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UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

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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 OF FACT RELATING TO THE SETTLEMENT WITH UPSHER-SMITH

VOLUME I

[PUBLIC VERSION]

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May 14, 2002

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Complaint counsel respectfully submit their reply to Schering-Plough's proposed findings of fact relating to the settlement with Upsher-Smith. 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*.

The investigational hearings of Schering officials that have been admitted against Schering but are used for the purpose of contradicting and impeaching the trial testimony of Upsher's Ian Troup (a purpose which is currently excluded) are marked by a superscript ($^{\#}$) following the exhibit number.

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.

I. SCHERING-UPSHER NEGOTIATIONS AND SETTLEMENT

A. The Schering-Upsher Patent Litigation

1.1. Schering manufactures and markets K-Dur-10 and K-Dur 20 ("K-Dur"), a potassium chloride supplement.(Schering Answer to FTC). Key Pharmaceuticals, Inc. ("Key"), a division of Schering, was awarded U.S. Patent No. 4,863,743 ("'743 patent") for K-Dur. (Schering Answer to FTC Complaint ¶ 34). The '743 patent, which claims a controlled release dispersible potassium chloride tablet, expires on September 5, 2006. (Schering Answer to FTC Complaint ¶ 34).

Complaint Counsel's Response to Finding No.1.1:

Complaint counsel has no specific response.

1.2. Upsher-Smith Laboratories, Inc. ("Upsher") is a pharmaceutical company engaged in the discovery, development, and marketing of drugs. (FTC Complaint ¶4). On November 3, 1995, Upsher notified Key that it had submitted an ANDA to the FDA seeking approval of a generic version of the 20mEq dosage strength of Schering's K-Dur. (CX 224). Upsher's ANDA contained a Paragraph IV certification asserting that Schering's '743 patent would not be infringed by Upsher's potassium chloride product. (CX 224 at SP 25 00032, SP 25 00036; 23 Tr. 5404 (Troup)). Upsher did not claim that Schering's patent was invalid. (CX 224).

Complaint Counsel's Response to Finding No. 1.2:

CX 224, cited for part of this finding, was not admitted into evidence. The proposed finding leaves out relevant evidence. While it is true that Upsher did not claim that the '743 patent was invalid in its Paragraph IV Certification sent to Schering, *see* CX

225 at SP 08 00021-34, in its answer to Schering's complaint, it asserted, as an affirmative defense, among others, that the claims of the '743 patent were invalid and that the '743 patent was unenforceable. It also filed a counterclaim for declaratory judgement that its product did not infringe the '743 patent and that the '743 patent was invalid and unenforceable. CPF 99; [redacted]

1.3. On December 15, 1995, Key sued Upsher for patent infringement. (CX 225). The lawsuit was vigorously contested by both sides. (16 Tr. 3815 (Cannella); (FTC Complaint ¶ 40). Trial of the patent case was scheduled to begin on June 18 or 19, 1997. (15 Tr. 3549 (Joel Hoffman)).

Complaint Counsel's Response to Finding No. 1.3:

The proposed finding is inaccurate and leaves out relevant evidence. The Schering/Upsher patent litigation was supposed to begin on June 18, 1997, the day after the Schering/Upsher settlement agreement was dated and the day the agreement was signed. CPF 187, 196. [redacted]

B. Initial Settlement Negotiations For Patent Split Date

1.4. In April or May 1997, Ian Troup, Upsher's president and chief operating officer, first approached Schering about a possible settlement of the litigation. (23 Tr. 5397, 5408-09 (Troup)). The parties held a series of meetings over the course of the month before trial in an

attempt to reach a settlement of the patent litigation. (*See infra*).

Complaint Counsel's Response to Finding No. 1.4:

This proposed finding is incomplete. The meetings actually spanned less than a month. The first meeting was on May 21, 1997, with the last meeting on June 16, 1997, and the settlement agreement was signed on June 18, 1997. CPF 190 (first meeting on May 21); CPF 196 (final meeting on June 16); Schering proposed finding 1.35 (agreement signed on June 18).

1. May 21, 1997 Meeting – Kenilworth, NJ

1.5. The initial meeting took place between Martin Driscoll, Vice President of Sales and Marketing for Key, and Troup at Schering's office in Kenilworth on May 21, 1997. (23 Tr. 5409-10 (Troup); 2 Tr. 316-17 (Driscoll IH)). At this first meeting, Mr. Driscoll recalls that Troup suggested that Schering should pay Upsher to settle the case and keep Upsher's generic version of K-Dur off the market. (2 Tr. 319-20 (Driscoll IH)). Mr. Driscoll "indicated very forcefully that Schering was not going to pay any sum to Upsher-Smith simply for them to stay off the market." (2 Tr. 326 (Driscoll IH)).

Complaint Counsel's Response to Finding No. 1.5:

The proposed finding is misleading because it leaves out relevant information. Despite Mr. Driscoll's statements to Mr. Troup, at subsequent meetings, Mr. Troup continued to ask for a payment and made a payment from Schering to Upsher a condition of any settlement. CPF 191 (Mr. Troup stressed his need for cash at the May 28 and June 3 meetings); CPF 192 (Mr. Troup again asked for $60-70 million at the June 12 meeting);

CPF 196 (Mr. Troup continued to insist on payments to settle at the June 16 meeting); CPF 197 (discussing the parties' negotiations on June 17 of the payments of $60 million); CPF 200-02, 204, 206-07 (summarizing Mr. Troup's demands to be paid to settle the patent infringement suit and his connecting the money Schering should pay Upsher to the revenue Upsher was losing by not entering the market and to the harm that Upsher's product would do to Schering's monopoly); CPF 210 (discussing the presentation to Schering's Board of Directors which said that providing Upsher an "income stream" to replace that which it was losing by not entering the market was a "prerequisite of any deal").

1.6. At this meeting or the next, Driscoll and Troup discussed the possibility that Schering might permit Upsher's generic version of K-Dur to come to market in late 2005 or early 2006 before the expiration of Schering's patent. (2 Tr. 326 (Driscoll IH); 23 Tr. 5412 (Troup)). Mr. Troup stated that Upsher wanted to be on the market at an earlier date (2 Tr. 323-24 (Driscoll IH)) and that it would have problems with money and cash flow if its entry was delayed until 2005. (23 Tr. 5413 (Troup)). Mr. Troup recalls that Mr. Driscoll immediately shut down any discussion of payment of money by Schering. (23 Tr. 5413 (Troup)). The men were unable to reach an agreement on a date for Upsher's entry. (2 Tr. 326-27 (Driscoll IH); 23 Tr. 5414-15 (Troup)).

Complaint Counsel's Response to Finding No. 1.6:

The proposed finding is misleading because it leaves out relevant information. *See* CPRF 1.5.

2. May 28 and June 3, 1997 Meetings – Minneapolis, MN

1.7. The parties met again on May 28 and June 3, 1997 at Upsher's headquarters in Minnesota. (23 Tr. 5416, 5423 (Troup); CX 1511 at 9:24-10:3 (Kapur dep.)). Mr. Driscoll and Raman Kapur, President of Schering's Warrick subsidiary, attended these meetings on behalf of Schering, and Troup and consultant Andrew Hirschberg attended on behalf of Upsher. (23 Tr. 5417 (Troup); CX 1511 at 8:20-10:3 (Kapur Dep.)).

Complaint Counsel's Response to Finding No. 1.7:

The proposed finding leaves out relevant information. Andrew Hirschberg was an outside consultant to Upsher who attended multiple negotiating sessions with Schering. CPF 191-92. He had done an analysis of Schering's potential loss as a result of Upsher's entry into the K-Dur 20 market, and this analysis was communicated to Schering. Tr. at 15:3544, 3559 (John Hoffman); CX 1508 35:15-25 (Hoffman IH); *see also* Tr. at 2:320-21 (Driscoll IH) (explaining that Mr. Troup derived his asking price of $60-70 million based on models which had been run, taking a percentage of the harm Upsher's product would have on Schering's K-Dur 20 monopoly).

1.8. During the course of these May 28 and June 3 meetings, Upsher again suggested that Schering make a payment in connection with a settlement of the patent suit. (2 Tr. 328-29 (Kapur III); CX 1511 at 18:20-19:13 (Kapur Dep.)). Mr. Driscoll responded, as he had in his previous discussion with Troup, that he would not entertain the idea of paying Upsher anything to stay off the market and that his attorneys would not allow him to make a financial settlement with Upsher. (2 Tr. 328-29 (Kapur IH); SPX 1242 at 21:5-25 (Kapur Dep.); SPX 1231 at 71:9-

19 (Driscoll IH)).

Complaint Counsel's Response to Finding No. 1.8:

Complaint counsel object to this proposed finding because it relies on attorney statements. It implies that the parties acted in accordance with the cited statements. However, complaint counsel was not allowed any discovery as to what advice said attorneys actually gave their clients, due to assertions of privilege by respondents' counsel. *See, e.g,* CX 1509 at 5:8-20 (Mr. Nields saying he would object to questions relating to privileged communications), 19:15-20:7 (privilege objection to question concerning whether Mr. Hoffman was bluffing during his negotiating with Upsher), 35:21-25 (privilege objection to question concerning whether Mr. Hoffman had talked with Mr. Rule about the Upsher patent infringement litigation (Hoffman dep). Drawing inferences based on attorneys' statements, while simultaneously asserting privilege as to underlying communications between those attorneys and their clients, is unfounded and impermissible. Tr. at 12:2617-18 (Judge Chappell reasoning that implying a client's conduct based on what his attorney said to a Magistrate without connecting the attorney's remarks to the client does not "add[] up"; Tr. at 16:3853-55 (Judge Chappell reasoning that it is impermissible to have attorney testify as to client's intentions without providing a foundation which does not rely on privileged communications.)

In addition this proposed finding leaves out relevant evidence and is therefore misleading. The request for payment by Schering to Upsher, referenced in this proposed finding, was sought to replace Upsher's lost revenues from Klor Con M20 not being on the market. CPF 191. Moreover, despite the statement by Mr. Driscoll, at subsequent

meetings, Mr. Troup continued to ask for a payment and made a payment from Schering to Upsher a condition of any settlement. CPRF 1.5.

1.9. At the May 28 and June 3 meetings, the parties continued to discuss potential entry dates for Upsher's generic version of K-Dur prior to expiration of the K-Dur patent. Mr. Troup pushed for an earlier entry date. (23 Tr. 5425 (Troup)). The parties decided to approach settlement by splitting the remaining life on Schering's K-Dur patent, permitting Upsher to come on the market in September 2001 (2 Tr. 336-37 (Kapur IH); 23 Tr. 5424-26 (Troup)). The negotiators' recollections differ regarding when the parties actually settled on the September 1, 2001 entry date for Upsher. *Compare* (SPX 1231 at 71:9-72:8 (Driscoll III)) (no agreement reached while Driscoll involved in negotiations) *with* (23 Tr. 5430, 5435-36 (Troup)) (parties agreed by end of June 3 meeting that Upsher could enter market on September 1, 2001); (15 Tr. 3562-63 (JOEL Hoffman) (only date mentioned at Kenilworth meeting on June 12 meeting was September 1, 2001); (CX 1488 at 64:18-65:3 (Cannella); SPX 1263 at 65:5-6, 12-15 (Cannella Dep.)) (parties had agreed on September 1, 2001 date prior to Kenilworth meeting on June 12). Nevertheless, it is undisputed that Schering never suggested that it would consider an entry date earlier than September 1, 2001. (23 Tr. 5500 (Troup)). Driscoll had communicated to Troup by the close of the June 3 meeting that September 1, 2001 was Schering's limit. (CX 1511 at 22:14-23:8 (Kapur Dep.)).

Complaint Counsel's Response to Finding No. 1.9:

This proposed finding is not supported by the evidence. The weight of the record establishes that the parties had not settled on the September 1, 2001 entry date by the end

of the June 3 meeting. CPF 183 (discussing Mr. Troup's position that the September 1, 2001, date was a "proposal" as of the June 3 meeting and that Mr. Troup ended that meeting telling Schering that he would get back to them after thinking about their proposed date); CPF 184 (discussing Mr. Troup holding out for earlier entry after June 3 meeting); CPF 185 (discussing Mr. Troup pushing for an entry date earlier than 2001 at the June 12 meeting); CPF 185 (discussing Mr. Hoffman's acknowledgment that even by the June 12 meeting there was no final entry date to which both sides had agreed); CPF 191 (discussing Mr. Troup's preference for an earlier entry date than 2001); CX 1488 at 65:5-6, 12-15 (Cannella dep) (testifying he does not recall when the patent suit issue had been settled and only has an impression).

This proposed finding leaves out relevant evidence. At the May 28 and June 3 meetings, Schering and Upsher negotiators attempted to settle the patent suit, while at the same time Mr. Troup continued to demand money to replace Upsher's lost income from not having a generic K-Dur 20 product on the market. CPF 191.

1.10. Schering was willing to explore at these May 28 and June 3 meetings whether Schering and Upsher could collaborate on some business venture that "would add value to both companies." (2 Tr. 328 (Kapur IH)). The parties discussed several possibilities for such business opportunities, such as a co-marketing arrangement with respect to Schering's K-Dur or a joint venture for Upsher research and development. (CX 1511 at 14:3-15:9 (Kapur Dep.)); 2 Tr. 327-29 (Kapur IH); 23 Tr. 5433-34 (Troup)). They also discussed the possibility that Schering might license one or more Upsher products, including cholestyramine, pentoxifylline

and Upsher's sustained release niacin product, Niacor-SR. (CX 1494 at 52:8-53:23 (Driscoll IH); CX 1511 at 14:3-10 (Kapur Dep.); SPX 1242 at 16:9-16 (Kapur Dep.); CX 1495 at 62:1-10 (Kapur Dep.); 23 Tr. 5420, 5430-34 (Troup)). Upsher described the expected clinical benefits of Niacor-SR, and Schering was aware of the market opportunity for Niacor-SR because it had been involved in evaluating the market for other, nearly identical projects. (CX 1495 at 70:25-71:11; SPX 1265 at 73:5-24 (Driscoll Dep.); CX 1494 at 85:2-5 (Driscoll IH)). Troup was willing to consider the possibility of licensing Niacor-SR to Schering outside the United States, as Upsher had no presence in Europe or elsewhere internationally. (23 Tr. 5432 (Troup)).

Complaint Counsel's Response to Finding No. 1.10:

The proposed finding leaves out relevant evidence. At the May 28 and June 3 meetings, Schering and Upsher negotiators attempted to settle the patent suit, while at the same time Mr. Troup continued to demand money to replace Upsher's lost income from not having a generic K-Dur 20 product on the market. CPF 191.

[redacted]

[redacted]

1.11. Some of the parties' discussions are reflected in notes taken by Mr. Troup during the June 3, 1997 meeting. (USX 477; 23 Tr. 5427 (Troup)). For example the notes of that meeting show the September 2001 date that the parties had discussed as the time when Upsher could come on the market. (USX 477). Schering's offer of a $14 million, five-year research and development agreement for Upsher is also noted. (USX 477). With respect to products, the notes reflect Schering was interested in either co-promoting or co-marketing Niacor-SR in the United States with milestones and royalty payments. (23 Tr. 5432 (Troup); USX 477).

Complaint Counsel's Response to Finding No. 1.11:

Complaint counsel has no specific response.

1.12. No agreements had been reached by the close of the June 3, 1997 meeting with respect to any of the potential business opportunities discussed. (23 Tr. 5435-36 (Troup)).

Complaint Counsel's Response to Finding No. 1.12:

Complaint counsel has no specific response.

C. Negotiations For The Niacor-SR License

1. Hoffman-Cannella Telephone Call – June 10, 1997

1.13. Prior to the parties' next face-to-face negotiation session, Mr. Hoffman spoke to Upsher's outside counsel, Nick Cannella, on or about June 10, 1997 to discuss logistics and ground rules for the upcoming meeting. (16 Tr. 3824-25 (Cannella)). Mr. Hoffman told Mr. Cannella that Schering viewed the upcoming meeting as an opportunity to discuss potential business opportunities between Schering and Upsher, not as an occasion to debate the merits of the underlying patent case. (16 Tr. 3826-27 (Cannella); 15 Tr. 3541 (JOEL Hoffman)). Mr. Cannella recalls that Mr. Hoffman said he had done antitrust work at a private firm before working at Schering and he wanted Mr. Cannella to be aware that there were sensitive issues with respect to antitrust in any business deal. (16 Tr. 3825 (Cannella)). Mr. Cannella responded that he had experience with these types of transactions and was familiar with the antitrust issues. (16 Tr. 3825-26 (Cannella)). Mr. Hoffman also stated that Schering "was not going to be paying Upsher-Smith to stay off the market" and that the settlement Schering and Upsher had discussed involved permitting Upsher's generic version of K-Dur to come on the market before the expiration of Schering's patent. (15 Tr. 3541 (JOEL Hoffman)).

Complaint Counsel's Response to Finding No. 1.13:

Complaint counsel object to this proposed finding because it improperly relies on attorney testimony. It implies that the parties acted in accordance with the cited

statements. However, complaint counsel was not allowed any discovery as to what advice said attorneys actually gave their clients, due to assertions of privilege by respondents' counsel. *See, e.g.* CX 1509 at 5:8-20 (Mr. Nields saying he would object to questions relating to privileged communications), 19:15-20:7 (privilege objection to question concerning whether Mr. Hoffman was bluffing during his negotiating with Upsher), 35:21-25 (privilege objection to question concerning whether Mr. Hoffman had talked with Mr. Rule about the Upsher patent infringement litigation) (Hoffman dep). Drawing inferences based on attorneys' statements, while simultaneously asserting privilege as to underlying communications between those attorneys and their clients, is unfounded and impermissible. Tr. at 12:2617-18 (Judge Chappell reasoning that implying a client's conduct based on what his attorney said to a Magistrate without connecting the attorney's remarks to the client does not "add[] up"; Tr. at 16:3853-55 (Judge Chappell reasoning that it is impermissible to have attorney testify as to client's intentions without providing a foundation which does not rely on privileged communications.)

The proposed finding is also contradicted by more reliable evidence. When testifying about his phone call with Mr. Hoffman before the June 12, 1997, meeting during his prior deposition, Mr. Cannella did not make any mention of a discussion of antitrust issues. He did not call any discussion other than setting up the logistics of the meeting and talking about the meeting not being another time to debate the merits of the patent case. Tr. at 16:3861-63 (Cannella).

2. June 12, 1997 Meeting – Kenilworth, NJ

1.14. Upsher representatives, Troup, Cannella and Hirschberg, and Schering representatives, Hoffman, Kapur, and Wasserstein, met in Kenilworth on June 12, 1997. (23 Tr. 5436-38 (Troup); 15 Tr. 3539, 3541-42 (JOEL Hoffman)). Mr. Troup attempted early in the meeting to gain an earlier entry date for Upsher's generic version of K-Dur. (23 Tr. 5439 (Troup)). Mr. Hoffman testified that despite Mr. Troup's "posturing," Mr. Hoffman does not recall discussion of any specific date other than September 1, 2001. (15 Tr. 3543 (JOEL Hoffman)). Mr. Hoffman stated to Mr. Troup that the September 1, 2001 entry had already been negotiated, and Schering wanted to discuss licensing opportunities. (2 Tr. 352 (JOEL Hoffman Dep.); 23 Tr. 5439-40 (Troup)). Similarly, when Upsher's consultant spoke of how much Schering could lose if it lost the patent case, Hoffman perceived the comments as an invitation to pay Upsher to stay off the market and stated that Schering was not going to do that. (15 Tr. 3544 (JOEL Hoffman); SPX 1242 at 46:7-14 (Kapur Dep.) ("Hoffman made clear on several meetings that there would be no payment for settlement of the litigation")).

Complaint Counsel's Response to Finding No. 1.14:

Complaint counsel object to this proposed finding because it improperly relies on attorney testimony. It implies that the parties acted in accordance with the cited statements. However, complaint counsel was not allowed any discovery as to what advice said attorneys actually gave their clients, due to assertions of privilege by respondents' counsel. *See, e.g.* CX 1509 at 5:8-20 (Mr. Nields saying he would object to questions relating to privileged communications), 19:15-20:7 (privilege objection to question concerning whether Mr. Hoffman was bluffing during his negotiating with

Upsher), 35:21-25 (privilege objection to question concerning whether Mr. Hoffman had talked with Mr. Rule about the Upsher patent infringement litigation (Hoffman dep). Drawing inferences based on attorneys' statements, while simultaneously asserting privilege as to underlying communications between those attorneys and their clients, is unfounded and impermissible. Tr. at 12:2617-18 (Judge Chappell reasoning that implying a client's conduct based on what his attorney said to a Magistrate without connecting the attorney's remarks to the client does not "add[] up"; Tr. at 16:3853-55 (Judge Chappell reasoning that it is impermissible to have attorney testify as to client's intentions without providing a foundation which does not rely on privileged communications.)

The proposed finding is not supported by the evidence. The weight of the record establishes that Mr. Wasserstein did not attend the June 12 meeting. CX 1510 at 54:15-24 (Kapur III) (discusses only himself and Mr. Hoffman attending meeting in Kenilworth as representatives from Schering); CX 1532 at 25:17-26:12 (Wasserstein) (testifying that he does not remember having attended the June 12 meeting in Kenilworth or meeting Mr. Nicholas Cannella, who was at the meeting); Schering First Admissions No. 17 (Schering unable to admit or deny that Mr. Wasserstein attended the June 12 meeting).

The proposed finding leaves out relevant evidence. The $60-70 million which Mr. Troup sought to settle the lawsuit was a percentage of the estimated impact that the entry of Upsher's generic would have on Schering's K-Dur 20 monopoly. CPF 192. The payment was thus tied directly to Upsher's agreement not to enter and thus spare Schering losing even more money.

1.15. Mr. Troup stated at the June 12 meeting that Upsher still had "cash needs" because all of the company's cash was tied up in two products in development, Upsher's generic version of K-Dur and its sustained release niacin product, Niacor-SR. (15 Tr. 3543 (JOEL Hoffman); 2 Tr. 353 (JOEL Hoffman Dep.)). Mr. Troup stressed that an up-front cash payment must be part of any licensing deal in order to meet Upsher's cash needs. (2 Tr. 357 (Wasserstein IH)). Mr. Hoffman told Mr. Troup that Schering would be "willing to do arm's length business deals that stand on their own two feet, and that's what we're here to discuss." (15 Tr. 3544 (JOEL Hoffman); 2 Tr. 351-52 (JOEL Hoffman IH)).

Complaint Counsel's Response to Finding No. 1.15:

Complaint counsel object to this proposed finding because it improperly relies on attorney testimony. It implies that the parties acted in accordance with the cited statements. However, complaint counsel was not allowed any discovery as to what advice said attorneys actually gave their clients, due to assertions of privilege by respondents' counsel. *See, e.g,* CX 1509 at 5:8-20 (Mr. Nields saying he would object to questions relating to privileged communications), 19:15-20:7 (privilege objection to question concerning whether Mr. Hoffman was bluffing during his negotiating with Upsher), 35:21-25 (privilege objection to question concerning whether Mr. Hoffman had talked with Mr. Rule about the Upsher patent infringement litigation (Hoffman dep). Drawing inferences based on attorneys' statements, while simultaneously asserting privilege as to underlying communications between those attorneys and their clients, is unfounded and impermissible. Tr. at 12:2617-18 (Judge Chappell reasoning that implying a client's conduct based on what his attorney said to a Magistrate without

connecting the attorney's remarks to the client does not "add[] up"; Tr. at 16:3853-55 (Judge Chappell reasoning that it is impermissible to have attorney testify as to client's intentions without providing a foundation which does not rely on privileged communications.)

