 16 C.F.R. § 3.45(b), of certain documents containing confidential trade secrets and technical information produced in this adjudicatory proceeding.

These documents were designated as "Confidential" according to the provisions of the protective order in this proceeding. Accordingly, these materials were provided only to outside counsel and certain individuals pursuant to paragraph 4(a) of the protective order. None of the parties objected to Schering's designation of these materials as "Confidential."

Moreover, these documents were initially produced during the discovery process in the underlying patent infringement cases, *Key Pharmaceuticals, Inc. v. Upsher-Smith*

Laboratories, Inc., Civil Action No. 95-6281 (D.N.J)("Upsher Litigation") and *Key Pharmaceuticals, Inc. v. ESI-Lederle, Inc.*, Civil Action No. 96-CV-1219 (E.D. Pa)("ESI Litigation). These documents were designated as "Confidential" pursuant to provisions of the respective protective orders governing these cases, and the "Confidential" designation of these protective orders afforded at least the same level of protection provided by the protective order in this proceeding.[1]

As set forth in greater detail below, these documents are proprietary in nature, revealing Schering's technical data and secret development processes. Public disclosure of such information would divulge Schering's most sensitive and confidential information to its competitors and result in irreparable harm to Schering. Accordingly, Schering respectfully requests that the Commission rule that these materials be used only *in camera* and maintain them under seal.

I. THE DOCUMENTS

A. NDA Submission

When pharmaceutical companies apply for approval of a new drug, they must make a submission to the Food and Drug Administration ("FDA") pursuant to section 505(b) of the Food, Drug and Cosmetic Act. (Declaration of James Nelson ("Nelson Decl.") at ¶ 3). In general terms, an NDA consists of technical data and proprietary information provided to the FDA by a drug manufacturer as evidence of the manufacturer's new drug's safety and effectiveness to obtain approval of the product before the manufacturer can begin marketing the product. (*Id.* at ¶ 4).

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[1] Pursuant to paragraph 7 of the protective order from the Upsher Litigation ("Upsher Protective Order"), the "Confidential – Subject to Protective Order" designation allows disclosure of information so designated to outside counsel and other designated individuals subject to a nondisclosure agreement pursuant to the Upsher Protective Order. Pursuant to paragraph 4 of the protective order from the ESI Litigation ("ESI Protective Order"), the "Confidential – Subject to Protective Order" designation allows disclosure of information so designated to outside counsel and other designated individuals.

The first of the documents in question is one such submission by Key Pharmaceuticals, Inc. ("Key")[2] for its Potassium Chloride Sustained Release Tablets, 20 mEq product ("K-Dur®) to the FDA on March 6, 1985 ("NDA submission").[3] This submission consists of three volumes and is a portion of a New Drug Application ("NDA") for "K-Dur®.

The NDA submission for K-Dur® at issue here included: 1) chemical formulations and manufacturing control information, which includes evidence from dissolution studies of slowed release of potassium chloride from K-Dur®; 2) an animal study comparing the gastrointestinal toxicity of K-Dur® with a marketed slow release potassium product, a placebo, and an enteric coated potassium chloride, serving as a positive control, was also included in the NDA submission; 3) a bioavailability study using steady state potassium balance in normal subjects with urinary excretion and potassium recovery as the index of bioavailability; and 4) a gastric irritation study in humans comparing K-Dur® with liquid potassium, microencapsulated potassium chloride, a wax matrix product and a placebo. These studies showed K-Dur® as non-irritating and non-toxic to the gastrointestinal tract with desirable absorption of potassium from the tablet. (*See* Volume 2 of Confidential Appendix to this memorandum at Tab 1, ESI EXH 002112-13).

The NDA submission for K-Dur®, like any NDA, contains trade secrets, such as chemical formulations and manufacturing control information as well as information concerning laboratory and clinical testing performed on K-Dur®. (Nelson Decl. at ¶5). In providing the NDA submission to the FDA, Key expressly stated that the material and data contained therein are confidential and legal protection as trade secrets are claimed

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2 Due to the merger of Key and Schering through which Schering acquired rights to K-Dur® and U.S. Patent No. 4,863,743, the patent-in-suit of the underlying patent cases, the terms Schering and Key are used interchangeably herein.

