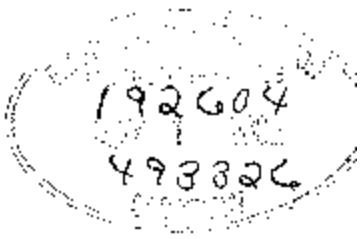
ORIGINAL



UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

In the Matter of **SCHERING-PLOUGH CORPORATION,** **a corporation,** **UPSHER-SMITH LABORATORIES, INC.** **a corporation,** **and** **AMERICAN HOME PRODUCTS CORPORATION,** **a corporation.**	**Docket No. 9297**

To: The Honorable D. Michael Chappell
Administrative Law Judge

COMPLAINT COUNSEL'S REPLY TO SCHERING-PLOUGH'S PROPOSED FINDINGS RELATING TO THE UNDERLYING PATENT CASES

[PUBLIC VERSION]

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Counsel Supporting the Complaint

May 14, 2002

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Complaint counsel respectfully submit their reply to Schering-Plough's proposed findings relating to the underlying patent cases. For the convenience of the court, we have reprinted each of proposed findings, followed by complaint counsel's reply. A separate reply brief accompanies these reply findings.

Respectfully submitted,

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INTRODUCTION

Respondent's proposed findings of fact should not be adopted by the Administrative Law Judge. Many of those findings are unsupported by the record, contrary to more reliable evidence, incomplete, misleading, or otherwise unreliable. On the following pages, we have reproduced each of respondent's proposed findings of fact. Complaint counsel's response ("CPRF") follows each finding or group of findings responded to. While we have attempted to address the most important issues posed by the proposed findings, we have not responded to every point made by respondent. Accordingly, the failure to address a particular proposed finding or part thereof does not signify endorsement of the finding, and should not be taken as agreement that the proposed finding be adopted.

The following citation forms are used in these reply findings.

CPRF - Complaint Counsel's Reply Finding

CPF - Complaint Counsel's Proposed Finding of Fact

CX - complaint counsel exhibit

SPX - Schering-Plough exhibit

USX - Upsher-Smith exhibit

Complaint - Complaint of the Federal Trade Commission, issued March 30, 2001.

Schering Answer - Answer of Schering-Plough Corporation, filed April 23, 2001.

Upsher Answer - Answer of Upsher-Smith Laboratories, Inc., filed April 23, 2001

AHP Answer - Answer of American Home Products Corporation, filed April 23, 2001.

Schering First Admissions - Schering-Plough Corporation's Objections and Responses to Complaint Counsel's First Requests for Admissions, filed August 6, 2001.

Schering Second Admissions - Schering-Plough Corporation's Objections and Responses to Complaint Counsel's Revised Second Requests for Admissions, filed November 14, 2001.

Upsher First Admissions - Upsher-Smith's Objections and Responses to Complaint Counsel's First Set of Requests for Admissions, filed Sept. 10, 2001.

Upsher Second Admissions - Upsher-Smith's Objections and Responses to Complaint Counsel's Second Set of Requests for Admissions, filed November12, 2001.

Upsher Third Admissions - Upsher-Smith's Objections and Responses to Complaint Counsel's Revised Third Set of Requests for Admissions, filed September 13, 2001.

Citations to the transcript include the volume, page number, and witness name: Tr. at 1:125 (Goldberg).

Pages of exhibits are referenced by bates number: CX 422 at SP 06 00009.

References to investigational hearing or deposition transcripts that have been included in the trial record as exhibits include the exhibit number, the page and lines of the deposition or investigational hearing transcript, the witness name, and the designation "IH" or "dep": CX 1516 at 40:7-12 (Lauda dep).

Citations to admissions include the designated abbreviation and the paragraph number of the request and response: Schering First Admissions No.1.

In camera material and citations are in italics.

Documents that were admitted subject to the limitation that they were not offered for the truth of the matters asserted are indicated by an asterisk after the exhibit number: SPX 693*.

AHP documents, depositions, and investigational hearings were admitted subject to the Administrative Law Judge's satisfaction that complaint counsel properly proved a conspiracy and all the required elements under the co-conspirator rule. These documents are marked by a superscript ([†]) following the exhibit number.

[NOTE: This volume starts at finding 3.387. Schering's proposed findings placed these "patent" findings in the same volume as its findings on "economic and policy" issues (findings 3.1 through 3.386). We have broken these volumes into two sets for ease of reference. This volume contains complaint counsel's replies to all of Schering's findings on patent issues.]

IV. U.S. PATENT NO. 4,869,743 ("'743 PATENT")

A. Background of the '743 Patent

1. Introduction to the United States Patent System

a. U.S. Constitution Provides Basis for Granting Patents

3.387. Article I, Section 8, of the Constitution of the United States grants Congress the authority to create a patent system. (15 Tr. 3307-08 (C. Miller)). Currently, U.S. patents are issued by the U.S. Patent and Trademark Office ("USPTO"), a branch of the U.S. Department of Commerce. (15 Tr. 3307, 3312 (C. Miller)). To receive a patent, an inventor must file a patent application with the USPTO. The USPTO assigns an examiner to the application to test the application against certain criteria set forth by the U.S. patent laws. (15 Tr. 3313 (C. Miller)). Patent examiners are technically trained in the relevant arts to which the patent applications they examine relate. (15 Tr. 3313 (C. Miller)).

Complaint Counsel's Response to Finding No. 3.387

Complaint Counsel has no specific response.

b. Parts of a U.S. Patent

3.388. Patents contain a description of the invention, one or more claims, and, when appropriate, drawings. (15 Tr. 3309 (C. Miller)). The specification of a patent consists of the description of the invention and the claims and is organized and referenced by column numbers

appearing on top of each page of the patent and line numbers appearing in the middle of the page between the columns. (15 Tr. 3309 (C. Miller)).

Complaint Counsel's Response to Finding No. 3.388

Complaint Counsel has no specific response.

3.389. One of the statutory requirements for the specification of a patent is that the specification must contain a written description of the invention in clear, concise and exact terms as to enable one of ordinary skill in the art to which the invention pertains to carry out the invention. (35 U.S.C. §112; 15 Tr. 3310 (C. Miller)).

Complaint Counsel's Response to Finding No. 3.389

Complaint Counsel has no specific response.

3.390. The specification must conclude with one or more claims that particularly point out and distinctly claim the subject matter that the applicant regards as the invention to be patented. (35 U.S.C. §112; 15 Tr. 3310 (C. Miller); SPX 1275 at ¶ 32 (C. Miller)).

Complaint Counsel's Response to Finding No. 3.390

Complaint Counsel has no specific response.

3.391. The requisites for a proper patent application (and consequently of the patent itself), in terms of the content of the specification, are set forth in the first two paragraphs of 35 U.S.C. § 112. (SPX 1275 at ¶ 32 (C. Miller)).

Complaint Counsel's Response to Finding No. 3.391

Complaint Counsel has no specific response.

c. **Enforcement of U.S. Patents**

3.392. A patent owner is given the exclusive right to preclude others from making, selling, using or vending the subject matter of the invention covered by the claim. (35 U.S.C. § 271(a); 15 Tr. 3310-11 (C. Miller)). The scope of the right to exclude others is defined by the claims of the patent. (15 Tr. 3311 (C. Miller)).

Complaint Counsel's Response to Finding No. 3.392

The proposed finding is incomplete and misleading by stating that the "scope of the right to exclude others is defined by the claims of the patent". [redacted]; SPX 687* at ESI PLD 001653-1663 (Defendant's Motion for *Markman* Ruling and/or Partial Summary Judgment of No Literal Infringement in *Key v. ESI*) (discussing interpretation of claims of '743 patent in view of specification).

3.393. To enforce a patent, the patentee is given the right to sue in a federal court for patent infringement. (35 U.S.C. § 271; 28 U.S.C. § 1338; 15 Tr. 3316 (C. Miller)). The party asserting the patent in an infringement suit must prove during trial that the party has ownership

of the patent and that the patent has been infringed. (15 Tr. 3316 (C. Miller)).

Complaint Counsel's Response to Finding No. 3.393

The proposed finding is incomplete and misleading in that it indicates that a party asserting a patent will succeed by simply proving ownership of a patent and infringement. When a party asserts a patent, the defendant may also assert affirmative defenses and counterclaims that relate to the invalidity and/or unenforceability of the patent. [redacted] Tr. at 15:3323 (Miller); [redacted] Tr. at 32:7729 (Adelman).

3.394. For example, the '743 patent gives Schering the right to "exclude others from making, using, offering for sale, and selling the invention throughout the United States," together with certain additional rights provided in the statute. 35 U.S.C. § 154. The '743 patent expires on September 5, 2006. (15 Tr. 3311 (C. Miller); (SPX 1275 at ¶ 8 (C. Miller)). Hence, Schering has the right to exclude others from making, using, offering for sale, and selling, the sustained release potassium chloride tablet claimed in the '743 patent and equivalents thereof. (15 Tr. 3311 (C. Miller)).

Complaint Counsel's Response to Finding No. 3.394

The proposed finding is incomplete and misleading in stating that Schering has the right to exclude others with respect to the sustained release potassium chloride tablet claimed in the '743 patent and equivalents thereof. [redacted]

[redacted] Tr. at 32:7832-33 (Adelman); [redacted].

The proposed finding is further misleading in overemphasizing Schering's right to exclude other competitors without acknowledging that competitors have a right to design around a patent to create a noninfringing substitute. Schering's own technical expert, Dr. Banker, acknowledged that ESI may legally invent around the '743 patent. Tr. at 14:3248-49 (Banker). Dr. Banker conceded that one way that a company may invent around a patent is to change the manufacturing process. Tr. at 14:3249 (Banker). When done appropriately, Dr. Banker agreed that inventing around patents is one way to advantage the public. Tr. at 14:3250 (Banker). Inventing around the '743 patent is a plausible option here, because the patent was on a formulation process not the underlying drug molecule, potassium chloride. Tr. at 14:3250-51 (Banker).

3.395. The filing of an Abbreviated New Drug Application ("ANDA") under 21 U.S.C. §355(j)(the "Hatch-Waxman Act") is an infringement under 35 U.S.C. §271 (e; 2; part of the Hatch-Waxman Amendments to the Patent Act) as opposed to an infringement of a patentee's exclusive right to make, use, vend or import as set forth in 35 U.S.C. §154(a; 1). (15 Tr. 3317 (C. Miller); SPX 1275 at ¶ 39 (C. Miller)).

Complaint Counsel's Response to Finding No. 3.395

Complaint Counsel has no specific response.

3.396. If the patentee prevails in an infringement action under 35 U.S.C. §271(e; 2; A), *supra*, then the court, under §271(e; 4) must order the postponement of the FDA's approval of the ANDA until at least the expiration date of the patent, or enjoin the commercialization of a drug whose ANDA has already been approved. (15 Tr. 3317 (C. Miller); SPX 1275 at ¶ 40 (C. Miller)).

Complaint Counsel's Response to Finding No. 3.396

Complaint Counsel has no specific response.

3.397. Thus, if Schering succeeded in the *Upsher* or *ESI* litigation, Schering was entitled to an order that would have precluded Upsher or ESI from marketing their generic products until the '743 patent expired in September 2006. (15 Tr. 3317 (C. Miller))

Complaint Counsel's Response to Finding No. 3.397

[redacted]

[redacted] Tr. at 15:3323 (Miller); [redacted] Tr. at 32:7729 (Adelman).

3.398. In defending a patent infringement suit, the alleged infringer may seek to prove that its alleged infringing device does not infringe the patent or challenge the validity and/or enforceability of the patent. (15 Tr. 3317 (C. Miller)). In doing so, however, the alleged infringer must prove invalidity or unenforceability of the patent by clear and convincing evidence. (15 Tr. 3317 (C. Miller)).

Complaint Counsel's Response to Finding No. 3.398

Complaint Counsel has no specific response.

2. Introduction to Potassium Chloride Supplements

3.399. The invention of the '743 patent is directed to a controlled release potassium chloride tablet. (13 Tr. 2947-48 (Banker); SPX 194, col. 1, ll. 11-12). One example for the use of potassium chloride supplements is for patients, especially elderly patients, with heart disease, congestive heart failure or edema associated with decreased cardiac function. (13 Tr. 2950 (Banker)). These ailments tend to result in excess fluid accumulation in the patient, such as swollen legs and angles, causing discomfort to the patient. (13 Tr. 2950 (Banker)).

Complaint Counsel's Response to Finding No. 3.399

Complaint Counsel has no specific response.

3.400. Patients are typically given diuretics to remove the excess fluid through urinary excretion. (13 Tr. 2950 (Banker)). It is well known that the administration of diuretics increases the excretion of potassium. (SPX 194, col. 1, ll. 22-5). Thus, patients receiving chronic administration of diuretics can experience substantial depletion of potassium. (13 Tr. 2950 (Banker)). Without potassium supplements, these patients may become hypokalemic, which in turn, may result in cardiac difficulties. (13 Tr. 2950 (Banker)).

Complaint Counsel's Response to Finding No. 3.400

Complaint Counsel has no specific response.

a. Benefits of A Higher Dose Sustained Release Potassium Chloride Supplement

3.401. As explained by Dean Banker, patients suffering from potassium depleting ailments require regular potassium chloride supplements.[1] (13 Tr. 2950 (Banker)). These patients typically require 20 to 40 milliequivalents ("mEq"), or 1.5 to 3.0 grams, of potassium chloride supplement per day. (13 Tr. 2951 (Banker)). Potassium is administered in the form of potassium chloride.

Complaint Counsel's Response to Finding No. 3.401

Complaint Counsel has no specific response.

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[1] Dean Banker recently retired as the Dean and John L. Lach Distinguished Professor of Drug Delivery Emeritus at the Colle of Pharmacy, University of Iowa, where he served as the Dean for over seven years. (13 Tr. 2936 (Banker)). Prior to that, Dea Banker was the Dean of the College of Pharmacy at the University of Minnesota for over seven years. (13 Tr. 2936-7 (Banker) During his tenure as a Dean at both the University of Iowa and University of Minnesota, Dean Banker maintained an active rese program during his tenure at the University of Iowa. (13 Tr. 2936 (Banker)). Dean Banker received his Ph.D. from Purdue University in 1957 and immediately joined the Purdue faculty. In 1967, Dean Banker became the Head of the Physical Pharma Department at Purdue, a position he held thereafter for 18 years. (13 Tr. 2938 (Banker)). Over the 45 years of teaching and research in the field of pharmaceutics and pharmaceutical coatings for over 45 years, Dean Banker has focused his efforts prima in the areas of coatings, polymer coatings, new polymers, new polymer excipients, non-drug components and sustained release product design. (13 Tr. 2941 (Banker)).

3.402. For example, the recommended dose of potassium chloride supplement for patients who are hypokalemic is about 40 milliequivalents ("mEq") per day in divided doses. (13 Tr. 3032 (Banker); SPX 194, col. 5, ll. 41-45). Prior to the invention of the '743 patent, the only potassium chloride supplement dosage available was 10 mEq. (13 Tr. 3033 (Banker); SPX 194, col. 5, ll. 42-5). Thus, two doses of 10 mEq is typically administered twice daily in order to obtain a daily dose of 40 mEq. (13 Tr. 3033 (Banker); SPX 194, col. 5, ll. 42-5).

Complaint Counsel's Response to Finding No. 3.402

Complaint Counsel has no specific response.

3.403. When patients require more than 40 mEq of potassium chloride per day, the number of doses and the number of administrations per day required increases. (13 Tr. 2952 (Banker)). To meet the daily requirement of 40 mEq, the patient would need to take two doses of 10 mEq of potassium chloride twice a day or one dose of 20 mEq twice a day. (14 Tr. 3033 (Banker)). In severe cases of hypokalemia, patient compliance becomes more problematic with lower dosage potassium chloride supplement due to the frequency of dosing and the large number of doses required per day, especially for elderly patients who have difficulty in ingesting medications. (13 Tr. 2951-2 (Banker); SPX 194, col. 5, ll. 56-64).

Complaint Counsel's Response to Finding No. 3.403

Complaint Counsel has no specific response.

3.404. Thus, as testified to by Dean Banker, one of the challenges in making potassium chloride supplements is to maximize the amount of potassium chloride in a single tablet, thus reducing the number of doses a patient had to take to meet the same daily requirements. (13 Tr. 2952 (Banker)).

Complaint Counsel's Response to Finding No. 3.404

Complaint Counsel has no specific response.

3.405. The invention of the '743 patent provides a higher dose, 20 mEq, of potassium chloride in a tablet, thus allowing patients to take only half the number of tablets to obtain same dosage required. (13 Tr. 2952 (Banker)).

Complaint Counsel's Response to Finding No. 3.405

Complaint Counsel has no specific response.

3.406. Key practices the invention described in the '743 patent by making and selling K-DUR® 20,[2] a sustained release tablet providing 20 mEq., which corresponds to 1500 milligrams of potassium chloride (SPX 194, col. 6, ll. 24-5; SPX 1274 at ¶ 10 (Banker)).

Complaint Counsel's Response to Finding No. 3.406

Complaint Counsel has no specific response.

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[2] K-DUR® 20 is the registered trademark for Schering's sustained release tablet that provides 20 mEq of potassium chloride.

3.407. Another dosing advantage of the '743 patent or Schering's K-DUR® 20, is the tablet's ability to retain sustained release characteristics even when the tablet is broken in half. (13 Tr. 2957 (Banker)).

Complaint Counsel's Response to Finding No. 3.407

Complaint Counsel has no specific response.

3.408. Schering's K-DUR® 20 tablet includes a score line in the middle of the tablet. (13 Tr. 2957 (Banker)). As Dean Banker testified, a patient could break a 20 mEq tablet into two 10 mEq halves to make a 30 or 50 mEq dose in combination with other tablets. (13 Tr. 2957 (Banker)). Schering's 20 mEq K-DUR® 20 delivers the same amount of potassium chloride as two 10 mEq doses, such that if a patient requires only 10 mEq of potassium chloride per day, the patient could break Schering's 20 mEq dose along the score line and take just half of the tablet. (13 Tr. 2957 (Banker)).

Complaint Counsel's Response to Finding No. 3.408

Complaint Counsel has no specific response.

3.409. Moreover, for higher doses in increments of 10 mEq, one could take half of K-DUR® 20, having 10 mEq of potassium chloride, with another manufacturer's potassium chloride supplement. (13 Tr. 3033-4 (Banker)). Another advantage of Schering's K-DUR® 20 product is its ability to retain the sustained release characteristics despite breakage of the tablet along the score line. (13 Tr. 2957 (Banker)).

Complaint Counsel's Response to Finding No. 3.409

Complaint Counsel has no specific response.

3. Challenges in Formulating Sustained Release 20 mEq Potassium Chloride Tablets

3.410. Dean Banker testified that many difficulties must be overcome in order to make tablets from microencapsulated potassium chloride. (13 Tr. 2964 (Banker); SPX 1274 at ¶ 17 (Banker)). The difficulties associated with tableting include the compression force that must be applied to the coated potassium chloride crystals in order to make a usable tablet and the potential for rupture of the coating material on the potassium chloride crystals from the compression forces applied during the tableting process. (13 Tr. 2964 (Banker); SPX 1274 at ¶ 17 (Banker)).

Complaint Counsel's Response to Finding No. 3.410

[redacted] CX 647 at USL PLD 001637-39

(Prosecution history of the '743 patent). [redacted]

[redacted]

3.411. The problem of potential coating rupture during tabletting is particularly critical in potassium chloride products. (13 Tr. 2964 (Banker); SPX 1274 at ¶ 18 (Banker)). The potassium chloride molecule is both very small and very highly soluble throughout the gastrointestinal tract, so that even slight cracking of the microcapsule coating will destroy the sustained release characteristic of the coating, leading to the immediate "dumping" of the entire potassium chloride content of those fragmented microcapsules into the gastric fluid once swallowed. (13 Tr. 2964 (Banker); SPX 1274 at ¶ 18 (Banker)).

Complaint Counsel's Response to Finding No. 3.411

[redacted]

3.412. The characteristics of potassium chloride crystals present difficulties regarding the tableting of microcapsules of a whole different order than those presented by tableting other coated compounds. (13 Tr. 2964 (Banker); SPX 1274 at ¶ 18 (Banker)). Moreover, to achieve the proper dosage release levels, *i.e.*, a sustained level of potassium chloride release, a large

number of potassium crystals must be evenly coated. (13 Tr. 2964 (Banker)).

Complaint Counsel's Response to Finding No. 3.412

[redacted]

3.413. Finally, these individually coated potassium chloride crystals, coated by a process known as microencapsulation, must be compressed into tablets. (13 Tr. 2964 (Banker)). The tableting process requires exposing the microencapsulated crystals to high compression forces. The difficulty in tableting potassium chloride crystals is compounded by the characteristics of the crystal itself. (13 Tr. 2953 (Banker)).

Complaint Counsel's Response to Finding No. 3.413

[redacted]

3.414. Potassium chloride is an inorganic, ionic molecule that forms a hard "cubic" crystal having sharp edges. (13 Tr. 2964 (Banker); SPX 1274 at ¶ 19 (Banker)). The crystalline

structure of potassium chloride, with its many hard edges, does not provide any appreciable "give" during tableting that might help to prevent coating rupture, and the sharp edges of the crystals increase the risk of rupture. (13 Tr. 2964 (Banker); SPX 1274 at ¶ 19 (Banker)).

Complaint Counsel's Response to Finding No. 3.414

[redacted]

The proposed finding also ignores conflicting evidence that suggests that it was possible to obtain other forms of potassium chloride crystals. In the original patent litigation, Dr. Carstenson, ESI's expert in that case, took the position that Dr. Banker's allegations were inaccurate with respect to the characteristics and processes of the materials involved. He said it was known that cubic crystals (such as inorganic potassium chloride crystals described by Banker) compress easily. Dr. Banker agreed with this view. Tr. at 14:3218-19 (Banker). Dr. Carstenson was prepared to testify that it was known since the early 1990s that one should select the optimum particle shape, Eurand produced roundish potassium crystals with minimized sharp edges. Tr. at 14:3220-21 (Banker). Dr. Banker testified that he did not know about the existence of rounded crystals manufactured by Eurand. Tr. at 14:3221 (Banker).

3.415. By contrast, organic molecules such as aspirin typically form much softer crystals, with substantially greater "give," and have edges that typically become rounded during the coating process. Accordingly, the inventors of the '743 patent were faced with constructing a permeable coating that permitted the sustained release of potassium chloride but resisted breakage during the tabletting process. (13 Tr. 2953 (Banker)).

Complaint Counsel's Response to Finding No. 3.415

[redacted]

The proposed finding is also irrelevant and misleading because potassium chloride crystals were also available in rounded form. *See* CPRF 3.414

3.416. Prior to Schering's development of the invention of the '743 patent, a number of other scientists had attempted to tablet microencapsulated potassium chloride. (13 Tr. 2965 (Banker)). Dean Banker testified that Dr. Larry Miller tried and failed for ten years, while at ESI-Lederle, Inc., to produce a 20 mEq potassium chloride tablet. (13 Tr. 2965 (Banker)). In addition, Dean Banker, noted that he, too, had attempted for many years and failed to make a sustained release potassium crystal tablet. (13 Tr. 2965 (Banker))

Complaint Counsel's Response to Finding No. 3.416

The proposed finding is misleading in that it states that "a number" of other scientists had been unable to tablet microencapsulated potassium chloride when it cites to only two such scientists: (1) Dr. Banker, an expert witness for Key/Schering who cannot be considered to be unbiased; and (2) Dr. Miller.

B. The Invention of '743 Patent

1. Introduction

3.417. The '743 patent, entitled *Controlled Release Potassium Chloride*, was granted on September 5, 1989 to Key as the assignee of an application filed on February 19, 1986 (Appln. No. 830,981) by Charles Hsiao and Chi T. Chou. (SPX 1275 at ¶ 7 (C. Miller)). The '743 patent will expire in September 2006 or 17 years from the issue date of the '743 patent. (15 Tr. 3311 (C. Miller; SPX 1275 at ¶ 8 (C. Miller)).