The proposed finding is contrary to more reliable evidence that Upsher tied its need for cash to any settlement of the patent litigation with Schering, not simply to any licensing deal. A contemporaneous document, the presentation to the Schering Board of Directors, clearly states that Upsher told Schering that "a prerequisite of any deal would be to provide [Upsher] with a guaranteed income stream for the next twenty-four months to make up for the income that they had projected to earn from sales of Klor Con had they been successful in their suit." CX 338 at SP 12 00270 (Schering Board of Directors presentation). Mr. Wasserstein recalled Mr. Troup making this specific demand that Schering would have to pay Upsher up-front money as a condition of any settlement deal. CX 1531 at 113:8-18 (Wasserstein III).

1.16. The bulk of the discussion at the June 12 meeting focused on the licensing opportunities for Niacor-SR and the Upsher generic products. (15 Tr. 3542-44 (JOEL Hoffman)). Mr. Troup brought a packet of information on Niacor-SR with him to the June 12 meeting. (23 Tr. 5441 (Troup)); 15 Tr. 3544-45 (JOEL Hoffman); CX 1510 at 56:23-57:19 (Kapur III)). This Niacor-SR packet was similar to the informational package distributed by Upsher at exploratory meetings with potential European partners. (23 Tr. 5436-37 (Troup)). Troup also made a presentation about Niacor-SR at the meeting. (23 Tr. 5441 (Troup)); 15 Tr.

3545 (JOEL Hoffman)). He discussed Niacor-SR's potential, including that its late-stage clinical work had been completed and that an FDA submission was planned by the end of 1997. (2 Tr. 338 (Kapur II); 23 Tr. 5441 (Troup)). Mr. Troup also used information indicating the value of Kos' similar sustained-release niacin product, describing the increase in the price of Kos' stock based on that product. (23 Tr. 5442 (Troup); 16 Tr. 3829-30 (Cannella); CX 1510 at 62:20-63:17 (Kapur II)). There was some discussion about the fact that Schering was familiar with the market for Niacor-SR based on its discussions with Kos regarding their sustained-release niacin product, Niaspan. (15 Tr. 3544 (JOEL Hoffman); CX 1509 at 17:20-25 (JOEL Hoffman Dep.); 23 Tr. 5443-44 (Troup)).

Complaint Counsel's Response to Finding No. 1.16:

The proposed finding is incomplete and misleading. Upsher's late-stage clinical work could not have been completed by June 12. Mr. Audibert could not have received the "results" of Upsher's two phase III pivotal clinical trials, as the second trial was not yet complete. CX 1042 at SP 16 00079 (the "package" of information received from Upsher noting that the "projected" completion date for the second pivotal trial (Protocol 900221) was June 1997). In addition, the "phase III-B" studies discussed in the proposed findings were merely planned studies. Mr. Audibert never inquired with Upsher as to the status of these studies or whether they would ever be undertaken. CPF 464 (discussing Mr. Audibert's failure to confirm or inquire about the status of these "draft" protocols).

The proposed finding leaves out relevant information. Prior to the June 12 meeting, neither party had conducted a formal evaluation of or had a specific offer for Niacor-SR, indicating what a license for it for non-NAFTA countries would be worth.

CPF 231-34 (Upsher performed no formal analysis); CPF 237-38 (no European company approached by Upsher made an offer for Niacor-SR); CPF 240-44 (Schering's assessment of Niacor-SR done after it had already agreed to pay $60 million).

1.17. Troup confirmed that Upsher's offer of a Niacor-SR license extended only to non-NAFTA territories. (15 Tr. 3545 (JOEL Hoffman); 23 Tr. 5440-41 (Troup)). Schering was disappointed that Upsher would not consider a partnership for Niacor-SR in the United States (CX 1511 at 26:21-27:9 (Kapur Dep.)), but remained interested in the opportunity to market the product internationally. (23 Tr. 5443-44 (Troup)). Mr. Kapur also expressed his continued interest in Upsher's cholestyramine and pentoxifylline products, although no agreement had been reached to include those products in any deal by the conclusion of the June 12 meeting. (15 Tr. 3545 (JOEL Hoffman)).

Complaint Counsel's Response to Finding No. 1.17:

The proposed finding is contradicted by more reliable evidence. Schering's behavior after the Schering/Upsher Agreement is not consistent with a company which had interest in developing or marketing Niacor-SR internationally. CPF § VII(D). Its actions are thus in conflict with the allegations of interest in the proposed finding.

The proposed finding also leaves out relevant evidence. The drugs that Schering licensed from Upsher, other than Niacor-SR, including cholestyramine and pentoxifylline, had little value. CPF § VII(B)(4).

1.18. The June 12 meeting included a preliminary discussion concerning the price of the Niacor-SR product. Mr. Troup asked for $70-80 million in his first offer to Schering. (23 Tr. 5449 (Troup); 15 Tr. 3545 (JOEL Hoffman); SPX 1242 at 44:22-45:9 (Kapur Dep.); 16 Tr. 3830 (Cannella)). Schering told Upsher it would continue to analyze the issues and the clinical data for Niacor-SR and would get back to Upsher about its interest in pursuing a deal for Niacor-SR. (15 Tr. 3545-46 (JOEL Hoffman); CX 1510 at 64:24-65:5 (Kapur IH); 16 Tr. 3832 (Cannella)).

Complaint Counsel's Response to Finding No. 1.18:

The proposed finding leaves out relevant information. CPRF 16 (no formal evaluation of Niacor-SR's value had been done by June 12).

The proposed finding also leaves out additional relevant information. Mr. Troup based his requested requests for money from Schering to settle the lawsuit not on the value of Niacor, but instead on Upsher's forgone revenues for not entering the market and the revenue impact its product would have on Schering's K-Dur 20 monopoly if Upsher entered the market. CPF 200-02 (discussing Mr. Troup repeatedly sought to replace revenues lost by not being on the market; CPF 204, 212-13 (discussing Mr. Troup requesting $60-70 million to end the litigation and basing that figure on a percentage of the harm that Upsher's product would do to Schering's monopoly); CPF 206-07 (discussing Mr. Kapur and Mr. Wasserstein's testimony that Mr. Troup wanted to replace the revenue Upsher was losing by delaying entry); CPF 210 (discussing presentation to Schering's Board of Directors which links the payment with lost income); 214-18 (discussing money requested to settle the lawsuit based on Upsher's lost revenues from not entering the generic K-Dur 20 market).

3. Cesan And Kapur Ask Schering's Global Marketing Division To Assess Niacor-SR

1.19. Shortly before or after the June 12, 1997 meeting with Upsher in Kenilworth, Messrs. Kapur and Driscoll briefed Raul Cesan, Schering's president of pharmaceuticals worldwide, on the Upsher negotiations. (CX 1510 at 66:18-67:4; SPX 1241 at 67:5-6, 9-15 (Kapur IH); SPX 1242 at 29:16-30:15, 30:23-25 (Kapur Dep.)). They explained that Mr. Driscoll had made a reasonable offer to settle the patent litigation by allowing Upsher's generic product to come on the market in September 2001, well before the expiration of Schering's patent, and that Schering was not willing to give Upsher anything else to settle the litigation. (CX 1510 at 67:18-22 (Kapur IH); SPX 1242 at 31:1-20 (Kapur Dep.)). Driscoll and Kapur told Mr. Cesan that they had discussed with Mr. Troup whether there were any potential business opportunities that would be valuable to both Schering and Upsher, and Mr. Troup had suggested a possible deal for Niacor-SR in markets outside of the United States. (SPX 1242 at 30:7-11 (Kapur Dep.); CX 1510 at 66:23-67:4 (Kapur IH)). Mr. Cesan asked Mr. Kapur to contact Tom Lauda, Schering's Vice President of Global Marketing, to see if he would be interested in marketing Niacor-SR internationally; if Global Marketing had no interest in Niacor-SR, then Schering would tell Upsher there would be no deal. (CX 1510 at 67:23-68:20 (Kapur IH); SPX 1242 at 31:8-20 (Kapur Dep.); CX 1489 at 14:18-25 (Cesan Dep.)).

Complaint Counsel's Response to Finding No. 1.19:

Complaint counsel has no specific response.

1.20. Following Mr. Cesan's instructions, Mr. Kapur telephoned Mr. Lauda and told him that Schering was considering a licensing opportunity for Upsher's sustained-release niacin product, that the opportunity would cost Schering approximately $60 million, and asked if Global Marketing would perform an assessment of the product to see if it would be worth $60 million to Schering. (19 Tr. 4342-43 (Lauda)). Mr. Lauda understood that the opportunity involved Schering marketing Niacor-SR internationally, primarily in Europe. (19 Tr. 4380-81 (Lauda)). Mr. Kapur did not tell Mr. Lauda that this licensing opportunity was connected to patent litigation (19 Tr. 4344 (Lauda)), and at the time of this conversation, Mr. Lauda did not know that Schering was in litigation with Upsher over the K-Dur patent (8 Tr. 1627-28 (Lauda IH)).

Complaint Counsel's Response to Finding No. 1.20:

The proposed finding is misleading because it leaves out relevant information. Mr. Kapur had the materials from Upsher on Niacor SR at the time he made the phone call. Tr. at 19:4343 (Lauda), so the call from Kapur to Lauda came on June 12, when Upsher gave Schering the data package, and when the information was faxed from Warrick to Mr. Lauda. CX 1042 (facsimile transmission line showing the document was sent from Mr. Kapur's Warrick Pharmaceuticals, reads June 12, 1997). At this phone call Mr. Lauda was told that Schering was going to pay $60 million for the Niacor SR license, before Mr. Lauda or Mr. Audibert had done any evaluation of the value of Niacor SR. CPF 242.

1.21. Mr. Lauda asked Jim Audibert, head of global marketing's cardiovascular unit, to perform an assessment of Upsher's Niacor-SR product. (19 Tr. 4344 (Lauda)). Mr. Lauda told

Mr. Audibert that a packet of information about the product would be delivered and Kapur was available to answer any questions that Mr. Audibert may have had. (19 Tr. 4404 (Lauda)). He did not tell Mr. Audibert any amount that Schering expected to pay for the license, and Mr. Audibert was unaware that the Niacor opportunity had any connection to a patent suit. (18 Tr. 4113 (Audibert)).

Complaint Counsel's Response to Finding No. 1.21:

The proposed finding is misleading because it leaves out relevant information. Mr. Audibert was asked to do a commercial assessment (or sales forecast) and a profit and loss statement and nothing else. Tr. at 18:4166-4168 (Audibert). Moreover, the proposed finding is contradicted by other evidence. Mr. Wasserstein testified that he spoke with Mr. Audibert "during the process of the license agreement," informing him of the terms of the proposed license agreement with Upsher and the amount of the payment. CX 1532 at 17:13-18:22 (Wasserstein dep); *see also* CX 1511 at 50:16-20, 51:7-16 (Kapur dep) (testifying about discussions with Mr. Audibert between June 13-16 and Mr. Audibert's interest in speaking with Mr. Wasserstein).

1.22. Mr. Kapur sent Upsher's Niacor-SR data package to Mr. Audibert the same day he received it from Troup. (CX 1511 at 40:8-12 (Kapur Dep.)). Mr. Audibert did not recall Mr. Lauda specifying a deadline for his review of Niacor-SR, but he knew from past experiences with similar requests that Mr. Lauda usually wanted the assessment to be completed quickly. (18 Tr. 4112-13 (Audibert)).

Complaint Counsel's Response to Finding No. 1.22:

The proposed finding is misleading because it leaves out relevant information. The trial was scheduled for June 18, 1997. CPF 187, 196. [redacted] The parties had to settle before that June 18 date in order to make certain that the settlement would preclude any decision on the patent case.

4. June 16, 1997 Meeting – Plymouth, Minnesota

1.23. The next meeting between Schering and Upsher took place in Upsher's office in Plymouth, Minnesota, on June 16, 1997. (23 Tr. 5452 (Troup); 15 Tr. 3550 (JOEL Hoffman)). Kapur, Hoffman, Wasserstein and Schering in-house attorney Paul Thompson attended for Schering; Troup, Hirschberg, and Cannella (via telephone) participated on behalf of Upsher. (15 Tr. 3546 (JOEL Hoffman); 2 Tr. 331-32 (Kapur IH)); 23 Tr. 5452 (Troup); 16 Tr. 3834 Cannella)).

Complaint Counsel's Response to Finding No. 1.23:

Complaint counsel has no specific response.

1.24. At this meeting, the main topic of discussion was licensing. (15 Tr. 3547 (JOEL Hoffman)). On the subject of settlement, Mr. Troup and Mr. Hoffman briefly debated the merits of the lawsuit, but then agreed to "move on to talk about the licensing prospects." (15 Tr. 3547 (JOEL Hoffman)). The date for Upsher's entry was not negotiated at this meeting. (16 Tr. 3850

(Cannella)). At no time was there any discussion that the payment or payment terms would be in consideration for delay of entry of Upsher's product. (23r. Tr. 5460 (Troup); 16 Tr. 3839 (Cannella); 15 Tr. 3572 (JOEL Hoffman)).

Complaint Counsel's Response to Finding No. 1.24:

The proposed finding is misleading because it leaves out relevant information. Mr. Wasserstein, who does not recall attending any meetings before the June 16 meeting in Minneapolis, recalls that Mr. Troup said that "he was looking for an income stream to replace what they would have earned on their own potassium chloride product," either at the meeting in Minneapolis or on subsequent phone conversations. CX 1531 at 100:25-102:1 (Wasserstein IH).

1.25. Discussion at the June 16 meeting focused on the valuation of the package of Upsher products, including Niacor-SR for the ex-NAFTA countries, cholestyramine worldwide and pentoxifylline for the ex-NAFTA countries. (23 Tr. 5453 (Troup)). Over the course of the meeting, Upsher also added for ex-NAFTA countries its wax matrix 8 and 10 mEq products and Klor Con M20, the subject of the litigation. (23 Tr. 5453 (Troup)).

Complaint Counsel's Response to Finding No. 1.25:

The proposed finding is misleading because it leaves out relevant information. *See* CPRF 1.24.

1.26. Both parties recognized the value of Niacor-SR. (23 Tr. 5454-55 (Troup); SPX 1242 at 68:14-16, 68:21-69:10 (Kapur Dep.)). The Schering negotiators came to the June 16

meeting armed with the knowledge that Schering's Global Marketing was definitely interested in licensing Niacor-SR based on Mr. Audibert's assessment of the product and its potential sales. (CX 1511 at 50:16-52:8, 53:12-22 (Kapur Dep.); SPX 1242 at 54:9-11, 14-20 (Kapur Dep.); CX 1510 at 71:13-24 (Kapur IH); 19 Tr. 4349 (Lauda)). Schering indicated at the June 16 meeting that it was impressed by and interested in the Niacor-SR product. (CX 1510 at 71:2-12 (Kapur IH); 23 Tr. 5454-55 (Troup)).

Complaint Counsel's Response to Finding No. 1.26:

The proposed finding is contradicted by other evidence. Schering had no basis upon which to value Niacor-SR independent from its agreement to pay Upsher $60 million to settle the patent infringement suit. CPF 240 (Mr. Kapur was not qualified to evaluate Niacor-SR); CPF 242 (Schering had already decided to pay $60 million before Mr. Kapur asked Mr. Lauda to evaluate Niacor-SR); CPF 243 (Mr. Kapur did not receive Mr. Audibert's analysis until June 17, after the June 16 negotiations in which Schering agreed to pay $ 60 million).

Mr. Audibert did not complete his commercial assessment of Niacor SR, and Mr. Lauda did not send it to Mr. Kapur, until June 17. CPF 242-43. On June 16, the Schering negotiators could not have relied upon Mr. Audibert's written analysis. Both Mr. Kapur and Mr. Wasserstein testified that they spoke to Mr. Audibert about his assessment of Niacor SR before the meeting on June 16. CX 1532 at 17:13-18:22, 27:9-28:7, 28:16-20 (Wasserstein dep) (testifying that he spoke with Mr. Audibert "during the process of the license agreement" and before the June 16 meeting); CX 1511 at 50:16-20, 51:7-16 (Kapur dep) (testifying about discussions with Mr. Audibert between June 13-16

and Mr. Audibert's interest in speaking with Mr. Wasserstein).

However, Mr. Audibert categorically denies speaking with either Mr. Wasserstein or Mr. Kapur. CX 1483 at 32:10-15, 33:7-25 (Audibert IH) (recalling talking with Mr. Kapur *after* commercial assessment completed); CX 1484 at 103:8-24 (Audibert dep) (testifying he does not recall speaking with anyone at Schering, other than Mr. Lauda, while doing his commercial assessment of Niacor-SR), 222:21-223:4 (testifying he does not recall talking with Mr. Wasserstein about Niacor-SR until after he gave Mr. Lauda commercial assessment).

Mr. Wasserstein also remembers that, prior to the meeting on June 16th, he told Mr. Audibert all about the deal with Upsher, including how much money Schering would pay for the license for Niacor. CX 1532 at 17:13-18:22, 27:9-28:7, 28:16-20 (Wasserstein dep) (testifying he provided information about the license to Mr. Audibert). Again, Mr. Audibert contradicts Mr. Wasserstein's assertion and denies knowing how much Schering was going to pay before he did his analysis. CX 1484 at 100:23-101:4 (Audibert dep) (testifying he did not know Schering was considering a license for Niacor-SR until after he did his assessment), 220:10-14, 221:16-222:5 (testifying he did not know the terms of the Niacor-SR license while doing his assessment).

If Mr. Audibert is correct, then Mr. Wasserstein and Mr. Kapur went to the meeting on June16 without knowing how much Mr. Audibert valued the Niacor-SR license. If Mr. Wasserstein and Mr. Kapur are correct, Mr. Audibert knew how much Schering was going to pay for the license before he completed his commercial

assessment, and his assessment cannot be considered independent from the patent settlement negotiations.

1.27. The parties negotiated the price for the Niacor-SR license. (CX 1510 at 71:2-72:3, 72:10-72:24 (Kapur IH); SPX 1241 at 72:4-9 (Kapur IH); 23 Tr. 5454 (Troup)). Mr. Troup still wanted $80 million and talked again about the fact that Kos' market capitalization was $400 million based on the strength of its similar niacin product, for which they projected sales of $250 million in annual sales by the third year. (23 Tr. 5455 (Troup); 15 Tr. 3547 (JOEL Hoffman); 16 Tr. 3835 (Cannella)). Schering made a counter-offer of $60 million. (16 Tr. 3835 (Cannella); 23 Tr. 5458 (Troup)). The parties discussed, either at the June 16 meeting or shortly thereafter, that the $60 million would be paid in installments. (23 Tr. 5459-60 (Troup); 15 Tr. 3547 (JOEL Hoffman); CX 1511 at 74:13-75:3 (Kapur Dep.)). To bridge the gap between Upsher's asking price and Schering's counter-offer, the parties negotiated milestone payments for launch of Niacor-SR in nine different countries throughout the world, including $2 million for Japan and $1 million each for eight other countries, totaling $10 million in milestones. (CX 1510 at 72:10-74:1 (Kapur IH); CX 1511 at 72:23-73:4 (Kapur Dep.); 16 Tr. 3836 (Cannella); 15 Tr. 3547 (JOEL Hoffman); 23 Tr. 5458-59 (Troup)). Troup also asked for two different levels of royalties on Niacor-SR: a 10% royalty on annual net sales up to $50 million and a 15% royalty on annual net sales in excess of $50 million. (23 Tr. 5459 (Troup); CX 1510 at 74:19-75:7 (Kapur IH); CX 347 at SP 12 00195).

Complaint Counsel's Response to Finding No. 1.27:

The proposed finding is misleading because it leaves out relevant information.

Mr. Troup told the Schering negotiators that the money he wanted was a prerequisite to any settlement of the patent litigation and tied the amount of money to replacing the money Upsher would have gotten from introducing Upsher's Klor Con M20 generic version of K-Dur 20, information that was passed on to the Schering Board of Directors when they were asked to approve the license. *See* CPRF 1.24; CPF 210 (discussing the presentation to Schering's Board of Directors which said that providing Upsher an "income stream" to replace that which it was losing by not entering the market was a "prerequisite of any deal")

1.28. The parties also discussed that Schering would retain the right to manufacture Niacor-SR itself, or, at its sole discretion, to require Upsher to manufacture and sell to Schering at cost the Niacor-SR, pentoxifylline, and potassium products, and to manufacture at cost plus 30 percent the cholestyramine product. (23 Tr. 5461 (Troup); CX 1510 at 75:5-7 (Kapur IH)). Troup considered this to be an "onerous obligation" for Upsher because these manufacturing obligations could be exercised in Schering's sole discretion. (23 Tr. 5461 (Troup)).

Complaint Counsel's Response to Finding No. 1.28:

This proposed finding is not supported by any contemporaneous evidence. There is no contemporaneous evidence that Mr. Troup felt this was an "onerous obligation."

1.29. By the end of the June 16 meeting, the parties had negotiated most of the principle terms of the licensing deal, although they had not reached a final agreement or put anything into writing. (15 Tr. 3548 (JOEL Hoffman); 23 Tr. 5459, 5461 (Troup); 2 Tr. 360

(Kapur IH); CX 1510 at 74:4-78:3 (Kapur IH)).

Complaint Counsel's Response to Finding No. 1.29:

The proposed finding is misleading because it leaves out relevant information. There never was a separate licensing deal; the license for Niacor-SR was contained in the settlement agreement, settling the patent litigation between Schering and Upsher. CX 348 at USL 03186-87 (the settlement agreement). By the end of the June 16 meeting, the parties had negotiated most of the principle terms of the settlement agreement, although they had not reached a final agreement or put anything in writing.

D. Final Negotiations And The June 17, 1997 Agreement

1.30. Trial in the patent case between Schering and Upsher was scheduled to begin on June 18 or 19 (15 Tr. 3549 (JOEL Hoffman)), and the parties wanted to settle the suit before the start of trial. (7 Tr. 1427 (JOEL Hoffman IH)). Schering and Upsher decided to cover the patent settlement and Niacor-SR license in one document. (7 Tr. 1426-27 (JOEL Hoffman IH)).

Complaint Counsel's Response to Finding No. 1.30:

The proposed finding leaves out relevant evidence. The Schering/Upsher patent litigation was supposed to begin on June 18, 1997, the day after the settlement agreement is dated and the day it was signed. CPRF 1.3.

1.31. The parties' first efforts to create a written agreement produced competing drafts. After the June 16 meeting, the Schering representatives flew back to Newark, and Paul Thompson worked on a draft agreement on the plane ride home. (15 Tr. 3549 (JOEL Hoffman)).

Mr. Cannella, meanwhile, drafted a document at Mr. Troup's request entitled "Points of Agreement" (16 Tr. 3840-41 (Cannella); USX 233). Mr. Cannella called Mr. Hoffman and inquired as to the status of the agreement. (16 Tr. 3842 (Cannella)). Mr. Hoffman told Mr. Cannella that they had received Upsher's draft but that they were working on a more detailed document. (16 Tr. 3842 (Cannella)). Schering eventually sent its draft of the agreement to Cannella and Upsher. (USX 105; 16 Tr. 3843 (Cannella); 15 Tr. 3549 (JOEL Hoffman)).