3 The NDA Submission is Schering's Trial Exhibit SPX-771, ESI EXH 001461-002358, a copy of which has been provided for *in camera* review as Exhibit 1 to the confidential appendix to this memorandum.

pursuant to 18 U.S.C. §1905[4] and 21 U.S.C. § 331(j).[5] (*See* Volume 2 of Confidential Appendix to this memorandum at Tab 1, ESI EXH 002113).

B. The Lab Notebook

The remaining documents in question are pages of a laboratory notebook issued to Mr. Richard Traitz and excerpts from his deposition transcript relating to the laboratory notebook that were attached as exhibits to Schering's Trial Exhibits SPX-684, 685 and 691 (collectively referred hereinafter as "the Lab Notebook"). Schering's Trial Exhibits SPX-684, 985 and 691 were submitted in the underlying Upsher and ESI Litigations.[6]

Mr. Traitz was a bench chemist at Key. Traitz Tr., pp. 14-15.[7] Generally, various types of analytical tests conducted by Key in its drug development efforts are recorded in lab notebooks. *Id.* at p. 16. These tests include friability, potency, methods comparison, and drug formulations. *Id.* at pp. 16-20. The Lab Notebook contains technical information that pertains to dissolution tests performed on various lots of trial potassium chloride tablets formulated by Key during the development of Key's sustained release potassium chloride "K-Dur" tablets. *Id.* at pp. 36-38.

Each page of the Lab Notebook details a different dissolution test of a particular lot of trial potassium chloride tablets. *Id.* at pp. 45-46. The figures and tables of each

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4 18 U.S.C. §1905 prohibits the disclosure of "trade secrets, processes, operations" submitted to an officer or employee of the United States in the course of his official duty by reason of examination.

5 21 U.S.C. §331(j) prohibits the disclosure of "any methods or process which as a trade secret is entitled to protection."

6 SPX-684 includes an excerpt of the Lab Notebook, USL PLD 005009-005011 (attached as Exhibit 2 to the Confidential Appendix to this memorandum) and excerpts of Richard Traitz's October 23, 1996 deposition transcript, USL PLD 005436-005446 (attached as Exhibit 3 to the Confidential Appendix to this memorandum). Additional excerpts from Mr. Traitz's Lab Notebook and deposition are included in SPX-685 (attached as Exhibits 4 and 5 to the Confidential Appendix to this memorandum). Finally, the Lab Notebook in its entirety was Exhibit L to SPX-691 (attached as Exhibit 6 to the Confidential Appendix to this memorandum).

7 Mr. Traitz's deposition was taken on October 17, 1996 in the ESI Litigation ("Traitz Tr"), relevant pages of which are attached as Exhibit 7 to the Confidential Appendix to this memorandum. This deposition was designated as "confidential" in accordance with the protective order in the ESI litigation. Traitz Tr., p. 17.

dissolution test indicate the chemical composition of a particular lot of potassium chloride tablets tested, the dissolution testing procedures utilized, and observations and assessments of the test results recorded by the particular technician who performed the dissolution test. *Id.* at pp. 48-55.

In addition to presenting the results of the various dissolution tests conducted by Schering in developing its sustained release potassium chloride tablets, the Lab Notebook discloses technical variables involved in Schering's product development process. *Id.* at pp. 81, 91-93 (research and development data and proprietary testing methods), at p. 136 (clinical release data). Thus, the compilations of the various technical data and test results described in the Lab Notebook reveal trade secrets relating not only the formulation and testing protocols used in the development of the particular drug at issue (in this case, K-Dur®), but also to the general processes that Schering utilizes in developing and testing new drug formulations. Nelson Decl., ¶ 6.

II. ARGUMENT

Pursuant to Rule 3.45(b), 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. Further, "[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). With respect to "trade secret" information such as secret formulas, research or processes, "motions 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." *H. P. Hood & Sons, Inc.*, 58 F.T.C. 1184, 1189 (1961).