Complaint Counsel's Response to Finding No. 3.417

Complaint Counsel has no specific response.

2. How the invention of the '743 patent works

3.418. The '743 patent claims a sustained release potassium chloride tablet that is designed to release potassium chloride in a patient's gastrointestinal tract over a sustained period of time while protecting the patient's gastrointestinal mucosa from direct contact with potassium

chloride crystals or harmful concentrations of potassium chloride in gastric or intestinal fluid. (13 Tr. 2948 (Banker); SPX 1274 at ¶ 10 (Banker)).

Complaint Counsel's Response to Finding No. 3.418

Complaint Counsel has no specific response.

3.419. This invention permits the delivery of a relatively high dose of potassium chloride in tablet form in a safe and effective manner. (13 Tr. 2948 (Banker); SPX 1274 at ¶ 10 (Banker)).

Complaint Counsel's Response to Finding No. 3.419

Complaint Counsel has no specific response.

3.420. Key's invention entails coating individual potassium chloride crystals, a process known as "microencapsulation," and then compressing the individually coated crystals (known as "micro-capsules" or "micro-pellets") into a tablet. (13 Tr. 2947-48 (Banker); SPX 1274 at ¶ 12 (Banker)).

Complaint Counsel's Response to Finding No. 3.420

The proposed finding is misleading in that it suggests that the '743 patent covers the process of coating potassium chloride crystals and then compressing them into a tablet. The '743 patent does not purport to cover such processes, only a tablet form of potassium chloride with a particular coating. CX 12 at FTC 0021322-23 (Claims of the '743 Patent).

3.421. The coating material in Key's invention is permeable to gastric fluids, providing the sustained release mechanism for the potassium chloride crystals to leach out. (SPX 1274 at ¶ 13 (Banker); SPX 194, col. 4, ll. 22-8).

Complaint Counsel's Response to Finding No. 3.421

Complaint Counsel has no specific response.

3.422. The material used to coat the potassium chloride crystals consists of ethylcellulose and hydroxypropylcellulose ("HPC"). (The patent also discloses the use of polyethylene glycol ("PEG") as a substitute for some or all of the HPC). (13 Tr. 2969-70 (Banker); SPX 194, col. 4, ll. 18-22, SPX 1274 at ¶ 12 (Banker)).

Complaint Counsel's Response to Finding No. 3.422

Complaint Counsel has no specific response.

3.423. Ethylcellulose, the "major component" of the crystal coating, serves as the primary film-former around the potassium chloride crystals. (SPX 194, col. 4, ll. 4-8; SPX 1274 at ¶ 13 (Banker)). Ethylcellulose is a highly water-insoluble polymer that forms a film having some permeability to water (and to gastric and intestinal fluids). (SPX 1274 at ¶ 13 (Banker)).

Complaint Counsel's Response to Finding No. 3.423

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[redacted]

3.424. "HPC", the "minor component" of the coating, is more supple than ethylcellulose, and it acts to modify the characteristics of the crystal coating. (SPX 1274 at ¶ 13 (Banker); SPX 194, col. 4, ll. 4-8).

Complaint Counsel's Response to Finding No. 3.424

[redacted]

3.425. Dean Banker testified that the patent discloses the use of HPC and PEG as plasticizing agents, in addition to ethylcellulose as a component of the coating material for the

potassium chloride crystal. (13 Tr. 2969-70 (Banker); SPX 1274 at ¶ 21 (Banker); SPX 194, col. 4, ll. 22-31; col. 5, ll. 19-24).

Complaint Counsel's Response to Finding No. 3.425

[redacted] Tr. at 26:6445 (Banakar); [redacted] Dr. Banakar further testified that the '743 invention relates to the dissolution or drug release ability of a controlled release potassium chloride tablet. Tr. at 26:6388 (Banakar).

Dr. Banakar also testified that Upsher's experts in the underlying patent litigation also did not believe that the '743 patent related to the use of a plasticizer. Tr. at 26:6449

(Banakar). [redacted]

[redacted] Tr. at 14:3121-22 (Banker); [redacted] He admitted that a mixture of two polymers will not necessarily act as a plasticizer. Tr. at 13:2917-18 (Banker). [redacted]

[redacted] Dr. Banker at the *Markman* hearing in the underlying patent litigation with ESI could not identify any place in the prosecution history of the '743 patent where HPC or PEG were asserted to be plasticizers. Tr. at 14:3123-24 (Banker). Schering's proposed finding of fact RPF 3.89 states that one of the statutory requirements for the specification of a patent is that the specification contain a written description of the invention in clear, concise and exact terms as to enable one of ordinary skill in the art to which the invention pertains to carry out the invention. It is notable that the '743 patent in its entirety makes no mention of the use of any plasticizer.

3.426. The use of a plasticizing agent with the ethylcellulose renders the coating more flexible and durable and therefore more able to resist the compression forces of tabletting without rupture. (13 Tr. 2970 (Banker); SPX 1274 at ¶ 21 (Banker)).

Complaint Counsel's Response to Finding No. 3.426

The proposed finding is irrelevant for the reasons stated in CPRF 3.425. In addition, it is not supported by the evidence because it was the EC and not the HPC or PEG that the '743 patent touts as making the coating more durable. Indeed, in its proposed finding 3.434, Schering makes this same point that the "patent discloses that coatings made from higher viscosity ethylcellulose have more tensile strength and are better able to withstand tabletting forces." Dr. Banker acknowledged that one of the original inventors of the '743 patent was not sure that HPC served as a plasticizer in the coating. Tr. at 14:3056-58 (Banker). Dr. Banker did not consider Dr. Hsiao's opinion that it was not clear that HPC had any plasticizing effect in the '743 invention. Tr. at 14:3057-58 (Banker). Dr. Banker acknowledged that Ms. Ku, the other original inventor, testified in the original litigation that the film-forming aspects of the EC and HPC were a minor attribute of the coating. Tr. at 14:3070-71 (Banker). Dr. Banker did not do any tests to determine whether HPC is a plasticizer with respect to EC. Tr. at 22:5213 (Banker). **********

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3.427. Dean Banker defined a plasticizer as "a material added to a polymer to enhance its elasticity, give it more stretch, to make it more flexible, to make it stronger, to make it more durable and to reduce brittleness." (13 Tr. 2970 (Banker)).

Complaint Counsel's Response to Finding No. 3.427

The proposed finding is irrelevant because the '743 patent does not disclose the use of a plasticizer. [redacted] Dr. Banakar testified that the '743 invention relates to the dissolution or drug release ability of a controlled release potassium chloride tablet. Tr. at 26:6388-89 (Banakar). A mixture of two polymers will not necessarily act as a plasticizer. Tr. at 13:2917-18 (Langer).

Assuming the '743 patent does disclose use of a plasticizer, the definition contained in the proposed finding places an emphasis on flexibility and durability that is not supported by the evidence. Dr. Hsiao, an inventor of the '743 patent, was not certain as to whether HPC had any effect on the flexibility of the coating. Tr. at 14:3057-58 (Banker). [redacted] Dr. Banker acknowledged that in the underlying patent litigation, Dr. Rhodes, Upsher's expert

witness, had taken the view that the durability of the EC coating was enhanced not by using HPC or EC but by a higher viscosity EC. Tr. at 22:5236 (Banker). [redacted]

The definition of a plasticizer contained in the proposed finding is also incomplete and misleading. [redacted] In sum, Dr. Banakar concluded that Dr. Banker used the term plasticizer as a "catch all" to attempt to show similarity between different coatings. Tr. at 26:6449-50 (Banakar). Dr. Banakar also testified that Schering's attorney never referred to a plasticizer in his responses to the examiner at the patent office. Tr. at 26:6445 (Banakar).

Finally, Dr. Rhodes, a colleague of Dr. Banker, who served as a technical expert for Upsher in the underlying patent litigation, characterized Dr. Banker's theory that HPC and EC are used as a plasticizer in the '743 patented invention as conjecture. Tr. at 26:6449-50 (Banakar).

3.428. Thus, in this manner, HPC serves as a plasticizer used to plasticize the ethylcellulose and to make the film more sustainable to the compression forces used in tabletting. (13 Tr. 2970 (Banker)).

Complaint Counsel's Response to Finding No. 3.428

[redacted] Also, the proposed finding is not supported by the evidence, because Dr. Banker had no basis for concluding that the invention claimed in the '743 patent related to a plasticizer. *See* CPRF 3.425-26. The proposed finding is also irrelevant because the described functions are not the central features of the invention claimed in the '743 patent. Dr. Banker admitted that he applies the term plasticizer to substances that may also perform other functions in a coating. Tr. at 22:5291 (Banker). Dr. Banker admitted that one skilled in the art would understand claim 1 of the '743 patent to be directed to a coating material that achieves a sustained release of potassium chloride in a tablet. Tr. at 22:5210 (Banker). Dr. Banker admitted that the '743 patent refers to a proper balance of EC to HPC being required. Tr. at

22:5210 (Banker). When the '743 patent discusses a "proper balance" it is in the context of achieving a sustained release of the potassium chloride. Tr. at 22:5215 (Banker). Dr. Banker agreed that the '743 patent shows that EC with a viscosity of 10 will provide a controlled release from coated crystals but not from a tablet. Tr. at 22:5219-20 (Banker). Dr. Banker agreed that a co-inventor of the '743 patent, Dr. Hsiao, believed that the HPC used in the '743 patent forms channels in the EC. Tr. at 14:3056 (Banker).

[redacted]

3.429. By using both ethylcellulose and HPC, a coating material for the potassium chloride crystals is created that is sufficiently flexible and durable to resist breakage during compression into a tablet and simultaneously sufficiently water permeable – but not unduly so as to release potassium chloride into the gastrointestinal tract in a controlled and sustained fashion following ingestion. (13 Tr. 2970, 2972 (Banker); SPX 194; SPX 1274 at ¶ 13 (Banker)).

Complaint Counsel's Response to Finding No. 3.429

The proposed finding is misleading because it ignores the fact that the permeability of the coating will vary depending on the viscosity of the EC and the other polymers used. Dr. Banker acknowledged that the Dow Chemical literature explains that by varying the type of Ethocel, the insoluble versus soluble, excipient ratio and the coating weight, wide variations of release rates can be achieved. Tr. at 22:5239 (Banker). Dr. Banker admitted that if you coat with a very high level of EC, the potassium chloride will not come out. Tr. at 14:3069 (Banker). Dr. Banker testified that HPC has some effect on promoting permeability in the '743 patented invention. Tr. at 14:3067 (Banker).

[redacted]

3.430. With this coating material, Key was able to develop the first sustained release 20 mEq potassium chloride tablet composed of individually coated potassium chloride crystals. This breakthrough allowed Key to make a potassium chloride tablet with double the dose of

potassium chloride, 20 mEq, that could be provided to patients in a single, solid oral dosage form. (SPX 1274 at ¶ 14 (Banker)).

Complaint Counsel's Response to Finding No. 3.430

[redacted]

3.431. The coating material also permitted potassium chloride crystals to be coated into tablets containing a very high (up to 86.5%) percentage of potassium chloride as compared to the total weight of the tablet. (SPX 1274 at ¶ 14 (Banker); SPX 194, col. 1).

Complaint Counsel's Response to Finding No. 3.431

Complaint Counsel has no specific response.

3.432. During the time of the Upsher and ESI cases, Key's invention was the only available 20 mEq potassium chloride solid oral dosage form available on the market. (SPX 1274 at ¶ 14 (Banker)).

Complaint Counsel's Response to Finding No. 3.432

Complaint Counsel has no specific response.

3.433. In addition to the dosing advantage, K-DUR® 20 contains a superdisintegrant which allows the coated potassium chloride crystals to immediately disperse throughout the gastrointestinal tract. (SPX 1274 at ¶ 15 (Banker)).

Complaint Counsel's Response to Finding No. 3.430

Complaint Counsel has no specific response.

3.434. The difficulties in tabletting potassium chloride microcapsules were overcome by the invention in the '743 patent. (SPX 1274 at ¶ 21 (Banker); SPX 194, col. 4, ll. 55-7). The patent discloses that coatings made from higher viscosity ethylcelluloses have more tensile strength and hence are better able to withstand tabletting forces. (SPX 1274 at ¶ 21 (Banker); SPX 194, col. 4, ll. 55-7).

Complaint Counsel's Response to Finding No. 3.434

[redacted]

[redacted]

[redacted]

3.435. The K-DUR® 20 dosage form has been described in the literature as a "simple, but elegant, formulation, which is a masterpiece of solid dosage form strategy to achieve clinical goals." E.M. Rudnic and M.K. Kottke, Tablet Dosage Forms, 334 Modern Pharmaceutics (G.S. Banker and C.T. Rhodes, eds., Marcel Dekker, Inc.; 3d ed. 1996)(SPX 721). (13 Tr. 2962 (Banker); SPX 1274 at ¶ 9 (Banker)).

Complaint Counsel's Response to Finding No. 3.435

The proposed finding is not supported by the evidence in that it cites an article, admitted as SPX 721, which is hearsay and was not offered for the truth of the matter asserted but rather to show the parties' positions during litigation. Tr. at 28:7794-95 (attorneys for Schering and complaint counsel discussing admissibility of patent related exhibits before Judge Chappell).

The proposed finding is incomplete and misleading to the extent it refers to K-DUR®20 as an "elegant" formulation. [redacted]

[redacted]

3. Specification of the '743 Patent

3.436. In the '743 patent, the specification begins at col. 1, line 1. (SPX 194; 15 Tr. 3309 (C. Miller)). The claims of the '743 patent are shown in col. 8 as numbered paragraphs from 1 through 12. (15 Tr. 3309-10 (C. Miller)).

Complaint Counsel's Response to Finding No. 3.436

Complaint Counsel has no specific response.

3.437. Particularly, the '743 patent describes and claims a "controlled release" potassium chloride supplement pharmaceutical dosage unit in tablet form dispersible in the gastrointestinal ("GI") tract (col. 1, 11, 11-20) and its therapeutic use comprising "polymer coated" potassium chloride "seed" crystals (col. 1, l. 15; col. 3, ll. 66-7) individually "coated with a polymeric coating which includes" (i) ethylcellulose and (ii) HPC and/or PEG (col. 4, ll. 4-21) through a process known as "microencapsulation" (col. 3, ll. 67-8) to form "micro pellets" (col. 4, ll. 7-8;

col. 5, ll. 65-8) that are "subsequently compressed into the tablet in a conventional manner (col. 3, l. 68 to col. 4, l. 1; col. 5, ll. 16-24). (13 Tr. 2969 (Banker); SPX 1275 at ¶ 9 (C. Miller)).

Complaint Counsel's Response to Finding No. 3.437

Complaint Counsel has no specific response.

3.438. In the context of the '743 patent, the term "controlled-release" (e.g., col. 3, ll. 8-9) is taken to be synonymous with "sustained-release" and "extended-release" appearing in other documents in this case. (SPX 1275 at ¶ 9 (C. Miller)).

Complaint Counsel's Response to Finding No. 3.438

Complaint Counsel has no specific response.

3.439. The '743 patent states that ethylcellulose is a water-insoluble polymer that comes in a range of viscosities (a measure of flow resistance and molecular weight) for use in pharmaceutical coating processes to form low water-impermeability films (SPX 194, col. 4, ll. 51-60; SPX 1275 at ¶ 14 (C. Miller)).

Complaint Counsel's Response to Finding No. 3.439

Complaint Counsel has no specific response.

3.440. The ethylcellulose viscosities in the '743 patent are expressed in units of

"centipoise" or "cp" (SPX 194, col. 4, ll. 62-3; SPX 1275 at ¶ 15 (C. Miller)).

Complaint Counsel's Response to Finding No. 3.440

Complaint Counsel has no specific response.

3.441. The disclosed ethylcelluloses are commercially available under the Dow Chemical trademark Ethocel®. The numerical designations for the Ethocel® series [*e.g.*, Ethocel® 100] generally correspond to the viscosity of the ethylcellulose, with a higher numerical designation indicating a greater viscosity and higher molecular weight (col. 4, ll. 57-63). (13 Tr. 2981 (Banker); SPX 194, col. 4, ll. 57-60).

Complaint Counsel's Response to Finding No. 3.441

Complaint Counsel has no specific response.

3.442. [redacted]

Complaint Counsel's Response to Finding No. 3.442

[redacted]

[redacted]

3.443. [A higher viscosity (which signifies a higher molecular weight) produces a stronger, tougher film, which is less susceptible to breakage during compression (tableting). (SPX 194, col. 4, ll. 55-7; [redacted]

Complaint Counsel's Response to Finding No. 3.443

Complaint Counsel has no specific response.

3.444. "Useful" ethylcellulose viscosities are described as being greater than 6 cp (SPX 194, col. 4, ll. 63-5), with "preferred" viscosities of more than 40 cp being specifically disclosed

(SPX 194, col. 4, ll. 65-6) for use in compressing potassium chloride crystals into tablets. (SPX 1275 at ¶ 17 (C. Miller)).

Complaint Counsel's Response to Finding No. 3.444

The proposed finding is misleading because it implies that a viscosities beginning above 6cp would be useful in producing tablets. During prosecution of the '743 patent, Schering took the position that the sustained release achieved by the invention only occurred at the 40 or greater viscosity. Tr. at 32:7716-17 (Adelman); CX 647 at USL PLD 001644 (Prosecution history of the '743 patent). The only data that the '743 patent provides for is for EC10 viscosity and EC100 viscosity. Tr. at 22:5242 (Banker). [redacted] Dr. Banker has asserted that EC 10 viscosity would not work to make tablets. Tr. at 22:5242 (Banker). [redacted]

3.445. With respect to the molecular weight of the ethylcellulose, the specification of the '743 patent discloses:

It is particularly preferred to use a higher molecular weight ethyl cellulose such as that designated as 100 and sold under the trademark Ethocel® Standard Premium 100 or Ethocel® Medium 100 by Dow Chemical. The use of higher molecular weight material like the 100 designation material limits breakage during compression. The numerical

designations for ethylcellulose generally correspond to the viscosity of the product, with a higher numerical designation indicating a greater viscosity and higher molecular weight. The 100 designation corresponds to a viscosity of about 85-100 cp as measured in a 5% solution in an 80% toluene-20% ethanol solvent. The useful ethylcellulose designations are 7 and higher, corresponding to a viscosity of at least 6 cp, preferably more than 40 cp (designation 45 or higher) for crystals to be compressed into tablets. The ethoxyl content can be about 45-49.5%, preferably 45-46.5%. The present inventors determined that ethylcellulose 100 was preferred as compared with other ethylcellulose products as there is less breakage during compression. The lower viscosity ethylcelluloses, such as the type 10, are especially useful in making coated crystals for administration in capsules, when breakage from compression is not a problem.

(SPX 194, col. 4, l. 51 – col. 5, l. 6; SPX 1275 at ¶ 17 (C. Miller)).

Complaint Counsel's Response to Finding No. 3.445

Complaint Counsel has no specific response.

3.446. There is no express disclosure in the '743 patent specification of any ethylcellulose viscosity between "at least 6 cp" (SPX 194, col. 4, ll. 64-5) and "more than 40 cp" (SPX 194, col. 4, ll. 5). (SPX 1275 at ¶ 18 (C. Miller)).

Complaint Counsel's Response to Finding No. 3.446

The proposed finding is incomplete and inconsistent with Respondent Schering's

Proposed Finding No. 3.447. The finding is inconsistent in that there is an express disclosure of a viscosity of 85-110 cp, which is a range that is "more than 40 cp", as indicated in Schering's Proposed Finding No. 3.447. The finding is incomplete in that it omits reference to the prosecution history of the '743 patent, in which Schering repeatedly argues the importance of using EC with a viscosity greater than 40 cp. Tr. at 32:7716-17 (Adelman).

3.447. Examples 1 and 2 of the '743 patent present comparative potassium chloride release rate data for coated potassium chloride crystals and tablets using ethylcellulose having a viscosity about 10 cp (Ethocel® 10) and ethylcellulose having a viscosity of 85-110 cp (Ethocel® 100), with PEG (Example 1) and HPC (Example 2). (SPX 194, col. 6, l. 10 – col. 7, l. 36; SPX 1275 at ¶ 19 (C. Miller)).

Complaint Counsel's Response to Finding No. 3.447

Complaint Counsel has no specific response.

3.448. The '743 patent specification states that HPC and PEG serve to facilitate the passage ("controlled release") of gastric fluids and potassium chloride through the coating after the micro pellets have been dispersed in the aqueous environment of the digestive tract when the tablet is disintegrated upon being swallowed. (SPX 194, col. 4, ll. 22-31, col. 5, ll. 19-24; SPX 1275 at ¶ 20 (C. Miller)).

Complaint Counsel's Response to Finding No. 3.448

Complaint Counsel has no specific response.

3.449. The specification further states, at column 4, lines 14-31:

> By providing the proper balance of the ethylcellulose to the hydroxypropylcellulose a polymer film can be formed on the seeds which will remain intact in the stomach (and afterwards) but which is permeable to gastric fluids, which dissolve and leach out the potassium chloride contained in the coated crystals (micro pellets). Further, these micro pellets will separate quickly upon reaching the stomach and thus avoid the accumulation of any large amount of KCl which could cause irritation.

(SPX 194; SPX 1275 at ¶ 21 (C. Miller)).

Complaint Counsel's Response to Finding No. 3.449

Complaint Counsel has no specific response.

3.450. The HPC and PEG described in the '743 patent have been commercially available under the trademarks Klucel® (Hercules) and Carbowax® (Union Carbide), respectively. (SPX 194, col. 4, ll. 14-21; SPX 1275 at ¶ 22 (C. Miller)).

Complaint Counsel's Response to Finding No. 3.450

Complaint Counsel has no specific response.

4. Prosecution History of the `743 Patent (SPX 676)

a. Application as Filed

3.451. The application for the '743 patent was a continuation-in-part ("c-i-p") application of an original, co-pending ("parent") application, bearing serial number 06/702,714, that was filed a year earlier on February 19, 1985 (Appln. No. 702,714). (SPX 1275 at ¶ 7 (C. Miller); SPX 676; SPX 194, col. 1, ll. 7-9).

Complaint Counsel's Response to Finding No. 3.451

Complaint Counsel has no specific response.

3.452. The '981 application as filed contained thirteen (13) claims and were all directed to a "pharmaceutical dosage unit for oral administration of potassium chloride" (claims 1-11), and administering the same to a patient in need of potassium (claims 12 and 13). (SPX 1275 at ¶ 23 (C. Miller); SPX 676).

Complaint Counsel's Response to Finding No. 3.452

Complaint Counsel has no specific response.

3.453. Claim 1 as originally filed, recites as follows:

1. A dosage unit for oral administration of potassium chloride comprising: a plurality of coated potassium chloride crystals, the amount of potassium chloride being in the range of about 68% to about 86.5% by weight based on the total weight of the dosage unit; a coating material for the individual potassium chloride crystals, the coating material comprising ethylcellulose in an amount in the range of about 9% to about 15 % by weight based on the total weight of the coated crystals and at least one member selected from hydroxypropylcellulose and polyethylene glycol in an amount in the range of about 0.5% to about 3% by weight based on the total weight of the coated crystals.

(SPX 676).

Complaint Counsel's Response to Finding No. 3.453

Complaint Counsel has no specific response.

3.454. ********** 32

Tr. 7707 (Adelman)).

Complaint Counsel's Response to Finding No. 3.454

Complaint Counsel has no specific response.

b. First Office Action, dated February 18, 1988 (SPX 706)

3.455. On February 18, 1988, the USPTO examiner in charge of examining the c-i-p application issued an initial office action rejecting claims 1-13 under the doctrine of obviousness-type double patenting over U.S. Patent No. 4,555,399, ("the Hsiao '399 patent"). (SPX 1275 at ¶ 24 (C. Miller); SPX 706 at 2).

Complaint Counsel's Response to Finding No. 3.455

The proposed finding is incomplete in that it omits additional statements by the examiner regarding his rejection for obviousness type double patenting. In the examiner's first office action, the examiner further stated that although the claims of the '743 patent application and the '399 patent are not identical, "they are not patentably distinct from each other because the substitution of potassium chloride for aspirin in the same formulation would appear to be at least prima facie obvious." Tr. at 32:7710-11 (Adelman); CX 647 at USL PLD 001601-04 (Prosecution history of the '743 patent).