Complaint Counsel's Response to Finding No. 1.31:

Complaint counsel has no specific response.

1.32. Cannella and Hoffman were ultimately unable to reach agreement on some terms of the Schering draft, (16 Tr. 3843 (Cannella)). They agreed to get the principals on the telephone to resolve these differences. (16 Tr. 3844 (Cannella)). The final details of the agreement, including the amounts of the installment payments that would make up the $60 million in up-front royalties, were worked out in a series of telephone calls between the parties over the next 24 hours. (CX 1511 at 74:13-75:3, 76:9-19 (Kapur Dep.); 15 Tr. 3548-50 (JOEL Hoffman); 23 Tr. 5459-60, 5464 (Troup); 2 Tr. 360 (Wasserstein, IH); 16 Tr. 3843-44 (Cannella)).

Complaint Counsel's Response to Finding No. 1.32:

Complaint counsel has no specific response.

1.33. During these telephone calls, the parties discussed the language of the provision that gave Upsher permission to market its generic version of K-Dur after September 1, 2001. (16

Tr. 3844 (Cannella)). Schering's proposed version of the agreement provided that Upsher "agrees that it will not market in the United States its Klor Con M20 potassium chloride product or any other 20 milliequivalent potassium chloride product prior to September 1, 2001." (USX 105; 16 Tr. 3848 (Cannella)). Mr. Cannella told Mr. Hoffman that the language "prohibited Upsher-Smith from doing too broad a spectrum of activities and was not acceptable." (16 Tr. 3849 (Cannella)). Mr. Cannella also explained this to Mr. Kapur, who agreed that the language was too broad. (16 Tr. 3849 (Cannella)). Together, the parties changed the language to reflect an agreement that Upsher "will not market in the United States its Klor Con M20 potassium chloride product or *any other sustained release microencapsulated potassium chloride tablet* prior to September 1, 2001." (16 Tr. 3847, 3849 (Cannella)).

Complaint Counsel's Response to Finding No. 1.33:

The proposed finding is misleading because it leaves out other relevant information. Upsher was then marketing a potassium chloride powder that was mixed with water that could be taken in a 20 mEq strength. Tr. at 20:4621, 29 (Dritsas). Schering's proposed language would have barred Upsher from continuing to market this product even though competition from existing products did not constrain the pricing of K-Dur 20. Upsher's proposed language would allow Upsher to continue marketing its 20 mEq powder, but not allow Upsher to market any other potassium chloride AB rated to K-Dur 20, whether or not that other product infringed the Schering 743 patent.

1.34. The September 1, 2001 date for entry of Upsher's generic version of K-Dur had been settled before these discussions, and the date was not the subject of negotiations during the

June 12 or June 16 meetings or the subsequent telephone calls between the parties on June 17. (16 Tr. 3850 (Cannella); CX 1488 at 64:18-65:3 (Cannella Dep.); SPX 1263 at 65:5-6, 12-15 (Cannella Dep.)).

Complaint Counsel's Response to Finding No. 1.34:

The proposed finding makes a nonsensical distinction and is contrary to more reliable evidence. Mr. Troup repeatedly demanded from Schering a payment to settle the patent infringement suit. CPF 190 (Mr. Troup asked for $60-70 million at the May 21 meeting); CPF 191 (Mr. Troup continued to stress his need for cash at the May 28 and June 3 meetings); CPF 192 (Mr. Troup again asked for $60-70 million at the June 12 meeting); CPF 196 (Mr. Troup continued to insist on payments to settle at the June 16 meeting); CPF 197 (discussing the parties' negotiations on June 17 of the payments of $60 million); CPF 200-02, 204, 206-07 (summarizing Mr. Troup's demands to be paid to settle the patent infringement suit and his connecting the money Schering should pay Upsher to the revenue Upsher was losing by not entering the market and to the harm that Upsher's product would do to Schering's monopoly); CPF 210 (discussing the presentation to Schering's Board of Directors which said that providing Upsher an "income stream" to replace that which it was losing by not entering the market was a "prerequisite of any deal"). Because Upsher demanded payment as part of any settlement, no date for Upsher's introduction of its generic 20 mEq potassium chloride could be finalized until Schering had agreed to pay Upsher the $60 million.

1.35. After the conference calls to fine-tune the agreement, the agreement was memorialized in writing in an initial fax copy on the early hours of June 18, 1997. (23 Tr. 5464 (Troup); 15 Tr. 3549-50 (JOEL Hoffman)). The settlement agreement, CX 347, bears the date of June 17, 1997. (CX 347; 15 Tr. 3550 (JOEL Hoffman)). However, it was actually signed at 2:00 or 3:00 a.m. on June 18, 1997. (15 Tr. 3550 (JOEL Hoffman); 23 Tr. 5467 (Troup)). Mr. Troup signed a fax copy on June 18 (23 Tr. 5467 (Troup)) and a hard copy of the final version on June 19, after returning to the office from a business trip. (23 Tr. 5465, 5467-68 (Troup); CX 348).

Complaint Counsel's Response to Finding No. 1.35:

Complaint counsel has no specific response.

E. Schering's Board of Directors Approves the Niacor-SR License

1.36. Schering's procedures dictated that the Board of Directors must approve any license with a value above a certain threshold. (SPX 1260 at 26:8-17 (Wasserstein IH)). The entire agreement executed between Schering and Upsher, including the first payment to be made by Schering, was contingent on approval by the Schering Board. (16 Tr. 3855-56 (Cannella); CX 347 at SP 12 00190). Mr. Wasserstein began working on a document to be presented to the Board of Directors soon after the agreement was signed. (2 Tr. 360-61 (Wasserstein IH)). In part, Mr. Wasserstein relied on clinical information and financial projections generated by Global Marketing group. (7 Tr. 1443-45 (Wasserstein IH)).

Complaint Counsel's Response to Finding No. 1.36:

Complaint counsel has no specific response.

1.37. The presentation to Schering's Board sought authorization to enter into the license agreement with Upsher. (CX 338). It states that, during the course of Schering's discussions with Upsher, Upsher "indicated that a prerequisite of any deal would be to provide them with a guaranteed income stream for the next 24 months to make up for the income that they had projected to earn from sales of Klor-Con had they been successful in their suit." (CX 338 at SP 12 00270). The Board was informed that Schering had made it clear to Upsher that any such deal would have "to stand on its own merit, independent of the settlement." (CX 338 at SP 12 00268; 2 Tr. 363 (Wasserstein IH)). By that, Wasserstein meant that "any licensing deal . . . that we were doing with Upsher-Smith had to be valued as a licensing deal without any consideration of the settlement." (2 Tr. 363 (Wasserstein IH)). Mr. Hoffman described this as an accurate description of what he told Upsher representatives at the meetings he attended. (15 Tr. 3573-74 (JOEL Hoffman)); CX 1531 at 105:12-25 (Wasserstein IH); SPX 1260 at 106:1-8 (Wasserstein III)). One Schering Board member testified that "it was made very clear to the directors that we were looking at this license agreement which had to stand on the merits of the license agreement." (SPX 1225 at 30:14-17 (Becherer Dep.)). Another Board member explained that "the licensing agreement that was being proposed would have to stand on its own merits," so that it "would be an agreement that would make sense in and of itself independent of anything else." (CX 1526 at 24:24-25:1, 25:5-7 (P. Russo Dep.)).

Complaint Counsel's Response to Finding No. 1.37:

The proposed finding leaves out relevant evidence. The Schering Board of Directors did not have the required information to evaluate the Schering/Upsher Agreement. In the materials provided to the Board for its meeting on June 24, 1997, there

is no mention of any of the following: the lack of due diligence by Schering concerning the patent situation of Niacor-SR; the lack of due diligence by Schering concerning FDA/regulatory issues with respect to Niacor-SR; the lack of due diligence by Schering concerning labeling with respect to Niacor-SR; the issue of FDA approval; or, that Schering-Europe earlier had rejected a deal for Niacor-SR with Upsher. CX 338 (Schering Board of Directors presentation). Additionally, the Board never saw the actual Schering/Upsher Agreement. CPF 220.

The Board also did not conduct an independent evaluation of the merits of the Schering/Upsher Agreement nor did it have the skills to do so. CPF 221 (discussing that Board members did not review the Niacor-SR license on its own, did not have the skills to do so, and accepted the judgement of management when deals such as the license for Niacor-SR were presented to them). The Board only considered the proposal for 15-20 minutes. CPF 220.

The Board knew that if a generic version of K-Dur 20 entered the market, Schering would lose revenues and profits. CPF 222.

1.38. · The Board presentation provided sales projections for Niacor-SR of $100 million plus in annual sales. (CX 338 at SP 12 00268). The presentation showed a net present value of $225-265 million for the Niacor license. (CX 338 at SP 12 00275). A Board member testified that "[t]he focus of this proposal was a licensing agreement for four products in a space that Schering was interested in for a $60 million investment and a $225 million plus economic value return. So, from the Board's standpoint, there was nothing about this that would cause any

questions." (CX 1526 at 51:17-22 (P. Russo Dep.)). Based on the information presented to them and their understanding that the payments were for the licensed products, the Board approved the license deal. (CX 340 at SP 07 00003).

Complaint Counsel's Response to Finding No. 1.38:

The proposed finding leaves out relevant evidence and is therefore misleading. The Schering Board of Directors did not have the required information to evaluate the Schering/Upsher Agreement. The Board also did not conduct an independent evaluation of the merits of the Schering/Upsher Agreement nor did it have the skills to do so. CPRF 1.37.

1.39. The payments provided for in the June 7 agreement were for Niacor-SR and the other products Schering licensed from Upsher. There is no testimony to the contrary.

Complaint Counsel's Response to Finding No. 1.39:

The proposed finding is contrary to more reliable evidence. Schering did not license six Upsher products in exchange for sixty million dollars. Three categories of evidence prove that, in fact, Schering paid Upsher $60 million to delay Upsher's entry into the K-Dur 20 market: (1) the circumstances of the negotiations and the Schering/Upsher Agreement itself; (2) an analysis of the license for Niacor-SR; and (3) the economic incentives of branded monopolies and potential generic entrants:

(1) First, the text of the Schering/Upsher Agreement and the circumstances of the negotiations indicates payment for delay. The Schering/Upsher Agreement itself indicates that the license and supply agreement was not a separate agreement for value

independent of the settlement agreement, but in fact that the $60 million and the agreement to settle the patent infringement suit were inextricably intertwined. CPF 176 (paragraph 11 of the Schering/Upsher Agreement explicitly states $60 million is for paragraphs 1-10 of the Schering/Upsher Agreement, which includes the settlement of the litigation, Upsher's agreement to delay entry until 2001, and its agreement not to help any other challengers to the '743 patent); CPF 178 (Mr. Hoffman concedes that the agreement on its face indicates some money paid for settlement); CPF 179 (paragraph 3 allows Upsher to come to market immediately if a court strikes down the Agreement (and thus Schering's requirement to pay the $60 million)); CPF 181 (paragraph 3 allows Upsher to come to market if Schering licenses another generic to enter); CPF 180 (paragraph 10 ("*force majeure*" clause) obligates Schering to pay $60 million to Upsher even if some unforeseen event causes the license to be worthless). This contemporaneous documentary evidence is more reliable than the self-serving, post-hoc testimony cited in the proposed finding.

There is also reliable evidence that Mr. Troup asked for money from Schering repeatedly in order to agree to settle the Schering/Upsher patent infringement suit. CPF 190, 200, 204 (Mr. Troup demands for $60-70 million to settle the lawsuit at the May 21 meeting); CPF 191, 206, 209 (Mr. Troup stresses his need for cash at the May 28 and June 3 meetings); CPF 192, 194, 200, 206 (Mr. Troup repeats his demand for money to settle the lawsuit at the June 12 meeting); CPF 196, 200 (Mr. Troup stressed a need for an income stream and up-front payments as part of a settlement at the June 16 meeting); CPF 201 (Mr. Troup repeats his need for revenue as part of a settlement at the June 17

meeting).

Mr. Troup based these requested requests for money from Schering to settle the lawsuit not on the value of Niacor, but instead on Upsher's forgone revenues for not entering the market and the revenue impact its product would have on Schering's K-Dur 20 monopoly if Upsher entered the market. CPF 200-02 (discussing how Mr. Troup repeatedly sought to replace revenues lost by not being on the market); CPF 204, 212-13 (discussing Mr. Troup requesting $60-70 million to end the litigation and basing that figure on a percentage of the harm that Upsher's product would do to Schering's monopoly); CPF 206-07 (discussing Mr. Kapur and Mr. Wasserstein's testimony that Mr. Troup wanted to replace the revenue Upsher was losing by delaying entry); CPF 214-18 (discussing money requested to settle the lawsuit based on Upsher's lost revenues from not entering the generic K-Dur 20 market).

(2) Second, the $60 million non-contingent payment made by Schering to Upsher cannot reasonably be considered to have been a license fee for Niacor-SR and the five generic products licensed under the settlement agreement. Tr. at 7:1307, 1338-39 (Levy); Tr. at 4:577 (Bresnahan). The $60 million non-contingent fee was grossly excessive for Niacor-SR and the other licensed products, CPF 287-372, Schering's due diligence was strikingly superficial relative to industry standards, CPF 373-663, Schering's and Upsher's post-license behavior does not comport with parties' who had just entered into a typical licensing deal, CPF 664-721, Schering had previously rejected an equal or better product, CPF 722-777, and no other company had offered Upsher any money for Niacor-SR, let alone $60 million, CPF 778-808.

(3) Third, economic theory proves Schering paid Upsher $60 million to delay Upsher's entry into the K-Dur 20 market. There is always an incentive for the monopolist to pay the entrant to delay its entry and for the entrant to agree to delay its entry, which harms consumers. CPF 1150 – 1157. A monopolist and potential entrants have those incentives to delay entry even with it is uncertain. CPF 1161 – 1165. Uncertain competition provides the same benefits qualitatively as certain entry, so delaying uncertain entry harms consumers. CPF 1166 – 1172. Applying the criteria to these settlements, Schering was a monopolist and Upsher and AHP were threats to that monopoly. Therefore, the parties had the incentives to delay uncertain entry. CPF 1173 – 1184 (applying economic theory to facts of this case and explaining how Schering, as a monopolist, had the incentive to pay Upsher to delay its entry and how Upsher, as a potential entrant, had the incentive to accept money to delay its entry). Schering paid Upsher net consideration for delay. CPF 1185 – 1206 (explaining Schering's and Upsher's incentives to agree to payment for delay, the actions of each which led to payment for delay, and that the $60 million was not for Niacor-SR).

1.40. Paragraph 11 of the agreement discusses up-front royalty payments, royalties, and milestone payments. (CX 347 at SP 12 00194; 23 Tr. 5472 (Troup)). The agreement refers to the installment payments of $28 million, $20 million and $20 million as "royalty" payments. (CX 348; 15 Tr. 3575 (JOEL Hoffman); 16 Tr. 3855 (Cannella); 23 Tr. 5474 (Troup)). Furthermore, "[a]ll of [the] discussions [between Schering and Upsher] relating to those payments dealt with those payments as consideration from Schering-Plough to Upsher-Smith for

Schering-Plough's acquiring of the rights in the four Upsher-Smith pipeline products." (16 Tr. 3855 (Cannella)); *see also* (23 Tr. 5472-73 (Troup)) (Upsher discussed with Schering that the sole purpose of these payments and milestones were for the licensing and the rights and obligations to manufacture the products for Schering). Any other interpretation of the purpose of these payments would be "directly contrary to every discussion" the parties had. (15 Tr. 3565 (JOEL Hoffman)).

Complaint Counsel's Response to Finding No. 1.40:

The proposed finding is contrary to more reliable evidence. The plain language of the Schering/Upsher Agreement indicates that the $60 million was paid to delay Upsher's entry. CPF 176 (paragraph 11 of the Schering/Upsher Agreement explicitly states $60 million is for paragraphs 1-10 of the Schering/Upsher Agreement, which includes the settlement of the litigation, Upsher's agreement to delay entry until 2001, and its agreement not to help any other challengers to the '743 patent); CPF 178 (Mr. John Hoffman concedes that the agreement on its face indicates some money paid for settlement); CPF 179 (paragraph 3 allows Upsher to come to market if a court strikes down the Agreement (and thus Schering's requirement to pay the $60 million)); CPF 181 (paragraph 3 allows Upsher to come to market if Schering licenses another generic to enter); CPF 180 (paragraph 10 ("*force majeure*" clause) obligates Schering to pay $60 million to Upsher even if some unforeseen event causes the license to be worthless). This contemporaneous documentary evidence is more reliable than the self-serving, post-hoc testimony cited in the proposed finding. *See also* CPRF 1.39.

1.41. Each of the Schering representatives who participated in the Upsher settlement negotiations testified that Schering refused to pay Upsher money to keep its generic version of K-Dur off the market. Professor Bresnahan concedes that these witnesses so testified. (6 Tr. 1092-93 (Bresnahan)).

Complaint Counsel's Response to Finding No. 1.41:

The proposed finding is inconsistent with more reliable evidence. *See* CPRF 1.39.

1.42. Mr. Driscoll testified that he and Mr. Troup, "had a discussion rather extensively about [Troup's] point about . . . us paying them to end the litigation, and he was pretty forceful in that, very forceful as a matter of fact, and I was very forceful in saying, [w]e simply cannot do that." (2 Tr. 325 (Driscoll IH)). Mr. Driscoll testified that he "indicated very forcefully that Schering was not going to pay any sum to Upsher-Smith simply for them to stay off the market." (2 Tr. 326 (Driscoll IH)).

Complaint Counsel's Response to Finding No. 1.42:

The proposed finding is misleading and leaves out reliable evidence. Contrary to the implications of the proposed finding, Mr. Troup asked Schering for money repeatedly in order to agree to settle the Schering/Upsher patent infringement suit. CPF 190, 200, 204 (Mr. Troup demands for $60-70 million to settle the lawsuit at the May 21 meeting); CPF 191, 206, 209 (Mr. Troup stresses his need for cash at the May 28 and June 3 meetings); CPF 192, 194, 200 (Mr. Troup repeats his demand for money to settle the lawsuit at the June 12 meeting); CPF 196, 200 (Mr. Troup stressed a need for an income

stream and up-front payments as part of a settlement at the June 16 meeting); CPF 201 (Mr. Troup repeats his need for revenue as part of a settlement at the June 17 meeting).

1.43. Mr. Kapur testified that Mr. Driscoll "was very clear [at meetings with Troup] that . . . his attorneys would not allow him to make any financial settlement and, therefore, he was not willing to – he ruled out making any payment to Upsher-Smith." (SPX 1242 at 21:16-20 (Kapur Dep.)). *See also* (2 Tr. 326, 335 (Kapur IH)) ("Marty [Driscoll] told Ian [Troup] that he could not entertain the idea of paying him anything for staying off the market" and "that his legal people would not allow him to do that"). Mr. Kapur specifically recalled that "Hoffman had made the point to Upsher-Smith repeatedly that there was no way [Schering] could make any payment for settlement of that litigation." (CX 1510 at 63:24-64:1 (Kapur IH)); *see also* (SPX 1242 at 46:11-14 (Kapur Dep.)) ("Hoffman made clear on several meetings that there would be no payment for settlement of the litigation").

Complaint Counsel's Response to Finding No. 1.43:

The proposed finding is inconsistent with more reliable evidence. *See* CPRF 1.39; CPRF 1.42.

1.44. Likewise, Mr. Hoffman testified that Schering never agreed to pay Upsher for delay in bringing its generic to market. (15 Tr. 3542 (JOEL Hoffman)). When Mr. Hoffman got involved directly in the negotiations, he told Upsher's counsel Mr. Cannella plainly that "Schering was not going to be paying Upsher-Smith to stay off the market." (15 Tr. 3541 (JOEL Hoffman)); *see also* (SPX 1240 at 32:7-12 (JOEL Hoffman Dep.)) (Hoffman told Cannella that

"if we were going to have a settlement between our two clients, we do it appropriately from an antitrust point of view . . . and that I thought the discussion should be about licensing of a product and that we were not going to pay Upsher to stay off the market"). Similarly, Mr. Hoffman testified that he "took [a comment by Upsher's consultant] to be an invitation to pay them to stay off the market and I said we weren't going to do that." (15 Tr. 3544 (JOEL Hoffman)). Mr. Hoffman also testified that "the consultant [Upsher] brought was doing some sort of analysis of how much we stood to lose if we lost the lawsuit. And I believe that's what led me to believe they thought it would be an appropriate thing for us to pay them to settle the lawsuit. And I told them we would not do that." (CX 1508 at 35:19-25 (JOEL Hoffman IH) *see also* (CX 1508 at 35:6-10)).

Complaint Counsel's Response to Finding No. 1.44:

The proposed finding is inconsistent with more reliable evidence. *See* CPRF 1.39; CPRF 1.42.

1.45. Upsher representatives also testified that Schering flatly rejected the idea of paying Upsher to settle the litigation. Mr. Troup testified that Driscoll told him at their first meeting that he "wasn't going to discuss the merits of the [patent] case, nor was he going to discuss money." (23 Tr. 5413 (Troup)). Mr. Troup testified that no one at Schering ever indicated during any of the negotiation sessions that Schering would pay Upsher for delay of its entry (23 Tr. 5499 (Troup)), or that the licenses Schering obtained from Upsher would be a cover or veil for a payment for delay. (23 Tr. 5499 (Troup)) ("These were valuable licenses. There was no veil of anything").

Complaint Counsel's Response to Finding No. 1.45:

The proposed finding is inconsistent with more reliable evidence. *See* CPRF 1.39; CPRF 1.42.

1.46. Mr. Cannella, testified that Mr. Hoffman had "mentioned the sensitivities of antitrust considerations" in relation to any deal between the Schering and Upsher. (16 Tr. 3826 (Cannella)). Mr. Cannella confirmed that, at the meetings in which he participated, there was no statement by anyone that Upsher should be paid for delayed entry. (16 Tr. 3839 (Cannella)).

Complaint Counsel's Response to Finding No. 1.46:

The proposed finding is inconsistent with more reliable evidence. *See* CPRF 1.39; CPRF 1.42.

1.47. Schering was willing to compensate Upsher if the parties could enter into an independent business venture that "would add value to both companies." (2 Tr. 328 (Kapur IH)). Mr. Troup expressed to Schering on several occasions that Upsher needed income to meet its cash needs. (23 Tr. 5413 (Troup); 15 Tr. 3543-44 (JOEL Hoffman); 2 Tr. 357 (Wasserstein IH)). Mr. Hoffman testified that he told Mr. Troup that Schering would be willing to pay Upsher for "arm's length business deals that stand on their own two feet." (15 Tr. 3544 (JOEL Hoffman); 2 Tr. 351-52 (JOEL Hoffman IH); *see also* CX 1508 at 36:15-22 (JOEL Hoffman IH)). (Mr. Hoffman told Mr. Troup that the parties could "do some other sort of deal so [Upsher] could have some income . . . as long as that deal stood on its own two feet"); (SPX 1239 at 37:7-12 (JOEL Hoffman IH) (any deal would have to be "a separately valued deal that we do, with or

without the settlement.").

Complaint Counsel's Response to Finding No. 1.47:

The proposed finding is inconsistent with more reliable evidence. *See* CPRF 1.39; CPRF 1.42.