Moreover, once a determination has been made that the information in question should be afforded *in camera* treatment, a determination must also be made of the duration for which the information will be held *in camera*. 16 C.F.R. § 3.45(b). Trade secrets are routinely afforded indefinite *in camera* protection. *See, e.g., Hood*, 58 F.T.C. at 1188.

A. The NDA Submission And The Lab Notebook Are Secret And Material

Pursuant to 21 C.F.R. 20.61, "[d]ata and information submitted or divulged to the Food and Drug Administration which fall within the definitions of a trade secret or confidential information are not available for public disclosure." 21 C.F.R. § 20.61(c). A "trade secret" is defined as "any commercially valuable plan, formula, process, or device that is used for making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." 21 C.F.R. § 20.61(a). Additionally, FDA expressly exempts from public disclosure information regarding the manufacturing methods or processes, including quality control

procedures, and other quantitative or semi-quantitative formulas of the drug even after the NDA has been approved.[8] 21 C.F.R. §314.430(g).

As stated previously, the data and information contained in the NDA submission reveal trade secrets relating to chemical formulations and manufacturing control information as well as information concerning laboratory and clinical testing performed on K-Dur®. (Nelson Decl., ¶ 5). As such, the NDA submission clearly fits the definition of a "trade secret" as defined by the FDA and is therefore exempt from public disclosure even when, as in the present case with K-Dur®, FDA has approved the marketing of the product. The NDA submission also clearly fits into the definition of a "trade secrets" as defined in *Hood*. *See Hood*, 58 F.T.C. at 1188 (defining "trade secret" as "secret formulas, research or processes," the disclosure of which "will almost invariably result in injury...")

Similarly, the data and information contained in the Lab Notebook clearly fit the definition of "trade secrets" as defined in *Hood*. Like the NDA submission for K-Dur®, the Lab Notebook contains chemical formulations and information concerning laboratory and clinical testing performed Schering in the development of K-Dur®. (Nelson Decl., ¶ 6). As set forth in *Hood*, invariable injury as a result of disclosure of such proprietary information can be easily inferred from the nature of the "trade secret" itself. 58 F.T.C. at 1189.

Due to the proprietary and sensitive nature of the information contained in the NDA submission and the Lab Notebook, disclosure of any type has been extremely limited. Schering generally takes extensive measures to protect the confidentiality of all aspects of its product development process. (Nelson Decl., ¶ 7). This information is not

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[8] Pursuant to 21 C.F.R. §314.430(e), portions of the data and information contained in the NDA become public after the FDA sends an approval letter to the applicant. The portions of the NDA that are publicly available upon approval of the drug include the safety and effectiveness of the drug, a Summary Basis of Approval document, and any adverse reaction reports. 21 C.F.R. §314.430(e)(2) provides a complete list of the data and information available for public disclosure upon approval of an application. Some of the data and information listed in §314.430(e)(2) are included in the "label" provided with the sale of the product.

voluntarily revealed to any third party, nor is it available to the public. *Id.* Moreover, all parties involved in this proceeding and the parties involved in the underlying Upsher Litigation and the ESI Litigation have maintained the confidentiality of the NDA submission and the Lab Notebook pursuant to the protective orders entered in those cases.

The information contained in the NDA submission and the Lab Notebook are clearly secret and material to the production of K-Dur® and the disclosure of which will lead to great detriment and competitive disadvantage to Schering. (Nelson Decl., ¶ 8). Thus, the NDA submission and the Lab Notebook certainly qualify as secret and material according to the *Bristol-Myers* criteria such that *in camera* treatment of these materials is required to prevent "serious competitive injury" to Schering.

B. Passage Of Time Will Not Diminish Injury Resulting From Disclosure

Unlike ordinary business records, the K-Dur® NDA submission and the K-Dur® Laboratory Notebook at issue here are extremely sensitive and proprietary in nature, revealing confidential and technical information utilized by Schering in developing its sustained release potassium chloride tablet. (Nelson Decl., ¶ 9). Because the documents reveal trade secrets that extend beyond the particular product at issue, the need to maintain the confidentiality of these documents does not dissipate with the approval of the NDA, the marketing of the product, or even the expiration of the patent on the subject product. (*Id.* at ¶ 10).