3.456. Additionally, the examiner stated that the invention covered by claim 10 is patently distinct from the invention covered by claim 11. (SPX 706 at 3). Thus, the examiner required Key to elect one of the two species recited in independent product claim 1 and dependent product claims 10 and 11. (SPX 706 at 3).

Complaint Counsel's Response to Finding No. 3.456

Complaint Counsel has no specific response.

3.457. In making this requirement, the examiner contended that these claims were mutually patentably distinct, i.e., potassium chloride crystals having a coating with HPC (claim 10) and potassium chloride crystals having a coating with PEG (claim 11) are different inventions. (SPX 1275 at ¶ 25 (C. Miller)).

Complaint Counsel's Response to Finding No. 3.457

Complaint Counsel has no specific response.

3.458. This "election of species" requirement does not mean that the USPTO was asking the applicants to narrow or limit the invention. (SPX 1275 at ¶ 25 (C. Miller)). [redacted]

Complaint Counsel's Response to Finding No. 3.458

Complaint Counsel has no specific response.

3.459. The election requirement had no effect on the scope of the claims. (SPX 1275 at ¶ 25 (C. Miller)). [redacted]

Complaint Counsel's Response to Finding No. 3.459

[redacted] See Schering's Proposed Findings 3.484 and 3.578.

c. First Response to Office Action dated June 22, 1988 (SPX 707)

3.460. In response to the Examiner's rejections in the February 18 Office Action, Key submitted a response on June 22, 1988. (SPX 707 at 1). In this response, Key argued that the Examiner's rejections were improper, and that the claims in the application should be allowed as a patent. (SPX 1275 at ¶ 26 (C. Miller); SPX 707 at 3, 7).

Complaint Counsel's Response to Finding No. 3.460

Complaint Counsel has no specific response.

d. Second Office Action dated August 31, 1988 (SPX 708)

3.461. On August 31, 1988 the examiner issued a second office action, in which he withdrew the double patenting rejection over the Hsiao '399 patent and the election of species requirement, and raised a new rejection of all the claims (1-14) over the prior art. (SPX 1275 at ¶ 27 (C. Miller); SPX 708 at 3).

Complaint Counsel's Response to Finding No. 3.461

The proposed finding is misleading in that it purports to decouple the rejection in the examiner's first office action, under the doctrine of obviousness double patenting, with the rejection in the examiner's second office action. Complaint counsel's patent law expert, Prof. Martin J. Adelman, testified that while in the second office action the examiner conceded that the double patenting rejection was technically incorrect. He nonetheless still rejected the pending claims of the '743 patent application as obvious over the '399 patent and other patents. Tr. at 32:7712-13 (Adelman); CX 647 at USL PLD 001637-39 (Prosecution history of the '743 patent). In effect, the examiner maintained his position that the claims of the '743 patent were obvious in view of certain prior art, notably the '399 patent, while adopting the technically correct type of rejection. Tr. at 32:7712-13 (Adelman).

3.462. The examiner based this new rejection a combination of the Hsiao '399 patent, U.S. Patent No. 3,538,214, issued to Polli et al., U.S. Patent Nos. 4,519,801 and 4,553,973, issued to Edgren, U.S. Patent No. 4,666,703, issued to Kopf and U.S. Patent No. 4,629,620, issued to Lindahl et al. (SPX 1275 at ¶ 27 (C. Miller); SPX 708 at 3).

Complaint Counsel's Response to Finding No. 3.462

The proposed finding is misleading in that it purports to decouple the rejection in the examiner's first office action, under the doctrine of obviousness double patenting, with the rejection in the examiner's second office action. *See* CPRF 3.461

3.463. The examiner argued that in view of the Hsaio '399 patent disclosure, it would be prima facie obvious to use a coating of ethylcellulose and HPC to coat potassium chloride. (SPX 708 at 3).

Complaint Counsel's Response to Finding No. 3.463

The proposed finding is misleading in that it purports to decouple the rejection in the examiner's first office action, under the doctrine of obviousness double patenting, with the rejection in the examiner's second office action. *See* CPRF 3.461

c. Second Response to Office Action dated March 1, 1989 (SPX 709)

3.464. In its March 1, 1989 response, Key deleted claims 2 and 8. Also, Key (i) amended the preamble of claim 1 to recite a "pharmaceutical" dosage unit "in tablet form", and (ii) amended the recitation of the coating material in claim 1 by adding the phrase "said ethylcellulose has a viscosity greater than 40 cp." (SPX 709 at 1-2; SPX 1275 at ¶ 28 (C. Miller)).

Complaint Counsel's Response to Finding No. 3.464

The proposed finding is incomplete in that it omits any reference to Schering's arguments in support of its amendments and misleading in that it attempts to decouple Schering's amendments from its arguments to the examiner in its response to the second office action. Complaint counsel's patent law expert, Prof. Adelman, testified that Schering responded to the PTO's second office action with more amendments, and its

arguments were primarily directed to pending claim 1 and were principally responsible for the change in the scope of claim 1 between the time of filing and issuance. Tr. at 32:7707-08, 7713-7718 (Adelman); CX 647 at USL PLD 001641-48 (Prosecution history of the '743 patent). Prof. Adelman testified that prior to the amendments, Schering had sought coverage under claim 1 for a coating material with ethylcellulose, without any limitation on its viscosity. Tr. at 32:7713-14 (Adelman); CX 647 at USL PLD 0001641-42 (prosecution history of the '743 patent).

3.465. In addition to distinguishing the cited Polli et al., Edgren, Kopf and Lindahl et al. references, Key noted that the Hsiao '399 patent describes a coating material different from that recited in the claims of the c-i-p application in that the coating material described in the Hsiao '399 patent (i) was intended for an aspirin tablet, and (ii) contained ethylcellulose having a viscosity of only about 10 cp. (SPX 709 at 5; SPX 1275 at ¶ 29 (C. Miller)).

Complaint Counsel's Response to Finding No. 3.465

[redacted]

See CPRF 3.466.

3.466. Citing Examples 1 and 2 of the application specification, Key argued that, because the present claims were amended to recite a material specifically for coating a potassium chloride tablet and which contains ethylcellulose with a higher viscosity (greater than 40 cp) than the viscosity (9-11 cp) disclosed in the Hsiao '399 patent, an unexpected advantageous result was obtained in regard to the potassium chloride release ratio in the tableted vs. untableted micro pellets, and on that basis the subject matter claimed in the application was represented as being patentable over the disclosure in the Hsiao '399 patent:

> There is no teaching that crystals of potassium chloride coated with a combination of polymeric materials containing ethylcellulose having a viscosity greater than 40 cp would provide a compressed tablet exhibiting sustained release properties whereas a similar compressed tablet made from potassium chloride crystals coated with a material containing an ethylcellulose polymer having a viscosity of 9-11 cp would not exhibit sustained release characteristics. The examples in the instant application clearly demonstrates this point. (SPX 709 at 7; SPX 1275 at ¶ 29 (C. Miller)).

Complaint Counsel's Response to Finding No. 3.466

The proposed finding is incomplete in that it does not fully disclose all arguments made by Schering in its response to the examiner's second office action, particularly those related to the viscosity of the ethylcellulose used in the claimed invention.

Schering's response to the second office action states, in pertinent part:

> A careful analysis of the ['399 patent] would not lead one skilled in the art to utilize an ethylcellulose polymer having a viscosity greater than 40 cp and preferably a viscosity of about 85-110 cp to produce a sustained release potassium

> chloride tablet. The ['399 patent] discloses that the major component of the polymeric coating used in coating the aspirin material is ethylcellulose, however, there is no teaching or indication as to the type of grade of ethylcellulose that can be utilized in preparing the aspirin tablet of the invention.

Tr. at 32:7716 (Adelman); CX 647 at USL PLD 001644-1645 (Prosecution history of the '743 patent). Schering further argued that the only disclosure of viscosity of ethylcellulose in the '399 patent was a viscosity of 10 cp and that "grade of ethylcellulose utilized in practicing the present invention is important to obtain potassium chloride tablets exhibiting controlled release properties". Tr. at 32:7716-17 (Adelman); CX 687 at USL PLD 001644-1645 (Prosecution history of the '743 patent). The proposed finding is also incomplete in that it omits any reference to the other options available to Schering, yet not pursued by it, in its response to the second office action. Prof. Adelman testified that Schering could have responded much differently to the examiner's repeated rejections of its pending claims. Prof. Adelman testified that while Schering could have maintained that the drug formulation in its invention, potassium chloride, was so different from the aspirin in the '399 patent that the '399 patent did not render its invention obvious, it did not. Tr. at 32:7718 (Adelman).. Schering could have submitted these arguments without amending or limiting its claims, but it did not. Tr. at 32:7718 (Adelman). **

[redacted]

3.467. Schering also indicated that the viscosity of the ethylcellulose was "important" in practicing the invention. (SPX 709 at 7).

Complaint Counsel's Response to Finding No. 3.467

[redacted] *See* CPRF 3.466.

f. Notice of Allowance, dated March 31, 1998 (SPX 676)

3.468. On March 31, 1989, the PTO, without further comment, allowed all of the claims remaining in the case (claims 1, 3-7 and 9-14) whereupon the application matured into the '743 patent containing product claims 1 through 9 and 12 (corresponding to application claims 1, 3-7, 9-11 and 14, respectively), and method-of-treatment claims 10 and 11 (corresponding to application claims 12 and 13, respectively). (SPX 1275, ¶ 30 (C. Miller)).

Complaint Counsel's Response to Finding No. 3.468

[redacted]

[redacted] See 3.466.

3.469. The patent issued in the normal course on September 5, 1989. (SPX 1275 at ¶ 7 (C. Miller)).

Complaint Counsel's Response to Finding No. 3.469

Complaint Counsel has no specific response.

V. KEY PHARMACEUTICAL INC., V. ESI-LEDERLE, INC. ("THE *ESI* CASE")

A. Procedural Background of the *ESI* Case

1. ESI's Abbreviated New Drug Application ("ANDA")

3.470. In 1995, ESI sought approval from the FDA to market a generic version of Schering's sustained release potassium chloride tablet, called K-DUR® 20. (SPX 678; CX 58).

Complaint Counsel's Response to Finding No. 3.470

Complaint Counsel has no specific response.

3.471. Schering's K-DUR® 20 product is protected by the '743 patent, and Schering had listed the '743 patent in the *Approved Drug* Product *with Therapeutic Equivalence Evaluations*, the so-called "*Orange Book*." (SPX 679 at 5). Therefore, as part of the approval process, ESI was required to make a certification and notify Schering regarding how its product compared to the '743 patent. *See* also 21 U.S.C. §355 (j)(2)(B)(ii). (15 Tr. 3321 (C. Miller); SPX 678 at 1).

Complaint Counsel's Response to Finding No. 3.471

Complaint Counsel has no specific response.

2. Paragraph IV Certification

3.472. ESI filed a Paragraph IV certification on December 29, 1995, notifying Key that it had submitted an ANDA to the FDA containing data from a bioequivalent study demonstrating Micro-K® 20's bioequivalency to Schering's K-DUR® 20 tablets.3 Additionally, ESI claimed that its product, called MICRO-K20, did not infringe the '743 patent. (SPX 678 at 1). In particular, ESI claimed that it did not infringe the '743 patent because it did not use a mixture of ethylcellulose with either HPC or PEG. (SPX 678 at 1).

Complaint Counsel's Response to Finding No. 3.472

Complaint Counsel has no specific response.

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3 ESI's product was called Micro-K® 20. (15 Tr. 3320 (C. Miller)).

3.473. Within 45 days of receiving this letter, Schering sued ESI for "willful and deliberate" infringement of the '743 patent, as required under 21 U.S.C. § 355(j)(5)(B)(iii). (15 Tr. 3319-20 (C. Miller)).

Complaint Counsel's Response to Finding No. 3.473

Complaint Counsel has no specific response.

3.474. Dean Banker and Mr. Miller both reviewed ESI's Paragraph IV certification in preparing their respective expert reports and testimony. (13 Tr. 2946 (Banker); 15 Tr. 3321 (C. Miller)). Dr. Banakar and Mr. Adelman did not review this certification. (23 Tr. 5427 (Banakar); 32 Tr. 7726 (Adelman)).

Complaint Counsel's Response to Finding No. 3.474

The proposed finding is misleading in that it does not cite any evidence supporting the proposition that review of ESI's paragraph IV certification was important in rendering opinions by the technical and patent law experts in this proceeding.

3. Pleadings from the ESI Case

3.475. Schering sued ESI for infringement in the U.S. District Court for the Eastern District of Pennsylvania on February 16, 1996. (15 Tr. 3319 (C. Miller); SPX 679, *Complaint*). The case was assigned to the Hon. Jan DuBois. (15 Tr. 3319 (C. Miller)). As was its right,

Schering sought an injunction that would have prevented ESI from marketing its generic version of K-DUR® 20 for the remaining life of the '743 patent. (15 Tr. 3320-21 (C. Miller)).

Complaint Counsel's Response to Finding No. 3.475

Complaint Counsel has no specific response.

3.476. ESI filed an answer and counterclaim for a declaratory judgment. (SPX 680). ESI made conclusory allegations of non-infringement and invalidity of the '743 patent. It again specifically claimed that the '743 patent was limited to a homogeneous mixture of ethylcellulose and HPC or PEG, and that ESI therefore did not infringe the '743 patent. (SPX 680)

Complaint Counsel's Response to Finding No. 3.476

The proposed finding is incomplete. AHP prepared a comprehensive defense to infringement. AHP's technical experts, Dr. Harold B. Hopfenberg and Mr. William O. Butler, filed expert reports. SPX 693* (Expert Report of Mr. Hopfenberg); SPX 695* (Expert Report of Dr. Hopfenberg with Mr. Butler). Furthermore, Dr. Hopfenberg testified at the Markman hearing and was prepared to testify at trial that the ESI product did not infringe the '743 patent. Tr. at 15:3379, 3381, 3390-92 (Miller); SPX 687* (Transcript of the *Markman* hearing including Dr. Hopfenberg's testimony); SPX 693* at ESI EXP 000723-728 (Expert Report of Dr. Hopfenberg); SPX 695* (Expert Report of Dr. Hopfenberg with Mr. Butler). Similarly, Dr. Hopfenberg was prepared to testify that the '743 patent was invalid. SPX 693* at ESI EXP 000728-735 (Expert Report of Dr. Hopfenberg).

3.477. During the course of the ESI case, Drs. Langer and Banker served as technical experts and duly prepared and submitted expert reports. (13 Tr. 2792 (Langer); 13 Tr. 2946 (Banker)). Both Drs. Langer and Banker were prepared to testify during trial. (13 Tr. 2792 (Langer); 13 Tr. 2946 (Banker)). Dean Banker, in fact, testified during the Markman Hearing. (13 Tr. 2946 (Banker)).

Complaint Counsel's Response to Finding No. 3.477

The proposed finding is incomplete in that it omits any reference to ESI's technical experts, Drs. Hopfenberg and Carstenson and Mr. Butler. Dr. Hopfenberg testified at the Markman hearing and was prepared to testify at the trial. Tr. at 15:3379, 3381, 3390 (Miller); SPX 687* (Transcript of *Markman* hearing including Dr. Hopfenberg's testimony); SPX 695* (Expert Report of Dr. Hopfenberg with Mr. Butler).

B. The "Mixing" Infringement Issue was the Dispositive Issue

3.478. Charles Miller, an experienced patent litigator with a Ph.D. in Chemistry, spent hundreds of hours reviewing the pleadings, depositions, expert reports, and documentary evidence in the ESI case.4 (15 Tr. 3321-23 (C. Miller)).

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4 Charles Miller is a senior partner at Pennie & Edmonds LLP in New York City. (15 Tr. 3275 (C. Miller)). Pennie & Edmo specializes in intellectual property law since its founding in 1883. Mr. Miller's practice at Pennie & Edmonds consists of advisi clients with respect to litigation, patent prosecution and counseling clients on intellectual property matters. (15 Tr. 3278 (C. Miller)). Mr. Miller has been the lead counsel in several patent infringement cases and has represented numerous clients in arbitration matters. (15 Tr. 3278 (C. Miller)). Mr. Miller has served as an arbiter under the auspices of the American Arbitratic Association, the International Chamber of Commerce and the World Intellectual Property Organization. (15 Tr. 3278-79 (C. Miller)). Mr. Miller was appointed by the U.S. District Court for the District of Massachusetts as a special master in a patent infringement litigation. (15 Tr. 3279 (C. Miller)). As a special master, Mr. Miller conducted evidentiary hearings, made rulings the admissibility of evidence and rendered a special master's report containing findings of fact and conclusions of law for a trail lasted over several months. (15 Tr. 3279 (C. Miller)). The parties subsequently settled the litigation after reviewing Mr. Miller

Complaint Counsel's Response to Finding No. 3.478

[redacted] Tr. at 15:3293-94 (Miller); [redacted]

[redacted] Tr. at 15:3287-88, 3392-93 (Miller); [redacted]

3.479. The dispositive issue that would have decided the ESI case was the infringement issue based on ESI's "mixing" contentions. 15 Tr. 3302-03 (C. Miller); 26 Tr. 6431-32 (Banakar)).

Complaint Counsel's Response to Finding No. 3.479

The proposed finding is incorrect in that its states that the dispositive issue in the ESI was infringement. In fact, even if Schering had carried its burden of proving that ESI's product infringed the '743 patent, ESI could still have won the litigation by

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report. (15 Tr. 3279-80 (C. Miller)).

Mr. Miller graduated from Columbia College with a Bachelor's Degree in Chemistry in 1963, and subsequently received a Master's of Science degree and a Ph.D. from Columbia University in Organic Chemistry in 1966. (15 Tr. 3277-78 (C. Miller)). Mr. Miller obtained his law degree from New York University in 1970. (15 Tr. 3277 (C. Miller)). Mr. Miller is a member of al four Federal District Courts in the State of New York, and is an active member of various bar associations. Additionally, Mr. M has been a member of the United States Patent and Trademark Office since 1967. (15 Tr. 3277 (C. Miller)).

showing that the patent was invalid and/or unenforceable. Tr. at 15:3323 (Miller).

The proposed finding is incorrect in its characterization of the "mixing" issue as the only infringement issue. [redacted] Tr. at 15:3326-27 (Miller); [redacted] Schering's Proposed Finding 3.494.

3.480. The affirmative defenses that ESI plead in its Amended Answer other than non-infringement included patent invalidity, unenforceability on the grounds of inequitable conduct and patent misuse. (SPX 680, *Amended Answer of Defendant ESI-Lederle, Inc.* at 8-17).

Complaint Counsel's Response to Finding No. 3.480

Complaint Counsel has no specific response.

3.481. ESI's defenses other than infringement were not strong and were not likely to effect the outcome. (15 Tr. 3323 (C. Miller)).

Complaint Counsel's Response to Finding No. 3.481

The proposed finding is incomplete and misleading in that the only evidence cited in support of the statement that the ESI's defenses were not strong and not likely to affect the outcome was the testimony of Mr. Miller, a patent law expert for Schering, *is not a*

technical expert qualified to offer opinions on dispositive technical issues in the underlying patent litigations. Tr. at 15:3287-88, 3392-95 (Miller). Accordingly, Mr. Miller is not qualified to render opinions as to the merits or likelihood of success of ESI's defenses.

The proposed finding is incomplete in that it omits reference to the fact that ESI was prepared to present evidence of the invalidity and/or unenforceability of the '743 patent. With respect to the issue of invalidity, ESI's technical expert in the underlying litigation, Dr. Harold Hopfenberg, was prepared to testify that the '743 patent was obvious in view of the '399 patent and another prior art patent, U.S. Patent No. 4,462,982. SPX 693* at ESI EXP 000728-735 (Expert Report of Dr. Hopfenberg).

With respect to the issue of unenforceability, ESI argued that the '743 patent was unenforceable due to certain omissions and misrepresentations by Schering during prosecution of the '743 patent before the PTO. SPX 685* at ESI PLD 002718-2736 (ESI's Opposition to Key's Motion for Summary Judgment on Defense of Inequitable Conduct). In its opposition, ESI argued, inter alia, that Schering intentionally withheld material data form the PTO showing that controlled release potassium chloride tablets could be prepared with EC with a viscosity of 10 cp. SPX 685* at ESI PLD 002718-2736 (ESI's Opposition to Key's Motion for Summary Judgment on Defense of Inequitable Conduct). ESI argued that this data directly contradicted the arguments Schering made to the examiner to secure allowance that related to the criticality of high viscosity EC to such an extent that its arguments were misrepresentations. SPX 685* at ESI PLD 002718-2736 (ESI's Opposition to Key's Motion for Summary Judgment on Defense of

Inequitable Conduct). In support of its assertions, ESI cited sworn deposition testimony by the inventors and documents prepared by other chemists at Schering. SPX 685* at ESI PLD 002718-2736 (ESI's Opposition to Key's Motion for Summary Judgment on Defense of Inequitable Conduct).

3.482. Thus, the dispositive issue that would have decided the ESI case was the infringement issue based on ESI's "mixing" contentions. (15 Tr. 3323 (C. Miller); 26 Tr. 6431-32 (Banakar)).

Complaint Counsel's Response to Finding No. 3.482

The proposed finding is identical to Schering's Proposed Finding No. 3.479, but for the addition of the word "thus". Accordingly, *See* CPRF 3.479.

3.483. Indeed, Dr. Banakar, Complaint Counsel's only witness testifying regarding the patent issues in the ESI case agreed and was prepared to testify on the issue of infringement only. (26 Tr. 6431-32 (Banakar)).

Complaint Counsel's Response to Finding No. 3.483

The proposed finding is incomplete and misleading in that it implies that because Dr. Banakar did not testify on the validity of the '743 patent, complaint counsel has conceded the validity and enforceability of the '743 patent. In fact, the district courts in the underlying patent litigation made no findings on the validity and/or unenforceability of the '743 patent. Schering Second Admissions Nos. 129-130. Moreover, complaint

counsel never has conceded that the '743 patent is valid and enforceable. Complaint Counsel's Supplemental Responses to Schering's Second Interrogatories Nos. 13-16

C. Claim 1 of the '743 Patent Covers a Coating Material Having one or more layers of ethylcellulose and HPC

3.484. The broadest product claim in the '743 patent, and the patent claim most relevant to the *ESI* litigation, is claim 1. (Miller 3320; Miller, SPX 1272 at ¶ 30).

Complaint Counsel's Response to Finding No. 3.484

Complaint Counsel has no specific response.

3.485. Reproduced below is SPX 2041 (demonstrative), which summarizes the infringement issue in the ESI case. (15 Tr. 3320 (C. Miller); SPX 1275 at ¶ 30 (C. Miller)).

Complaint Counsel's Response to Finding No. 3.485

The chart contained in the proposed finding of fact is a demonstrative and not in evidence.

ESI's Product Infringes the Schering Patent

Claim 1 of U.S. Patent No. 4,963,743	ESI's Product
A pharmaceutical dosage unit in tablet form for oral administration of potassium chloride, comprising:	**YES.** ESI's Product is an orally administrated potassium chloride tablet.
a plurality of coated potassium chloride crystals, the amount of potassium chloride being in the range of about 68% to about 86.5% by weight based on the total weight of the dosage unit;	**YES.** ESI's Product contains a plurality of coated potassium chloride crystals in an amount of about 70% to about 79% of the total weight of the tablet.
a coating material for the individual potassium chloride crystals, the coating material comprising ethylcellulose in the amount in the range of about 9% to about 15% by weight based on the total weight of the coated crystals and	**YES.** The coating material in ESI's Product contains ethylcellulose. The amount of ethylcellulose in ESI's Product is between about 10% and about 13% by weight based on the total weight of the coated crystals.
at least one member selected from hydroxypropylcellulose and polyethylene glycol in an amount in the range of about 0.5% to about 3% by weight based on the total weight of the coated crystals and	**YES.** The coating material in ESI's Product contains hydroxypropylcellulose ("HPC"). The amount of HPC in ESI's Product is approximately 1% of the total weight of the coated crystals.
said ethylcellulose has a viscosity greater than 40 cp.	**YES.** ESI's Product uses Ethocel® 100 with a viscosity of 85 to 110.