1.48. The agreement between Schering and Upsher was contingent on the license for Niacor-SR receiving the approval of Schering's Board of Directors (CX 347 at SP 12 00190). The summary of the proposed license conveyed to the Board that "any such deal should stand on its own merit independent of the settlement." (CX 338 at SP 12 00268). Raul Cesan presented the proposed license agreement to Schering's Board with the same understanding. (SPX 1264 at 62:20-63:8 (Cesan Dep.); CX 1489 at 66:17-25 (Cesan Dep.)). Mr. Cesan testified that he had requested "a review of the products be made to make sure that they had value for Schering-Plough by themselves . . . that they could create value on their own" and recommended the deal to the Board "as a good deal based on the products we were licensing." (CX 1489 at 66:17-25 (Cesan Dep.)).

Complaint Counsel's Response to Finding No. 1.48:

The proposed finding leaves out relevant evidence. The Schering Board of Directors did not have the required information to evaluate the Schering/Upsher Agreement. The Board also did not conduct an independent evaluation of the merits of the Schering/Upsher Agreement nor did it have the skills to do so. CPRF 1.37.

1.49. Schering's Board of Directors approved the license with the understanding that the $60 million payments were for Niacor-SR. The Schering Board minutes indicate the Board's approval of the proposed "license agreement which contemplates guaranteed payments of $60 million in license fees over a three-year period" plus milestone payments. (CX 340 at SP 07 00003). One Schering Board member testified that the Board assessed the proposal as if there were no settlement since "it was made very clear to the directors that we were looking at this license agreement which had to stand on the merits of the license agreement." (SPX 1225 at 30:14-17 (Becherer Dep.)). Another Board member explained that "the licensing agreement that was being proposed would have to stand on its own merits," so that it "would be an agreement that would make sense in and of itself independent of anything else." (CX 1526 at 24:24-25:1, 25:5-7 (P. Russo Dep.)).

Complaint Counsel's Response to Finding No. 1.49:

The proposed finding leaves out relevant evidence. The Schering Board of Directors did not have the required information to evaluate the Schering/Upsher Agreement. The Board also did not conduct an independent evaluation of the merits of the Schering/Upsher Agreement nor did it have the skills to do so. CPRF 1.37.

II. SCHERING'S INTEREST IN THE MARKET FOR CHOLESTEROL LOWERING DRUGS AND NEGOTIATIONS WITH KOS PHARMACEUTICALS

A. Kos Pharmaceuticals' Sustained Release Niacin Product

1.50. Kos Pharmaceuticals is a small pharmaceutical company in Florida. (18 Tr. 4101 (Audibert)). Kos was founded by Michael Jaharis, who also founded Key Pharmaceuticals and had been its CEO until Key was acquired by Schering in 1986. (18 Tr. 4101 (Audibert); SPX 223).

Complaint Counsel's Response to Finding No. 1.50:

Complaint counsel has no specific response.

1.51. In the mid-1980s, Key Pharmaceuticals ("Key") was a company that specialized in the use of sustained release technology to develop new products from old compounds that were limited by issues related to side effects. (18 Tr. 4083-84 (Audibert)). Through the use of sustained release technology, Key developed a series of successful products including Theo-Dur, which became the best selling asthma product in the United States, and K-Dur, which is the subject of the present litigation. (18 Tr. 4084, 4088-89 (Audibert); (31 Tr. 7552 (Patel); SPX 557 at FTC 0006127). Each of these sustained release pharmaceuticals became a market leader, and each generated sales in the range of $200 to $300 million annually. (18 Tr. 4087-89 (Audibert)).

Complaint Counsel's Response to Finding No. 1.51:

Complaint counsel has no specific response.

1.52. After Schering's acquisition of Key in 1986, Mr. Jaharis, the founder of Key, established Kos as a company that would employ sustained release technology in exactly the same way that had been used successfully at Key - developing new products by overcoming known limitations of old compounds. (18 Tr. 4100-01 (Audibert); SPX 557 at FTC 0006127; SPX 605, at Kos 0054). In its March 1997 IPO prospectus, Kos summarized its strategy in focusing on reformulations of known drugs: "Kos believes that developing proprietary products based on currently approved drugs, rather than new chemical entities ("NCEs"), may reduce regulatory and development risks . . ." (SPX 605 at Kos 0073).

Complaint Counsel's Response to Finding No. 1.52:

Complaint counsel has no specific response.

1.53. Right out of the blocks, and fresh off Mr. Jaharis' success with Key, Kos set its sights on niacin as the old compound it would transform through sustained release technology into a new and successful cholesterol lowering drug known as Niaspan. (SPX 605 at Kos 0054-55). The flushing side effect of immediate release niacin products is caused by spikes in the level of niacin in the blood when the drug is released into the system over a very short period of time. (16 Tr. 3627-28 (Horovitz)). By altering the release rate of niacin through a sustained release formulation, Kos hoped to minimize the flushing side effect that had limited the use and marketability of immediate release niacin products, without causing the significant elevations in liver enzymes associated with over-the-counter sustained release niacin products sold as dietary supplements. (SPX 605 at Kos 0076-77).

Complaint Counsel's Response to Finding No. 1.53:

The proposed finding is incomplete. Kos developed Niaspan with the intention of reducing both the side effects and safety problems (*e.g.*, liver toxicity) associated with then-available niacin products. Flushing was not the only, or even primary, concern. Moreover, Kos' Niaspan was believed to be safer and more efficacious not simply as a result of its controlled-release technology, but also because of the particular dosing regimen it had developed. SPX 605 (Kos' IPO Prospectus) at Kos 055 ("Niaspan's controlled-release formulation and dosing regimen reduced the liver toxicity and intolerable side effects generally associated with currently available niacin") (emphasis added on portions of exhibit not reflected in respondent's proposed finding); SPX 605 at Kos 0077 ("Niaspan Product Development: Kos has developed a controlled-release hydrogel matrix formulation of niacin that reduces the intolerable side effects and frequent safety problems characteristic of currently available niacin formulations. Kos believes that it is the unique controlled-release nature of its Niaspan formulation in conjunction with Niaspan's specific dosing regimen that minimizes adverse events while maintaining niacin's positive effect on lipids. Kos also believes the recommended dosing regimen for Niaspan contributes to the positive effects on lipid levels because of the chronobiology of lipid metabolism") (emphasis added on portions of exhibit not reflected in respondent's proposed finding). *See* CPF 728-731 (describing the extensive research and development work required for Kos' Niaspan); CPF 612 (Schering's own notes from a meeting with Kos indicate that Schering was aware of the importance of both sustained-release technology and the particular dosing regimen used with Niaspan); CPF 611

(discussing Schering's knowledge of sustained-release niacin products' side effects and safety problems, which Schering learned, in part, from Kos' IPO Prospectus); CPF 614 (discussing Kos' characterization of how its controlled-release mechanism and dosing regimen affected both side effects and safety parameters).

B. Niacin's Role in the Market for Cholesterol Lowering Drugs as of June 1997

1. Conditions Treated with Cholesterol Lowering Drugs

1.54. Coronary Artery Disease ("CAD") is the number one cause of death in most industrialized countries, including the United States. (SPX 608 at SP 16 00346). One of the most studied aspects of CAD is the risk factors associated with the development of atherosclerosis. (SPX 608 at SP 16 00365). Atherosclerosis is a condition involving a build-up of lipids and other factors in the arteries ("plaque") which can inhibit the flow of blood through the arteries. (16 Tr. 3754 (Horovitz); SPX 608 at SP 16 00354).

Complaint Counsel's Response to Finding No. 1.54:

Complaint counsel has no specific response.

1.55. Hyperlipidemia, sometimes referred to as hypercholesterolemia, is one of the main risk factors for CAD caused by atherosclerosis, along with other factors such as age, smoking, diabetes, high blood pressure and obesity. (SPX 608 at SP 16 00355-356; 17 Tr. 3901 (Halvorsen); 21 Tr. 4980 (Freese); SPX 235). Hyperlipidemia is a condition involving abnormal levels of various lipids, including low-density lipoprotein (LDL), high-density lipoprotein

(HDL), triglycerides (TGs), and lipoprotein a (Lp(a)). (SPX-608 at SP 16 0034, 354-357). The main concern for patients with hyperlipidemia is the potential development of atherosclerosis, which, if left untreated, can lead to CAD, myocardial infarction and death. (SPX-608 at SP 16 00365). Hyperlipidemia, smoking and high blood pressure are the most important preventable risk factors for CAD. (SPX-608 at SP 16 00365).

Complaint Counsel's Response to Finding No. 1.55:

Complaint counsel has no specific response.

1.56. Cholesterol and triglycerides are each transported through the body by one of a variety of lipoproteins, including LDL, HDL, and Lp(a). (SPX-608 at SP 16 00357). Hyperlipidemia manifests itself in several standard configurations which involve variations in the levels of LDL, HDL, Lp(a) or TGs. (SPX-608 at SP 16 00356). As a result of numerous studies conducted prior to 1997, the National Institutes of Health and the American Heart Association recognized elevated levels of LDL ("bad cholesterol"), low levels of HDL ("good cholesterol") and high levels of TGs as risk factors for CAD. (SPX 924 at SP 002780; SPX 608 at SP 16 00356, 363; USX 141, at Moreton 00080). In addition, studies completed in 1996 and 1997 linked Lp(a) with atherosclerosis and CAD. (SPX 608 at SP 16 000362; SPX 235 at SP 16 00003; SPX 924 at SP 002780).

Complaint Counsel's Response to Finding No. 1.56:

The proposed finding is incomplete. Although SPX 608 at SP 16 000362-63 does discuss a 1995 study in which Lp(a) was "associated with atherosclerosis," it also explains that this link is not well-established. The exhibit points to other evidence

supporting the claim that Lp(a) may not be an independent risk factor for CAD, but, instead, that reducing LDL is a primary concern. "A 1995 study showed that when elevated LDL is substantially reduced, CAD progression and clinical events are reduced as well, even though Lp(a) levels exhibit little alteration. This result not only supports Lp(a)'s dependence on LDL for its atherogenic effect, it also suggests that physicians should be vigilant in treating elevated LDL in patients with elevated Lp(a)." The exhibit continues by explaining that niacin is among several compounds that "appear to have some Lp(a)-lowering effect," but that "[t]he long-term benefits of lowering Lp(a) have not yet been demonstrated."

1.57. To address the need for more effective treatment of high cholesterol, the National Institutes of Health convened a panel of cholesterol research experts, the National Cholesterol Education Program ("NCEP"), to establish guidelines for the treatment of high cholesterol. (SPX 605 at Kos 000076; SPX 608 at SP 16 00344, 347; SPX 924 at SP 002780; 21 Tr. 4964-4695 (Freese)). In addition to observing NCEP guidelines, an expert panel was also convened in Europe, the European Society for Atherosclerosis, to establish similar guidelines to help physicians identify and treat hyperlipidemic patients. (SPX 608 at SP 16 00344, 347; SPX 235 at SP 16 00002; **********

Complaint Counsel's Response to Finding No. 1.57:

Complaint counsel has no specific response.

1.58. A steady upward trend in hyperlipidemia diagnoses was anticipated in both the U.S. and Europe, fueled by aging populations, greater recognition of the role of hyperlipidemia in CAD, and increased health care consumer awareness. (SPX 608 at SP 16 00351). This trend was expected to result in increased sales in the cholesterol lowering market. (SPX 235 at SP 16 00001).

Complaint Counsel's Response to Finding No. 1.58:

Complaint counsel has no specific response.

2. The Market for Cholesterol Lowering Drugs as of June 1997

a. The Large and Growing Market for Cholesterol Lowering Drugs in June 1997

1.59. Although relatively inexpensive hyperlipidemic agents, including niacin, had been available for decades, annoying side effects interfered with patient compliance. (SPX 608 at SP 16 00344-345). In the late 1980's, however, the market for cholesterol lowering drugs began to take off with the widespread use of the newly developed and more expensive HMG-CoA reductase inhibitors, known as the statins. (SPX 608 at SP 16 00345). In the mid-1990's, there were five major classes of cholesterol lowering drugs, including the statins that dominated the market, the fibrates, the bile acid sequestrants, niacin and probucol. (SPX 235 at SP 16 00001).

Complaint Counsel's Response to Finding No. 1.59:

The finding is incomplete and misleading. Niacin cannot be considered a "major" class of drugs because, as the cited document SPX 235 states, niacin "accounts for less

than 0.1% of the worldwide cholesterol-reducer sales." SPX 235 at SP 16 00001 (Schering prepared document entitled "Niacor-SR Supplementary Information," dated June 23, 1997). The same document reveals that niacin is "[n]ot used or available in most European countries." SPX 235 at SP 16 00001. Lastly, the same document concludes that among the anti-cholesterol drugs "[s]tatin use [is] expected to remain [the] baseline therapy; until new R&D therapies become available." SPX 235 at SP 16 00001.

1.60. By the mid-1990s, the worldwide market for cholesterol lowering drugs had grown to become the seventh best selling drug class in the world. (SPX 235 at SP 16 00001). By the time of Schering's evaluation of Niacor-SR in June 1997, annual worldwide sales in the cholesterol lowering market were approximately $7 billion. (9 Tr. 1763-64 (Levy); 28 Tr. 6876 (Kerr)). According to the IMS data available to Schering in June 1997, the market for cholesterol lowering drugs outside the U.S., Canada and Mexico (Ex-NAFTA) was approximately $4 billion annually. (SPX 5 at SP 16 00447). As indicated in other documents available to Schering in June 1997, the U.S. market for cholesterol lowering drugs was somewhat less than $3 billion annually. (CX 1042 at SP 16 00112).

Complaint Counsel's Response to Finding No. 1.60:

Complaint counsel has no specific response.

1.61. At the time, the significant growth in the market for cholesterol lowering drugs was expected to continue beyond 1997. (SPX 235 at SP 16 00001; 16 Tr. 3623 (Horovitz); 18 Tr. 4125 (Audibert)). According to complaint counsel's pharmaceutical licensing expert, annual

worldwide sales of cholesterol lowering has grown from approximately $6-8 billion in 1997 to more than $13-14 billion today. (9 Tr. 1763-64 (Levy)).

Complaint Counsel's Response to Finding No. 1.61:

Complaint counsel has no specific response.

b. The Market for Cholesterol Lowering Drugs Ex-NAFTA was Equal to or Larger Than the U.S. Market in June 1997

1.62. In 1995, sales in the United States represented somewhat less than half of this worldwide market. (SPX 924 at SP 002780; USX 141 at Moreton 00080; SPX 924 at SP 002780). According to documents available to Schering in June 1997, the market for cholesterol lowering drugs outside the U.S., Canada and Mexico ("worldwide Ex-NAFTA") was larger than the U.S. market for cholesterol lowering drugs. (SPX 5 at SP 16 00447; CX 1042 at SP 16 00112). In 1997, according to complaint counsel's pharmaceutical licensing expert, Dr. Nelson Levy, U.S. sales represented "roughly" half of worldwide sales of cholesterol lowering drugs. (9 Tr. 1914-15 (Levy)).

Complaint Counsel's Response to Finding No. 1.62:

Complaint counsel has no specific response.

3. Niacin's Established Profile as a Cholesterol Lowering Agent

1.63. Niacin, or nicotinic acid, is a B vitamin that was first discovered to have hypolipidemic qualities in 1955. (SPX 608 at SP 16 00390). Niacin decreases LDL (known as "the bad cholesterol"), raises HDL (known as "the good cholesterol"), decreases TGs, and

decreases Lp(a). (SPX 608 at SP 16 00390-391; 16 Tr. 3620 (Horovitz); 18 Tr. 4099 (Audibert)). Niacin has a unique profile in that it is the only drug shown to alter each of these lipids in the desired direction, and is one of the most effective compounds in increasing HDL. (17 Tr. 3903 (Halvorsen); 16 Tr. 3620 (Horovitz); 9 Tr. 1761 (Levy); CX 1042 at SP 16 00072).

Complaint Counsel's Response to Finding No. 1.63:

The proposed finding is incomplete. Although niacin does modify each of the major lipids in the desired direction, the majority of physicians prescribing cholesterol-lowering drugs are mainly concerned with lowering LDL. In 1997, while considering a co-promotional opportunity with Kos for Niaspan, Schering commissioned a marketing research survey of expert lipidologists who indicated that "the primary goal for the vast majority of patients [was] to lower LDL." Furthermore, as of 1997, the same experts reported that there was "no hard data to say that raising HDL to a certain level alters risk or progression of atherosclerosis." Hence, it was unknown whether the fact that niacin effectively raises HDL had any clinical value circa 1997. CX 576 at SP 020710, 13 (Schering marketing research survey indicating that the focus of most cholesterol management is reduction in LDL and that the clinical significance of raising HDL was unknown).

1.64. Niacin is also one of the only compounds known to decrease Lp(a). (SPX 608 at SP 16 00390-391; 17 Tr. 3903 (Halvorsen); SPX 235 at SP 16 00002). Prior to 1997, several studies had associated Lp(a) with atherosclerosis and CAD, and treatment of Lp(a) was considered by European and U.S. experts to be one of the major unmet needs. (SPX 608 at SP

16 000362; SPX 235 at SP 16 00003; SPX 924 at SP 002780; CX 1042 at SP 16 00068-69). Recent studies have confirmed that Lp(a) is an independent risk factor for CAD. (17 Tr. 3904 (Halvorsen)).

Complaint Counsel's Response to Finding No. 1.64:

The proposed finding is incomplete. The therapeutic significance of niacin's capacity to decrease Lp(a), if any, was unknown as of 1997. Schering's own experts were "unsure of the importance of lipoprotein (a) and pointed out that the assay is not yet widely available and is not standardized. Specialists use this measure primarily for risk stratification: there is increasing evidence that Lp(a) is useful in identifying patients at high risk for premature atherosclerosis, but no data to suggest that lowering it is beneficial." CX 576 at SP 020713; SPX 308 at SP 16 00363 ("The long-term benefits of lowering Lp(a) have not yet been demonstrated, however.") (emphasis added to indicate omitted portion of exhibit). Furthermore, achieving reduction in Lp(a) with niacin treatment is possible only with higher doses. SPX 608 at 16 00391 ("Niacin is also one of the few compounds known to affect Lp(a), albeit at high doses") (emphasis added to indicate portion of exhibit not cited). Even if treatment of Lp(a) was considered an unmet need among experts, it is improbable that niacin would ever be accepted among physicians in Europe. Respondent's own document (SPX 608) indicates that "Niacin is not used for treatment in most European countries, particularly in France, Germany, and Spain, where it is available only as a component of multivitamin supplements." SPX 608 at SP 16 00391 (1996 Cardium study discussing cholesterol-lowering market; received by

Schering in June 1997). *See also* CPF 285 (explaining that, circa 1997, niacin treatments were viewed as outdated in the European market).

1.65. More significant than niacin's ability to alter lipid parameters, long-term clinical outcome trials sponsored by the National Institutes of Health had demonstrated that treatment with niacin reduced morbidity and mortality. (16 Tr. 3624-25, 3798 (Horovitz); SPX 924 at SP 002781; SPX 52 at Upsher-Smith FTC 110463; SPX 608 at SP 16 00391; 9 Tr. 1761 (Levy); 18 Tr. 4099 (Audibert); USX 535 at USL 11513).

Complaint Counsel's Response to Finding No. 1.65:

The proposed finding is incomplete. The proposed finding does not acknowledge recognized clinical drawbacks of niacin therapy, such as patient compliance, which would seriously impede niacin's ability to reduce mortality and morbidity. SPX 608 at SP 16 00391: "Studies have shown that niacin therapy decreased [acute myocardial infarctions] by 27% and [coronary artery disease] mortality by 11%, despite difficulties with patient compliance" (emphasis added to indicate omitted portion of exhibit).

1.66. In addition to its known efficacy profile when used as monotherapy, niacin had also been shown prior to 1997 to be an effective agent when used in combination with other cholesterol lowering drugs, such as statins. (SPX 608 at SP 16 00382, 391; 21 Tr. 4962-64, 4989 (Freese); SPX 52 at Upsher-Smith FTC 110463-110464; USX 141 at Morton 00082; CX 1042 at SP 16 00074). As a result, physicians also prescribe niacin in combination with statins. (16 Tr. 3670 (Horovitz); 14 Tr. 3146-47 (Brown); 21 Tr. 4989 (Freese); 7 Tr. 1410-11 (Driscoll IH)).

Complaint Counsel's Response to Finding No. 1,66:

The proposed finding is incomplete and misleading. It implies that niacin is typically used in monotherapy, although it may "also" be used in combination with statins. Conventional use of niacin is actually in combination with another agent, rather than in monotherapy. CX 576 at SP 020709 (Schering market research survey of ten expert lipidologists in April 1997 finding that "[a]lthough there is some solo use in mixed hypercholesterolemia/hypertryglyceridemia when LDLs are only moderately elevated and cost is an issue, most experts reported that the majority of their use of niacin has been in combination with a statin . . ."). *See* CPF 275 (describing niacin as filling merely an "adjunctive role" in cholesterol treatment); CPF 606 (indicating that Schering's own experts reported that the majority of their niacin use is in combination therapy, and that a Schering document describes niacin as "add-on" therapy for use with a statin.); CPF 639, 641, 646 (regarding data on use of niacin in combination with statins as requisite information for several European pharmaceutical companies considering in-licensing Niacor-SR).

4. Niacin's Limited Role in the Market for Cholesterol Lowering Drugs as of June 1997

a. Immediate Release Niacin

1.67. Despite niacin's known profile as an effective cholesterol reducing agent, the immediate release formulations of the drug were not widely used prior to 1997 due to a side effect known as flushing. (16 Tr. 3620-21, 3625-26 (Horovitz); USX 141 at Moreton 00082;

SPX 924 at SP 002781; 18 Tr. 4100 (Audibert)). Flushing is a result of increased blood flow near the skin, which causes redness, tingling and itching in almost all patients who use niacin. (16 Tr. 3625-26 (Horovitz); 17 Tr. 3906 (Halvorsen); 14 Tr. 3150 (Brown)). Although flushing does not present a safety risk, it is a nuisance side effect that significantly reduces patient compliance. (17 Tr. 3906 (Halvorsen); 16 Tr. 3620-21, 3625-26 (Horovitz); 18 Tr. 4105 (Audibert)). This flushing side effect prevented widespread use of what was recognized in the pharmaceutical industry as an otherwise effective cholesterol lowering agent. (16 Tr. 3620-21 (Horovitz); 18 Tr. 4099-100 (Audibert)).

Complaint Counsel's Response to Finding No. 1.67:

The proposed finding is incomplete and is contradicted by the evidence. First, the finding implies that the year 1997 was a turning point in the use of niacin throughout the medical community. Not only was niacin's use extremely limited prior to 1997, but its use remains extremely limited. The only niacin product – sustained release or otherwise – ever to be approved for hyperlipidemia by the FDA is Kos' Niaspan. *See* CPF 284 (explaining that no sustained-release niacin product other than Niaspan had ever been approved); CPF 588-590 (responding to Schering's assertion that niacin products had a "straightforward" history in the market).