Moreover, the compilations of the various technical data and test results described in the Lab Notebook reveal trade secrets relating not only the formulation and testing protocols used in the development of the particular drug at issue (in this case, K-Dur®), but also to the general processes that Schering utilizes in developing and testing new drug formulations. (*Id.* at ¶ 6). Maintaining the competitive sensitivity and the proprietary value of such information is material to Schering's success in its future drug development

efforts. (*Id.* at ¶ 8). The disclosure of such information could allow competitors to reconstruct Schering's product development process at great detriment to Schering. (*Id.*).

Technical information involving secret formulas, research and development processes, such as those contained in the NDA submission and the Lab Notebook are routinely granted permanent *in camera* treatment in an F.T.C. adjudicatory proceeding due to the clear and on-going threat of competitive injury that would result from their disclosure to competitors. *See, e.g., Hood*, at 1188; *Hoechst*, 2000 FTC LEXIS 151, *6 ("Examples of documents meriting indefinite *in camera* treatment are trade secrets, such as secret formulas, processes, and other secret information"); *Kaiser Aluminum & Chemical Corp*, 1977 F.T.C. Lexis 1, 10-11 (1977)(holding that specifications of production process are secret and material and should therefore be afforded *in camera* treatment permanently.)

The competitive sensitivity and the proprietary value of the information relating to Schering's future drug developments efforts contained in the NDA submission and the Lab Notebook will not diminish, and may actually increase, with the passage of time. *See, Coca-Cola Co.*, 1990 FTC LEXIS 364 (1990)(preferring indefinite *in camera* treatment of certain types of documents for which threat of injury from disclosure in on-going, over "becoming embroiled in future disputes" regarding continuation of such treatment.) Thus, as the competitive injury resulting from the disclosure of the confidential information contained in the NDA submission and the Lab Notebook will not be stated by the passage of time, indefinite *in camera* treatment of these materials is required to prevent "serious competitive injury" to Schering.

III. CONCLUSION

For the foregoing reasons, Schering respectfully requests that the Court grants the motion directing *in camera* treatment of the NDA submission and the Lab Notebook discussed herein.

Respectfully submitted,

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Dated: December 27, 2001

UNITED STATES OF AMERICA
BEFORE 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 JAMES NELSON

I, James Nelson, 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.

2. I am Staff Vice President and Associate General Counsel for Patents and Trademarks for Schering-Plough Corporation ("Schering").

3. When pharmaceutical companies apply for approval of a new drug, they must make a submission to the Food and Drug Administration ("FDA") pursuant to section 505(b) of the Food, Drug and Cosmetic Act ("NDA submission").

4. In general terms, an NDA submission consists of technical data and proprietary information provided to the FDA by the drug manufacturer as evidence of safety and effectiveness of the manufacturer's new product in order to obtain approval to market the product.

5. The NDA submission for K-Dur® at issue here, like any NDA, contains trade secrets, such as chemical formulations and manufacturing control information as well as information concerning laboratory and clinical testing performed on K-Dur®.

6. Similarly, the compilations of the various technical data and test results described in laboratory notebooks reveal trade secrets relating not only the formulation and testing protocols used in the development of the particular drug at issue (in this case, K-Dur®), but also to the general processes that Schering utilizes in developing and testing new drug formulations.

7. Schering generally takes extensive measures to protect the confidentiality of all aspects of its product development process. This information is not voluntarily revealed to any third party, nor is it available to the public.

8. Maintaining the confidentiality and proprietary value of such information is critical to Schering's success in its future drug development efforts. A competitor with access to such information could reconstruct Schering's product development process at great detriment and competitive disadvantage to Schering.

9. Unlike ordinary business records, the K-Dur NDA Submission and the K-Dur laboratory notebook are extremely sensitive and proprietary in nature, revealing confidential and technical information utilized by Schering in developing its sustained release potassium chloride tablet.

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 Certain Documents, 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
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and one paper copy was hand delivered upon:

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