Source: Expert Report of Dean Gilbert S. Banker, ¶19, 20. SPX 2041

1. Parties Agreed On All Other Elements of Claim 1 Except the Interpretation of the term "Coating Material"

3.486. With respect to infringing claim 1 of the '743 patent, the parties are in agreement regarding all the elements of the claim except for the interpretation of the claim term "coating

material." (13 Tr. 2976-81 (Banker); 26 Tr. 6387, 6391 (Banakar); 19 Tr. 4362 (Banakar); 15 Tr. 3328 (C. Miller)).

Complaint Counsel's Response to Finding No. 3.486

Complaint Counsel has no specific response.

3.487. Aside from the question of whether the term "coating material" requires a mixture all of the elements of claim 1 were found in the ESI product. (13 Tr. 2976-81 (Banker); 26 Tr. 6387, 6391 (Banakar); 19 Tr. 4362 (Banakar); 15 Tr. 3328 (C. Miller)).

Complaint Counsel's Response to Finding No. 3.487

Complaint Counsel has no specific response.

3.488. ESI used potassium chloride, ethylcellulose, and HPC, all within the ranges required by claim 1. (13 Tr. 2976-81 (Banakar); 26 Tr. 6432-33 (Banakar); 15 Tr. 3328 (C. Miller)).

Complaint Counsel's Response to Finding No. 3.488

Complaint Counsel has no specific response.

3.489. Claim 1 of the '743 patent calls for a pharmaceutical dosage in tablet form for orally administering potassium chloride. (13 Tr. 2979 (Banker)). ESI did not dispute that its product was a tablet and thus met the '743 patent's preamble, which called for "[a] pharmaceutical dosage unit in tablet form." (13 Tr. 2981 (Banker); SPX 194, col. 8, ll. 18-33; 15 Tr. 3329 (C. Miller)).

Complaint Counsel's Response to Finding No. 3.489

Complaint Counsel has no specific response.

3.490. Claim 1 of the '743 patent also recites a tablet comprised of a plurality of coated potassium chloride crystals with the amount of potassium chloride being in the range of about 68 to 86.5 percent by weight based on the total weight of the dosage unit. (13 Tr. 2979 (Banker)). ESI also did not dispute that its product contained "a plurality of coated potassium chloride crystals…." in the range the claim required. (13 Tr. 2979-81 (Banker); SPX 194; 15 Tr. 3329 (C. Miller)).

Complaint Counsel's Response to Finding No. 3.490

Complaint Counsel has no specific response.

3.491. A third element of the '743 patent claims a coating material in an amount in the range of about 9 percent to about 15 percent by weight based on the total weight of the coated crystals. (13 Tr. 2980 (Banker)). In the ESI product, the coating material contains ethylcellulose in an amount between 10 and 13 percent by weight based on the total weight of the coated crystals, well within the range recited in the '743 patent. (13 Tr. 2980 (Banker)). Additionally, ESI did not dispute that its product contained ethylcellulose in the amount required by claim 1. (13 Tr. 2981 (Banker); 15 Tr. 3330 (C. Miller)).

Complaint Counsel's Response to Finding No. 3.491

The statement is misleading in that it refers to ESI's "coating material" rather than

ESI's product. The proper construction of "coating material" and the nature of ESI's "coating material" were disputed issues in the underlying litigation. Schering's Proposed Finding No. 3.494.

3.492. The fourth element of the '743 patent claims the use of at least one member selected from HPC and PEG in an amount in the range of about 0.5 to 3 percent by weight of the total weight of the coated crystals. (13 Tr. 2980 (Banker)). ESI also did not dispute that its product used HPC in the coating the range required by the claim. (13 Tr. 2980-81 (Banakar); 15 Tr. 3330 (C. Miller)).

Complaint Counsel's Response to Finding No. 3.492

Complaint Counsel has no specific response.

3.493. Finally, the '743 patent recites the use of ethylcellulose with a viscosity greater than 40. (13 Tr. 2980 (Banker)). ESI's product uses ethylcellulose having a viscosity of about 100 cp. (13 Tr. 2981 (Banker); 15 Tr. 3330 (C. Miller)). Thus, ESI also did not dispute that its product used ethylcellulose with a viscosity of greater than 40 cp. (13 Tr. 2981 (Banker); 15 Tr. 3330 (C. Miller)).

Complaint Counsel's Response to Finding No. 3.493

Complaint Counsel has no specific response.

3.494. The only issue in dispute was the construction of the term "a coating material"

and whether ESI's product met that claim element when properly construed. (13 Tr. 2793 (Langer); 13 Tr. 2982 (Banker); 15 Tr. 3331 (C. Miller); 26 Tr. 6433 (Banakar)).

Complaint Counsel's Response to Finding No. 3.494

Complaint Counsel has no specific response.

3.495. ESI's position, as explained in its brief and at the Markman hearing before Judge DuBois, was that the term "coating material" required a complete homogeneous mixture of ethylcellulose and either HPC or PEG. (SPX 687, Defendant's Memorandum *of Law in Support of Its Motion for a Markman Ruling on Patent Claim Construction and/or for Partial Summary Judgment of No Literal Infringement at* 8; *Markman* Hearing Transcript, Jan. 21, 1998 at 34 and Jan. 22, 1998 at 22).

Complaint Counsel's Response to Finding No. 3.495

Complaint Counsel has no specific response.

3.496. ESI intended to argue that its coating was not mixed, as ESI applied the ethylcellulose and HPC in separate and distinct layers. (13 Tr. 2982, 2990-93 (Banker); 13 Tr. 2818 (Langer); 15 Tr. 3336 (C. Miller); 26 Tr. 6387 (Banakar); 17 Tr. 3989 (Banakar); *Defendant's Memorandum of Law in Support of Its Motion for a Markman Ruling on Patent Claim Construction and/or for Partial Summary Judgment of No Literal Infringement*, at 18, 25-6).

Complaint Counsel's Response to Finding No. 3.496

The proposed finding is incomplete in terms of its characterization of ESI's

product and in terms of ESI's arguments supporting noninfringement. In ESI's Motion for Partial Summary Judgment, ESI stated that ESI's product's comprised two separate and distinct coating layers: (a) an inner layer of EC on the potassium chloride crystals which controls the release of potassium chloride; and (b) an outer layer of HPC on the EC coating which acts a binder for tableting. SPX 687* at ESI PLD 001638-39 (AHP's Motion for a *Markman* Ruling on Patent Claim Construction and/or Partial Summary Judgment of No Literal Infringement). ••

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The proposed finding is further incomplete in that it omits any reference to the opinions of Dr. Hopfenberg regarding the issue of mixing of the layers of the ESI product. Dr. Hopfenberg was prepared to testify, as indicated by his expert reports, that the ESI product comprises (a) an undercoat of substantially pure EC deposited by a process called coacervation, and (b) a separate and distinct topcoat of HPC. SPX 693* at ESI EXP 000723-25 (Expert Report by Dr. Hopfenberg). Dr. Hopfenberg opined that the coacervated EC coating —free from HPC — is the release coat that controls the release characteristics of the ESI product. SPX 693* at ESI EXP 000724 (Expert Report by Dr. Hopfenberg). Dr. Hopfenberg opined that the HPC topcoat functions as a binder which, because it is water soluble, readily dissolves in gastric fluids upon ingestion of the tablet and does not contribute to or affect the controlled release properties of the EC undercoat.

SPX 693* at ESI EXP 000724-25 (Expert Report by Dr. Hopfenberg). Dr. Hopfenberg concluded that the ESI product does not apply the polymeric mixture claimed in the patent in a layer over potassium chloride crystals. SPX 693* at ESI EXP 000725 (Expert Report by Dr. Hopfenberg).

2. Claim 1 Does Not Include a Process Limitation

3.497. ESI contended that the meaning of the claim term "coating material" must be construed to require that the ethylcellulose and the HPC be intermixed in a completely homogenous mixture. ESI argued that because the specification of the '743 patent discloses the use of a coating process that results in an intermixed coating material of ethylcellulose and HPC the term "coating material" must be so construed. (SPX 687, *Defendant's Memorandum of Law in Support of Its Motion for a Markman Ruling on Patent Claim Construction and/or for Partial Summary Judgment of No Literal Infringement at* 8; *Markman* Hearing Transcript, Jan. 21, 1998 at 34 and Jan. 22, 1998 at 22).

Complaint Counsel's Response to Finding No. 3.497

The proposed finding is incomplete and misleading in that it lists only one of several bases offered by ESI as support for its position on the proper construction of "a coating material". In ESI's Motion for a *Markman* Ruling on Patent Claim Construction and/or Partial Summary Judgment of No Literal Infringement of the '743 Patent (hereinafter, "Motion for Partial Summary Judgment"), ESI supported its interpretation of the phrase "a coating material" as requiring single-layer coating by resort to the patent

itself, including the claims, wherein the coating material is referred to in the singular form, without exception. SPX 687* at ESI PLD 001654-55 (ESI's Motion for a *Markman* Ruling on Patent Claim Construction and/or Partial Summary Judgment of No Literal Infringement). ESI further supported its interpretation of the phrase "a coating material" as requiring a polymeric mixture of EC with HPC and/or PEG by resort to the specification of the '743 patent. According to ESI, the specification clearly indicates that the coating material is a "polymeric mixture" of EC and HPC wherein the EC is a major component and HPC is a minor component. SPX 687* at ESI PLD 001655 (ESI's Motion for a *Markman* Ruling on Patent Claim Construction and/or Partial Summary Judgment of No Literal Infringement). Were the phrase "a coating material" be interpreted to cover a two layered product, ESI argued, then the foregoing notion of major and minor components in a mixture would be nonsensical. ESI also relied upon the fact that the "polymeric coating" material of the '743 patent is further described as a "combination of EC and HPC". SPX 687* at ESI PLD 001656 (ESI's Motion for a *Markman* Ruling on Patent Claim Construction and/or Partial Summary Judgment of No Literal Infringement).

ESI further supported its claim interpretation of the phrase "a coating material" as requiring a mixture of EC with HPC by reference to the other parts of the specification of the '743 patent other than the nature of the coating process. ESI argued that the specification discloses that the EC and HPC must be in a "proper balance" to each other in the claimed mixture. SPX 687* at ESI PLD 001657 (ESI's Motion for a *Markman* Ruling on Patent Claim Construction and/or Partial Summary Judgment of No Literal

Infringement). ESI argued that the specification taught that the "balance" of EC and HPC in one layer was responsible for the controlled release of potassium chloride, as provided by the claimed invention. SPX 687* at ESI PLD 001657 (ESI's Motion for a *Markman* Ruling on Patent Claim Construction and/or Partial Summary Judgment of No Literal Infringement). Hence, ESI argued, the very purpose of the '743 patent would be defeated if the "proper balance" of EC and HPC in a single layer was not achieved. SPX 687* at ESI PLD 001657 (ESI's Motion for a *Markman* Ruling on Patent Claim Construction and/or Partial Summary Judgment of No Literal Infringement).

ESI further supported its position by offering the testimony of its technical expert, Dr. Hopfenberg, at the *Markman* hearing that the proper interpretation of the '743 patent requires that the phrase "a coating material" is a single homogeneous layer of EC mixed with HPC and/or PEG. In his testimony at the *Markman* hearing, only one basis of Dr. Hopfenberg's opinion regarding claim construction related to the coating process disclosed in the specification of the '743 patent. Indeed, Dr. Hopfenberg supported his position that the '743 patent requires a mixture of EC with HPC and/or PEG by reference to the plain language of claim 1, which per se requires "a coating material comprising two separate components". SPX 687* at ESI HRG 000053-54 (Transcript of *Markman* hearing). Dr. Hopfenberg further testified that claim 1 per se deals with two polymers in a single coating at very specific ratios, as in a mixture. SPX 687* at ESI HRG 000055 (Transcript of *Markman* hearing). Dr. Hopfenberg also supported his opinion by the plain meaning of the word "coating material", which typically refers to a composition of matter, not a state of aggregation. SPX 687* at ESI HRG 000056 (Transcript of

Markman hearing). Dr. Hopfenberg testified at the *Markman* hearing that his construction was further supported by the specification of the '743 patent, which states that the invention relates specifically to a tablet in which potassium chloride crystals are coated by a polymeric mixture. SPX 687* at ESI HRG 000056-57 (Transcript of *Markman* hearing). Dr. Hopfenberg also testified that the specification discloses that the coating material is formed by providing a proper balance of EC to HPC to effect permeability of the EC, thereby allowing release of the potassium chloride crystals. SPX 687* at ESI HRG 000057 (Transcript of *Markman* hearing). Dr. Hopfenberg testified that he could not conceive of HPC of affecting permeability, as described in the '743 patent, were it to be present as a separate layer. SPX 687* at ESI HRG 000059 (Transcript of *Markman* hearing).

3.498. However, particular embodiments or limitations appearing in the descriptive portion of the specification of a patent are not to be "read into" the claims. The scope of what is patented is ordinarily not limited to the examples or specific limitations in the descriptive portion of the specification, but rather by the express language of the claims themselves. (15 Tr. 3332 (C. Miller); SPX 1275 at ¶ 34 (C. Miller)).

Complaint Counsel's Response to Finding No. 3.498

The proposed finding is incomplete in that it emphasizes a general principle while omitting more significant axioms of claim construction that state that the specification is critical to interpretation of the claims of a patent. More particularly, ESI argued that:

"To ascertain the meaning of claims, we consider three sources, the claims the specification, and the prosecution history." *Markman v. Westview Instr.*, 52 F.3d 967, 979 (Fed. Cir. 1996)(*en banc*). Claims "must be read in view of the specification, of which they are part". *Id.* The specification is the "single best guide in the meaning of a disputed term". *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996).

SPX 687* at ESI PLD 001667 (ESI's Motion for a Markman Ruling on Patent Claim Construction and/or for Partial Summary Judgment of No Literal Infringement).

3.499. The purpose of the examples in a patent's specification is to enable one of ordinary skill in the art to carry out the invention. (15 Tr. 3332 (C. Miller)). The examples in a specification also function to inform the public that the patentee was in the possession of the invention defined by the claims. (15 Tr. 3333 (C. Miller)).

Complaint Counsel's Response to Finding No. 3.499

The proposed finding is incomplete in that it emphasizes a general principle while omitting more significant axioms of claim construction that state that the specification is critical to interpretation of the claims of a patent. *See* CPRF 3.498.

3.500. An inventor is not required to disclose every possible, conceivable way to practice the claimed invention. (15 Tr. 3333 (C. Miller)). As such, claims are often broader than the

examples contained in the specification. (15 Tr. 3333 (C. Miller)).

Complaint Counsel's Response to Finding No. 3.500

The proposed finding of fact is unsupported by the evidence to the extent it states that claims are "often" broader than the examples in the specification. Schering cites no evidence to support this contention other than Mr. Miller's opinion, which is not based on any empirical study or review of patterns of claim interpretation by either district courts or the appeals court. The proposed finding is incomplete in that it emphasizes a general principle while omitting more significant axioms of claim construction that state that the specification is critical to interpretation of the claims of a patent. *See* CPRF 3.498.

3.501. Thus, the examples contained in the '743 specification do not limit the scope of the patent's claims. (15 Tr. 3332 (C. Miller)).

Complaint Counsel's Response to Finding No. 3.501

The proposed finding is incomplete and misleading in that it relies on an improper statement regarding the relationship of the specification to the interpretation of patent claims. *See* CPRF 3.498, 3.500. The proposed finding of fact is also incomplete and misleading in that it purports to render judgement on claim construction, which was never decided by any district court in the underlying litigations. The proposed finding is also incomplete in that it implies that the only relevant issues as to claim construction of the '743 patent was the effect of the examples in the specification. *See* CPRF 3.497.

3. Proper Construction of "coating material" includes one or more layers

3.502. The plain meaning of the words of the claim embraces a coating having either one layer or multiple layers of coating. (13 Tr. 2983 (Banker)).

Complaint Counsel's Response to Finding No. 3.502

The proposed finding is not supported by the evidence because it is contradicted both by testimony in the underlying patent litigation from an inventor of the '743 patent and by complaint counsel's technical expert witness, Dr. Banakar. Dr. Banker acknowledged that the original inventor testified that the '743 patent does not refer to two separate films. Tr. at 14:3063 (Banker). Dr. Banakar concluded that the plain language of the '743 patent is that the coating material has to be applied in a single uniform coating that is a mixture. Tr. at 26:6392 (Banakar).

The proposed finding is incomplete and misleading in that it omits contrary testimony offered by ESI's technical expert, Dr. Hopfenberg, during the Markman hearing that the plain meaning of the claim terms requires a single uniform layer of EC mixed with HPC. *See* CPRF 3.497.

3.503. One of ordinary skill in the art would understand the term "coating material" to mean "a substance comprised of one or more layers that enrobes or coats a particle or a tablet."[5] (13 Tr. 2983 (Banker)).

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[5] Dean Banker was asked to render an opinion as to what the level of ordinary skill in the pertinent art would be. (Banker 30 Dean Banker opined that a person with ordinary skill in the art would have " a college degree in pharmacy, chemistry, biology, possibly engineering, and several years of experience...." (Banker 3035).

Complaint Counsel's Response to Finding No. 3.503

The proposed finding is not supported by the evidence because in the underlying patent litigation, the district judge expressed skepticism during the *Markman* hearing that someone of ordinary skill reading the '743 patent would know that the invention would work with separate coatings. Tr. at 14:3038 (Banker). Dr. Banker further testified that the district judge in the ESI case felt the interpretation of "coating material" was far from a clear issue. Tr. at 14:3038-39 (Banker).

The finding is incomplete and misleading in that it ignores contrary testimony by ESI's technical expert during the *Markman* hearing in the underlying patent litigation. *See* CPRF 3.497.

3.504. In the '743 patent, the term "coating material" is a technical term. (15 Tr. 3334 (C. Miller)). Thus, the court may refer to a technical dictionary to define the term "coating material". (15 Tr. 3334 (C. Miller)).

Complaint Counsel's Response to Finding No. 3.504

The finding is incomplete and misleading in that it omits the fact that the Dictionary of Pharmacy is referred to in a patent law as extrinsic evidence that may not be used to for purpose of varying or contradicting the meaning of the claim terms derived from the patent itself, notably the specification. SPX 687* at 001667 (ESI's Motion for a

Markman Ruling on Patent Claim Construction and/or for Partial Summary Judgment of No Literal Infringement).

3.505. The Dictionary of Pharmacy is a technical dictionary generally accepted as reliable in the pharmaceutical industry and pharmacy communities. (13 Tr. 2985 (Banker); [26 Tr. 6516 (Banakar)).]

Complaint Counsel's Response to Finding No. 3.505

The proposed finding is irrelevant in that Schering seeks to offer the dictionary as only extrinsic evidence for claim construction, and as such, it cannot be used to vary the meaning of the claim terms as derived from the patent itself. *See* CPRF 3.504.

3.506. The Dictionary of Pharmacy defines "coating" as "covering a tablet or pill with one or more protective layers." (SPX 724; 13 Tr. 2986 (Banker)). The Dictionary of Pharmacy further gives examples of pill coatings with one more protective layers. (SPX 724; 13 Tr. 2986 (Banker)).

Complaint Counsel's Response to Finding No. 3.506

The finding is irrelevant in that the Dictionary of Pharmacy is referred to in a patent law as extrinsic evidence that may not be used to for purpose of varying or contradicting the meaning of the claim terms derived from the patent itself, notably the specification. SPX 687* at 001667 (ESI's Motion for a Markman Ruling on Patent

Claim Construction and/or for Partial Summary Judgment of No Literal Infringement).

The proposed finding is also irrelevant and misleading because it refers to a definition of a "coating" instead of a "coating material." Dr. Banker admitted that the definition of a coating that he relied on from the Dictionary of Pharmacy does not have the word "material" in it. Tr. at 14:3095-96 (Banker). Dr. Banker acknowledged that the word "material" as used in the '743 patent's claim of "a coating material" must have meaning. Tr. at 14:3093 (Banker). Dr. Banker also admitted that the Dictionary of Pharmacy had a definition for coacervate separate from coating. Tr. at 14:3096 (Banker).

3.507. The evidence establishes that many pharmaceutical products have multiple layers and that the Wurster coating process used by ESI and Schering lends itself to a layered coating material. (13 Tr. 2983-85 (Banker)).

Complaint Counsel's Response to Finding No. 3.507

The proposed finding of fact is irrelevant to the extent that it refers to "many pharmaceutical products" rather than the ESI product. It is also misleading and not supported by the evidence to the extent that it asserts that both Schering and ESI's coating process "lent itself" to a layered coating material and that the evidence established this as a fact. Dr. Banker acknowledged that the inventors of the '743 patent required a uniform coating of EC and HPC. Tr. at 14: 3061-62. Dr. Banker agreed that the more uniform coating described in the '743 patent would produce a more uniform dissolution. Tr. at 14:3059-60 (Banker). Dr. Banker admitted that the description of the invention in the

'743 patent refers to a polymeric mixture. Tr. at 14:3047 (Banker). Dr, Banker agreed that description of the invention in the '743 patent refer to a polymeric coating which includes EC and HPC. Tr.14:3047-48 (Banker). Dr. Banker also agreed that the '743 patent refers to the polymeric coating as being a combination of EC and HPC. Tr. at 14:3048 (Banker). Dr. Banker further agreed that the manufacturing process called for by the '743 patent refers to a "controlled and uniform" coating. Tr. at 14:3049 (Banker). Dr. Banker also agreed that the inventors of the '743 patent felt that the Wurster spray fluidized bed process described in the '743 patent provides a controlled, uniform coating. Tr. at 14:3049-50 (Banker). Dr. Banakar testified that the '743 patent clearly states that the coating material is a combination or mixture of two polymers. Tr. at 26:6387 (Banakar).

Dr. Banakar testified that, in the process called for by the '743 patent, two polymers are applied in a single phase solution in which both polymers are mixed uniformly. Tr. at 26:6389 (Banakar). **
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*** Dr. Banker acknowledged that Schering represented to the Patent Office that the '743 patent refers to a coating composition containing a combination of two polymeric materials. Tr. at 3112-13 (Banker).

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••••••••••••••••••••••••• Dr. Banakar testified that in ESI's product there are two distinct coats of EC and HPC. Tr. at 26:6389-90 (Banakar). Dr. Banakar testified that these two distinct coats are separate and independent of each other and mutually exclusive. Tr. at 26:6390 (Banakar). Dr. Banakar testified that ESIs product is structurally different compared to '743 patented invention. Tr. at 26:6390 91 (Banakar). Dr Banakar concluded that ESI's product did not have a coating material as per the plain language '743 patent, because the patent discloses a mixture form, uniformly mixed and applied as a single uniform coat, whereas ESI's product has two different coating steps. Tr. at 26:6391-6392. Dr. Banakar described a coating material as a mixture as two or more components intimately mixed together, whereas ESI's product is a coating with one layer of EC and then another layer of HPC. Thus, ESI's product has two distinct coats or two steps which are separate and independent of each other. Tr. at 26:6389-90 (Banakar).

The proposed finding is also incomplete and misleading in that it omits reference to the opinions by ESI's technical expert, Dr. Hopfenberg, regarding the differences in the coating process disclosed in the '743 patent and used to make ESI's product. In his expert report, Dr. Hopfenberg, opined that while the specification of the '743 patent disclosed spray coating the crystals in a Wurster column with a homogenous solution of a polymeric mixture of EC and HPC, ESI's product was prepared in a two step process that first involved a process of coacervation in which a substantially pure EC layer was applied, followed by spray coating the HPC. SPX 693* at ESI EXP 000722-725 (Expert Report of Dr. Hopfenberg).

3.508. The plain language of claim 1 do not contain any requirement as to how the tablet must be made, nor do they require whether the ethylcellulose and the HPC have to be mixed. (13 Tr. 2974 (Banker)).