Second, the finding implies that the irritating side effect known as flushing is the only reason for which immediate-release niacin is not widely used in cholesterol management. There are a variety of other debilitating and irritating side effects associated with niacin treatment, including gastrointestinal distress, itching, liver toxicity, and contraindications with other medications. All of these also contribute to patient

compliance issues that inhibit niacin from gaining widespread use in cholesterol management. *See* CPF 276-279 (describing how niacin's "trivial" share of the cholesterol market is attributed to a variety of side effects); Tr. at 14:3179-82 (Brown) (Upsher witness discussing various side effects associated with niacin products).

b. Sustained Release Niacin

1.68. Prior to 1997, a number of different sustained release niacin formulations were sold as over-the-counter dietary supplements. (18 Tr. 4100 (Audibert); 16 Tr. 3628-29 (Horovitz)). As dietary supplements, these products had not been tested for the treatment of high cholesterol in the types of well-controlled clinical trials required for regulatory approval of prescription medications. (16 Tr. 3628-29 (Horovitz)). However, published literature regarding some of these sustained release niacin formulations reported a greater incidence of elevations in patients' liver enzyme levels than experienced by patients taking immediate release niacin. (18 Tr. 4104-05 (Audibert); 16 Tr. 3629 (Horovitz); SPX 18 at SP 002776).

Complaint Counsel's Response to Finding No. 1.68:

The proposed finding is incomplete. Problems associated with sustained-release niacin products were not limited to greater incidence in liver enzyme levels, nor were the problems recognized solely in the medical literature. Physicians, pharmaceutical companies, and regulatory bodies were well-aware that sustained-release niacin products were associated with toxic damage to the liver. *See* CPF 280-281, 284, 585 (indicating that sustained-release niacin products were associated with greater liver toxicity and, as a result, that no sustained-release niacin product had been approved by the FDA); CPF 588-

592 (explaining that there were known problems associated with all sustained-release niacin products as of the time of the settlement agreement); CPF 596-619 (indicating that Schering was aware of problems associated with sustained-release niacin products at the time of the settlement agreement); CPF 282-283 (indicating that problems associated with sustained-release niacin products make it difficult for clinical use).

1.69. When liver cells come under stress, liver enzymes are released into the blood stream, which leads to a higher than normal level of those enzymes in the blood. (16 Tr. 3630 (Horovitz)). Although not alone conclusive, significant and continuous elevations in liver enzyme levels are a possible sign of liver toxicity, or hepatotoxicity. (16 Tr. 3630 (Horovitz)). As a result, liver function tests are commonly used to screen for potential impairment of liver function by measuring liver enzyme levels in the blood. (16 Tr. 3631-32 (Horovitz); 18 Tr. 4122-23 (Audibert)). The two liver enzymes typically measured are alanine transaminase ("ALT") and aspartate transaminase ("AST"). (16 Tr. 3631-32 (Horovitz)).

Complaint Counsel's Response to Finding No. 1.69:

Complaint counsel has no specific response.

1.70. What constitutes a "normal" liver enzyme level can vary even when measured within the same sample of individuals. (16 Tr. 3632, 3637 (Horovitz); 18 Tr. 4120 (Audibert)). In addition, the "normal" level can vary from one laboratory to another. (16 Tr. 3633 (Horovitz)). As a result, a laboratory will gauge the results of an individual's liver function tests against a range of normal results seen in a large sample population. (16 Tr. 3632-34, 3637

(Horovitz)). The outer limits of this normal range are referred to as the upper limit of normal and the lower limit of normal. (16 Tr. 3632-34, 3637 (Horovitz)).

Complaint Counsel's Response to Finding No. 1.70:

Complaint counsel has no specific response.

1.71. There are numerous causes of elevated liver enzymes. (16 Tr. 3630, 3634 (Horovitz)). Exercise and alcohol consumption are known to cause elevations in liver enzyme levels, as are a variety of infections or diseases. (16 Tr. 3634 (Horovitz); 14 Tr. 3156 (Brown)). In addition, a variety of prescription and non-prescription pharmaceutical products, including aspirin, can cause elevated liver enzymes. (16 Tr. 3631, 3634 (Horovitz)).

Complaint Counsel's Response to Finding No. 1.71:

Complaint counsel has no specific response.

1.72. Significant or meaningful elevations of liver enzymes are considered to be elevations of greater than three times the upper limit of normal, sometimes referred to as 3xULN. (16 Tr. 3632-35 (Horovitz); 18 Tr. 4120 (Audibert); 14 Tr. 3152-53, 3156 (Brown)). For example, during the clinical trials of Niacor-SR, the FDA advised Upsher that the criterion it considered to be of clinical significance was successive elevations of liver enzymes above three times the upper limit of normal. (16 Tr. 3634-35 (Horovitz); SPX 267 at Upsher-Smith FTC 095037).

Complaint Counsel's Response to Finding No. 1.72:

The proposed finding is incomplete and contradicted by other evidence in the

record. A consultant to Upsher specifically proposed to the FDA that the FDA adopt a standard of 1.2 times the upper limit of normal level of liver enzymes to evaluate potential liver toxicity for Niacor-SR. The following minutes of a meeting between Upsher and the FDA from 1991 concerning Niacor-SR state the following:

> In the opinion of Dr. Kotke [consultant for Upsher from the Mayo Clinic], any value 1.2 times upper limit of normal (ULN) should be a signal to discontinue medication. Dr. Kotke feels that patients could become jaundiced if the medication is continued. The feeling of the FDA is that using 1.2 ULN as the cut-off could lead to a biased view of the actual degree of liver toxicity problems associated with niacin treatment. The FDA is willing to allow 1.5 times ULN (2 results 1 week apart) as a trigger to reduce dose; and 3.0 times ULN as a signal to stop medication. Patients who have any GI symptoms should report it to their physician immediately.

CX 1376 at Upsher-Smith FTC 127100 (summary of September 23, 1991 meeting between Upsher and the FDA regarding development of Niacor-SR).

In addition, Schering's own proposed finding 1.241 specifically notes that the information package provided by Upsher to Schering on Niacor-SR (the information package that Mr. Audibert used in his commercial assessment) included data at the 1.5 upper limit of normal level. The proposed finding describes data on the "overall incidence of liver enzyme elevations of 1.5 times the upper limit of normal" and additional data breaking down the incidence of such elevations into groupings "including 1.5-2.0, 2.0-3.0, 3.0-5.0, above 5.0, and above 3.0." *See* Schering proposed finding 1.241 (emphasis added).

1.73. All cholesterol lowering drugs have been associated with increases in liver enzymes levels in a small percentage of patients. (16 Tr. 3631 (Horovitz); 18 Tr. 4121-22

(Audibert)). For example, the Physician's Desk Reference reports that studies with the market dominating statins have shown successive elevations above three times the upper limit of normal in anywhere from 1% to 5% of patients, depending on the particular drug and dosage. (16 Tr. 3651 (Horovitz); 9 Tr. 1812 (Levy); SPX 1208; 18 Tr. 4121 (Audibert)). Similarly, the Physician's Desk Reference reports that studies with Tricor, one of the cholesterol lowering drugs known as the fibrates, is associated with elevations of three times the upper limit of normal in as many as 13% of patients, with successive elevations in more than 5% of patients. (16 Tr. 3651-52 (Horovitz); SPX 1209). This did not prevent Tricor's success in the marketplace: during the period January to November 2001, Tricor achieved sales of more than $270 million in the United States. (9 Tr. 1821 (Levy); SPX 1205).

Complaint Counsel's Response to Finding No. 1.73:

The proposed finding is incomplete and misleading. Dr. Levy testified regarding the statins that only the "occasional patient may have a problem" with liver function. Tr. at 9:1812 (Levy). He further testified that the type of potential liver toxicity that had been seen with niacin compounds was not merely a trivial elevation, it was "destructive liver disease." In comparison, the statins had been shown through use in millions of patients to have an exceedingly low incidence of serious liver problems. Tr. at 10:2142 (Levy).

1.74. The market for cholesterol lowering drugs has grown despite the presence of these elevations in some patients, because the elevations in liver enzyme levels caused by cholesterol lowering drugs have been shown to return to normal upon discontinuation of the drug. (16 Tr. 3649-3650, 3652 (Horovitz); 18 Tr. 4122-23 (Audibert)). This reversibility allows

physicians who prescribe these medications to address this potential side effect by simply monitoring patients' liver enzyme levels periodically during treatment. (16 Tr. 3631-34 (Horovitz); 18 Tr. 4122-23 (Audibert)).

Complaint Counsel's Response to Finding No. 1.74:

The proposed finding is incomplete. Dr. Levy testified that the type of potential liver toxicity that had been seen with niacin compounds was not merely a trivial liver enzyme elevation, it was "destructive liver disease." In comparison, the statins had been shown through use in millions of patients to have an exceedingly low incidence of serious liver problems. Tr. at 10:2142 (Levy).

1.75. The procedure for monitoring liver enzyme levels is incorporated into the labeling for cholesterol lowering drugs. (16 Tr. 3631 (Horovitz)). The labeling defines periodic intervals at which prescribing physicians should take a blood sample to test for liver enzymes elevations. (16 Tr. 3631 (Horovitz); SPX 1208; SPX 1209). Because transient liver enzyme elevations frequently occur, the labeling indicates repeat testing for patients who experience significantly elevated liver enzymes, and discontinuation of the drug in patients who experience persistent elevations of liver enzymes above three times the upper limit of normal. (16 Tr. 3633-34 (Horovitz); SPX 1208; SPX 1209).

Complaint Counsel's Response to Finding No. 1.75:

Complaint counsel has no specific response.

1.76. In contrast to the small percentage of patients who experienced significantly elevated liver enzymes with cholesterol lowering drugs, small studies published in the 1990s reported the occurrence of significant elevations in more than half of patients treated with some over-the-counter formulations of sustained release niacin. (16 Tr. 3629-31 (Horovitz); 18 Tr. 4103-05 (Audibert)). The most well known of these, published in the Journal of the American Medical Association by Dr. McKenney, reported the results of a study with a sustained release niacin product manufactured by a company called Gold Line in which 60% to 70% of patients experienced liver enzyme levels above three times the upper limit of normal. (16 Tr. 3629-30, 3635-36 (Horovitz); 18 Tr. 4103-4105 (Audibert)). Based on this study and a review of prior literature, Dr. McKenney reported his conclusion that all sustained release niacin products caused hepatotoxicity. (16 Tr. 3629-30 (Horovitz)).

Complaint Counsel's Response to Finding No. 1.76:

The proposed finding is incomplete. *See* CPRF No. 1.68, indicating that the hepatotoxicity -- not simply elevations in liver enzymes – associated with sustained-release niacin products was widely known at the time of the settlement agreement.

C. Schering's Negotiations With Kos For Its Sustained Release Niacin Product, Niaspan

1. Niaspan's Early Promise And Kos' Initial Public Offering

1.77. As its very first product it would bring to market, Kos developed a sustained release niacin product called Niaspan. (31 Tr. 7497 (Patel); 10 Tr. 2067 (Levy); SPX 605 at Kos 0054-55). Kos viewed Niaspan as a very promising product. (30 Tr. 7542 (Patel); CX 1484 at

35:18-36:7 (Audibert Dep.)). Market analysts viewed Niaspan favorably as well. (28 Tr. 6872-73 (Kerr); USX 535 at USL 11514). Market analyst Dillon Read projected that Niaspan would make $250 million in the U.S. by the third year of sales. (28 Tr. 6872-73 (Kerr); (USX 535 at USL 11514). Dillon Read further projected that Niaspan could achieve a "few hundred million in sales overseas." (USX 535; 28 Tr. 6872 (Kerr)).

Complaint Counsel's Response to Finding No. 1.77:

The proposed finding is contradicted by other evidence. The projected sales for Niaspan were exaggerated by both Kos and its investment bankers. First, these sales projections were exaggerated according to Schering's own sales estimates for Niaspan. As discussed below in Schering's proposed finding 1.316, Schering estimated third year sales of Niaspan at $101 million (as compared to the between "$220 and $250 million" estimated by the market analysts). In addition, as expressly stated in Schering's proposed finding 1.314, "Schering did not agree with market analysts' public projections of Niaspan sales of $250 million." Second, according to complaint counsel's expert Dr. Levy, "it is not atypical for a startup company doing an IPO to grossly overstate its potential earnings. That's how they pump up their stock price. And it's not atypical for investment bankers to comport with that behavior." Tr. at 9:1856 (Levy).

In addition, the proposed finding is incomplete and misleading. The financial market referenced in the proposed finding refers to analysts whose objectives were to underwrite the initial public offering of Kos' stock and to promote the company to achieve high stock value. Dillon, Read & Co., Cowen & Company, and Salomon Brothers Inc. are identified on the front page of Kos' initial public offering prospectus as

the underwriters of the Kos IPO. USX 21 at AAA 0000052. Also noted on the first page of the prospectus is the interest that these firms have in the company; all three underwriters were offered substantial shares of the company. The underwriters are required by the SEC to disclose this interest, and consequently, their incentive to strongly support and promote the company.

1.78. In early 1997, Kos was preparing for an initial public offering of stock. (SPX 143). Prior to the IPO, Kos' operations were funded by Mr. Jaharis, Kos' CEO. (31 Tr. 7572 (Patel)).

Complaint Counsel's Response to Finding No. 1.78:

Complaint counsel has no specific response.

1.79. In preparation for its IPO, Kos approached Upsher to try to license from Upsher two patents that Upsher held for Niacor-SR. The O'Neill patent (CX 785) and the Evenstad patent (CX 784) covered two different aspects of Upsher's niacin product: nighttime dosing and formulation. (23 Tr. 5478 (Troup)). Mr. Troup met with Kos' president and CEO, Dan Bell, at Upsher's offices and finalized an agreement whereby Upsher would license the two patents to Kos. (23 Tr. 5478-79 (Troup)).

Complaint Counsel's Response to Finding No. 1.79:

Complaint counsel has no specific response.

1.80. Kos' license agreement with Upsher strengthened its intellectual property on Niaspan before it proceeded with its IPO. (23 Tr. 5478-79 (Troup)). The agreement included a provision that allowed Upsher to license Niacor-SR outside the United States. (CX 568; 21 Tr. 5027-28 (Kralovec); 23 Tr. 5481 (Troup); ***

Complaint Counsel's Response to Finding No. 1.80:

The proposed finding is incomplete. Under section 2 of the cross-licensing agreement, Upsher retained its rights to license its technology in all territories. CX 568 at Upsher-Smith FTC 145286-87 (Upsher-Kos cross-licensing agreement). The agreement did, however, limit Upsher's ability to sub-license any technology obtained from its license from Kos. Under Article 6 of the agreement, Upsher's license from Kos is "non-assignable and non-transferrable." CX 568 at Upsher-Smith FTC at 145292 (cross-licensing agreement referring to Kos' patent application). In contrast, pursuant to Article 2, Kos has a worldwide license and retains the right to sub-license its rights to Upsher's technology. CX 568 at 145287.

In addition, at the time of the settlement agreement in June 1997, Upsher was unaware of the scope of its rights to Kos' technology. In July 1997 Upsher sought clarification of the rights it had obtained from Kos via Kos' patent counsel. *See* CX 571 (letter from Kos CEO Daniel Bell to Ian Troup of Upsher, dated July 24, 1997, regarding Upsher's co-marketing rights under the cross-licensing agreement); CX 572 (letter from Ian Troup to Daniel Bell, dated July 30, 1997, requesting that Kos' patent counsel provide clarification of Upsher's rights under the cross-licensing agreement with respect to the claims of Kos' U.S. patent application); CX 574 (letter from Upsher's counsel to Kos'

counsel, dated August 19, 1997, indicating that Upsher has been advised of its rights under the cross-licensing agreement).

1.81. In March 1997, Kos issued an initial public offering of stock. (31 Tr. 7544 (Patel)). Kos' IPO stock price was $15 per share. (10 Tr. 2069-70 (Levy); 26 Tr. 6293 (Kerr); (USX 21; USX 1606). Kos raised over $62 million by selling 29% of its stock to the public. (USX 21; 31 Tr. 7545 (Patel)). The remainder of Kos' stock was primarily owned by Kos' Mr. Jaharis. (USX 21; 31 Tr. 7545 (Patel)). The market capitalization of Kos as of March 1997 was approximately $200 million. (USX 21; 10 Tr. 2070 (Levy)).

Complaint Counsel's Response to Finding No. 1.81:

The proposed finding is not relevant. There is no evidence that Schering valued Niaspan, or Niacor-SR on the basis of outside analysts' projections. In fact, Schering conducted its own due diligence and completed projections to evaluate the Niaspan opportunity. CX 548, 549, 550. Tr. at 15:3472, 3476-77 (Ray Russo) at 3472 (confirming that he completed sales projections for Niaspan); 3476-77 (acknowledging that sales projections were completed for Niacor-SR).

1.82. At that time, Kos had no sales. (31 Tr. 7572 (Patel)). Kos' market capitalization was primarily based on the promise of Kos' one product, Niaspan. (9 Tr. 1854-56 (Levy), 10 Tr. 2067-68, 2075-78 (Levy); 33 Tr. 7982 (Egan); 28 Tr. 6982 (Kerr)). Between March and September 1997, Kos stock and market capitalization were rising. (10 Tr. 2077 (Levy)). Indeed, by the summer of 1997, Kos had a market capitalization of over $500 million. (31 Tr. 7574

(Patel 7574)).

Complaint Counsel's Response to Finding No. 1.82:

The proposed finding is not relevant. There is no evidence that Schering valued Niaspan, or even Niacor-SR on the basis of outside analysts' projections. *See* CPRF 1.81

2. Schering's Interest In Niaspan

1.83. Schering initially looked at Niaspan in 1994. (SPX 29). Schering thought a sustained release niacin that solved flushing and liver problems would potentially be a big product that addressed an unmet need in the market. (CX 1494 at 85:1-25 (Driscoll IH); CX 1495 at 73:1-4 (Driscoll Dep.) SPX 1265 at 73:5-25 (Driscoll Dep.); 18 Tr. 4115-17 (Audibert)). Niacin is a well-characterized product that elevates "good" cholesterol. (15 Tr. 3438 (Russo); 18 Tr. 4116 (Audibert)). Schering believed that a sustained release niacin product like Niaspan would be a particularly good potential product if "someone could get around some of [its] issues." (15 Tr. 3438 (Russo); 18 Tr. 4115-17 (Audibert)). In 1994, however, Schering determined that there was not yet enough available data on Niaspan to determine if it addressed that unmet need. (SPX 29).

Complaint Counsel's Response to Finding No. 1.83:

Complaint counsel has no specific response.

1.84. Kos filed its Niaspan NDA with the FDA in May 1996. (SPX 18). The NDA filing renewed Schering's interest in Niaspan, and Schering and Kos began to discuss Niaspan again in January 1997. (15 Tr. 3433-34 (Russo); SPX 559; SPX 561). In January 1997, Karin

Gast of Schering had several telephone conversations with Mukesh Patel. (15 Tr. 3441 (Russo); 31 Tr. 7543 (Patel); CX 518; CX 530).

Complaint Counsel's Response to Finding No. 1.84:

Complaint counsel has no specific response.

1.85. Schering was interested in Niaspan in early 1997 for two major reasons. First, Schering continued to believe that a sustained release niacin product that solved flushing caused by immediate release niacins and did not elevate liver enzymes to the degree that some over-the-counter sustained release niacins had done could be commercially successful. (CX 1494 at 85:1-25 (Driscoll IH); CX 1495 at 73:1-4 (Driscoll Dep.); SPX 1265 at 73:5-25 (Driscoll Dep.); 18 Tr. 4116-17 (Audibert)). Niaspan presented a particularly attractive opportunity because it was a late stage product that would provide revenues very quickly. (18 Tr. 4108-09 (Audibert)).

Complaint Counsel's Response to Finding No. 1.85:

Complaint counsel has no specific response.

1.86. The second reason for Schering's interest in Niaspan related to another product, ezetemibe, that Schering was developing for the cholesterol market. (18 Tr. 4108-09 (Audibert)). At the time Schering was in discussions with Kos about the Niaspan opportunity, the projected launch of ezetemibe was still several years away. (18 Tr. 4094 (Audibert)). Kos expected that Niaspan would be launched sometime in 1997. (18 Tr. 4101-02 (Audibert)). Marketing a niacin product in the near future would allow Schering to prepare for the launch of its "blockbuster drug," ezetimibe, by learning the therapy area and the disease state and understanding its

customers. (15 Tr. 3438 (Russo); SPX 1265 at 113:23-114:8 (Driscoll Dep.)). Thus, Niaspan offered a real opportunity to enter the cholesterol lowering market and begin to understand it before marketing ezetimibe. (18 Tr. 4108-09 (Audibert)).

Complaint Counsel's Response to Finding No. 1.86:

The proposed finding is not relevant. When asked to approve the Schering/Upsher settlement agreement, the Schering Board was not informed about ezetemibe as a justification for the Niacor-SR license. *See* CX 338 at SP 12 00268–70 ("Niacor-SR" portion of Schering Board presentation on the Schering/Upsher settlement agreement).

1.87. In 1997, Raymond Russo was Key's marketing director for cardiovascular products in the United States. (18 Tr. 4110 (Audibert); 15 Tr. 3433-34 (Russo)). Mr. Russo participated in the negotiations with Kos regarding its Niaspan product. (15 Tr. 3449 (Russo)). James Audibert was Ray Russo's counterpart on the international side of Schering's business. (18 Tr. 4109 (Audibert); 15 Tr. 3439 (Russo)).

Complaint Counsel's Response to Finding No. 1.87:

Complaint counsel has no specific response.

1.88. Mr. Audibert and Mr. Russo discussed the concept of using Niaspan strategically to bridge to ezetimibe. (18 Tr. 4111 (Audibert); SPX 21; 15 Tr. 3437-38 (Russo); (CX 576 at SP 020717). Mr. Russo shared Mr. Audibert's view of the merits of entering the cholesterol market in advance of ezetimibe to "earn your bumps and bruises with a product before we get to

ezetimibe." (18 Tr. 4109 (Audibert)). Indeed, Mr. Russo and Mr. Audibert shared the vision of growing Schering's cardiovascular portfolio, and both the importance of developing strategies to make Schering more successful with ezetimibe through earlier market entry with another cholesterol product. (18 Tr. 4110-11 (Audibert); SPX 21).

Complaint Counsel's Response to Finding No. 1.88:

The proposed finding is incomplete and misleading. Mr. Audibert had limited involvement in Schering's discussions with Kos regarding Niaspan. In fact, he only participated in one conference call with Kos in March 1997, and then dropped out of Schering's evaluation of Niaspan. Tr. at 15:3516-17 (Ray Russo) (confirming that Mr. Audibert only participated in one conference call which occurred in March 1997 (per CX 543)). In addition, when assessing Niacor-SR in June 1997, Mr. Audibert did not consult the Schering officials (e.g., Mr. Russo) involved in the full discussions with Kos regarding Niaspan. *See* CPF 425 (discussing Mr. Audibert's failure to consult Schering officials regarding Niaspan).

In addition, the proposed finding is not relevant. When asked to approve the Schering/Upsher settlement agreement, the Schering Board was not informed about ezetemibe as a justification for the Niacor-SR license. *See* CX 338 at SP 12 00268–70 ("Niacor-SR" portion of Schering Board presentation on the Schering/Upsher settlement agreement).