Complaint Counsel's Response to Finding No. 3.508

The proposed finding is misleading and incomplete because it omits any reference to the expert testimony in the underlying litigation by Dr. Hopfenberg that the proper construction of the term "coating material" requires a single, homogeneous layer of EC with HPC. *See* CPRF 3.497, 3.507.

3.509. Thus, the term "coating material" as used in the '743 patent should be construed to cover the components of ethylcellulose and a member selected from the group of HPC or PEG, in one or more layers, whether mixed, in separate layers, or a little of both. (13 Tr. 2986-88 (Banker); 15 Tr. 3334 (C. Miller)).

Complaint Counsel's Response to Finding No. 3.509

The proposed finding is misleading and not supported by the evidence because it ignores the evidence mentioned above in CPRF 3.508 and in the *Markman* hearing in the underlying litigation that the district judge raised the issue of whether one of ordinary skill reading the '743 patent would know that the invention would work with separate coatings. Tr. at 14:3038 (Banker). He felt this was far from a clear issue. Tr. at 14:3038

(Banker). Dr. Banker acknowledged that in the underlying patent litigation, the district judge framed the issue as whether the '743 patent is broad enough to be read as including a separately layered coating of the substances mentioned in the '743 patent. The judge told the trial counsel for Schering that this was "far from a clear issue" and that Schering did not have a "slam dunk case." Tr. 14:3038-39 (Banker).

The proposed finding is misleading and incomplete because it omits contrary evidence regarding the proper claim construction, notably the testimony by ESI's technical expert, Dr. Hopfenberg, during the *Markman* hearing. *See* CPRF 3.497, 3.507.

3.510. This construction of the term coating material stems from the plain meaning of the term and the definition given the term "coating material" by a technical treatise. (15 Tr. 3335 (C. Miller)). This construction is further supported by the fact that the patent specification and the prosecution history do not suggest a more narrow interpretation of the term "coating material." (15 Tr. 3335 (C. Miller)).

Complaint Counsel's Response to Finding No. 3.510

The proposed finding is irrelevant in that it cites a technical treatise, i.e., extrinsic evidence, for primary support for the proper construction, whereas to resort to such evidence is improper when the construction is clear from the patent itself and the prosecution history. *See* CPRF 3.504, 3.506.

D. ESI's Product Literally Infringes Claim 1 of the '743 Patent Under Plain Meaning Construction of "Coating Material"

3.511. To prove literal infringement, Schering had to show that each and every element of claim 1 of the '743 patent was present in ESI's product. (15 Tr. 3363 (C. Miller)). Literal infringement cases are often straightforward, involving a direct comparison of the claim, properly construed, to the accused product. (15 Tr. 3363 (C. Miller)).

Complaint Counsel's Response to Finding No. 3.511

The proposed finding is misleading to the extent that it ignores the issue of claim interpretation that was at issue in the Markman hearing. *See* CPRF 3.509. In addition, Dr. Banker acknowledged that the merits of the ESI/Schering case were "up in the air" at the time that the matter was settled. Tr. at 14:3245 (Banker). Dr. Banker acknowledged that he does not know how Schering would have done if its patent infringement suit against ESI had gone to trial. Tr. at 14:3253-55 (Banker).

3.512. Under the proper construction of the term "coating material," encompassing one or more layers, all of the elements of claim one are met by ESI's product. (15 Tr. 3336-37 (C. Miller); 13 Tr. 2986-88 (Banker)).

Complaint Counsel's Response to Finding No. 3.512

The proposed finding of fact is misleading and incomplete for the reasons stated in CPRF 3.497, 3.502 and 3.503.

3.513. In fact, if one applies the plain meaning of the term "coating material" as provided by for the Dictionaty of Pharmacy, ESI's product infringes the Schering's patent even if ESI were successful in establishing that its product contained two distinct layers in its coating material. (13 Tr. 2987 (Banker)).

Complaint Counsel's Response to Finding No. 3.513

The proposed finding of fact is also not supported by the evidence and is misleading for the reasons stated in CPRF 3.504, 3.506. See also CPRF 3.497, 3.502, 3.503.

3.514. Similarly, if ESI's coating material were mixed, the product would still infringe claim 1 because the plain meaning of the term "coating material" encompasses "one or more protective layers." (13 Tr. 2986-88 (Banker)).

Complaint Counsel's Response to Finding No. 3.514

The proposed finding is misleading and unsupported by the evidence in that it assumes a factual issue, the level of mixing in ESI's product, and a legal issue, the construction of the term "coating material", that were never resolved in the underlying litigation. Tr. at 15:3382-84 (Miller); Tr. at 13:2988-89 (Banker); Schering Second Admission Nos 127-128.

The proposed finding is also incomplete and misleading because it omits any reference to conflicting opinions offered by ESI's technical expert, Dr. Hopfenberg,

during the *Markman* hearing in the patent litigation. See 3.497.

The proposed finding is also misleading in that it omits any reference to the inclination of the judges in the underlying patent litigation regarding the merits of the patent case. The district judge stated during the *Markman* hearing that this was "far from a clear issue" and that Schering did not have a "slam dunk case." Tr. 14:3038-39 (Banker). Moreover, in private meetings with ESI, the magistrate judge told ESI that he thought ESI had somewhat the better of the infringement case. CX 1482† at 61:3-8, 62:9-22, 65:14-18 (Alaburda IH).

3.515. Accordingly, under the plain meaning definition of a "coating material," ESI's product falls within the every limitation contained in claim 1 of the '743 patent and therefore literally infringes the claim. (13 Tr. 2983 (Banker); 15 Tr. 3336-37 (C. Miller)).

Complaint Counsel's Response to Finding No. 3.515

The proposed finding is misleading and unsupported by the evidence. AHP documents, depositions, and investigational hearings were admitted subject to the Administrative Law Judge's satisfaction that complaint counsel properly proved a conspiracy and all the required elements under the co-conspirator rule. These documents are marked by a superscript (†) following the exhibit number. *See* CPRF 3.514.

E. ESI's Product Literally Infringes Claim 1 of the '743 Patent Even If "Coating Material" Requires an Intermixed Layer of Ethylcellulose and HPC

3.516. On the other hand, if the term "coating material" is construed to require a intermixed layer of ethylcellulose and HPC, the ethylcellulose and HPC used in ESI's coating material are in fact intermixed. (13 Tr. 2822, 2932, 2906 (Langer); 13 Tr. 2995, 3012 (Banker)).

Complaint Counsel's Response to Finding No. 3.516

The proposed finding is misleading in that it is contradicted by Schering's own patent law expert, Mr. Miller. Mr. Miller testified that if the district court had adopted ESI's claim interpretation of "coating material", which required a complete, homogeneous mixing of the EC with HPC, then Schering could not have established literal infringement. Tr. at 15:3397 (Miller).

The proposed finding is also misleading and incomplete in that it omits ESI's evidence in support of noninfringement, including the opinions of its expert, Dr. Hopfenberg. In ESI's Motion for Partial Summary Judgment, ESI argued that the under the proper construction of the phrase "coating material", its product did not literally infringe the '743 patent. SPX 687* at ESI PLD 001655 (ESI's Motion for a *Markman* Ruling on Patent Claim Construction and/or Partial Summary Judgment of No Literal Infringement). In ESI's Motion for Partial Summary Judgment, ESI stated that the nature of the ESI product was beyond factual dispute. ESI stated that there was no serious dispute that ESI product's comprised two distinct coating layers: (a) an inner layer of EC on the potassium chloride crystals which controls the release of potassium chloride; and

(b) an outer layer of HPC on the EC coating which acts a binder for tableting. SPX 687* at ESI PLD 001638-39 (ESI's Motion for a *Markman* Ruling on Patent Claim Construction and/or Partial Summary Judgment of No Literal Infringement). According to ESI, the potassium chloride crystals in its product are first coated with EC alone by a coacervation process, and then spray coated with HPC such that the two polymers are never mixed together. SPX 687* at ESI PLD 001656 (ESI's Motion for a *Markman* Ruling on Patent Claim Construction and/or Partial Summary Judgment of No Literal Infringement).

Dr. Hopfenberg was prepared to testify, as indicated by his expert reports, that the ESI product comprises (a) an undercoat of substantially pure EC deposited by a process called coacervation, and (b) a separate and distinct topcoat of HPC. SPX 693* at ESI EXP 000723-25 (Expert Report by Dr. Hopfenberg). Dr. Hopfenberg opined that the coacervated EC coating —free from HPC — is the release coat that controls the release characteristics of the ESI product. SPX 693* at ESI EXP 000724 (Expert Report by Dr. Hopfenberg). Dr. Hopfenberg opined that the HPC topcoat functions as a binder which, because it is water soluble, readily dissolves in gastric fluids upon ingestion of the tablet and does not contribute to or affect the controlled release properties of the EC undercoat. SPX 693* at ESI EXP 000724-25 (Expert Report by Dr. Hopfenberg). Dr. Hopfenberg concluded that the ESI product does not apply the claimed polymeric mixture in a layer over potassium chloride crystals and therefore does not literally infringe the '743 patent. SPX 693* at ESI EXP 000725 (Expert Report by Dr. Hopfenberg).

Dr. Hopfenberg was prepared to testify that his conclusion regarding mixing was

supported by his two studies, a SEM study and a release rate study. SPX 693* at ESI EXP 000697-705 (Expert Report by Dr. Hopfenberg); SPX 695* at ESI EXP 00753-766 (Expert Report by Dr. Hopfenberg with Mr. Butler). Dr. Hopfenberg was prepared to testify that the SEM studies performed by Mr. Butler indicate that the HPC forms "a separate and distinct layer deposited upon the ethylcellulose (EC) layer in ESI's product, whereas the HPC and EC in Key's product[, an embodiment of the '743 patent,] form a single polymeric coating. SPX 695* at ESI EXP 00753-766 (Expert Report by Dr. Hopfenberg with Mr. Butler). Dr. Hopfenberg was prepared to testify that release rate studies he performed show that HPC is readily removed by water from the ESI microcapsules whereas, under the same conditions, no HPC is removed from Key's product. SPX 693* at ESI 000697-705 (Expert Report by Dr. Hopfenberg). Dr. Hopfenberg was prepared to testify that this data demonstrates that the HPC forms a separate and distinct binder layer deposited upon the EC release layer in ESI's product. SPX 693* at ESI 000697-705 (Expert Report by Dr. Hopfenberg).

The proposed finding is misleading and irrelevant to the extent that it equates any level intermixing with the uniform and homogeneous mixture required to produce the invention claimed by the '743 patent. It is also not supported by the evidence to the extent that there is no evidence that ESI's product was a uniform and homogeneous mixture of EC and HPC. Dr. Banakar testified that ESI's product is constructed with a first coat of ethylcellulose over the potassium chloride and then HPC is applied as a second coat. Tr. at 26:6387 (Banakar). Dr. Banakar testified that in ESI's product there are two distinct coats of EC and HPC. Tr. at 26:6389-90 (Banakar). Dr. Banakar

testified that these two distinct coats are separate and independent of each other and mutually exclusive. Tr. at 26:6390 (Banakar). Dr. Banakar testified that ESI's product is structurally different compared to '743 patented invention. Tr. at 26:6390–91 (Banakar).

3.517. In response to ESI's defense that its product contained layered components, Dr. Langer testified that he was asked by Schering during the original ESI case to determine whether the ethylcellulose and HPC and ESI's coating material were in fact mixed. (13 Tr. 2793, 2829-2830 (Langer)).

Complaint Counsel's Response to Finding No. 3.517

Complaint Counsel has no specific response.

3.518. In making this determination, Dr. Langer conducted different experiments on various samples provided by ESI. (13 Tr. 2794 (Langer)).

Complaint Counsel's Response to Finding No. 3.518

Complaint Counsel has no specific response.

3.519. ESI provided two types of samples. ESI calls the first type of samples "intermediates," which are potassium chloride crystals coated with ethylcellulose only. (13 Tr. 2794 (Langer)). The second type of samples is called "compressibles," which are potassium chloride crystals coated first with ethylcellulose, or the intermediates, then coated with HPC. (13

Tr. 2795 (Langer)).

Complaint Counsel's Response to Finding No. 3.519

Complaint Counsel has no specific response.

1. Differential Scanning Calorimetry ("DSC") Proved Intermixing of Ethylcellulose and HPC (SPX 714)

3.520. Heat of fusion, or Differential Scanning Calorimetry ("DSC"), tests were performed on ESI's samples under the direction of Dr. Langer. (13 Tr. 2795, 2816 (Langer)). The heat of fusion test measures the amount of energy required to change a compound from solid to liquid form. (13 Tr. 2815-16, 2927 (Langer)).

Complaint Counsel's Response to Finding No. 3.520

The proposed finding is incomplete to the extent that it does not disclose Dr. Langer's lack of prior use of the DSC test for any similar experiment. When the DSC tests were done, Dr. Langer had very little if any experience with experiments that looked at the interface of one polymer applied to another. Tr. at 13:2880 (Langer). Dr. Langer did not know of anyone who had used DSC to examine mixing at the molecular level of two polymers. Tr. at 13:2880-81 (Langer). Dr. Langer had not previously done a DSC study to examine the interface of one polymer on another. Tr. at 13:2881 (Langer).

3.521. Dr. Langer testified that compounds having a crystal structure would require a

certain amount of energy to change from a solid to a liquid. (13 Tr. 2816 (Langer)). Intermixing of different compounds would affect a crystal's structure and would lower the amount of energy required to change the sample from a solid to liquid (13 Tr. 2816 (Langer)).

Complaint Counsel's Response to Finding No. 3.521

The proposed finding is incomplete and misleading in that it does not disclose that there may be other factors besides mixing that affect a crystal's structure. Dr. Langer acknowledged that processing conditions can change the crystallinity of the EC. Tr. at 13:2878 (Langer). Dr. Langer also acknowledged that a solvent can change the EC crystallinity. Tr. at 13:2878 (Langer).

3.522. Dr. Langer's test showed that the heat of fusion for ESI's sample coated with both ethylcellulose and HPC was significantly different from the heat of fusion of ESI's intermediate samples coated with ethylcellulose only. (13 Tr. 2816 (Langer)).

Complaint Counsel's Response to Finding No. 3.522

The proposed finding is irrelevant to the extent that it does not specify the degree of intermixing of EC and HPC, and it is not supported by the evidence to the extent that there may have been other factors contributing to the difference in the heat of fusion. Dr. Langer acknowledged that processing conditions can change the crystallinity of the EC. Tr. at 13:2878 (Langer). Dr. Langer also acknowledged that a solvent can change the EC crystallinity. Tr. at 13:2878 (Langer). Dr. Langer acknowledged that if he had used the DSC test to compare the Schering K-Dur product to ESI's product, the results could have

been very different because of the presence of other components like stearates. Tr. at 13:2878 (Langer). Therefore, it is possible that other ingredients could have effected the results under the FTIR or DSC tests. Dr. Langer did not use a control with a separate EC and HPC layer. Tr. at 13:2934 (Langer). Dr. Langer did not look at Schering's K-Dur product as a comparison of a mixture of EC and HPC in the DSC study. Tr. at 13:2824 (Langer).

3.523. Accordingly, these studies show [] that there had to be some intermolecular mixing since the heat of fusion of the sample coated with HPC was changed significantly from the sample with ethylcellulose only. This would only occur if the HPC and ethylcellulose were mixed at a molecular level. (13 Tr. 2816 (Langer)). The heat of fusion tests conclusively establish that the HPC and ethylcellulose are intermixed in the coating material of ESI's product. (13 Tr. 2816-17 (Langer); 13 Tr. 2993 (Banker)).

Complaint Counsel's Response to Finding No. 3.523

The proposed finding is irrelevant to the extent that it does not specify the degree of intermixing of EC and HPC, and it is not supported by the evidence to the extent that there may have been other factors contributing to the difference in the heat of fusion. See. CPRF 3.522. The proposed finding is misleading and incomplete in that it omits any reference to the opinions regarding Dr. Hopfenberg indicating that there was no mixing in ESI's product. Dr. Hopfenberg was prepared to testify about SEM studies performed at his direction.

2. Fourier Transform Infrared Spectroscopy Proved Intermixing of Ethylcellulose and HPC ("FTIR") (SPX 713)

3.524. Dr. Langer also testified to the Fourier Transform Infrared Spectroscopy ("FTIR") tests performed under his direction to determine whether the ethylcellulose and HPC used in ESI's product formed distinct layers. (13 Tr. 2798-99, 2810 (Langer)).

Complaint Counsel's Response to Finding No. 3.524

The proposed finding is incomplete to the extent that it does not disclose that Dr. Langer had very little prior experience using FTIR tests for this experimental purpose. When the FTIR tests were done, Dr. Langer had very little if any experience with experiments that looked at the interface of one polymer applied to another. Tr. at 13:2880 (Langer).

3.525. In conducting FTIR tests, light is transmitted through a test compound and the absorption of particular frequencies by the compound is measured. (13 Tr. 2810 (Langer)). The absorption frequencies are then plotted to graphically represent the absorbed spectra, which are the unique peaks and valleys representing the wavelength of absorbed light for the particular compound being studied. (13 Tr. 2810-12 (Langer)).

Complaint Counsel's Response to Finding No. 3.525

The proposed finding is irrelevant to the extent that the FTIR tests do not demonstrate the extent of intermixing of EC and HPC. Dr. Langer's FTIR test merely showed that two "fingerprints" of EC and HPC and differed from each other. Tr. at

13:28675 (Langer). It is not clear that the "fingerprints" differed because of mixing. Dr. Langer acknowledged that he did not attempt to understand what causes a "peak" in an FTIR test result. Tr. at 13:2869-70 (Langer). In his FTIR tests, Dr. Langer acknowledged that he did not know exactly what chemical bond stretching or rotation was involved with the EC and HPC. Tr. at 13:2869-70 (Langer).

3.526. Each sample studied contains a unique set of absorption data, or "fingerprint", that can be compared to other sample compounds. (13 Tr. 2810-12 (Langer)).

Complaint Counsel's Response to Finding No. 3.526

The proposed finding is irrelevant to the extent that the FTIR tests do not demonstrate the extent of intermixing of EC and HPC. See. CPRF 3.525.

3.527. Dr. Langer performed the FTIR analysis on the following samples: ethylcellulose only, HPC only, potassium crystals coated with ethylcellulose only (the intermediate sample), ESI's ethylcellulose/HPC coated potassium crystal (the compressible sample), and a sample containing a 15:1 blend of ethylcellulose and HPC, respectively. (13 Tr. 2811-15 (Langer)).

Complaint Counsel's Response to Finding No. 3.527

The proposed finding is irrelevant to the extent that the FTIR tests do not demonstrate the extent of intermixing of EC and HPC. See. CPRF 3.525. The proposed finding is also incomplete because it does not disclose that Dr. Langer failed to use two

other types of very relevant controls. Dr. Langer did not use any control with a separate EC and HPC layer. Tr. at 13:2934 (Langer). Dr. Langer also did not look at Schering's K-Dur product as a comparison mixture of EC and HPC in the FTIR studies. Tr. at 13:2824 (Langer).

3.528. The spectra of the ethylcellulose only, HPC only, and ethylcellulose coated potassium chloride crystals ("intermediates") served as experimental controls to identify the unique spectra associated with the individual compounds. (13 Tr. 2810-14 (Langer)).

Complaint Counsel's Response to Finding No. 3.528

The proposed finding is incomplete and misleading for the reasons stated in CPRF 3.527.

3.529. Dr. Langer explained that the test results conclusively showed that ESI's product did not display IR spectra of a sample in which the ethylcellulose and HPC are in distinct and separate layers. (13 Tr. 2814 (Langer)).

Complaint Counsel's Response to Finding No. 3.529

The proposed finding is not supported by the evidence and is incomplete and misleading for the reasons stated in CPRF 3.524-3.528

3.530. Dr. Langer's studies using the ethylcellulose only sample identified a unique

absorption band with a peak associated with ethylcellulose. (13 Tr. 2811-12 (Langer)). Dr. Langer's studies using the HPC only sample also identified a different unique absorption band with a different peak associated with HPC. (13 Tr. 2812 (Langer)).

Complaint Counsel's Response to Finding No. 3.530

The proposed finding is irrelevant to the extent that the FTIR tests do not demonstrate the extent of intermixing of EC and HPC. Dr. Langer's FTIR test merely showed that two "fingerprints" of EC and HPC and differed from each other. Tr. at 13:2875 (Langer). It is not clear that the "fingerprints" differed because of mixing. Dr. Langer acknowledged that he did not attempt to understand what causes a "peak" in an FTIR test result. Tr. at 13:2869-70 (Langer). In his FTIR tests, Dr. Langer acknowledged that he did not know exactly what chemical bond stretching or rotation was involved with the EC and HPC. Tr. at 13:2869-70 (Langer).

3.531. Dr. Langer's FTIR tests showed that the test sample of potassium chloride coated with only ethylcellulose, ESI's intermediate, displayed an absorption band with a peak matching that of the ethylcellulose only sample. (13 Tr. 2813-14 (Langer)).

Complaint Counsel's Response to Finding No. 3.531

The proposed finding is irrelevant to the extent that the FTIR tests do not demonstrate the extent of intermixing of EC and HPC. Dr. Langer's FTIR test merely showed that two "fingerprints" of EC and HPC and differed from each other. Tr. at 13:2875 (Langer). It is not clear that the "fingerprints" differed because of mixing. Dr.

Langer acknowledged that he did not attempt to understand what causes a "peak" in an FTIR test result. Tr. at 13:2869-70 (Langer). In his FTIR tests, Dr. Langer acknowledged that he did not know exactly what chemical bond stretching or rotation was involved with the EC and HPC. Tr. at 13:2869-70 (Langer).

3.532. The absorption signature of ESI's product, however, did not display the unique absorption bands seen in the ethylcellulose only spectra, the HPC only spectra, or the intermediate (layered) spectra. (13 Tr. 2814-15 (Langer)). Instead, IR test results of ESI's product showed a "broad peak" indicating a totally different absorption range due to molecular changes in ESI's product with no distinct peaks matching either ethylcellulose or HPC. (13 Tr. 2811, 2815, 2930 (Langer)).

Complaint Counsel's Response to Finding No. 3.532

The proposed finding is misleading because it implies that Dr. Langer knows what causes the height of a peak, or that any molecular change in ESI's product must be related to a mixture of EC and HPC. It is also irrelevant to the extent that the '743 patent claims only a uniform mixture of EC and HPC. In his FTIR tests, Dr. Langer acknowledged that he did not know exactly what chemical bond stretching or rotation was involved with the EC and HPC. Tr. at 13:2869-70 (Langer). Dr. Langer did an FTIR test on ground up samples of EC and HPC and the ESI microcapsule. Tr. at 13:2868-69 (Langer). Dr. Langer's FTIR test merely showed that two "fingerprints" of EC and HPC and differed from each other. Tr. at 13:2875 (Langer). It is not clear that the "fingerprints" differed because of mixing. Dr. Langer acknowledged that he did not attempt to understand what

causes a "peak" in an FTIR test result. Tr. at 13:2869-70 (Langer).

3.533. Dr. Langer testified that the molecular change in ESI's product was due to the intermolecular mixing of ethylcellulose and HPC in the coating material. (13 Tr. 2811, 2815, 2930 (Langer)). This conclusion is fully supported by the IR spectra data indicating that ESI's product contained different absorption signals than what one would expected from a layered product. (13 Tr. 2814-15 (Langer)). (13 Tr. 2992-93 (Banker)).

Complaint Counsel's Response to Finding No. 3.533

The proposed finding is misleading because it implies that Dr. Langer knows what causes the height of a peak, or that any molecular change in ESI's product must be related to a mixture of EC and HPC. It is also irrelevant to the extent that the '743 patent claims only a uniform mixture of EC and HPC. The proposed finding is not supported by the evidence. *See* CPRF 3.524, 3.528, 3.532.

3. Scanning Electron Microscopy ("SEM") Photomicrographs Proved Intermixing of Ethylcellulose and HPC (SPX 713)

3.534. Dr. Langer conducted experiments to determine whether one could visually detect ESI's alleged layering. (13 Tr. 2805, 2838 (Langer)). Scanning Electron Microscopy ("SEM") photomicrographs of various ESI samples, both the intermediates and the compressibles, and other samples were taken.

Complaint Counsel's Response to Finding No. 3.534

The proposed finding is misleading to the extent that it fails to disclose that he

was not present when the studies were conducted and thus has no first hand knowledge of how the SEM studies were done. Dr. Langer merely read the studies once they were completed. Tr. at 13:2834-35 (Langer).

3.535. These photomicrographs showed that there was no visual confirmation of layers in ESI's coating material. (13 Tr. 2809-10, 2859 (Langer)).

Complaint Counsel's Response to Finding No. 3.535

The proposed finding is misleading because Dr. Langer provided no testimony to establish the scientific methodology under which these SEM photographs were produced or read. Dr. Langer acknowledged that of 26 views taken in his SEM study, only three were at the highest magnification and with a cross section of a microcompressible tablet that included both EC and HPC. Tr. at 13:2848 (Langer). The prosed finding is also not supported by the evidence because Dr. Banakar testified that one of the three SEM's that Dr. Langer took of a cross section of the ESI tablet, Figure 8d in CX 1679, showed two distinct layers composed of EC and HPC. Tr. at 26:6405-06 (Banakar). Dr. Banakar also testified that one of the three SEM's that Dr. Langer took of a cross section of the ESI tablet, Figure 8d in CX 1679, showed that the ESI tablet was not a uniform mixture of both the polymers that were applied. Tr. at 26:6405-06 (Banakar).

3.536. In performing SEM, a sample is prepared by coating the sample with a spray

containing gold atoms. (13 Tr. 2805 (Langer)). Electrons are then shot at the gold covered sample. (13 Tr. 2805, 2834 (Langer)). The microscopy apparatus then detects the electrons reflected from the sample and the data is subsequently processed to display a visual representation of the sample. (13 Tr. 2805 (Langer)). The photomicrographs can show the molecular composition of the object being studied. (13 Tr. 2848 (Langer)).

Complaint Counsel's Response to Finding No. 3.536

Complaint Counsel has no specific response.

3.537. By comparing paired photomicrographs of ESI's intermediate (ethylcellulose coated only) samples with compressible (ethylcellulose and HPC coated) samples, Dr. Langer testified that the photographs of ESI's compressibles did not display different layers. (13 Tr. 2808-2809, 2859 (Langer)).

Complaint Counsel's Response to Finding No. 3.537

The proposed finding is misleading and not supported by the evidence. *See CPRF.* 3.535.

3.538. Dr. Langer further noted that had the components of ESI's product been in layers, one would expect to see the layering in the photomicrographs, especially when compared with the intermediates. (13 Tr. 2810 (Langer)).

Complaint Counsel's Response to Finding No. 3.538

The proposed finding is misleading because Dr. Langer has never seen a control that had either separate EC and HPC layers or that had a uniform mixture. Dr. Langer did not use a control with a separate EC and HPC layer. Tr. at 13:2934 (Langer). Dr. Langer never looked at Schering's K-Dur product as a comparison mixture of EC and HPC. Tr. 13:2824 (Langer). Dr. Langer acknowledged that one would have expected the Schering tablet to have been mixed at the molecular level. Tr. at 13:2823 (Langer).

3.539. Accordingly, Dr. Langer concluded that ESI's product did not contain layered components in the potassium crystal's coating material. (13 Tr. 2809-10 (Langer)).

Complaint Counsel's Response to Finding No. 3.539

The proposed finding is not supported by the evidence for the reasons stated in CPRF 3.535 and 3.538.

3.540. Dean Banker testified that he also reviewed the SEM photomicrographs of ESI's product taken under Dr. Langer's direction and agreed with Dr. Langer's conclusion that the pictures showed "no discernable boundaries between HPC and ethylcellulose." (13 Tr. 2992 (Banker)).

Complaint Counsel's Response to Finding No. 3.540

The proposed finding is not supported by the evidence to the extent that Dr. Banker's opinion depends on the validity and reliability of Dr. Langer's work, which

has not been established. *See* CPRF 3.534-3.539.

3.541. Dr. Langer also reviewed photomicrographs taken by ESI. (13 Tr. 2862 (Langer)). Dr. Langer was unable to reach any conclusion regarding layering based on the ESI slides because the slides were prepared by freezing them in liquid nitrogen, a procedure that cracks the sample's coating. (13 Tr. 2862, 2901, 2921 (Langer)). Dr. Langer testified that the use of nitrogen to freeze samples is "not an accepted method of preparing samples for microscopy." (13 Tr. 2921 (Langer)). Because of the sample's faulty preparation, Dr. Langer could not interpret the data as the photographs were incomprehensible. (13 Tr. 2921 (Langer)).

Complaint Counsel's Response to Finding No. 3.541

The proposed finding is incomplete and misleading because Dr. Langer admitted that freezing will work if the sample is cut in thin sections, and that his reference lab also does that. Tr. at 13:2862 (Langer). The proposed finding also ignores a contradictory opinion from Dr. Hopfenberg in the underlying patent litigation. Dr. Hopfenberg reached the conclusion that the SEM studies conducted by Dr. Butler for ESI showed HPC forms a separate and distinct layer deposited upon the ethylcellulose layer in the ESI product. Tr. at 13:2901 (Langer); SPX 695* at ESI EXP 000753-765) (Expert Report by Dr. Hopfenberg with Mr. Butler).

3.542. Dr. Banakar never saw the originals of the SEMs. Despite this, he testified that two of Dr. Langer's photomicrographs, figures 7d and 8d, showed demarcations that indicates

separate and distinct layers of HPC and ethylcellulose. (26 Tr. 6439 (Banakar)).

Complaint Counsel's Response to Finding No. 3.542

The proposed finding of fact is misleading to the extent that Mr. Lavelle assured the court that the originals could not be found and that he thought the copies were "clear, and they were more than adequate for cross examination in his deposition." Tr. at 13:2803 (Statement by Mr. Lavelle, counsel for Schering).

3.543. Figures 7d and 8d are paired lots of ethylcellulose only and ethylcellulose with HPC samples, where the odd numbered lots correspond to a system without HPC and the even numbered lots correspond to a system with both ethylcellulose and HPC. (13 Tr. 2807 (Langer); SPX 713). Thus, figure 7d is a photomicrograph of ESI's intermediate product, which are the potassium chloride crystals coated with ethylcellulose only. (13 Tr. 2807 (Langer); SPX 713). There is no HPC at all in the sample shown in figure 7d. (13 Tr. 2807 (Langer); SPX 713). In fact, none of the ESI experts in the underlying case saw any evidence of distinct layer of ethylcellulose and HPC and figures 7d and 8d. (26 Tr. 6444 (Banakar)).

Complaint Counsel's Response to Finding No. 3.543

The proposed finding of fact is misleading because Dr. Banakar testified that he did not recall whether the ESI experts in the underlying case saw any evidence of a distinct layer of EC and HPC, not that they had not done so. Tr. at 26:6444 (Banakar).

3.544. As explained by Dr. Langer, the appearance of a demarcation in figures 7d and 8d represent the exterior surface of the samples tested and not a separate layer of a cross section of the samples. (13 Tr. 2846-48 (Langer)).

Complaint Counsel's Response to Finding No. 3.544

The proposed finding of fact is incomplete and misleading because Dr. Langer admitted that there was an optical contrast and a more granular appearance in figure 8d, which only did not "necessarily" mean they were different layers. Tr. at 13:2860-61 (Langer).

4. Dissolution Testing Proved Intermixing of Ethylcellulose and HPC

3.545. Dr. Langer reviewed dissolution tests conducted by ESI in the underlying litigation (13 Tr. 2818 (Langer)). ESI recruited a company called Ricerca to conduct the dissolution tests. (13 Tr. 2819 (Langer)). Dr. Langer had a number of concerns with the Ricerca dissolution tests. (13 Tr. 2819 (Langer)). Dr. Langer noted that the test result from one of Ricerca's tests showed the HPC dissolving very slowly out of the system. (13 Tr. 2819, 2920 (Langer)). Ricerca's other tests showed the HPC dissolving out of the system very quickly. (13 Tr. 2819, 2923 (Langer)). Thus, Dr. Langer noted that the test results were at best "ambiguous." (13 Tr. 2819, 2923 (Langer)). Dr. Langer was not able to draw any conclusions regarding HPC from these particular studies. (13 Tr. 2820, 2821, 2923 (Langer))Dr. Langer also reviewed dissolution tests conducted by Dr. Peppas. (13 Tr. 2821, 2923 (Langer)). Dr. Langer testified

that Dr. Peppas' dissolution test results were more reliable because the tests were in compliance with USP standards and were repeated many times with consistent results. (13 Tr. 2821, 2923 (Langer)).

Complaint Counsel's Response to Finding No. 3.545

The proposed finding is incomplete, misleading, and not supported by the evidence. It is incomplete in that it does not disclose that Dr. Langer had not looked with any detail into how a water soluble polymer applied to a layer of a water insoluble polymer would interpenetrate EC. Tr. at 13:2880. Dr. Langer acknowledged that if HPC was removed quickly from the ESI tablet in water the theory would be that its not intermixed with EC. Tr. at 13:2891 (Langer). Dr. Langer acknowledged that in one of the tests that Ricerca performed the HPC did not dissolve out of the Schering K-Dur tablet even though it did from the ESI tablet in less than a minute. Tr. at 13:2824-25 (Langer).

The proposed finding is not supported by the evidence in that it ignores the conflicting opinion of Dr. Hopfenberg, an expert witness for ESI in the underlying patent litigation, who took the position that HPC was removed quickly from the EC in the ESI tablet. Tr. at 13:2892-93 (Langer). The purpose of the extraction test was to see if the HPC could be extracted quickly from the ESI product. Tr. at 13:2897 (Langer). Dr. Hopfenberg took the position that the HPC does not function as a sustained release agent in the ESI tablet. Tr. at 13:2895 (Langer); SPX * 693 at ESI EXP 000697-700 (Expert Report by Dr. Hopfenberg).

The proposed finding is misleading in that it suggests that ESI should have used a

methodology for dissolution testing of a drug coating that was not appropriate. Dr. Banakar testified that Dr. Hopfenberg's results show the HPC dissolved out rapidly in the ESI tablet, and this clearly indicates that the EC and HPC form two distinct layers in the ESI tablet. Tr. at 26:6407-08 (Banakar). Dr. Banakar testified that Dr. Langer made a fundamental error in relying on USP dissolution tests to draw a conclusion that EC and HPC were mixed. Dr. Banakar criticized use of the USP test to measure the dissolution of HPC from the EC in ESI's product, because the USP test is intended to be used to measure dissolution for a finished dosage form rather than an intermediate or an excipient. Tr. at 26:6409 (Banakar). An excipient is a component in a formulation which is inert and is used to structure the product. Tr. at 26:6410 (Banakar). The USP dissolution tests require the quantification of amount of drug released and not the amount of excipient released. Tr. at 26:6409 (Banakar). Dr. Banakar testified that in looking at the ESI product to analyze whether it is a mixture of EC and HPC, the issue is the rate of excipient release. Tr. at 26:6409 (Banakar). Thus, Dr. Banakar concluded that the USP dissolution test relied on by Dr. Langer was the wrong test to use determine whether the HPC, a water soluble component, will solubilize rapidly. Tr. at 26:6409-10 (Banakar). Dr. Banakar disagreed with Dr. Langer's reliance on USP dissolution tests because those test have no meaning when used to measure dissolution of an excipient that is not the active drug substance. Tr. at 26:6410 (Banakar). Thus, Dr. Banakar concluded that Dr. Langer used the wrong type of dissolution test to determine whether the EC and HPC were mixed in ESI's product.

3.546. HPC dissolves quickly in water. (13 Tr. 2818, 2820 (Langer)). Dr. Peppas' tests showed that HPC did not dissolve quickly from the test tablets. (13 Tr. 2821 (Langer)). Instead, Dr. Peppas tests showed that less than 30% of the HPC came out after five minutes. (13 Tr. 2821 (Langer)). These tests also indicated that even after three hours, all of the HPC did not come out. (13 Tr. 2821 (Langer)).

Complaint Counsel's Response to Finding No. 3.546

The proposed finding's reference to Dr. Peppas' tests is incomplete to the extent that it does not disclose that Peppas' USP test was not the appropriate test to show if HPC would dissolve quickly and that ESI obtained different results from Ricerca labs. Tr. at 26:6407, 6409-11 (Banakar)

The proposed finding is misleading and incomplete in that it omits Dr Hopfenberg's opinions based on ESI's release rate studies that the HPC overcoat layer was not mixed with the EC release layer. *See* CPRF 3.545.

3.547. Dr. Langer concluded based on his review of Dr. Peppas' tests that the HPC and ethylcellulose in ESI's product were mixed. (13 Tr. 2821, 2926 (Langer)). In fact, Dr. Langer estimated that the degree of mixing was at least 50%. (13 Tr. 2821, 2926 (Langer)). Dr. Langer's conclusion is based on the premise that if there were no intermolecular mixing of the HPC and ethylcellulose, all of the HPC would have come out in one minute. (13 Tr. 2821, 2822 (Langer)).

Complaint Counsel's Response to Finding No. 3.547

The proposed finding of fact's reference to Dr. Peppas' tests is incomplete to the extent that it does not disclose that Peppas' USP test was not the appropriate test to show if HPC would dissolve quickly and that ESI obtained different results from Ricerca labs. *See* CPRF 3.546.

5. ESI's Release Rate Studies Proved Intermixing of Ethylcellulose and HPC

3.548. Dean Banker testified that during the underlying ESI case, he studied ESI's own release rate studies. These release rate studies measured the rate of potassium chloride release in both ESI's intermediates and compressibles. (13 Tr. 2992, 3005 (Banker)).

Complaint Counsel's Response to Finding No. 3.548

Complaint Counsel has no specific response.

3.549. ESI's release rate studies showed an increase in the release rate of potassium chloride from ESI's final product as compared with the intermediate product, which was potassium chloride crystals coated with ethylcellulose only. (13 Tr. 3008 (Banker)).

Complaint Counsel's Response to Finding No. 3.549

The proposed finding is misleading because it implies that the increase in the release rate of potassium chloride in ESI's product was significantly different from that in

the intermediate. Dr. Hopfenberg, an expert in the underlying patent litigation, reviewed the release rate data studied by Dr. Banker and found that the data did not establish that HPC affects the release rate characteristics of the EC release coating. According to Dr. Banker, Dr. Hopfenberg held the opinion that the comparison demonstrated that the HPC overcoating does not affect release from the ESI microcapsules in comparison to the significant effect of the HPC in an embodiment of the '743 patent, i.e., Key's product, which uses of a mixture of EC with HPC in a single layer. Tr. at 14:3214-16 (Banker).

3.550. The increased release rate of potassium chloride was relevant to addressing the issue of mixing because HPC, when intermixed with ethylcellulose, facilitates the release of potassium chloride from the tablet. (13 Tr. 3009 (Banker)).

Complaint Counsel's Response to Finding No. 3.550

The proposed finding is misleading in that it states as a fact that there was an "increased" release rate after the HPC overcoating is applied to ESI's EC release coat. *See* CPRF 3.549.

3.551. As water penetrates the coating material of ESI's product, the HPC molecules hydrate the coating material, causing the film to swell. (13 Tr. 3009, 3073 (Banker)). Dean Banker explains that this mechanism enables more water to diffuse through the coating and reach the potassium chloride crystals, ultimately dissolving the potassium chloride and allowing it to leach out through the film. (13 Tr. 3009, 3073 (Banker)).

Complaint Counsel's Response to Finding No. 3.551

The proposed finding is not supported by the evidence because it is based on speculation. Dr. Banker did not do any study to confirm that his theory was correct. Dr. Langer had not looked with any detail into how a water soluble polymer applied to a layer of a water insoluble polymer would interpenetrate. Dr. Hopfenberg concluded that Dr. Banker imagined that the conditions under which ESI applies HPC will cause the HPC to interpenetrate the previously applied ethylcellulose coating. Dr. Banker acknowledged that in the underlying patent litigation, Dr. Hopfenberg thought Dr. Banker was "crazy" for saying that water could interpenetrated EC films and carry HPC along with it. Tr. at 14:3212-16 (Banker). More particularly, Dr. Hopfenberg stated in his expert report that Dr. Banker's opinion is belied by the known low water swelling of EC, which is insufficient to afford interpenetration of polymeric molecules such as HPC into the EC coating. SPX 693* at ESI EXP 000727 (Expert Report by Dr. Hopfenberg).

3.552. If the HPC did not intermix with the ethylcellulose, one would expect to see no change in release rates. (13 Tr. 3009 (Banker)).

Complaint Counsel's Response to Finding No. 3.552

The proposed finding is misleading and incomplete. *See* CPRF 3.549.

3.553. Thus, the fact that the release rate of potassium chloride increased in ESI's

product after HPC had been added further demonstrates that the ethylcellulose and HPC are intermixed in ESI's product. (13 Tr. 2992, 3005 (Banker)).

Complaint Counsel's Response to Finding No. 3.553

The proposed finding is misleading and incomplete. *See* CPRF 3.549.

6. ESI's Argument for Its Coating Material Having Two Separate and Distinct Layers are not Persuasive

3.554. ESI presented only one argument intending to prove that its coating material has two separate and distinct layers. (13 Tr. 2990 (Banker)). ESI claims that its "layering" manufacturing process, wherein the potassium chloride crystals are first coated by the ethylcellulose in a coacervation process and then coated with HPC in a fluidized bed process, produces two separate and distinct layers of ethylcellulose and HPC. (SPX 687, *Defendant's Memorandum of Law in Support of Its Motion for a Markman Ruling on Patent Claim Construction and/or for Partial Summary Judgment of No Literal Infringement*, at 18, 25-26).

Complaint Counsel's Response to Finding No. 3.554

The proposed finding is incomplete because it ignores the argument that the ESI product worked differently from that claimed in the '743 patent. Dr. Banker acknowledged that ESI contended that unless the EC and HPC were mixed, the '743 patented invention would not work as a sustained release agent. Tr. at 14:3089 (Banker). Dr. Hopfenberg took the position in the underlying patent litigation that the HPC in the ESI product formed a separate and distinct top coat over the EC. Tr. at 14:3206-07 (Banker). Dr. Hopfenberg took the position in he

underlying patent litigation that the release rate did not change much after the application of the EC. Tr. at 14:3208-09 (Banker). ESI's position was that the HPC dissolves quickly, leaving behind the ethylcellulose. Tr. at 14:3207 (Banker). ESI contended that the EC in its product was the remaining functioning release coat. Tr. at 14:3207 (Banker). ESI contended that the HPC top coat did not contribute to the controlled release properties of the ESI tablet. Tr. at 14:3207 (Banker).

3.555. In ESI's manufacturing process, the potassium chloride crystals are first coated with ethylcellulose in an coacervation process. The HPC is thereafter applied to ESI's intermediate (ethylcellulose coated) product using the Wurster air suspension process. (13 Tr. 3002 (Banker)).

Complaint Counsel's Response to Finding No. 3.555

The proposed finding is incomplete because it does not disclose that coacervation is a different coating process than the spray mixture specified in the '743 patent. The coating in ESI's product was produced through a coacervation process where the EC is applied as a first layer and then HPC is applied. Tr. at 14:3080-81 (Banker). ESI contended that its manufacturing process produced two distinct coatings of EC and HPC. Tr. at 14:3201 (Banker).

Dr. Banker testified that coacervation is a different coating process from the sprayed system described in the '743 patent. Tr. at 14:3085-86 (Banker). Dr. Banker admitted that the fluidized bed process called for in the '743 patent may produce a more uniform

coating, particularly with respect to the thickness of the coating, around the particles of potassium chloride as compared with coacervation that was used to coat the ESI process. Tr at 14:3078 (Banker). The coating in Schering's K-Dur product was sprayed in a mix of EC and HPC. Tr. at 14:3080 (Banker).

3.556. In the Wurster process, is HPC is applied to the ethylcellulose coated potassium chloride crystals at very high temperatures (on the order of 140 degrees Fahrenheit) over a period of four to six hours. (13 Tr. 2991, 3002-03 (Banker)). These conditions tended to induce inter-penetration of HPC into the ethylcellulose by expanding the ethylcellulose film and thereby increasing molecular motion. (13 Tr. 2991, 3003 (Banker)).

Complaint Counsel's Response to Finding No. 3.556

The proposed finding is not supported by the evidence because it is based on speculation. Dr. Banker did not do any study to confirm his theory was correct. Dr. Langer had not looked into with any detail how a water soluble polymer applied to a layer of a water insoluble polymer would interpenetrate. Dr. Hopfenberg concluded that Dr. Banker imagined that the conditions under which ESI applies HPC will cause the HPC to interpenetrate the previously applied ethylcellulose coating. Dr. Banker acknowledged that, in the underlying litigation, Dr. Hopfenberg thought Dr. Banker was "crazy" for saying that water could interpenetrate EC films and carry HPC along with it. Tr. at 14:3212-16 (Banker). In his expert report, Dr. Hopfenberg stated that Dr. Banker's assertions regarding interpenetration are contradicted by the characteristically

low water swelling of EC, which is insufficient to afford interpenetration of polymeric molecules such as HPC into the EC coating. SPX 693* at ESI EXP 000727 (Expert Report of Dr. Hopfenberg).

3.557. Additionally, water is used to spray the HPC onto the ethylcellulose in the Wurster process. (13 Tr. 2991, 3003 (Banker)). The use of water induces mixing because water has a slow evaporation rate and may tend to cause the HPC to penetrate into the ethylcellulose. (13 Tr. 2992, 3003 (Banker)).

Complaint Counsel's Response to Finding No. 3.557

The proposed finding is not supported by the evidence because it is based on speculation. *See* CPRF 3.556.

3.558. Thus, despite its two step coating process, ESI's coating components nonetheless became mixed upon application to the potassium crystals. (13 Tr. 2818 (Langer); 13 Tr. 2992, 3003 (Banker)).

Complaint Counsel's Response to Finding No. 3.558

The proposed finding is not supported by the evidence because it is based on speculation and contrary to other record evidence. *See* CPRF 3.556. Dr. Banakar testified that in ESI's product there are two distinct coats of EC and HPC. Tr. at 26:6389-90 (Banakar). Dr. Banakar testified that these two distinct coats are separate and

independent of each other and mutually exclusive. Tr. at 26:6390 (Banakar). Dr. Banakar testified that ESIs product is structurally different compared to '743 patented invention. Tr. at 26:6390_91 (Banakar). Dr. Banker acknowledged that there may be some differences in coating morphology and structure between particles that are coated with a sprayed system as compared with particles coated through coacervation. Tr. at 14:3086 (Banker). Dr. Banker acknowledged that the different process result in different structural morphologies of the resultant coating. Tr. at 14:3088 (Banker). Dr. Banker acknowledged that the different morphologies could lead to different release rates from the "raw" EC. Tr. at 14:3247 (Banker).

The proposed finding is also incomplete and misleading in that it omits contrary opinions by Dr. Hopfenberg in his expert report. In that report, Dr. Hopfenberg stated that the ESI coating process results in two separate and distinct layers, such that the HPC layer does not contribute to nor affect the controlled release properties of the EC undercoating while the '743 patent teaches that the HPC in the polymeric mixture of EC and HPC regulates the release properties of the EC. SPX 693* at ESI EXP 000725 (Expert Report of Dr. Hopfenberg).

7. Ethylcellulose and HPC in ESI's Product are Intermixed

3.559. In view of the many different scientific experiments conducted under his direction and tailored to study the amount of mixing between HPC and ethylcellulose, the evidence supports the conclusion that there was a significant amount of intermolecular mixing between the

ethylcellulose and the HPC in ESI's product (13 Tr. 2822, 2932 (Langer)).