3. Schering's Discussions with Kos

1.89. Schering requested information about Niaspan from Kos. (15 Tr. 3442 (Russo)).

The parties signed a confidentiality agreement, and in February 1997, Kos sent Schering some materials relating to Niaspan. (31 Tr. 7544 (Patel); CX 519; CX 540). These materials included a product profile on Niaspan from the initial public offering documents Kos was having prepared, proposed labeling, a one-page document showing various treatment indications Kos hoped to get from FDA, and a reprint of a published article about some Niaspan clinical trials. (31 Tr. 7544 (Patel); 15 Tr. 3442 (Russo); CX 540).

Complaint Counsel's Response to Finding No. 1.89:

Complaint counsel has no specific response.

1.90. By the time of Schering's discussions with Kos, the FDA had completed its medical review of Niaspan, and was discussing labeling with Kos. (15 Tr. 3445 (Russo); CX 543; 18 Tr. 4102, 4105 (Audibert)). The fact that the medical review had been completed meant that the FDA had judged the product to be safe and efficacious, and that it was just a matter of finalizing the actual labeling on the product. (18 Tr. 4105-06 (Audibert)).

Complaint Counsel's Response to Finding No. 1.90:

Complaint counsel has no specific response.

1.91. During the first half of 1997, Kos was seeking a co-promotion arrangement for Niaspan, meaning that both parties to the deal would be involved in the sales and marketing of the Niaspan product. (15 Tr. 3449 (Russo)). Under a co-promotion arrangement, the parties would split efforts in the field force and divide the cost of the marketing. (15 Tr. 3449 (Russo)). A co-promotion arrangement differs from a license, in which the company licensing the product

would retain all control and all sales proceeds after royalties are paid. (15 Tr. 3449-50 (Russo)). In a license arrangement, the licensee alone would be responsible for all the expenditures, investment and strategic direction associated with the product. (15 Tr. 3449 (Russo)).

Complaint Counsel's Response to Finding No. 1.91:

Complaint counsel has no specific response.

1.92. Kos wanted a co-promotion partner with sales and marketing muscle for Niaspan. (31 Tr. 7542 (Patel)). Kos' preference was that it would contribute the product, the partner would put in the majority of the marketing muscle, and the two companies would share the profits. (31 Tr. 7542 (Patel)). Kos was looking for a large company with which to partner, and had talked to more than one company in its search. (31 Tr. 7542 (Patel)).

Complaint Counsel's Response to Finding No. 1.92:

Complaint counsel has no specific response.

1.93. Specifically, Kos was looking for a marketing partner for Niaspan in the U.S. (31 Tr. 7541 (Patel)).

Complaint Counsel's Response to Finding No. 1.93:

The proposed finding is incomplete and misleading. Kos was looking for a marketing partner in the United States, but was also going ahead with plans to market overseas. However, Kos recognized that the "market potential in Europe (and probably also in Japan) is quite limited." CX 1047 at SP 002748 (Schering summary of meeting with Kos in April 1997, discussing Kos' plans for submitting Niaspan for approval in

Europe).

1.94. Martin Driscoll, Schering's Vice President of Sales and Marketing for Schering's Key division, thought Kos' product labeling looked interesting. (CX 1495 at 96:23-25 (Driscoll Dep.); 7 Tr. 1420; 12 Tr. 2702 (Driscoll)). Schering asked Kos for more information, including Niaspan's clinical results supporting the labeling. (CX 1495 at 96:23-25 (Driscoll Dep.); 7 Tr. 1420-21)). Kos was not forthcoming with additional information. (CX 1495 at 97:1-98:2 (Driscoll Dep.); SPX 1265 at 98:7-99:5 (Driscoll Dep); 7 Tr. 1421 (Driscoll IH)). (Driscoll Dep. 97-99) (Transcript 1421).

Complaint Counsel's Response to Finding No. 1.94:

Complaint counsel has no specific response.

1.95. On February 11, 1997, the information about Niaspan that Schering had been able to obtain from Kos was sent to Schering's cardiovascular licensing group. (18 Tr. 4102 (Audibert); SPX 924). The cardiovascular licensing group includes Mr. Audibert, who was for a time involved in the negotiations with Kos regarding Niaspan. (SPX 1224 at 77:7-24 (Audibert Dep.); CX 1484 at 132:7-75 (Audibert Dep.); 11 Tr. 2450, 2452). Mr. Audibert was involved because Mr. Russo, who was particularly focused on a U.S. deal, wanted to ensure that the parties did not overlook a potential worldwide deal for Niaspan. (15 Tr. 3454 (Russo); SPX 112). Accordingly, Mr. Audibert was asked to evaluate a Niaspan co-promotion deal, in which Schering would be promoting the product along with Kos, from the perspective of Global Marketing. (18 Tr. 4100-01 (Audibert)).

Complaint Counsel's Response to Finding No. 1.95:

The proposed finding is incomplete and misleading. Mr. Audibert did not evaluate the proposed Niaspan co-promotion deal. In fact, Mr. Audibert had limited involvement in Schering's discussions with Kos regarding Niaspan. He only participated in one conference call with Kos in March 1997, and then dropped out of Schering's evaluation of Niaspan (which had begun in January 1997 and concluded in June 1997). Tr. at 15:3516-17 (Ray Russo) (confirming that Mr. Audibert only participated in one conference call which occurred in March 1997 (per CX 543)). In addition, when assessing Niacor-SR in June 1997, Mr. Audibert did not consult the Schering officials (e.g., Mr. Russo) involved in the full discussions with Kos regarding Niaspan. *See* CPF 425 (discussing Mr. Audibert's failure to consult Schering officials regarding Niaspan).

1.96. In his discussions with Kos and evaluation of Kos' materials, Mr. Audibert learned that it was possible to develop a sustained-release niacin product that was both safe and effective. (CX 1484 at 132:7-25 (Audibert Dep.); 11 Tr. 2452-53; SPX 18; SPX 21). For Mr. Audibert, Niaspan proved that the concept of a sustained release niacin that reduced flushing and solved liver toxicity issues could work. (CX 1484 at 132:7-25 (Audibert Dep.); 11 Tr. 2454; 18 Tr. 4115-16 (Audibert)).

Complaint Counsel's Response to Finding No. 1.96:

The proposed finding is incomplete and misleading. Mr. Audibert had limited involvement in Schering's discussions with Kos regarding Niaspan. In fact, he only participated in one conference call with Kos in March 1997, and then dropped out of

Schering's evaluation of Niaspan. Tr. at 15:3516-17 (Ray Russo) (confirming that Mr. Audibert only participated in one conference call which occurred in March 1997 (per CX 543)). In addition, when assessing Niacor-SR in June 1997, Mr. Audibert did not consult the Schering officials (e.g., Mr. Russo) involved in the full discussions with Kos regarding Niaspan. *See* CPF 425 (discussing Mr. Audibert's failure to consult Schering officials regarding Niaspan).

a. March 13, 1997 Conference Call With Kos

1.97. On March 13, 1997, about a month after Schering received Kos' first packet of information, Schering and Kos had a conference call to discuss Niaspan. (SPX 18; 18 Tr. 4103 (Audibert)). Included on the call from Schering were Mr. Russo, Mr. Audibert and Ms. Gast. (18 Tr. 4103 (Audibert); (SPX 18). On the call from Kos were Dan Bell and David Heatherman. (SPX 18).

Complaint Counsel's Response to Finding No. 1.97:

The proposed finding is incomplete and misleading. During the approximately five months that Schering held discussions with Kos regarding Niaspan, the March 13, 1997, conference call was the only discussion in which Mr. Audibert participated. Tr. at 15:3516-17 (Ray Russo) (confirming that Mr. Audibert only participated in one conference call, which occurred in March 1997 (per CX 543)).

1.98. Mr. Audibert asked about the safety profile for Niaspan. (SPX 18; 15 Tr. 3443-44 (Russo); CX 543). Kos told Mr. Audibert that Niaspan had a much better profile than

immediate release niacin in terms of flushing. (18 Tr. 4104 (Audibert); SPX 18). Flushing is not dangerous, but it makes patients very uncomfortable. (18 Tr. 4105 (Audibert)). If patients get enough flushing, they will discontinue the therapy. (18 Tr. 4105 (Audibert)). Thus, a product with less frequent or less extreme flushing side effects would provide a real opportunity to improve patient compliance. (7 Tr. 1313-14 (Levy); CX 558).

Complaint Counsel's Response to Finding No. 1.98:

The proposed finding is incomplete and misleading. During the approximately five months that Schering held discussions with Kos regarding Niaspan, the March 13, 1997, conference call was the only discussion Mr. Audibert participated in. Tr. at 15:3516-17 (Ray Russo) (confirming that Mr. Audibert only participated in one conference call which occurred in March 1997 (per CX 543)).

1.99. Kos also told Schering that Niaspan had a very low incidence of elevated liver enzymes. (18 Tr. 4105 (Audibert)). Kos referenced a study by a Dr. McKinney using a particular sustained release niacin on the market at that time. (SPX 18; 18 Tr. 4104 (Audibert)). That product had a weak sustained release delivery system. (15 Tr. 3504-05, 3511 (Russo)). Mr. Audibert is familiar with this study, and he recalls that a large percentage of the patients, about 66 or 67 percent, showed liver enzymes above three times the upper limit of normal. (Audibert 4105)). Kos told Mr. Audibert that Niaspan showed much lower elevated enzyme levels. (Audibert 4105)).

Complaint Counsel's Response to Finding No. 1.99:

The proposed finding is incomplete and contrary to more reliable evidence. There

is no testimony that Mr. Audibert considered the McKenney study as part of his commercial assessment of Niacor-SR. In fact, Mr. Audibert did not have a level of liver enzyme elevations in mind when he looked at Upsher's clinical data. According to his investigational hearing transcript (from September 21, 2000) as opposed to his trial testimony (nearly a year and half later on February 19, 2002), Mr. Audibert stated that he "did not have a specific number in mind" when looking at data for people who were "prematurely discontinued" from Upsher's clinical trial due to potential liver damage. CX 1483 at 74:6-12 (Audibert IH).

1.100. Schering and Kos also discussed the possibility of a worldwide deal. (SPX 18; 18 Tr. 4106 (Audibert)). Kos was not interested an international launch in the short term, and admitted that it had no real understanding, expertise or resources to get a product registered outside the United States. (11 Tr. 2449 (Audibert Dep.)). Kos was concerned with just getting its product on the market in the U.S., and would deal with other opportunities "later down the road." (11 Tr. 2439-40, 2448-49 (Audibert Dep.); 18 Tr. 4106 (Audibert)).

Complaint Counsel's Response to Finding No. 1.100:

The proposed finding is contradicted by more reliable evidence. The proposed finding that Kos was not interested in an international launch is inconsistent with documents created at the time of the negotiations between Schering and Kos. As a Schering executive reported based on a March 1997 phone call, Kos was moving ahead with its plans to seek regulatory approval for Niaspan outside of the United States. Furthermore, Kos fully expected to receive regulatory approval, at least in the United

Kingdom, eighteen months after Niaspan was approved in the U.S. SPX 18 at SP 002776-77 (Schering contact summary of conference call with Kos, dated March 13, 1997 noting that Kos "believe[s] that they will have approval approximately 18 months after the US approval").

1.101. At end of the March 16, 1997 telephone call, Kos described its view of a co-promote deal. (SPX 18). Kos wanted to maintain control over Niaspan's marketing and strategic positioning, while its partner gave Niaspan primary promotional positioning. (SPX 18). In other words, Kos wanted to have Niaspan promoted by Schering's sales representatives in the "primary position," meaning that it would be the first product a sales representative would discuss in a doctor's office. (18 Tr. 4106 (Audibert)). Kos wanted Schering to commit that Niaspan would always be in the primary position. (18 Tr. 4106 (Audibert)). Schering explained that it could not guarantee that, as it had products, such as Claritin, that would be detailed first during particular seasons. (18 Tr. 4107 (Audibert)). Schering did offer to give Niaspan enough details in the secondary position to create a "noise level in the marketplace." (18 Tr. 4107 (Audibert)). Kos, however, was adamant that it wanted guaranteed primary positions. (18 Tr. 4107 (Audibert)).

Complaint Counsel's Response to Finding No. 1.101:

The proposed finding is contradicted by other evidence. [redacted]

[redacted]

[redacted]

1.102. Mr. Audibert viewed Kos' demands as "unrealistic in terms of what their expectations were from us" regarding co-promotion activity. (7 Tr. 1448 (Audibert Dep.)) Mr. Audibert viewed Kos' demands for support from Schering's sales force as irrational, and very difficult for Schering to agree to. (18 Tr. 4106 (Audibert)).

Complaint Counsel's Response to Finding No. 1.102:

The proposed finding is contradicted by other evidence. [redacted]

[redacted]

In addition, the proposed finding is incomplete and misleading. Mr. Audibert had limited involvement in Schering's discussions with Kos regarding Niaspan. In fact, he only participated in one conference call with Kos in March 1997, and then dropped out of Schering's evaluation of Niaspan. Tr. at 15:3516-17 (Ray Russo) (confirming that Mr. Audibert only participated in one conference call which occurred in March 1997 (per CX 543)). In addition, when assessing Niacor-SR in June 1997, Mr. Audibert did not consult the Schering officials (e.g., Mr. Russo) involved in the full discussions with Kos regarding Niaspan. *See* CPF 425 (discussing Mr. Audibert's failure to consult Schering officials regarding Niaspan).

b. Schering's Market Research Regarding Sustained Release Niacin

1.103. Mr. Russo and Mr. Audibert continued to discuss the Niaspan opportunity. (15 Tr. 3516-17 (Russo); SPX 1265 at 111:25-113:2 (Driscoll Dep.); CX 543). The next day, March 14, 1997, Mr. Audibert sent a memorandum to Schering's overseas subsidiaries, who would ultimately be responsible for selling and marketing Niaspan outside the United States. (15 Tr. 3445-46 (Russo); CX 544). Mr. Audibert asked them about their interest in a sustained release niacin product. (15 Tr. 3445-46 (Russo); CX 544). A number of subsidiary directors gave very favorable responses; while others gave less than favorable responses. (15 Tr. 3447 (Russo)).

Complaint Counsel's Response to Finding No. 1.103

The proposed finding is incomplete and misleading. CX 544, the marketing survey, specifically asks the Schering overseas subsidiaries whether there is an opportunity for sustained-release niacin in their country and whether it would be reimbursed by the local health authority. CX 544 at FTC 0001407. To the extent Mr. Russo's testimony can be credited that some subsidiaries gave unfavorable responses, this survey is inconsistent with Mr. Audibert's assumption in his commercial assessment of Niacor-SR that the product could be reimbursed in most major markets. CX 1044 at SP 16 00047 (Audibert's commercial assessment).

In addition, the proposed finding refers to responses to CX 544, a questionnaire sent to Schering's overseas subsidiaries about their interests in a sustained-release niacin product. Complaint counsel's first document request specifically requested any responses to CX 544 in Schering's possession. *See* (Complaint Counsel's First Request for the

Production of Documents and Things Specification 15 c.) Schering never produced any responses to CX 544.

The proposed finding also includes inadmissible hearsay. The testimony cited to support the proposed finding cannot be used for the truth of the matter asserted. Mr. Russo's testimony of the substance of the responses from Schering's overseas subsidiaries is unsupported by any admissible evidence and is unreliable. Furthermore, Mr. Audibert, the author of the survey, testified that he did not recall receiving any responses to the questionnaire. Tr. at 18:4107-08 (Audibert) (confirming this point).

1.104. Following the March 13, 1997 call with Kos, Schering also performed market research in the United States to determine doctors' interest in sustained release niacin. (12 Tr. 2393-94 (Audibert); 15 Tr. 3447-48, 3501-02 (Russo); CX 576). The market research included telephone interviews with ten prominent lipidologists that had attended Schering's recent meetings in New York concerning ezetimibe. (11 Tr. 2393-94 (Audibert Dep.); 15 Tr. 3447-48, 3501-02 (Russo); CX 576). Schering found that doctors would welcome a sustained release niacin product that reduced flushing and avoided liver toxicity issues, but would want more evidence that the product met those needs. (15 Tr. 3532 (Russo); CX 576).

Complaint Counsel's Response to Finding No. 1.104:

The proposed finding is contradicted by other evidence. Schering's survey in April 1997 of ten cholesterol-management experts reported on the numerous difficulties faced with developing and marketing a sustained-release niacin drug. Those experts reported to Schering the following concerning sustained-release niacin drugs: (1) general

practitioners "avoid use of sustained release preparations . . . because of diminished efficacy and concern regarding hepatotoxicity"; (2) "niacin and, particularly sustained release niacin, has such a bad reputation among primary care physicians" that successful marketing of Niaspan will require "compelling data" and strong support from lipid specialists; and (3) data from clinical studies of a sustained release niacin product "will be scrutinized very carefully" as a result of "niacin's history, and, especially, the safety issue with sustained release niacin." CX 576 at SP 020709, 15, 17 (April 1997 Decker Research Associates report entitled "A Qualitative Evaluation of the Opportunity for Niaspan in Multiple Lipid Disorders"). *See generally* CPF 598-609 (discussing the Decker report in detail and how it indicated that Niacor-SR was not a straightforward licensing opportunity).

1.105. The lipidologists described the numerous benefits associated with niacin. (15 Tr. 3508 (Russo); CX 576). Niacin is inexpensive, lowers LDLs and triglycerides and is the best agent for raising HDLs. (15 Tr. 3508 (Russo); CX 576). The experts stated that niacin is effective as a first line therapy in patients with moderately elevated LDLs, and one physician indicated that niacin is unique in its effect on lipoprotein A. (15 Tr. 3508 (Russo); CX 576).

Complaint Counsel's Response to Finding No. 1.105:

The proposed finding is contradicted by other evidence. Schering's survey in April 1997 of ten cholesterol-management experts reported on the numerous difficulties faced with developing and marketing a sustained-release niacin drug. *See* CPRF 1.104.

1.106. Schering presented the lipidologists with a published paper from Kos that demonstrated a certain level of efficacy and showed that Kos had ameliorated some of the side effects associated with earlier sustained release niacin products. (15 Tr. 3506, 3510-11 (Russo); CX 576)). The experts indicated that they would welcome and frequently use an effective, safe, FDA-approved sustained release niacin. (15 Tr. 3532 (Russo); CX 576). The experts liked the dosing of the product, its apparent efficacy and safety, which was essentially equal to immediate release niacin, its reduced flushing, and the fact that patients could receive a consistent product from prescription to prescription. (15 Tr. 3533 (Russo)). The single study alone did not sell the lipidologists on Niaspan, however. (15 Tr. 3532 (Russo); CX 576). The experts told Schering that they needed more compelling evidence, such as clinical data, to alleviate concerns regarding sustained release niacin's side effects. (15 Tr. 3504-06; 3510-11(Russo)).

Complaint Counsel's Response to Finding No. 1.106:

The proposed finding is contradicted by other evidence. Schering's survey in April 1997 of ten cholesterol-management experts reported on the numerous difficulties faced with developing and marketing a sustained-release niacin drug. *See* CPRF 1.104.

1.107. Schering was hopeful that Niaspan's delivery system would overcome the experts' reservations regarding sustained release niacin and flushing, liver toxicity and diminished efficacy. (15 Tr. 3503, 3509 (Russo)). Accordingly, Schering wanted to see the rest of the NDA filing for Niaspan for additional data that would support Kos' representations. (15 Tr. 3511 (Russo)). Schering also wanted to see the final labeling submitted to the FDA for Niaspan because Schering believed that if it showed no contraindications and better side effect

profile than other Niacin products, Niaspan would be a very good product for Schering. (15 Tr. 3511-12 (Russo)).

Complaint Counsel's Response to Finding No. 1.107:

The proposed finding is incomplete and misleading. Schering's demands for extensive information on Niaspan is inconsistent with its lack of due diligence requests for Niacor-SR. CPF 417-445 (noting that Schering's review of Niacor-SR was superficial and did not comport with its own customary practices). Kos completed numerous clinical studies on the safety and efficacy of Niaspan and provided Schering with detailed summaries of the outcomes of those studies. CX 540 (Niaspan product information provided to Schering, dated February 11, 1997). Schering was not satisfied with the initial data provided, and requested further information to substantiate Kos's claims. This is inconsistent with Mr. Lauda and Mr. Audibert's assertion that niacin was a known product, and therefore, Niacor-SR did not require due diligence. *See* CPRF 581-659 (noting Schering's justification for its absence of due diligence for Niacor-SR, and discussing why Niacor-SR was not a straightforward licensing opportunity).

c. April 9, 1997 Meeting With Kos

1.108. On April 9, 1997, Schering met with Kos representatives at Kos' corporate headquarters in Miami. (15 Tr. 3451 (Russo); CX 1047). Mr. Russo, David Grewcock, a Schering product manager, Toni DeMola, Schering's manager of marketing research, and Karin Gast, Schering's business development director, attended the meeting on behalf of Schering. (15 Tr. 3451-52, 3513 (Russo); CX 769, 1047; 31 Tr. 7545 (Patel)). This was the only face-to-face

meeting between Schering and Kos. (15 Tr. 3517 (Russo)).

Complaint Counsel's Response to Finding No. 1.108:

Complaint counsel has no specific response.

1.109. Mr. Audibert chose not to attend the April 9 meeting with Kos in Miami. (15 Tr. 3513-14 (Russo); CX 1047; 11 Tr. 2450-51 (Audibert Dep.)). By this time, Mr. Audibert had determined that Kos was primarily interested in a U.S., rather than a worldwide, deal. (15 Tr. 3513-14 (Russo); CX 1047; 18 Tr. 4106 (Audibert)). Moreover, Mr. Audibert believed that Kos' demands for primary detailing of Niaspan were unrealistic, and that it was unlikely that a deal with Kos could be worked out. (18 Tr. 4106 (Audibert); 11 Tr. 2450-51 (Audibert Dep.)).

Complaint Counsel's Response to Finding No. 1.109:

The proposed finding is incomplete and therefore misleading. Prior to the April 9, 1997 meeting, Kos still considered a non-U.S. licensing arrangement a possibility with Schering. Kos executives shared their plans for Niaspan in Europe with Schering. Schering's contemporaneous notes of the March 13, 1997 conference call reflect this. *See* SPX 18 at SP 002776-77 (Schering contact summary noting that Kos discussed plans to obtain European registration for Niaspan). While Kos focused its efforts on a U.S. launch first, it did not abandon its plans to launch Niaspan in Europe.

It was during the April 9, 1997 meeting that Schering suggested limiting the discussions to the United States, and Kos agreed. CX 1047 at SP 002748 (Schering contact report of April 9, 1997 meeting at Kos headquarters noting, "we suggested that . . . we concentrate on this territory first and leave ex-U.S. discussions for later. Bell did not

have a problem with this."). In addition, Kos recognized that the "market potential in Europe (and probably also in Japan) is quite limited." CX 1047 at SP 002748 (Schering summary of meeting with Kos in April 1997 discussing Kos' plans for submitting Niaspan for approval in Europe).

Mr. Audibert's conclusion that it was unlikely that Schering and Kos could reach an agreement is not relevant to this proceeding. Mr. Audibert only had a limited participation in the review of the Niaspan opportunity. *See* CPRF 1.88.

In addition, a more likely reason that Mr. Audibert did not attend the meeting was that he asked the recipients of his survey on sustained-release niacin (CX 544) to get back to him by April 1. On March 26, Ray Russo reported that the process of assessing the worldwide potential was the underway (presumably Mr. Audibert's survey). On April 1, Mr. Audibert was to get the results of his survey back. By April 9, Mr. Audibert stopped working on Niaspan and Schering asked Kos to focus on the U.S. market and not overseas markets. The obvious inference is that Mr. Audibert's surveys indicated little or no interest on the part of Schering's subsidiaries surveyed.