Complaint Counsel's Response to Finding No. 3.559

The proposed finding is not supported by the evidence because it is merely a summary of other findings which in turn are incomplete, misleading, or not supported by the evidence. In particular, Dr. Langer acknowledged that from his SEM studies he could not draw conclusions about the degree of uniformity of any mixture that may exist of EC and HPC in the ESI product. Tr. at 13:2852 (Langer). Dr. Langer acknowledged that from the SEM studies he can say what degree of depth of mixing that may exist in the EC and HPC in the ESI product. Dr Langer acknowledged that from the SEM studies he can not quantify the degree of mixing that may exist in the EC and HPC in the ESI product. Tr. at 13:2852 (Langer). Dr. Langer acknowledged that with respect to the DSC and FTIR studies he also could not quantify the degree of any mixing of EC with HPC that might have existed in the ESI product. Tr. at 13:2855-2856 (Langer).

The proposed finding is also misleading and incomplete in that omits any reference to opinions and studies offered in the underlying patent litigation by ESI's technical experts indicating that there was little, if any, intermixing between the EC and the HPC in ESI's product. Dr. Hopfenberg was prepared to testify that his own SEM studies demonstrated that, in ESI's product, the HPC forms a separate and distinct layer deposited upon the EC layer, that does not fall within the proper interpretation of the limitation in the '743 patent of "a coating material". SPX 695* at ESI EXP 00753-765 (Expert Report of Dr. Hopfenberg with Mr. Butler). In addition, Dr. Hopfenberg was

prepared to testify that his HPC release studies indicated that HPC forms a separate and distinct layer from EC in ESI's product. SPX 693* at ESI EXP 000697-700 (Expert Report of Dr. Hopfenberg). Dr. Hopfenberg opined that his studies demonstrated that the HPC binder layer in ESI's microcapsules is quickly removed from water, whereas no HPC is removed from the coating material in Key's product, an embodiment of the '743 patent. SPX 693* at ESI EXP 000697 (Expert Report of Dr. Hopfenberg). The HPC release data, according to Dr. Hopfenberg, demonstrated that the ESI product did not have a coating material that was a mixture of EC with HPC as claimed by the '743 patent and reflected in its embodiments. SPX 693* at ESI EXP 000697-700 (Expert Report of Dr. Hopfenberg).

3.560. In Dr. Langer's expert opinion on the issue of mixing, "the overwhelming weight, from a scien[tific] standpoint, went to Schering." (13 Tr. 2906 (Langer)).

Complaint Counsel's Response to Finding No. 3.560

The proposed finding is not supported by the evidence because it is merely a summary of other findings which in turn are incomplete, misleading, or not supported by the evidence. *See* CPRF 3.516-3.559.

3.561. Dean Banker noted that the experiments did not contradict each other and that "[i]n this particular case, every single test indicated mixing...." (13 Tr. 3012 (Banker)).

Complaint Counsel's Response to Finding No. 3.561

The proposed finding is not supported by the evidence because Dr. Banker's opinion depends on the validity and reliability of Dr. Langer's work which has not been established. *See* CPRF 3.516-3.559.

3.562. Thus, even if the term "coating material" in claim 1 of the '743 patent were construed to require mixing, ESI's product met each and every limitation of the '743 patent's claim. (13 Tr. 3013 (Banker)). ESI's product literally infringed claim 1 of the '743 patent. (15 Tr. 3367 (Miller)).6

Complaint Counsel's Response to Finding No. 3.562

The proposed finding is incomplete and misleading in that it is contradicted by Schering's own patent law expert, Mr. Miller. Mr. Miller testified that if the district court had adopted ESI's claim interpretation of "coating material", which required a complete, homogeneous mixing of the EC with HPC, then Schering could not have established literal infringement. Tr. at 15:3397 (Miller).

The proposed finding is also misleading and incomplete in that it omits the fact that Dr. Hopfenberg was prepared to testify that the EC and HPC in ESI's product were

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6 Although ESI contested the issue of literal infringement, ESI's lawyer testified that ESI's tablet would infringe the '743 patent under the doctrine of equivalents. (CX 1482 at 104-5 (Alaburda I.H.)). Dr. Banker testified that the HPC in ESI's product performed substantially the same function, in substantially the same way, to reach the same result as the result claimed in the '743 patent, namely the production of potassium chloride tablets made up of coated crystals of potassium chloride. (14 Tr. 3028 (Banker)).

not mixed in the manner required under the '743 patent. See 3.559.

The proposed finding is misleading and irrelevant to the extent that it equates any level of intermixing with the uniform and homogenous mixture required to produce the invention claimed by the '743 patent. It is also not supported by the evidence to the extent that there is no evidence that ESI's product was a uniform and homogenous mixture of EC and HPC. Dr. Banakar testified that ESI's product is constructed with a first coat of ethycellulose over the potassium chloride and then HPC is applied as a second coat. Tr. at 26:6387 (Banakar). Dr. Banakar testified that in ESI's product there are two distinct coats of EC and HPC. Tr. at 26:6389-90 (Banakar). Dr. Banakar testified that these two distinct coats are separate and independent of each other and are mutually exclusive. Tr. at 26:6390 (Banakar). Dr. Banakar testified that ESI's product is structurally different compared to the '743 patented invention. Tr. at 26:6390–91 (Banakar).

The proposed finding is not supported by the evidence because it depends on the validity and reliability of Dr. Langer's work which has not been established. *See* CPRF 3.516-3.559.

F. The ESI Settlement Provided No Delay in ESI's Entry

1. Merits of Infringement Case Indicate Likely ESI Entry after Patent Term Expires

3.563. Schering had a very strong case on the merits of the ESI case and therefore had a

very high probability of prevailing on the infringement issue. (15 Tr. 3323, 3351 (Miller)).

Complaint Counsel's Response to Finding No. 3.563

[redacted] Tr. 15:3287, 3392-95 (Miller); [redacted] Accordingly, Mr. Miller is not qualified to render opinions as to the merits or probability of Schering's success on the infringement issue. Tr. 15:3287, 3392-95 (Miller).

The proposed finding is further irrelevant and unsupported by the evidence in that cites Mr. Miller's opinion as its only basis, even though Mr. Miller's methodology of assessment of the likely outcome of the case is unreliable and untested. *See* CPRF 3.479, CPF 1360-1363.

The proposed finding is not supported by the evidence, because Schering appears to have not sufficiently proved its case during the *Markman* hearing in the underlying patent litigation against ESI. Dr. Banker acknowledged that the district court judge would have had to rule on the controversies in the *Markman* hearing between Schering and ESI. Tr. at 14:3248 (Banker). In the *Markman* hearing in the underlying litigation, the district judge raised the issue of whether one of ordinary skill reading the '743 patent would know that the invention would work with separate coatings. Tr. at 14:3038 (Banker). Dr. Banker acknowledged that in the underlying patent litigation the district

judge framed the issue as whether the '743 patent is broad enough to be read as including a separately layered coating of the substances mentioned in the '743 patent. Dr. Banker testified the district judge indicated that this was "far from a clear issue" and that Schering did not have a "slam dunk case." Tr. 14:3038-39 (Banker).

3.564. If the term "coating material" was construed to cover one or more layers, ESI's product infringed the '743 patent. (15 Tr. 3361 (C. Miller)). Similarly, if it was determined that the HPC and ethylcellulose in ESI's product mixed, ESI's product would infringe the '743 patent. (15 Tr. 3362 (C. Miller)).

Complaint Counsel's Response to Finding No. 3.564.

The proposed finding is incomplete and misleading in that it is contradicted by Schering's own patent law expert, Mr. Miller. Mr. Miller testified that if the district court had adopted ESI's claim interpretation of "coating material", which required a complete, homogeneous mixing of the EC with HPC, then Schering could not have established literal infringement. Tr. at 15:3397 (Miller).

The proposed evidence is misleading in that it is not supported by the evidence. *See* CPRF 3.516-3.559.

3.565. If Key had won the patent case, the court would have ordered the FDA to defer the approval of ESI's ANDA. (15 Tr. 3320 (C. Miller)). If ESI's ANDA had already been approved,

the court would have enjoined ESI from marketing its product until the expiration of the '743 patent. (15 Tr. 3321 (C. Miller)).

Complaint Counsel's Response to Finding No. 3.565

Complaint Counsel has no specific response.

3.566. The split of the patent term in the ESI settlement agreement is a fair representation of the likely outcome of the case. (15 Tr. 3369 (C. Miller)). As the '743 patent was set to expire September of 2006, the settlement agreement effectively allowed ESI entry to the marketplace approximately 33 months before the expiration of the '743 patent. (15 Tr. 3341 (C. Miller)).

Complaint Counsel's Response to Finding No. 3.566

The proposed finding is irrelevant in that it only cites Mr. Miller's opinion as its basis, even though Mr. Miller is only a patent law expert who is not qualified to render opinions on technical issues critical to resolution of the underlying patent litigations. Tr. 15:3287, 3392-95 (Miller). Accordingly, Mr. Miller is not qualified to render opinions as to the merits or probability of Schering's success on the infringement issue. Tr. 15:3287, 3392-95 (Miller).

The proposed finding is further irrelevant and misleading in that it cites Mr. Miller's opinion as its only basis, even though Mr. Miller's methodology for assessing of the likely outcome of the case is unreliable and untested. *See* CPRF 3.479, CPF 1360-1363.

The proposed finding is further irrelevant and misleading in that Mr. Miller's opinion as to whether the settlement constitutes a "fair representation" is only an opinion of a patent lawyer, not an economist, who never considered the impact of the reverse payment by Schering to ESI in this assessment. See CPF 1374-1377.

VI. THE UPSHER LITIGATION

A. Procedural Background of the *Upsher* Case

3.567. In 1995, Upsher-Smith Laboratories, Inc. ("Upsher") provided Schering a Paragraph IV certification asserting that Upsher's proposed formulation for a generic tablet for a sustained release potassium chloride did not infringe the '743 patent.[7] (SPX 1274 at ¶ 3 (Banker)); SPX 1275 at ¶ 42 (C. Miller); SPX 677).

Complaint Counsel's Response to Finding No. 3.567

Complaint Counsel has no specific response.

3.568. In December 1995, Schering sued Upsher for infringement of the '743 patent in the federal court for the United States District Court for the District of New Jersey. *Key Pharmaceuticals, Inc. v. Upsher-Smith Labs, Inc.*, No. 956281 (WHW) (D. N.J.). (SPX 1274 at ¶ 3 (Banker)); SPX 1275 at ¶ 42 (C. Miller); SPX 677).

Complaint Counsel's Response to Finding No. 3.568

[7] Upsher's product was called KLOR-CON M20. (SPX 1274 at ¶ 22 (Banker); SPX 1275 at ¶42 (C. Miller)).

Complaint Counsel has no specific response.

3.569. The case was assigned to Judge William Walls. The case was fully discovered by the parties and prepared for trial. Summary judgment motions were filed and argued. The case settled in June 1997, on the day before the trial was to begin. (SPX 1274 at 3 (C. Miller); SPX 1275, ¶42 (Banker)).

Complaint Counsel's Response to Finding No. 3.569

Complaint Counsel has no specific response.

1. **********

3.570. **********

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Complaint Counsel's Response to Finding No. 3.570

Complaint Counsel has no specific response.

3.571. **********

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[redacted]

Complaint Counsel's Response to Finding No. 3.571

Complaint Counsel has no specific response.

3.572. [redacted]

Complaint Counsel's Response to Finding No. 3.572

Complaint Counsel has no specific response.

B. Infringement Under the Doctrine of Equivalents was the Dispositive Issues

3.573. [redacted]

Complaint Counsel's Response to Finding No. 3.573

[redacted]

1. Upsher's Other Defenses Lack Merit

3.574. Upsher's other arguments, regarding the invalidity of the '743 patent and whether Schering engaged in inequitable conduct before the Patent Office, were not strong. (SPX 1275 ¶ 62 (C. Miller)).

Complaint Counsel's Response to Finding No. 3.574

The proposed finding is misleading and not supported by the evidence [redacted]

The proposed finding is misleading and incomplete [redacted]

[redacted]

The proposed finding is also unsupported by the evidence [redacted]

3.575. On the validity issue, Upsher's contention was that the '743 patent was invalid as "obvious" in view of the prior art. (SPX 679, *Answer* at 6-7). However, Upsher did not rely on prior art references that are more pertinent than the art already considered by the PTO. (SPX 1275 ¶ 62 (C. Miller)). The principle reference relied on by Upsher, the Hsiao '399 patent, was already considered by the PTO in granting the '743 patent. (SPX 1275 at ¶ 62 (C. Miller)). Thus, Upsher's invalidity defense was not persuasive. (SPX 1275 at ¶ 62 (C. Miller)); SPX 1274 at ¶ 25 (Banker)).

Complaint Counsel's Response to Finding No. 3.575

[redacted]

[redacted]

3.576. [redacted] Upsher's allegations of inequitable conduct were not persuasive (SPX 1275 at ¶ 62 (C. Miller)).

Complaint Counsel's Response to Finding No. 3.576

[redacted]

[redacted]

3.577. [redacted] Similarly, Complaint Counsel's patent law expert, Mr. Adelman agreed and stated that the only points of contention between Schering and Upsher are directed to the infringement issue. (32 Tr. 7728, 7824 (Adelman)).

Complaint Counsel's Response to Finding No. 3.577

The proposed finding is incomplete and misleading in that it implies that because Dr. Banakar did not testify on the validity of the '743 patent, complaint counsel has conceded the validity and enforceability of the '743 patent. Complaint counsel has never made such a concession. *See* CPRF 3.483

3.578. Hence, the dispositive issue in the Upsher case was the question of whether Upsher infringed claim 1 of the '743 patent under the doctrine of equivalents. (SPX 1275 at ¶ 4 (C. Miller)).

Complaint Counsel's Response to Finding No. 3.578

The proposed finding is nearly identical to Schering's Proposed Finding No. 3.573 In any event, the proposed finding is incorrect. *See* CPRF 3.573-3.577.

2. Infringement Issues Under the Doctrine of Equivalents was Dispositive

3.579. The broadest product claim in the '743 patent, and the patent claim most relevant to the *Upsher* litigation, is claim 1. ((Tr. 3320 (C. Miller); SPX 1275 at ¶ 30 (C. Miller)).

[redacted]

Complaint Counsel's Response to Finding No. 3.579

The claim chart is a demonstrative, and is not in evidence.

[redacted]

3.580. [redacted]

Complaint Counsel's Response to Finding No. 3.580

Complaint Counsel has no specific response.

3.581. The subject matter of the '743 patent uses a coating material comprising, among other ingredients, ethylcellulose with a viscosity greater than 40 cp. (SPX 1274 at ¶ 26 (Banker)); SPX 194, col. 8, ll. 18-33). [redacted]

Complaint Counsel's Response to Finding No. 3.581

Complaint Counsel has no specific response.

3.582. The parties agree that Upsher's KLOR-CON M product was an orally administered potassium chloride tablet. (SPX 1274, ¶ 23 (Banker))[redacted]

Complaint Counsel's Response to Finding No. 3.582

Complaint Counsel has no specific response.

3.583. [redacted]

Complaint Counsel's Response to Finding No. 3.583

Complaint Counsel has no specific response.

3.584. [redacted]

Complaint Counsel's Response to Finding No. 3.584

Complaint Counsel has no specific response.

3.585. [redacted]

Complaint Counsel's Response to Finding No. 3.585

Complaint Counsel has no specific response.

3.586. [redacted]

Complaint Counsel's Response to Finding No. 3.586

Complaint Counsel has no specific response.

3.587. [redacted]

Complaint Counsel's Response to Finding No. 3.587

Complaint Counsel has no specific response.

3.588. [redacted]

[redacted]

Complaint Counsel's Response to Finding No. 3.588

[redacted]

3. [redacted]

3.589. [redacted]

Complaint Counsel's Response to Finding No. 3.589

Complaint Counsel has no specific response.

3.590. [redacted]

Complaint Counsel's Response to Finding No. 3.590

Complaint Counsel has no specific response.

3.591. Claim 1, as originally filed, did not contain an ethylcellulose limitation based on viscosity, although certain of the narrower, dependent claims did specify a particular viscosity of ethylcellulose. (SPX 1275 at ¶ 53 (C. Miller); 32 Tr. 7757 (Adelman); SPX 709 at 1).

Complaint Counsel's Response to Finding No. 3.591

Complaint Counsel has no specific response.

3.592. The ethylcellulose viscosity limitation in claim 1 was added in the March 1, 1989 (SPX 1275 at ¶ 53 (C. Miller); 32 Tr. 7757 (Adelman); SPX 709 at 1-2).

Complaint Counsel's Response to Finding No. 3.592

Complaint Counsel has no specific response.

3.593. Amending claims during prosecution is a common practice in the pursuant of a patent. (32 Tr. 7740 (Adelman)). Moreover, under the law at the time of the Upsher case, not all such amendments or arguments created an estoppel. (32 Tr. 7740 (Adelman)).

Complaint Counsel's Response to Finding No. 3.593

[redacted] *See* CPRF 3.464-3.468.

3.594. [redacted]

Complaint Counsel's Response to Finding No. 3.594

The proposed finding is incomplete and therefore misleading in that it omits any reference to the arguments made by Schering in support of allowance of its pending

claims as novel over prior art in view of the viscosity limitation. *See* CPRF 3.464-3.468, •••••••

3.595. Key amended claim 1 by adding the language "greater than 40 cp" in conjunction with amending the scope of the claim from "a dosage unit for oral administration" to a pharmaceutical dosage unit "in tablet form." (SPX 1275 at ¶ 53 (C. Miller)).

Complaint Counsel's Response to Finding No. 3.595

The proposed finding is incomplete and therefore misleading in that it omits reference to the arguments submitted by Key in connection with its amendments, notably those arguments related to the viscosity amendment only and directed at the importance of that added limitation. *See* CPRF 3.464-3.468, ••••••••••••••

3.596. Prior to these amendments, the scope of claim 1 could have covered, in theory, liquids, capsules, tablets, or other oral formulations. (SPX 1275 at ¶ 53 (C. Miller)); SPX 709 at 1).

Complaint Counsel's Response to Finding No. 3.596

The proposed finding is incorrect in that it uses "amendments" rather than stating that it is only the amendment that added "tablet form" and not the amendment relating to viscosity of EC that is relevant to the prior scope of claim 1 in terms of different formulations. *See* CPRF 3.464-3.468, ••••••••••••••

3.597. In other words, Key amended claim 1 to make clear that it was claiming only a "pharmaceutical dosage unit in tablet form," rather than all potential "dosage unit[s] for oral administration" irrespective of dosage form. (SPX 1275 at ¶ 54 (C. Miller)).

Complaint Counsel's Response to Finding No. 3.597

The proposed finding is misleading in that it attempts to couple the two amendments in a way so as to obfuscate the distinction between the two amendments. The statements and arguments related to the amendment, "greater than 40 cp", related primarily to Key's efforts to surmount an obviousness rejection, while the amendment regarding "tablet form" was primarily directed to the issues of dosage units. *See* CPRF 3.461, 3.464-3.468, 3.596.

3.598. Indeed, had Key intended to amend its claims to distinguish the '399 patent, it would have claimed ethylcellulose with a viscosity greater than the 10 cp disclosed in the '399 patent. (SPX 1275 at ¶ 54 (C. Miller)).

Complaint Counsel's Response to Finding No. 3.598

The proposed finding is incorrect in that it omits any reference to Prof. Adelman's testimony that Key could have amended its claims to recite a viscosity limitation of "greater than 10 cp" but did not and instead chose to argue that the "greater than 40 cp" limitation was important in terms of patentability over the '399 patent. *See* CPRF 3.464-3.466. [redacted]

3.599. When Schering amended its claim to recite a viscosity of greater than 40 it may have surrendered coverage to a viscosity of 10, but no more. (SPX 1275, ¶ 59 (C. Miller)).

Complaint Counsel's Response to Finding No. 3.599

[redacted] *See* CPRF 3.464-3.468.

3.600. [redacted]

Complaint Counsel's Response to Finding No. 3.600

The proposed finding is incorrect and not supported by the evidence. *See* CPRF [redacted] 3.596-3.599.

4. [redacted]

3.601. [redacted]

Complaint Counsel's Response to Finding No. 3.601

Complaint Counsel has no specific response.

3.602. Claim 1 of the '743 patent claims an ethylcellulose having a viscosity greater than 40 cp. (SPX 194, col. 8, ll. 18-33).

Complaint Counsel's Response to Finding No. 3.602

Complaint Counsel has no specific response.

3.603. [redacted]

Complaint Counsel's Response to Finding No. 3.603

[redacted]

[redacted]

3.604. [redacted]

Complaint Counsel's Response to Finding No. 3.604

[redacted]

[redacted]

a. [redacted]

3.605. [redacted]

Complaint Counsel's Response to Finding No. 3.605

[redacted]

[redacted]

3.606. Viscosity is a measure of the resistance of a fluid to flow. It is measured in units called "centipoises," abbreviated as "cp." (SPX 1274, ¶ 50 (Banker)).

Complaint Counsel's Response to Finding No. 3.606

Complaint Counsel has no specific response.

3.607. In the context of the '743 patent, the primary significance of the ethylcellulose viscosity is its impact on the durability of the ethylcellulose coating and hence the ability of that coating to withstand compression forces. (SPX 1274 at ¶ 28 (Banker)).

Complaint Counsel's Response to Finding No. 3.607

The proposed finding is misleading in that the finding omits any reference to prosecution history of the '743 patent in which Key argued that the viscosity of the ethylcellulose was critical to its novelty over the prior art. *See* CPRF 3.464-3.468; [redacted]

The proposed finding also is not supported by the evidence. [redacted]

[redacted]

3.608. [redacted]

[redacted]

Complaint Counsel's Response to Finding No. 3.608

[redacted]

[redacted]

3.609. [redacted]

Complaint Counsel's Response to Finding No. 3.609

The proposed finding is not supported by the evidence, which includes Dr. Banakar's testimony and an admission by Dr. Banker that at the time of the underlying patent litigation, Dow literature described only Ethocel Standard 45 and 100 premium as viscosities recommended for use in microencapsulated pharmaceutical products. Tr. at 22:5233-34 (Banker). Dr. Banker acknowledged that Dow literature from May 1996 lists only Ethocel Standard 45 and 100 Premium viscosities recommended for use in microencapsulated pharmaceutical products. Tr. at 22:5235 (Banker). [redacted]

3.610. [redacted]

Complaint Counsel's Response to Finding No. 3.610

The proposed finding is not supported by the evidence. There is no empirical data in the '743 patent that describes the properties of EC 40 or 45 viscosity. Tr. at 22:5242 (Banker). Dr. Banker acknowledged that the Dow Chemical literature explains that by varying the type of Ethocel, the insoluble versus soluble, excipient ratio and the coating weight, wide variations of release rates can be achieved. Tr. at 22:5239-40 (Banker). The only data that the '743 patent provides for is for EC10 viscosity and EC100 viscosity. Tr. at 22:5241-42 (Banker). [redacted] Dr. Banker has asserted that EC 10 viscosity would not work to make tablets. Tr. at 22:5242 (Banker). [redacted]

3.611. [redacted]

Complaint Counsel's Response to Finding No. 3.611

[redacted] It is not

supported by the evidence because it conflicts with Dr. Banakar's opinion and Dow literature concerning recommended viscosities for microencapsulated products. *See* CPRF 3.609.

3.612. [redacted]

Complaint Counsel's Response to Finding No. 3.612

[redacted] It is not supported by the evidence because it conflicts with Dr. Banakar's opinion and Dow literature concerning recommended viscosities for microencapsulated products and because Schering can provide no data to support this conclusion. *See* CPRF [redacted] 3.609.

3.613. [redacted]

Complaint Counsel's Response to Finding No. 3.613

[redacted]

[redacted] It is not supported by the evidence because it conflicts with Dr. Banakar's opinion and Dow literature concerning recommended viscosities for microencapsulated products and because Schering can provide no data to support this conclusion. *See* CPRF [redacted] 3.609.

3.614. [redacted]

Complaint Counsel's Response to Finding No. 3.614.

[redacted] It is not supported by the evidence because it conflicts with Dr. Banakar's opinion and Dow literature concerning recommended viscosities for microencapsulated products. *See* CPRF 3.609. [redacted]

3.615. [redacted]

[redacted]

Complaint Counsel's Response to Finding No. 3.615

[redacted] It is not supported by the evidence because it conflicts with Dr. Banakar's opinion and Dow literature concerning recommended viscosities for microencapsulated products. *See* CPRF 3.609.

3.616. [redacted]

Complaint Counsel's Response to Finding No. 3.616

[redacted] In addition, Dr. Banker acknowledged that Dow literature from May 1996 lists only Ethocel Standard 45 and 100 Premium viscosities recommended for use in microencapsulated pharmaceutical products. Tr. at 22:5235 (Banker).

3.617. [redacted]

Complaint Counsel's Response to Finding No. 3.617

[redacted] Dr. Banker acknowledged that Dow literature from May 1996 lists only Ethocel Standard 45 and 100 Premium viscosities recommended for use in microencapsulated pharmaceutical products. Tr. at 22:5235 (Banker).

b. [redacted]

3.618. [redacted]

[redacted]

Complaint Counsel's Response to Finding No. 3.618

Complaint Counsel has no specific response.

3.619. [redacted]

Complaint Counsel's Response to Finding No. 3.619

Complaint Counsel has no specific response..

3.620. [redacted]

Complaint Counsel's Response to Finding No. 3.620

[redacted]

[redacted]

3.621. [redacted]

Complaint Counsel's Response to Finding No. 3.621

The proposed finding is incomplete and misleading. [redacted]

5. SMO is Equivalent to HPC

3.622. [redacted]

Complaint Counsel's Response to Finding No. 3.622

The proposed finding is not supported by the evidence. [redacted]

[redacted]

3.623. SPX 2259 (*demonstrative*) is a chart that summarized the evidence in the Upsher case on the question of whether the use of SMO was equivalent to the claimed invention. [redacted] SPX 1274, ¶ 49 (Banker)).

Complaint Counsel's Response to Finding No. 3.623

The demonstrative is not in evidence.

Evidence of Sorbitan Monooleate Equivalency

Evidence of Alleged Non-Equivalency	Evidence of Equivalency
Upsher disputes whether sorbitan monooleate is a plasticizer.	Dr. Banker refused to work with Upsher because he believed sorbitan monooleate worked the same way as HPC.
Sorbitan monooleate does not dissolve to form holes in the ethylcellulose.	Sorbitan monooleate, like HPC and PEG, is a plasticizer of ethylcellulose.
Sorbitan monooleate is used only as an anti-static agent during the coating process.	Upsher's Development Report listed sorbitan monooleate as a plasticizer.
Sorbitan monooleate is not a polymer.	Various peer-reviewed publications showed sorbitan monooleate as a plasticizer.
	Authoritative text book, The Theory and Practice of Industrial Pharmacy, in the chapter by Seitz refers to SMO as a plasticizer.
	Various other US patents directed to coating material for pharmaceutical tablets disclose sorbitan monooleate as a plasticizer.
	Sorbitan monooleate contains the same functional group as ethylcellulose and HPC.

SPX 2958

a. Dr. Banker Refused to Work with Upsher

3.624. Dean Banker testified that, on or before April 16, 1996, he was contacted by Bruce C. Haas, a lawyer representing Upsher, to serve as a consultant or an expert witness for Upsher in its defense against Key in the Upsher Litigation. (SPX 1274 at ¶ 6 (Banker); 22 Tr. 5205-6 (Banker)).

Complaint Counsel's Response to Finding No. 3.624

[redacted]

3.625. During this initial contact, Dean Banker agreed to review preliminary materials from Mr. Haas to determine the issues involved in the *Upsher* Litigation. (SPX 1274 at ¶ 6 (Banker); 22 Tr. 5205-6 (Banker)).

Complaint Counsel's Response to Finding No. 3.625

Complaint Counsel has no specific response.

3.626. On May 6, 1996, Dean Banker returned all the preliminary materials to Mr. Haas and a cover letter declining Upsher's engagement as a consultant or expert witness. In this letter, Dean Banker explained to Mr. Haas that upon based on his view of the preliminary materials, he knew that he could not represent Upsher in its defense because he knew full well from his research that sorbitan monooleate is a plasticizer. (SPX 1274 at ¶ 6 (Banker); 22 Tr. 5205-6 (Banker)).

Complaint Counsel's Response to Finding No. 3.626

[redacted]

[redacted]

b. [redacted]

3.627. [redacted]

Complaint Counsel's Response to Finding No. 3.627

[redacted]

[redacted]

[redacted]

3.628. [redacted]

Complaint Counsel's Response to Finding No. 3.628

[redacted]

c. [redacted]

3.629. Dean Banker testified that he has long-standing familiarity with the effects of sorbitan monooleate, and other oleates, in film coatings, including sustained release coatings. (22 Tr. 5206 (Banker); SPX 1274 at ¶ 29 (Banker)).

Complaint Counsel's Response to Finding No. 3.629

[redacted]

[redacted]

3.630. [redacted] (22 Tr. 5206 (Banker)

[redacted]

Complaint Counsel's Response to Finding No. 3.630

The proposed finding is misleading [redacted]

[redacted]

[redacted]

The proposed finding is also irrelevant [redacted] Dr. Rhodes, a colleague of Dr. Banker, [redacted] Dr. Banakar also testified that Upsher's experts in the underlying patent litigation also did not believe that the '743 patent related to the use of a plasticizer. Tr. at 26:6449 (Banakar).

[redacted]

[redacted] In sum, Dr. Banakar concluded that Dr. Banker used the term plasticizer as a "catch all" to attempt to show similarity between different coatings. Tr. at 26:6449-50 (Banakar).

3.631. Dean Banker explained that sorbitan monooleate molecule contains functional groups identical to those found in ethylcellulose, and this similarity of molecular structure permits the dispersion of the sorbitan monooleate molecules throughout the ethylcellulose coating structure, resulting in a film that has increased strength for resisting compression forces. (SPX 1274 at ¶ 29 (Banker)).

Complaint Counsel's Response to Finding No. 3.631

The proposed finding is incomplete. [redacted]

3.632. [redacted]

Complaint Counsel's Response to Finding No. 3.632

[redacted]

3.633. [redacted]

[redacted]

Complaint Counsel's Response to Finding No. 3.633

The proposed finding is misleading and irrelevant. [redacted]

The proposed finding is also incomplete and misleading [redacted]

[redacted]

3.634. [redacted]

[redacted]

Complaint Counsel's Response to Finding No. 3.634

The proposed finding is incomplete and misleading. Dr. Banker acknowledged that Dow Chemical literature has very clearly stated that HPC and PEG are used to affect the release patterns of EC. Tr. at 22:5239 (Banker).

The proposed finding is incomplete and misleading [redacted]

3.635. [redacted]

[redacted]

Complaint Counsel's Response to Finding No. 3.635

[redacted]

[redacted]

[redacted]

3.636. [redacted]

Complaint Counsel's Response to Finding No. 3.636

The proposed finding is not supported by the evidence. [redacted]

[redacted]

3.637. [redacted]

Complaint Counsel's Response to Finding No. 3.637

[redacted]

[redacted]

d. Authoritative Texts Showed SMO as a Plasticizer

3,638. [redacted]

[redacted]

Complaint Counsel's Response to Finding No. 3.638

[redacted]

[redacted]

3.639. [redacted]

Complaint Counsel's Response to Finding No. 3.639

Complaint counsel has no specific response.

c. SMO Enhances Permeability in the Same Way as HPC

3.640. SMO effects the permeability of the coating in KLOR-CON® M 20 in an equivalent and insubstantially different fashion from the coating claimed in the '743 patent. (SPX 1274 at ¶ 30 (Banker)). [redacted]

Complaint Counsel's Response to Finding No. 3.640

[redacted]

The proposed finding also is unsupported by the evidence in that Schering has

cited no experiments or data to support its contention that SMO is a permeability enhancer.

The proposed finding is not supported by the evidence. [redacted]

Dr. Banker acknowledged that the Dow Chemical literature explains that by varying the type of Ethocel, the insoluble versus soluble, excipient ratio and the coating weight, wide variations on release rates can be achieved. Tr. at 22:5239 (Banker).

3.641. [redacted]

Complaint Counsel's Response to Finding No. 3.641

[redacted]

[redacted]

3.642. [redacted]

Complaint Counsel's Response to Finding No. 3.642

[redacted]

6. Klor-Con® M20 Infringes Claim 1 of the '743 Patent Under the Doctrine of Equivalence

3.643. There is no substantial difference between Upsher's KLOR-CON® M 20 and the invention claimed in the '743 patent. (SPX 1274 at ¶ 22 (Banker)).

Complaint Counsel's Response to Finding No.3.643

[redacted]

3.644. Upsher's KLOR-CON® M 20 has the substantially same function and acts in the substantially same way to produce the substantially same result as the subject matter of the '743

patent. (SPX 1274 at ¶ 23 (Banker)).

Complaint Counsel's Response to Finding No.3.644

The proposed finding is not supported by the evidence. [redacted]

3.645. Like the tablet forming the subject matter of the '743 patent, KLOR-CON® M 20 functions as an orally administered, immediately dispersible sustained release potassium chloride tablet that minimizes gastric irritation. (SPX 1274 at ¶ 23 (Banker)).

Complaint Counsel's Response to Finding No.3.645

Complaint counsel has no specific response.

3.646. In both cases, the ethylcellulose coating of the potassium chloride crystals remains intact as the drug formulation travels through the gastrointestinal tract. (SPX 1274 at ¶ 31 (Banker)). Thereafter, the gastric and intestinal fluid diffuses through the ethylcellulose coating and dissolves the potassium chloride. (SPX 1274 at ¶ 31 (Banker)). The dissolved potassium chloride within the coated particles then diffuses back out through the coating, thereby releasing the drug into the gastrointestinal tract. This mechanism is known as diffusion. (SPX 1274 at ¶ 31 (Banker)).

Complaint Counsel's Response to Finding No.3.646

Complaint counsel has no specific response.

3.647. Klor-Con® M20 performs this function by creating potassium chloride microcapsules and compressing them into a tablet. (SPX 1274 at ¶ 23 (Banker)). The microcapsules may be rapidly dispersed, and the potassium chloride released, following administration. (SPX 1274 at ¶ 23 (Banker)). The result is that potassium chloride microcapsules are rapidly dispersed throughout the gastrointestinal tract, providing sustained release of potassium chloride in a way that minimizes gastric irritation. (SPX 1274 at ¶ 23 (Banker)).

Complaint Counsel's Response to Finding No.3.647

Complaint counsel has no specific response.

3.648. The materials used in KLOR-CON® M 20 are either the same as, or obviously interchangeable with, those disclosed in the '743 patent, as would be recognized by a person of ordinary skill in the pharmaceutical coating and tableting art. (SPX 1274 at ¶ 24 (Banker)).

Complaint Counsel's Response to Finding No.3.648

The proposed finding is not supported by the evidence. **********

3.649. Claim 1 of the '743 patent, for example, contains two elements: (1) a tablet comprised of a plurality of coated potassium chloride by weight of the tablet and (2) a coating material for the potassium chloride crystals. (SPX 1274 at ¶ 24 (Banker)).

Complaint Counsel's Response to Finding No.3.649

The proposed finding is incomplete and misleading in that it omits several claimed limitations on the coating material, i.e., that the material is comprised of EC with HPC and/or PEG wherein the EC has a viscosity of greater than 40 cp. CX 12 at FTC 0021322 (the '743 patent).

3.650. [redacted]

Complaint Counsel's Response to Finding No.3.650

Complaint counsel has no specific response.

3.651. The coating material used in KLOR-CON® M 20 is equivalent and obviously interchangeable with and insubstantially different from that claimed in the '743 patent. (SPX 1274 at ¶ 24 (Banker)).

Complaint Counsel's Response to Finding No.3.651

The proposed finding is incorrect and not supported by the evidence in that it omits any reference to the evidence regarding substantial differences in Upsher's coating material. [redacted]

3.652. [redacted]

Complaint Counsel's Response to Finding No.3.652

[redacted]

3.653. [redacted]

Complaint Counsel's Response to Finding No.3.653

The proposed finding is incomplete, misleading and not supported by the evidence. [redacted]

3.654. The coating material used in KLOR-CON® M 20 is also equivalent to and obviously interchangeable with and insubstantially different from that claimed in the '743 patent from the perspective of release rate and coating permeability. (SPX 1274 at ¶ 30 (Banker)).

Complaint Counsel's Response to Finding No.3.654

[redacted]

[redacted]

3.655. Upsher-Smith's ANDA states that KLOR-CON® M 20 is bioequivalent to K-DUR® 20 and that the release rate for KLOR-CON® M 20 does not differ in any meaningful way from that for K-DUR® 20. This means that the rate of release of potassium chloride from the two products is interchangeable for the purpose of using those products as a tableted pharmaceutical dosage form. (SPX 1274 at ¶ 32 (Banker)).

Complaint Counsel's Response to Finding No.3.655

The proposed finding is misleading and incorrect [redacted] Moreover, the specific release rate is not an element of the claims of the '743 patent such that it is irrelevant to any inquiry into the issue of infringement. CX 12 at FTC 0021322-23 (the '743 patent).

3.656. KLOR-CON® M 20 has a release rate substantially identical to that of K-DUR® 20, and the release rate is established in the KLOR-CON® M 20 in substantially the same way as in K-DUR® 20. (SPX 1274 at ¶ 30 (Banker)).

Complaint Counsel's Response to Finding No.3.656

The proposed finding is irrelevant, misleading and unsupported by the evidence. See CPRF3.655.

3.657. In other words, KLOR-CON® M 20 functions as a sustained release potassium chloride tablet in substantially the same way, to achieve the substantially same result, as K-DUR® 20. (SPX 1274 at ¶ 30 (Banker)).

Complaint Counsel's Response to Finding No.3.657

The proposed finding is irrelevant, misleading and unsupported by the evidence. See CPRF3.655.

3.658. The coating material used in KLOR-CON® M 20 is equivalent and obviously interchangeable with that claimed in the '743 patent from the perspective of film strength and coating durability. (SPX 1274 at ¶ 25 (Banker)).

Complaint Counsel's Response to Finding No.3.658

The proposed finding is misleading and not supported by the evidence. [redacted]

3.659. The ethylcellulose coating used in KLOR CON® M 20 has a film strength and durability to withstand tableting compression forces equivalent to that claimed in the '743 patent. As indicated by Dean Banker's crushing studies. (SPX 1274 at ¶ 41 (Banker)).

Complaint Counsel's Response to Finding No.3.659

[redacted]

[redacted]

3.660. The patent claims and discloses the use of ethylcellulose as the primary coating material in order to obtain sustained release of the potassium chloride and that is also the primary coating material used in KLOR-CON® M 20 to achieve the same result. The grade and purity of ethylcellulose suggested by the patent, namely that marketed by Dow Chemical as Ethocel® premium, is that used in KLOR-CON® M 20. (SPX 1274 at ¶ 40 (Banker)).

Complaint Counsel's Response to Finding No.3.660

[redacted]

3.661. An overall comparison of KLOR-CON® M 20 to the '743 patent also confirms the equivalence of that tablet to the invention claimed in the '743 patent also confirms the equivalence of that tablet to the invention claimed in the '743 patent. (SPX 1274 at ¶ 24 (Banker)).

Complaint Counsel's Response to Finding No.3.661

[redacted]

3.662. Both KLOR-CON® M 20 and the '743 patent involve the same active ingredient – namely, potassium chloride – and both are designed for potassium supplementation therapy. As Upsher-Smith's ANDA states, both products are designed for the same conditions of use. (SPX 1274 at ¶ 36 (Banker)).

Complaint Counsel's Response to Finding No.3.662

Complaint counsel has no specific response.

3.663. KLOR-CON® M 20 and the subject matter of the '743 patent employ the same dosage form – an immediately dispersible, sustained release tablet designed for or al administration. (SPX 1274 at ¶ 37 (Banker)).

Complaint Counsel's Response to Finding No.3.663

Complaint counsel has no specific response.

3.664. KLOR-CON® M 20 contains a dosage level of 20 mEq of potassium chloride, which is the same dosage level described in the '743 patent. (SPX 1274 at ¶ 38 (Banker)).

Complaint Counsel's Response to Finding No.3.664

The foregoing finding is irrelevant in that the '743 patent does not claim a dosage level of potassium chloride in mEq. Indeed, the patent itself does not refer in any way to milliequivalency. [redacted]

3.665. [redacted]

Complaint Counsel's Response to Finding No.3.665

Complaint counsel has no specific response.

3.666. Both the '743 patent and KLOR-CON® M 20 use a relatively small amount of excipients and thus have a relatively high percentage composition of active ingredient (that is, potassium chloride). (SPX 1274 at ¶ 42 (Banker)). [redacted]

Complaint Counsel's Response to Finding No.3.666

Complaint counsel has no specific response.

3.667. [redacted]

Claim 1 of the '743 patent claims a range down to about 0.5% by weight of the coated crystals, and the coated crystals in KLOR-CON® M 20 contain 0.425% sorbitan monooleate. (SPX 1274 at ¶ 42 (Banker)). [redacted]

Complaint Counsel's Response to Finding No.3.667

The proposed finding irrelevant [redacted]

[redacted]

3.668. KLOR-CON® M 20 functions to achieve sustained release of high dosages of potassium chloride in substantially the same way as the subject matter of the '743 patent. (SPX 1274 at ¶ 45 (Banker)).

Complaint Counsel's Response to Finding No.3.668

The proposed finding is misleading, incomplete and therefore not supported by the evidence. [redacted]

3.669. [redacted]

Complaint Counsel's Response to Finding No.3.669

[redacted]

[redacted]

3.670. Through compression of coated potassium chloride crystals into a tablet along with a superdisintegrant, the coated potassium chloride crystals in Upsher's product can be made to disperse quickly upon ingestion without impairing the sustained release effect. (SPX 1274 at ¶ 45c (Banker)).

Complaint Counsel's Response to Finding No.3.670

The proposed finding is misleading in that the '743 patent never discloses or claims a "superdisintegrant", CX 12 at FTC0021318-21324 (the '743 patent), such that the issue of compression with a superdisintegrant is irrelevant to any inquiry into infringement of the '743 patent by Upsher's product

3.671. In Upsher's product, potassium chloride is released in a sustained fashion by controlled diffusion through the plasticized film coating over a prolonged period, and the release

rate for KLOR-CON® M 20 is not substantially different from that for K-DUR®. (SPX 1274 at ¶ 45d (Banker)).

Complaint Counsel's Response to Finding No.3.771

The proposed finding is incomplete and misleading in that it refers to Upsher's product as having a plasticized coating. [redacted]

[redacted]

3.672. Thus, Upsher-Smith's sustained release potassium chloride tablet, KLOR-CON® M 20, is insubstantially different from the subject invention claimed in the '743 patent, that the components of KLOR-CON® M 20 are either the same as or obviously interchangeable with and insubstantially different from those disclosed in the '743 patent, and that KLOR-CON® M 20 performs the substantially same function in substantially the same way to obtain the substantially same result as the subject mater claimed in the '743 patent. (SPX 1274 at ¶ 46 (Banker)).

Complaint Counsel's Response to Finding No.3.672

The proposed finding unsupported by the evidence, incomplete, or misleading. [redacted]

C. Upsher Settlement Provided No Delay in Upsher's Entry

1. Merits of Infringement Case Indicated Likely Upsher Entry After Patent Term Expires

3.673. Factual disputes existed in connection with Upsher's motion for summary judgment of non-infringement and such disputes render summary judgment inappropriate. (SPX 1275 at ¶ 58 (C. Miller)).

Complaint Counsel's Response to Finding No.3.673

The proposed finding is incorrect. [redacted]

3.674. Upsher's argument that prosecution history estoppel precluded the application of the doctrine of equivalents was not correct. (SPX 1275 at ¶ 59 (C. Miller)). [redacted]

[redacted]

Complaint Counsel's Response to Finding No.3.674

The proposed finding is incomplete, misleading and unsupported by the evidence. *See CPRF* 3.593-3.599, 3.461-3.468.

3.675. [redacted]

Complaint Counsel's Response to Finding No.3.675

[redacted]

[redacted]

3.676. [redacted]

Complaint Counsel's Response to Finding No.3.676

[redacted]

[redacted]

3.677. [redacted]

Complaint Counsel's Response to Finding No.3.677

[redacted]

[redacted]

3.678. [redacted]

Complaint Counsel's Response to Finding No.3.678

[redacted]

3.679. [redacted]

Complaint Counsel's Response to Finding No.3.679

[redacted]

3.680. Accordingly, based on the record in the *Upsher* case, there was a substantial evidentiary support for Key's position on the infringement issue. (SPX 1275 at ¶ 5 (C. Miller)).

Complaint Counsel's Response to Finding No.3.680

The proposed finding is incorrect, incomplete and not supported by the evidence.

[redacted]

2. Settlement Agreement Provided Entry Before Patent Expiry

3.681. On June 17, 1997, following oral argument on the parties' dispositive motions, and with trial scheduled to begin the following day, the parties agreed in writing to an out-of-court settlement whereby Upsher's generic product was permitted to enter the market prior to the expiry of the '743 patent. (SPX 1275 at ¶ 57 (C. Miller); SPX 92).

Complaint Counsel's Response to Finding No.3.681

Complaint counsel has no specific response.

3.682. Under the terms of the settlement agreement, Upsher, on September 1, 2001, would have a royalty-free non-exclusive license under the '743 patent to market its KLOR-CON®M20 product in the United States. (SPX 1275 at ¶ 57 (C. Miller)); SPX 92 at (i)).

Complaint Counsel's Response to Finding No.3.682

The proposed finding is incomplete. The Schering/Upsher agreement also prevented Upsher from marketing its Klor-Con M20 or any other sustained release microencapsulated potassium chloride tablet until September 1, 2001, although Upsher had neither admitted infringement nor been found to have infringed Schering's patent. CX 348 at USL03186 (neither Upsher nor Schering admits liability to any claim with respect to the patent); CPF 116 (court did not find infringement by Upsher); CPF 902-05 (discussing Hatch-Waxman exclusivity not being reliant on a successful defense).

3.683. The split of the patent license term in the Key-Upsher settlement agreement fairly reflects the relative strengths of the parties' positions on the merits as set forth in and supported by the record before the district court. (SPX 1275 at ¶¶ 6, 63 (C. Miller)).

Complaint Counsel's Response to Finding No.3.683

[redacted] Accordingly, Mr. Miller is not qualified to render opinions as to the merits or probability of Schering's success on the infringement issue. Tr. at 15:3287, 3392-93 (Miller).

[redacted]

The proposed finding is further irrelevant and misleading in that Mr. Miller's opinion as to whether the settlement constitutes a "fair representation" is only an opinion of a patent lawyer, not an economist, who never considered the impact of the reverse payment by Schering to Upsher in this assessment. *See* CPF 1374-1377.

The proposed finding is further irrelevant and misleading in that Mr. Miller's opinion on the relationship of the split in the patent life to the likely outcome of the case considered only the nominal life of the patent as opposed to its economic life. As a result, if the later years of patent life were less valuable than the earlier years, Mr. Miller's opinion would be based on an incorrect assessment of the fraction of total possible competition that is permitted by the settlement. *See* CPF 1366-1373.

CERTIFICATE OF SERVICE

I, Pamela L. Timus, hereby certify that on May 14, 2002, I caused two copies of the "Public Version" of the following:

- Complaint Counsel's Reply to Schering-Plough's Proposed Findings of Fact Relating to the Settlement with ESI-Lederle
- Complaint Counsel's Reply to Schering-Plough's Proposed Findings Relating to the Underlying Patent Cases
- Complaint Counsel's Reply to Schering-Plough's Proposed Findings of Fact Relating to the Settlement with Upsher-Smith (Volumes 1 & 2)
- Complaint Counsel's Reply Brief
- Complaint Counsel's Reply to Schering-Plough's Proposed Economic and Policy Findings
- Complaint Counsel's Reply to Upsher-Smith's Proposed Findings of Facts (Volumes1 thru 3)

to be served by hand delivery upon:

The Honorable D. Michael Chappell
Administrative Law Judge
Federal Trade Commission
600 Pennsylvania Avenue, NW
Washington, DC 20580

and one copy upon the following persons via Federal Express:

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