Mr. Audibert's conclusion that Kos' request for primary detailing was unrealistic is also irrelevant. [redacted]

[redacted]

1.110. Kos CEO Dan Bell, Vice President of Sales and Marketing David Heatherman, head of Licensing and Business Development, Mukesh Patel, and Niaspan Project Manager John Kalimtsis participated in the April 9 meeting on behalf of Kos. (15 Tr. 3452 (Russo); SPX 112; CX 769). Mr. Patel testified that he had in his mind during the meeting that Kos wanted three things from a co-promotion deal: 1) up-front payments; 2) an equity investment in Kos; and 3) a big company as a partner. (CX 769; 31 Tr. 7560 (Patel)). There's no evidence that Mr. Patel told Schering these points during the meeting. (31 Tr. 7562-63 (Patel); *compare* CX 769 *with* SPX 112).

Complaint Counsel's Response to Finding No. 1.110:

The proposed finding is incomplete and misleading. Mr. Patel testified that he doesn't recall whether he brought these items up or whether it was Mr. Bell who raised these issues. However, Mr. Patel did testify they these issues were discussed with Schering. Tr. at 31:7560 (Patel).

1.111. At the meeting, Schering made a presentation aimed at demonstrating Schering's commitment to the cholesterol therapy area. (15 Tr. 3453 (Russo); SPX 112). Schering's representatives said that Schering had a current emphasis on cardiovascular products, and particularly mentioned ezetimibe, a cholesterol product Schering had in Phase II development. (15 Tr. 3453 (Russo); 31 Tr. 7546-47(Patel); CX 769). Schering explained that it

hoped to establish a presence in the cholesterol marketplace in anticipation of the eventual launch of this new product. (31 Tr. 7546-47 (Patel); CX 769). Schering also mentioned Integrelin, a cardiovascular product Schering was co-promoting with another company. (31 Tr. 7547 (Patel); CX 769).

Complaint Counsel's Response to Finding No. 1.111:

The proposed finding is not relevant. When asked to approve the Schering/Upsher settlement agreement, the Schering Board was not informed about ezetemibe as a justification for the Niacor-SR license. *See* CX 338 at SP 12 00268–70 ("Niacor-SR" portion of Schering Board presentation on the Schering/Upsher settlement agreement).

1.112. Schering summarized its presence in the cardiovascular market and its expertise in managed care, its total number of representatives, and the experience of some of the individuals at the meeting. (31 Tr. 7548 (Patel); CX 769; 15 Tr. 3454 (Russo)).

Complaint Counsel's Response to Finding No. 1.112:

Complaint counsel has no specific response.

1.113. Schering also described its unique advantages as a partner, including its superior field force, particularly in the area of cardiovascular medicine. (31 Tr. 7548-49 (Patel); CX 769; 15 Tr. 3454 (Russo)). Schering promoted its experience and expertise with managed care. (31 Tr. 7552 (Patel); SPX 112 at SP 002751). Schering also described its capabilities with respect to distribution, direct to patient efforts, and clinical trial and phase IV efforts as a means of helping

Kos in those areas. (31 Tr. 7549, 7552 (Patel); SPX 112 at SP 02753; CX 769). Schering told Kos about its communications with its international subsidiaries as part of what Schering had done to gain additional marketing information about a possible launch of Niaspan. (31 Tr. 7553 (Patel); SPX 112 at SP 02753).

Complaint Counsel's Response to Finding No. 1.113:

Complaint counsel has no specific response.

1.114. Schering and Kos representatives exchanged views and ideas about the possible co-promotion of Niaspan. (31 Tr. 7545-46 (Patel); CX 769). Schering said it had done some market research on Niaspan and had contacted its advisory board of cardiologists and experts in the field. (31 Tr. 7547(Patel); CX 769). Schering expressed its view that a successful launch of Niaspan would require promotional muscle at the outset and a significant physician education effort. (31 Tr. 7550 (Patel); SPX 112 at SP 002751). In that regard, Schering discussed its experience with direct to patient promotion, the strategic fit of Niaspan with Schering's cardiovascular franchise, and Schering's long term commitment to lipid reduction. (31 Tr. 7551-52 (Patel); SPX 112 at SP 002751-3). Schering also stated that its field force had demonstrated cardiovascular success with regard to Imdur, Nitro-Dur, and K-Dur. (31 Tr. 7550 (Patel); SPX 112 at SP 002751).

Complaint Counsel's Response to Finding No. 1.114:

Complaint counsel has no specific response.

1.115. Mr. Russo believes that Schering was successful at the April 9 meeting in convincing Kos that Schering would make a good partner. (15 Tr. 3454 (Russo)).

Complaint Counsel's Response to Finding No. 1.115:

Complaint counsel has no specific response.

1.116. Kos reiterated that it wanted any co-promotion partner to guarantee a significant amount of primary details to doctors concerning Niaspan. (31 Tr. 7531, 7554 (Patel); CX 769). A primary detail means that when a representative goes to a doctor's office, he will give priority to one product, either by mentioning it first or mentioning it most. (31 Tr. 7554 (Patel); 15 Tr. 3450 (Russo)). Primary detail/positioning is a very valuable commodity, and one that Schering would have rather reserved for its own products, on which it would receive all of the profit. (15 Tr. 3450-51 (Russo)). Kos' demand for primary positioning, therefore, was "not in sync" with Schering's field force availability. (15 Tr. 3451 (Russo)).

Complaint Counsel's Response to Finding No. 1.116:

The proposed finding is not relevant. [redacted]

1.117. Further, Kos was seeking guarantees with respect to the level of call activity, asking for specific numbers of specific types of calls through the launch period. (15 Tr. 3451 (Russo)). Schering did not feel that it could accommodate the level of call activity that Kos wanted. (15 Tr. 3451 (Russo)). Schering responded that it would be more comfortable with

secondary detailing. (31 Tr. 7555 (Patel)). Kos stated that it wanted "absolute maximum commitment from Schering in the form of first line details." (31 Tr. 7555 (Patel)). The detailing issue was not resolved at this meeting. (31 Tr. 7555 (Patel)).

Complaint Counsel's Response to Finding No. 1.117:

The proposed finding is not relevant. [redacted]

1.118. Kos also was demanding strategic control over the marketing and promotion of Niaspan. (7 Tr. 1423 (Driscoll Dep.); (31 Tr. 7557 (Patel)). This issue was not resolved at the April 9, 1997 meeting. (31 Tr. 7557 (Patel)).

Complaint Counsel's Response to Finding No. 1.118:

The proposed finding is not relevant. [redacted]

1.119. Schering and Kos also discussed the issue of who would "book" sales. (31 Tr. 7556 (Patel)). Booking sales refers to which company records the sales that have been made. (31 Tr. 7556 (Patel)). Kos wanted to record, or "book," Niaspan's sales to show significant sales as a company. (31 Tr. 7556 (Patel)). Booking sales was therefore an important issue to Kos. (31 Tr. 7556 (Patel)). The issue also was important to Schering because Schering did not want its sales force used as simply a "rent a sales force." (31 Tr. 7556 (Patel)). Ms. Gast of Schering

described booking sales as a "hot button issue." (31 Tr. 7556 (Patel)). The issue was also left unresolved at the meeting. (31 Tr. 7557 (Patel)).

Complaint Counsel's Response to Finding No. 1.119:

The proposed finding is not relevant. [redacted]

1.120. Ms. Gast also asked again if Kos would be willing to discuss worldwide sales. (31 Tr. 7558 (Patel)). Kos wanted to concentrate on the U.S. first and defer cooperation on Europe and the rest of the world until later. (31 Tr. 7558 (Patel)).

Complaint Counsel's Response to Finding No. 1.120:

The proposed finding is incomplete. *See* CPRF No. 1.109 (discussing the parties discussion regarding non-U.S. rights for Niaspan).

1.121. The parties also discussed other issues, including labeling, launch timing, distribution, manufacture, patents, and Kos' cross-license agreement with Upsher. (31 Tr. 7558 (Patel)). At the end of the April 9 meeting, the parties agreed to consider further the issues they had discussed, and get back in touch later. (31 Tr. 7558 (Patel)).

Complaint Counsel's Response to Finding No. 1.121:

Complaint counsel has no specific response.

4. Schering's Forecast For Niaspan Sales

1.122. Following the April 9, 1997 meeting with Kos, Schering worked to put together broad deal terms that it ultimately would present to Kos. (15 Tr. 3455 (Russo)). Part of that process involved an assessment of the product's value to Schering and the preparation of sales forecasts. (15 Tr. 3455 (Russo)).

Complaint Counsel's Response to Finding No. 1.122:

Complaint counsel has no specific response.

1.123. Schering created three sales forecasts: a base, which was the most realistic, a downside, which tracked the lowest potential of the product, and an upside, which assumed a more aggressive market penetration and higher market share. (15 Tr. 3456 (Russo); CX 550). Mr. Russo prepared the base case scenario, and Ms. DeMola created the downside case scenario. (15 Tr. 3456, 3482-83 (Russo)).

Complaint Counsel's Response to Finding No. 1.123:

Complaint counsel has no specific response.

1.124. In connection with its sales forecasts, Schering considered two different price scenarios. (15 Tr. 3457 (Russo); CX 550). One pricing assumption was based on an existing product on the market, a low-priced niacin sustained release product not approved for treatment of cholesterol; the second scenario used a comparable generic product called gemfibrozil. (15 Tr. 3457 (Russo); CX 550). The price of generic gemfibrozil was higher than the price of the sustained release niacin product, but was significantly less than the price of other cholesterol-

lowering drugs. (15 Tr. 3458-59 (Russo)).

Complaint Counsel's Response to Finding No. 1.124:

Complaint counsel has no specific response.

1.125. Schering believed that if Niaspan could reduce flushing and avoid liver toxicity issues, it could be priced at the level of generic gemfibrozil, rather than at the level of the sustained release niacin product, which was not widely used. (15 Tr. 3458 (Russo)). Accordingly, Mr. Russo believed that the base case with the price of gemfibrozil (scenario II) was the most realistic, and this base case scenario II reflected his best business judgment at the time. (15 Tr. 3457, 3459-60 (Russo); CX 550). As the senior director of marketing, Mr. Russo had the "final say" on the assumptions to be used in the Niaspan sales forecasts, and once he and Mr. Driscoll agreed that price scenario II was the most realistic, scenario II was used in the financial evaluation of Niaspan. (15 Tr. 3482 (Russo)).

Complaint Counsel's Response to Finding No. 1.125:

The proposed finding is incomplete and misleading. Despite Mr. Russo's forecasts, Schering decided not to proceed with discussions with Kos regarding Niaspan. The recommendation to discontinue discussions with Kos was made by Mr. Russo's boss, Martin Driscoll (Schering's vice president of marketing and sales for its Key division). Mr. Driscoll made this recommendation for the "principal reason" that the product did not "represent a large-enough opportunity in the marketplace . . .". Mr. Driscoll's memorandum was prepared on June 9, 1997, just eight days before Mr. Audibert completed his commercial assessment of Niacor-SR. In reaching this recommendation on

Niaspan, Mr. Driscoll noted that the "current market dynamics of the 'statin' category" was another "important factor" that would impact Niaspan's acceptance in the marketplace. He observed that because of the apparent potency and benign side-effect profile of statins like Pfizer's Lipitor, "Niaspan's market opportunity is narrowing even prior to its introduction [and that i]ndeed, the use of other classes of cholesterol-lowering agents such as niacin, gemfibrozil, and cholestyramine has declined since the introduction of Lipitor." CX 558 at SP 002720 (Driscoll memorandum recommending discontinuation of discussions with Kos).

1.126. Russo's base case forecasted significant Niaspan sales, reaching $101 million in 1999:

Sales ($)	1997	1998	1999	2000	2001	2002	2003	2004	2005
Millions	7.022	48.247	101.659	106.941	126.872	133.662	140.816	152.989	174.128

(SPX 45; 15 Tr. 3529 (Russo)).

Complaint Counsel's Response to Finding No. 1.126:

The proposed finding is incomplete. Schering's employees have offered conflicting testimony about the value of a sustained-release niacin product to the company. The proposed finding suggests that Niaspan sales of $101 million in 1999 are significant. Other employees testimony and Schering's documents suggest that $100 million does not represent a significant value to the company. In Mr. Lauda's trial testimony, he testifies that a product with $100 million in annual sales is not a major product. Tr. at 19:4434 (Lauda); *see also* CPF 337.

In addition, the proposed finding only reports the higher of the two "base case" projections performed by Mr. Russo. It does not include the two "downside" forecasts done for Mr. Russo that were substantially lower than Mr. Audibert's projections for Niacor-SR, as follows:

Sales ($ millions)	1997	1998	1999	2000	2001	2002	2003	2004	2005
Niaspan (Price Scenario I)	.5	11	21	33	42	44	47	51	64
Niaspan (Price Scenario II)	.7	17	32	52	66	69	74	80	84

CX 550 at SP 002744.

1.127. Schering's Niaspan forecasts were not connected with any patent litigation in any way. (15 TR. 6460 (Russo)).

Complaint Counsel's Response to Finding No. 1.127:

Complaint counsel has no specific response.

1.128. The based case forecast with pricing scenario II represented Mr. Russo's best business judgment and his best estimate of what Schering could achieve with Niaspan. (15 Tr. 3459-60 (Russo)). The Schering-Kos negotiations were independent and carried on in the normal course of business. (15 Tr. 3460 (Russo)).

Complaint Counsel's Response to Finding No. 1.128:

The proposed finding is incomplete. Schering's employees have offered conflicting testimony about the value of a sustained-release niacin product to the

company. In addition, the proposed finding only discusses the higher of the two "base case" projections performed by Mr. Russo. *See* CPRF 1.126.

1.129. Schering also completed a net present value analysis regarding Niaspan. (15 Tr. 3461 (Russo); CX 551). According to Mr. Russo, the critical issue in generating a net present value is arriving at a correct profit and loss statement that takes into account the costs of goods, the cost to manufacture the product, expected royalties, anticipated cash discounts, and additional costs such as marketing costs for promotion and field force. (15 Tr. 3461-62 (Russo)).

Complaint Counsel's Response to Finding No. 1.129:

Complaint counsel has no specific response.

1.130. To calculate net present value, the estimated corporate tax rate is applied to the profit and loss statement to achieve a profit after tax. (15 Tr. 3461-62 (Russo)). Then, making some assumptions regarding inventory levels, a cash flow figure is generated from the profit after tax. (15 Tr. 3461-62 (Russo)). The cash flow is then discounted based on internal hurdle rates - 13 percent in the Niaspan analysis - to arrive at the net present value of the product. (15 Tr. 3461-62 (Russo)).

Complaint Counsel's Response to Finding No. 1.130:

Complaint counsel has no specific response.

1.131. The base case sales forecast with pricing scenario II that Mr. Russo created for Niaspan was used in analyzing the product's net present value. (15 Tr. 3462-63 (Russo); CX

550; CX 551). Assuming Schering would receive 50 percent of the profits from sales of Niaspan, Niaspan would have a net present value to Schering of $127 million, and a total net present value of $254 million. (SPX 47) (6 Tr. 1115-1116 (Bresnahan)).

Complaint Counsel's Response to Finding No. 1.131:

Complaint counsel has no specific response.

1.132. On April 21, 1997, stock analysts estimated that Niaspan would reach $250 million in sales in 2000. (USX 535).

Complaint Counsel's Response to Finding No. 1.132

The proposed finding is incomplete and misleading. The financial market referenced in the proposed finding refers to analysts whose objectives were to underwrite the initial public offering of Kos' stock and to promote the company to achieve high stock value. Dillon, Read & Co. , Cowen & Company, Salomon Brothers Inc., are identified on the front page of Kos' initial public offering prospectus as the underwriters of the Kos IPO. USX 21 at AAA 0000052. Also noted on the first page of the prospectus is the interest that these firms have in the company; all three underwriters were offered substantial shares of the company. The underwriters are required by the SEC to disclose this interest, and consequently, their incentive to strongly support and promote the company. Upsher, however, chose not to include this point in its finding.

In addition, the proposed finding on Kos' capitalization and outside analysts projections is not relevant to this proceeding. There is no evidence that Schering valued Niaspan, or even Niacor-SR on the basis of outside analysts projections. In fact, Schering

conducted its own due diligence and completed projections to evaluate the Niaspan opportunity. CX 548 (Niaspan financial analysis prepared by Ray Russo and Toni DeMola of Schering, dated April 17, 1997); CX 549 (additional Niaspan financial analysis prepared by Ray Russo and Toni DeMola, dated April, 1997); CX 550 (Niaspan sales forecasts prepared by Ray Russo and Toni DeMola, indicating "base," "downside," and "upside" sales forecast). Tr. at 15:3472, 3476-77 (Ray Russo) at 3472 (confirming that he completed sales projections for Niaspan); 3476-77(acknowledging that sales projections were completed for Niacor-SR).

5. Schering's Offer to Kos for Niaspan

1.133. [redacted] Schering told Kos that it was in the process of preparing a written offer. (31 Tr. 7565 (Patel); [redacted]

Complaint Counsel's Response to Finding No. 1.133:

Complaint counsel has no specific response.

1.134. [redacted]

[redacted]

Complaint Counsel's Response to Finding No. 1.134:

Complaint counsel has no specific response.

1.135. [redacted]; SPX 565).

Complaint Counsel's Response to Finding No. 1.135:

The proposed finding is not relevant. [redacted]

1.136. [redacted]

Complaint Counsel's Response to Finding No. 1.136:

Complaint counsel has no specific response.

1.137. [redacted]

[redacted]

Complaint Counsel's Response to Finding No. 1.137:

The proposed finding is not relevant. [redacted]

1.138. [redacted]

Complaint Counsel's Response to Finding No. 1.138:

Complaint counsel has no specific response.

1.139. Around this time, market analysts viewed Niaspan very favorably. On May 2, 1997, market analyst Cowen & Company forecasted Niaspan sales of $20 million in 1997 and $250 million by 2000. (SPX 225; 28 Tr. Kerr 6876-77 (Kerr)). Cowen & Company rated Kos' stock as a "strong buy," projecting that Kos' stock price would reach $35 per share in 12 to 18 months. (SPX 225; SPX 1284; 10 Tr. 2071 (Levy)).

Complaint Counsel's Response to Finding No. 1.139:

The proposed finding is incomplete and misleading. The financial market

referenced in the proposed finding refers to analysts whose objectives were to underwrite the initial public offering of Kos' stock and to promote the company to achieve high stock value. *See* CPRF 1.132.

1.141. On May 9, 1997, Salomon Brothers estimated that Niaspan would reach sales of $220 million in 2000. (SPX 226; 10 Tr. 2072 (Levy)). Salomon Brothers characterized Kos' stock as a "buy," projecting that Kos' stock price would reach $85-$90 in 3 years. (SPX 226; 10 Tr. 2072 (Levy)).

Complaint Counsel's Response to Finding No. 1.140:

The proposed finding is incomplete and misleading. Salomon Brothers' objectives was to underwrite the initial public offering of Kos' stock and to promote Kos to achieve high stock value. *See* CPRF 1.132.

1.410. On May 12, 1997, Kos' stock price was $25. (SPX 224; 10 Tr. 2073 (Levy)). Market analyst Dillon Read also rated Kos as a "buy." (SPX 223; SPX 224; SPX 226; SPX 239; SPX 569; 10 Tr. 2072 (Levy)). Kos' market capitalization was over $300 million. (10 Tr. 2074 (Levy)).

Complaint Counsel's Response to Finding No. 1.141:

The proposed finding is incomplete and misleading. Dillon Read's objective was to underwrite the initial public offering of Kos' stock and to promote Kos to achieve high stock value. *See* CPRF 1.132.

1.142. On May 15, 1997, Schering provided a written proposal to Kos for a co-promotion of Niaspan. (15 Tr. 3463-64 (Russo); CX 554; SPX 619). Schering is the only company that gave Kos a written proposal before Niaspan was launched. (31 Tr. 7543 (Patel)).

Complaint Counsel's Response to Finding No. 1.142:

Complaint counsel has no specific response.

1.143. [redacted]; CX 554). [redacted]

Complaint Counsel's Response to Finding No. 1.143:

Complaint counsel has no specific response.

1.144. Schering would provide about 255,000 details in the launch year, and half the other promotional expenditures. [redacted]; CX 554). The cost of these detailings to Schering would be $25 million in the first year. [redacted]; SPX 619). In addition, Schering committed to promotional spending of an additional $5 million. [redacted]; SPX 619).

Complaint Counsel's Response to Finding No. 1.144:

The proposed finding is not relevant. [redacted]

[redacted]

The proposed finding is also incomplete and misleading. Schering's proposed agreement contained a provision whereby if the amounts of expenses contributed by each party was not equal, then that party would be compensated. As Mr. Patel testified, if Schering contributed more towards the marketing efforts for Niaspan than Kos did, then Kos would make up for that cost. CX 554 at AAA 0000155 (Schering draft proposal, dated May 15, 1997, discussing sales and marketing expenses); Tr. at 31:7588 (Patel) (confirming this point).

1.145. Schering proposed a 50/50 profit and loss split. [redacted]; CX 554; [redacted]; SPX 619). Schering also suggested that it would give Kos a 10 to 15 percent royalty payment on the total sales of its product. [redacted]; CX 554).

Complaint Counsel's Response to Finding No. 1.145:

Complaint counsel has no specific response.

1.146. Schering proposed that it would book sales of Niaspan. [redacted]; CX 554; [redacted]; SPX 619). In exchange for the right to record sales, Schering offered Kos a product that it could help promote and for which Schering would provide it with remuneration. [redacted]; CX 554; [redacted]; SPX 619). [redacted].

Complaint Counsel's Response to Finding No. 1.146:

The proposed finding is not relevant. [redacted]

1.147. Schering's proposal did not contain upfront payments to Kos or equity investments. [redacted]; CX 554).

Complaint Counsel's Response to Finding No. 1.147:

Complaint counsel has no specific response.

1.148. On May 21, 1997, one week after submitting its proposal, Schering had a conference call with Kos to discuss the written proposal. (SPX 230; SPX 35; 31 Tr. 7667 (Patel)). Ray Russo, Karin Gast, and Toni DeMola participated in the call for Schering. (SPX 230) (SPX 35). Dan Bell, David Heatherman, and Mukesh Patel participated on behalf of Kos. (SPX 230) (SPX 35).

Complaint Counsel's Response to Finding No. 1.148:

Complaint counsel has no specific response.

1.149. Kos did not react favorably to Schering's proposal. (15 Tr. 3465 (Russo)). Mr. Bell told Schering that its offer was practically "insulting," and that he was "offended" by it. (SPX 230; [redacted]

Complaint Counsel's Response to Finding No. 1.149:

Complaint counsel has no specific response.

1.150. [redacted] Kos wanted an upfront payment to compensate for its research and development costs, and to reassure Kos that Schering was committed to the venture. (31 Tr. 7531-32 (Patel); [redacted] CX 769). Mr. Heatherman indicated that Kos wanted a very heavy early payment and very significant milestone payments. (15 Tr. 3465-66 (Russo)).

Complaint Counsel's Response to Finding No. 1.150:

The proposed finding is incomplete. During Schering's negotiations with Kos over the Niaspan opportunity, Kos requested an upfront payment explaining that the concept of such a payment by itself was significant to Kos. Tr at. 31:7533 (Patel) (explaining that "[i]t was important for us to make sure that the concept was conveyed so that they would in principle accept the concept of an up-front payment"); CX 557 at SP 002721 (Schering contact summary of May 21, 1997 conference call with Kos, noting that Kos' chief executive officer "would consider our approach only if we came back with a reasonable up-front payment (to partially compensate for all the money they have already spent)"); [redacted]

1.151. In addition, Kos wanted a higher level of promotion and field sales force activity than Schering was offering to commit. (15 Tr. 3465 Russo)).

Complaint Counsel's Response to Finding No. 1.151:

The proposed finding is not relevant. [redacted]

1.152. Kos was specifically seeking to retain marketing control of Niaspan and split the resulting profit from the effort. (15 Tr. 3450 (Russo)). Mr. Bell told Schering that Kos wanted a sliding scale profit split such that Schering would not obtain a 50/50 split until a certain sales level had been reached. (31 Tr. 7567 (Russo); [redacted]

Complaint Counsel's Response to Finding No. 1.152:

The proposed finding is incomplete and misleading. Schering's proposed agreement contained a provision whereby if the amounts of expenses contributed by each party was not equal, then that party would be compensated. As Mr. Patel testified, if Schering contributed more towards the marketing efforts for Niaspan, then Kos would make up for that cost. CX 554 at AAA 0000155 (Schering draft proposal, dated May 15, 1997, discussing sales and marketing expenses); Tr. at 31:7588 (Patel) (confirming this point).

1.153. [redacted]

[redacted]

Complaint Counsel's Response to Finding No. 1.153:

The proposed finding is not relevant. [redacted]

1.154. [redacted]

Complaint Counsel's Response to Finding No. 1.154:

Complaint counsel has no specific response.

1.155. Kos never made a counterproposal to Schering's offer. (31 Tr. 7568 (Patel).

Complaint Counsel's Response to Finding No. 1.155:

Complaint counsel has no specific response.

1.156. After receiving Kos' reaction to Schering's first proposal, Schering did not submit another proposal to Kos. (15 Tr. 3466, 3488 (Russo); (CX 558). There was a "wide gulf" between Kos' and Schering's views on Niaspan's commercial potential. (CX 1494 at 86:1-7 (Driscoll I.H.); 15 Tr. 3519-20 (Russo); (CX 558). Schering "could not bridge the gap" and therefore it was clear that the two parties were "not even close" to agreeing to terms. (15 Tr.

3466 (Russo)). Accordingly, it "[was not] worth [Schering's] time to continue the negotiations, and Schering ended them. (15 Tr. 3466 (Russo); 6 Tr. 1122 (Bresnahan)).

Complaint Counsel's Response to Finding No. 1.156:

The proposed finding is contradicted by other evidence. [redacted]

1.157. It also had become clear that Kos would be a difficult partner to deal with. (11 Tr. 2450 (Audibert Depo.); 6 Tr. 1122 (Bresnahan)). (Bresnahan 1122). For example, Kos had not been forthcoming regarding information on the product. (7 Tr. 1421 (Driscoll Depo.)). Kos became progressively less willing to share any clinical data that would substantiate its claims that the incidence of hepatotoxicity and flushing was diminished with its niacin product. (15 Tr. 3520-22 (Russo); CX 558 6 Tr. 1123-24 (Bresnahan); CX 1495 at 129:12-130:15). Similarly, Kos refused to provide Schering with its own sales forecasts and market research. (SPX 230); CX 1491 at 88:21-89:6 (Demola Dep).

Complaint Counsel's Response to Finding No. 1.157:

The proposed finding is incomplete. After the negotiations on Niaspan, the same people from Schering and Kos participated in discussions for other product opportunities. Tr. at 31:7611 (Patel) (confirming this point).

1.158. Given these difficulties, it was apparent that the Kos and Schering teams would not be able to create an appropriate relationship that was necessary for a successful partnership.

(7 Tr. 1411 (Driscoll I.H.)). (Driscoll I.H. 86) (Transcript 1411). In any co-promotion situation, trust between partners is essential. (7 Tr. 1423 (Driscoll Depo.)). Kos, however, was treating Schering employees with "great disrespect." (7 Tr. 1411 (Driscoll I.H.)). The manner in which Kos' people were treating Schering's people was an "important factor" in Mr. Driscoll's decision to end discussions with Kos. (7 Tr. 1423 (Driscoll Depo.)).

<u>Complaint Counsel's Response to Finding No. 1.158:</u>

The proposed finding is incomplete. ••
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1.159. At the time Schering ended its discussions with Kos, Kos' stock price was continuing to rise. On June 17, 1997, Kos' stock closed at $29.50, roughly double the IPO offering price. (10 Tr. 2074 (Levy); USX 1026). The total market capitalization of the company was around $400 million. (10 Tr. 2075 (Levy); 26 Tr. 6295 (Kerr); USX 1607).

<u>Complaint Counsel's Response to Finding No. 1.159:</u>

The proposed finding is not relevant. There is no evidence that Schering valued Niaspan, or Niacor-SR on the basis of outside analysts projections. In fact, Schering conducted its own due diligence and completed projections to evaluate the Niaspan opportunity. CX 548 (Niaspan financial analysis prepared by Ray Russo and Toni DeMola of Schering, dated April 17, 1997); CX 549 (additional Niaspan financial analysis prepared by Ray Russo and Toni DeMola, dated April, 1997); CX 550 (Niaspan sales forecasts prepared by Ray Russo and Toni DeMola, indicating "base," "downside,"

and "upside" sales forecast). Tr. at 15:3472, 3476-77 (Ray Russo) at 3472 (confirming that he completed sales projections for Niaspan); 3476-77 (acknowledging that sales projections were completed for Niacor-SR).

1.160. Kos' stock price and market capitalization were based primarily on Niaspan. (28 Tr. 6830, 6833, 6875, 6878, 6895, 6982 (Kerr); SPX 224 at 8; SPX 225; SPX 237; USX 239; USX 535 at USL 11517). Assuming that Kos' only product was Niaspan, the market capitalization shows the market's valuation of Niaspan's worldwide prospects. (6 Tr. 1129 (Bresnahan)).

Complaint Counsel's Response to Finding No. 1.160:

The proposed finding is not relevant. There is no evidence that Schering valued Niaspan, or Niacor-SR on the basis of outside analysts projections. *See* CPRF 1.159.

6. Kos' Discussions With Other Potential Partners Regarding Niaspan

1.161. Kos' Niaspan entered the market in August 1997. (7 Tr. 1404 (Driscoll I.H.)).

Complaint Counsel's Response to Finding No. 1.161:

Complaint counsel has no specific response.

1.162. At the time of Niaspan's launch, Kos was still looking for a co-promotion partner for Niaspan in the U.S. (31 Tr. 7577 (Patel)).

Complaint Counsel's Response to Finding No. 1.162:

The proposed finding is incomplete. [redacted]

1.163. Kos used the market analysts' sales projections for Niaspan in its discussions with potential partners. (31 Tr. 7574 (Patel)). Kos spoke with a number of companies that had interest in a sustained-release niacin product. For example, Bristol-Myers Squibb had expressed interest in co-promoting Niaspan, and the two companies had met in Miami in early June 1997 to discuss the potential deal. (CX 1729). [redacted]

Complaint Counsel's Response to Finding No. 1.163:

The proposed finding is incomplete. As part of Kos search for a European licensing partner, Kos made presentations to several companies. [redacted]

1.164. In the fall of 1997, Kos had conversations with Searle. 31 Tr. 7576 (Patel); 33 Tr. 7895-96; 7898 (Egan)). On October 6, 1997, the two companies signed a confidentiality

agreement. (CX 522); 31 Tr. 7577 (Patel)). Kos provided Searle with a presentation on Niaspan, including its clinical trial results, sales force planning, commercial plan, and sales, pricing, and market forecasts. (33 Tr. 7901 (Egan)).

Complaint Counsel's Response to Finding No. 1.164:

Complaint counsel has no specific response.

1.165. Searle's scientists reviewed clinical data from Kos and found Niaspan to be an attractive product. (33 Tr. 7969 (Egan)). Mr. Egan understood that Niaspan was simply a reformulation and new dose regimen recasting of an existing, well-established generic and that Niaspan was not a very novel composition of matter. (33 Tr. 7996 (Egan)). Mr. Egan believed that this formulation change would improve compliance on niacin therapy versus other dosing regimens and had some commercial promise. (33 Tr. 7917 (Egan)).

Complaint Counsel's Response to Finding No. 1.165:

Complaint counsel has no specific response.

1.166. On November 3, 1997, Searle and Kos discussed Kos' demands for a U.S. co-promotion deal for Niaspan. (CX 523). Searle was interested in European as well as U.S. rights. (CX 523; 33 Tr. 7978-79 (Egan)). Searle's European group wanted at least a right of first refusal with respect to European rights. (33 Tr. 7979 (Egan)). Searle wanted to have its European colleagues involved in the discussions with Kos, but Kos wanted to defer discussion of European rights and to delink them from the discussion of U.S. issues. (CX 523; 33 Tr. 7979-80 (Egan)). Kos stated to Searle that the U.S. was Kos' first priority. (31 Tr. 7583 (Patel)).

Complaint Counsel's Response to Finding No. 1.166:

The proposed finding is incomplete. As part of Kos search for a European licensing partner, Kos made presentations to several companies. [redacted]

In addition, the proposed finding asserts that Kos and Searle discussed Kos' "demands" for a co-promotion arrangement in the United States, citing CX 523. This document, an e-mail from Mr. Egan to a group of other Searle employees, does not use the word "demands" to describe Kos. To the contrary, Mr Egan wrote: "Mukesh Patel from Kos has called back. He talked with their CEO Mr. Bell who wants to be personally engaged in discussions at this point. He has asked for a small meeting with one or two Searle representatives in the 'near future' to get a 'feeling' for what Searle would be prepared to discuss in the form of a co-promotional deal for the United States."

1.167. The November 3, 1997 conversation between Kos and Searle took place nine days before the announcement of Kos' first quarter sales results. (31 Tr. 7579 (Patel); CX 523). At the time of the November 3, 1997 call with Searle, Kos was aware of Niaspan's sales numbers that had not been made public yet. (31 Tr. 7579 (Patel)). Kos knew that Niaspan's first quarter sales were disappointing, and attributed this to the fact that Kos lacked a partner with a lot of sales muscle. (31 Tr. 7576 (Patel)). If Kos had a marketing partner, it would have had a better chance of making its sales numbers. (Patel 7576). (31 Tr. 7576 (Patel)).

<u>Complaint Counsel's Response to Finding No. 1.167:</u>

Complaint counsel has no specific response.

1.168. Kos knew that Niaspan's disappointing sales were going to be announced in early November. (31 Tr. 7579 (Patel)). Kos continued to look for a U.S. co-promotion partner. (31 Tr. 7580 (Patel)).

<u>Complaint Counsel's Response to Finding No. 1.168:</u>

The proposed finding is incomplete. As part of Kos search for a European licensing partner, Kos made presentations to several companies. [redacted]

1.169. Kos wanted to meet with Searle as soon as possible to discuss co-promotion rights in the U.S. (31 Tr. 7580-81 (Patel)). Kos had an immediate focus on the development and marketing of Niaspan in the U.S. in the short term. (31 Tr. 7577, 7579 (Patel); (CX 523).

<u>Complaint Counsel's Response to Finding No. 1.169:</u>

Complaint counsel has no specific response.

1.170. In early November, Searle met with Kos and the parties discussed Kos' demands for a U.S. co-promotion agreement. (CX 524). Kos demanded from Searle a large number of details for Niaspan. (33 Tr. 7986-88 (Egan)). Searle found Kos' demands unreasonable. (33 Tr.

7982 (Egan)). Kos was expecting approximately 900,000 details annually, which is the level of detailing one reserves for a blockbuster product. (CX 524; 33 Tr. 7986-87 (Egan)). Kos expected Searle to deliver about 700,000 of those details, which would require Searle to spend at least $35 million in marketing annually. (33 Tr. 7987-88 (Egan)).

Complaint Counsel's Response to Finding No. 1.170:

Complaint counsel has no specific response.

1.171. In Searle's view, the vast majority of Niaspan's value would derive from sales and marketing detailing of the product, not from the product's development and intrinsic characteristics. (33 Tr. 7996 (Egan)). Under Kos' co-promotion proposal, Searle would be contributing the lion's share of the value and the effort, and Kos would receive a disproportionate share of the income. (33 Tr. 7986 (Egan)).

Complaint Counsel's Response to Finding No. 1.171:

Complaint counsel has no specific response.

1.172. Kos wanted an up-front payment in the $10-20 million range. (33 Tr. 7982 (Egan)); CX 525). Kos also wanted a "ridiculous" and unreasonable percentage of the profits from any co-promote arrangement. (33 Tr. 7984-85 (Egan)). Kos' demands were ridiculous because Searle would be doing most of the promotion of the product with an established sales force, in comparison to Kos' sales force, which was new and relatively small. (33 Tr. 7985 (Egan)). Kos' name was hardly known, while Searle was established. (33 Tr. 7985 (Egan)). Searle had a franchise; Kos did not. (33 Tr. 7985 (Egan)). Searle perceived that the promotional

investment sought by Kos was not worth it, given the profit split that Kos was seeking. (33 Tr. 7988 (Egan)).

Complaint Counsel's Response to Finding No. 1.172:

The proposed finding is incomplete. As part of Kos search for a European licensing partner, Kos made presentations to several companies. [redacted]

1.173. On November 11, 1997, the day before Niaspan's sales results were announced, Kos' stock price was $30.94. (USX 1027). [redacted] Niaspan's sales results were very low. (18 Tr. 4143 (Audibert); 23 Tr. 5480 (Troup)). The stock price dropped almost 50 percent in one day, to $16.56. (SPX 1104; USX 1028; USX 1029; 28 Tr. 6867 (Kerr); 18 Tr. 4143 (Audibert)). [redacted]

Complaint Counsel's Response to Finding No. 1.173:

Complaint counsel has no specific response.

1.174. After Niaspan's disappointing sales were announced, Searle declined the Kos opportunity. (33 Tr. 7980 (Egan)). Searle believed it could have made some money on Niaspan

but felt that Searle could have made "more doing something else." (33 Tr. 7907 (Egan)). Searle did not believe it could recover the productivity of its sales force for the product, because the "detailing of the product would have been particularly intense and expensive." (33 Tr. 7908 (Egan)). Accordingly, Searle decided not to pursue a license with Kos for Niaspan. (33 Tr. 7907 (Egan)).

Complaint Counsel's Response to Finding No. 1.174:

Complaint counsel has no specific response.

1.175. At Kos' insistence, Searle nonetheless met with Kos' CEO, Mr. Bell on December 17, 1997 in New York. (CX 525; 33 Tr. 7977, 7981 (Egan)). Searle did not pursue the opportunity after that. (33 Tr. 7982 (Egan)).

Complaint Counsel's Response to Finding No. 1.175:

Complaint counsel has no specific response.

1.176. During the summer and fall of 1997, Kos was also pursuing discussions with SmithKline Beecham concerning a co-promotion arrangement for Niaspan.

Complaint Counsel's Response to Finding No. 1.176:

The proposed finding is incomplete. As part of Kos search for a European licensing partner, Kos made presentations to several companies. [redacted]

1.177. [redacted]

Complaint Counsel's Response to Finding No. 1.177:

The proposed finding is incomplete. As part of Kos search for a European licensing partner, Kos made presentations to several companies. [redacted]

1.178. In August 1997, Mr. Patel discussed with SmithKline the broad terms of a potential co-promotion partnership for Niaspan. (31 Tr. 7678 (Patel); CX 508). As with Schering, Kos stated that it needed guaranteed detailing for Niaspan, that Kos wanted to book

sales, and that Kos wanted the opportunity to co-promote a SmithKline product. (31 Tr. 7678-79 (Patel); CX 508). SmithKline and Kos also discussed SmithKline's interest in non-U.S. rights to Niaspan. (CX 508).

Complaint Counsel's Response to Finding No. 1.178:

The proposed finding is incomplete. As part of Kos search for a European licensing partner, Kos made presentations to several companies. [redacted]

1.179. [redacted]

Complaint Counsel's Response to Finding No. 1.179:

The proposed finding is incomplete. As part of Kos search for a European licensing partner, Kos made presentations to several companies. [redacted]

1.180. On October 16, 1997, SmithKline wrote to Kos, stating that SmithKline had sent Kos' regulatory materials to its European clinical group. (CX 507; 31 Tr. 7683 (Patel)). SmithKline congratulated Kos on being listed as a "stock pick" by the market analyst company, Cowen & Co. (CX 507).

Complaint Counsel's Response to Finding No. 1.180:

Complaint counsel has no specific response.

1.181. On November 6, 1997, Kos and SmithKline had a conference call to discuss, among other things, Kos' progress toward preparing any European regulatory filings. (Patel 6584) (CX 513).

Complaint Counsel's Response to Finding No. 1.181:

Complaint counsel has no specific response.

1.182. [redacted]

Complaint Counsel's Response to Finding No. 1.182:

Complaint counsel has no specific response.

1.183. The following week, Kos made public the results from Niaspan's first quarter of sales. [redacted]; 10 Tr. 2076-77 (Levy)). The first published figures were a major disappointment to investors. (23 Tr. 5480 (Troup)). The stock price dropped almost 50 percent. (SPX 1104; USX 1028; USX 1029; 28 Tr. 6867 (Kerr); 10 Tr. 2075-78 (Levy)).

Complaint Counsel's Response to Finding No. 1.183:

Complaint counsel has no specific response.

1.184. Mr. Patel attributes Niaspan's low sales to the fact that Kos had only 65 to 75 representatives launching Niaspan in August and September 1997, which created only a low noise level in front of physicians. (31 Tr. 7576 Patel)).

Complaint Counsel's Response to Finding No. 1.184:

Complaint counsel has no specific response.

1.185. Following the disappointing Niaspan sales, and the accompanying collapse of Kos' stock price, SmithKline and Kos did not to enter into an arrangement regarding Niaspan. (Patel 7540).

Complaint Counsel's Response to Finding No. 1.185:

Complaint counsel has no specific response.

1.186. Kos had other discussions with potential partners about a European license for Niaspan after November 1997. (31 Tr. 7589 (Patel)). Kos believed that Niaspan had value outside the U.S. (31 Tr. 7587 (Patel)). [redacted]; SPX 1287

Complaint Counsel's Response to Finding No. 1.186:

The proposed finding is incomplete. As part of Kos search for a European licensing partner, Kos made presentations to several companies. [redacted]

1.187. Kos did not find a European partner for its Niaspan product. (31 Tr. 7540 (Patel)). [redacted]. Kos' sales from 1997 through 1999 were less than a fifth of what each of the market analysts had projected. (31 Tr. 7584-86, [redacted]; SPX 2338 (demonstrative)).

Complaint Counsel's Response to Finding No. 1.187:

The proposed finding is incomplete. As part of Kos search for a European licensing partner, Kos made presentations to several companies. [redacted]

1.188. Overall, Kos' Niaspan has had a spotty history in the marketplace. (26 Tr. 6329 (Kerr)). Initially Niaspan did not achieve nearly the expected sales levels predicted and Kos' stock price plummeted. (26 Tr. 6329, 6331 (Kerr); USX 1607).

Year	1997	1998	1999
Analysts Projections[1]	**$20**	**$90**	**$175**
Actual Sales[2]	**$1.7**	**$16**	**$37**

(SPX 2338) (demonstrative).

Complaint Counsel's Response to Finding No. 1.188:

Complaint counsel has no specific response.

1.189. In 1998, sales were poor. Sales for the first 6 months of 1998 totaled $3.8 million and in August 1998, after being in the market one year, Niaspan's share of new prescriptions for the month was only 1.1%. (18 Tr. 4159 (Audibert); SPX 15). Kos stock price in September 1998 was 5 7/16, down from 44 in October 1997. (SPX 15; 18 Tr. 4159 (Audibert)). Total sales for 1998 were only $15 million. (7 Tr. 1405 (Driscoll I.H.)).

Complaint Counsel's Response to Finding No. 1.189:

The proposed finding is incomplete and contradicted by other evidence. The proposed finding represents "only 1.1 percent" consistuted "poor" sales for Niaspan. However, that sales level was consistent with (and exceeded in individual years) Mr. Audibert's projections of sales for Niacor-SR in his commercial assesment. That assesment projected that Niacor-SR would achieve the following sales levels in Europe:

Year	'99	'00	'01	'02	'03	'04	'05	'06	'07	'08
Market Share %	.75	1.0	1.5	1.5	1.25	1.25	1.25	1.0	1.0	1.0

CX 1044 at SP 16 0047.

1.190. Two years after introduction, in 1999, Niaspan's sales were only $37 million. (26 Tr. 6331 (Kerr); USX 1613). Analysts had projected Niaspan sales to be close to $200 million by 1999. 26 Tr. 6331 (Kerr); (USX 1613).

Complaint Counsel's Response to Finding No. 1.190:

The proposed finding is incomplete and misleading. The analysts referenced in the proposed finding refers to analysts whose objectives were to underwrite the initial public offering of Kos' stock and to promote the company to achieve high stock value. Dillon, Read & Co. , Cowen & Company, Salomon Brothers Inc., are identified on the front page of Kos' initial public offering prospectus as the underwriters of the Kos IPO. USX 21 at AAA 0000052. Also noted on the first page of the prospectus is the interest that these firms have in the company; all three underwriters were offered substantial shares of the company. The underwriters are required by the SEC to disclose this interest, and consequently, their incentive to strongly support and promote the company. Upsher, however, chose not to include this point in its finding.

In addition, the proposed finding is not relevant to this proceeding. There is no evidence that Schering valued Niaspan, or even Niacor-SR on the basis of outside analysts projections. In fact, Schering conducted its own due diligence and completed projections to evaluate the Niaspan opportunity. CX 548 (Niaspan financial analysis prepared by Ray Russo and Toni DeMola of Schering, dated April 17, 1997); CX 549 (additional Niaspan financial analysis prepared by Ray Russo and Toni DeMola, dated April, 1997); CX 550 (Niaspan sales forecasts prepared by Ray Russo and Toni DeMola, indicating "base," "downside," and "upside" sales forecast). Tr. at 15:3472, 3476-77

(Ray Russo) at 3472 (confirming that he completed sales projections for Niaspan); 3476-77 (acknowledging that sales projections were completed for Niacor-SR).

1.191. After four years, Niaspan is now moderately successful with last year's sales equal to about $100 million. (26 Tr. 6331 (Kerr)).

Complaint Counsel's Response to Finding No. 1.191:

Complaint counsel has no specific response.

III. NIACOR-SR

A. Schering's Evaluation of Niacor-SR

1.192. In June 1997, Messrs. Kapur and Driscoll briefed Raul Cesan, Schering's executive vice president of worldwide pharmaceuticals, on the status of Schering's settlement negotiations with Upsher. (CX 1510, at 66:1-25, 67:1-4 (Kapur I.H.)). Mr. Cesan instructed Mr. Kapur to contact Tom Lauda, Schering's executive vice president in charge of global marketing, and to ask Mr. Lauda to arrange for an evaluation of Niacor-SR. (CX 1510, at 67:18-25, 68:1-25 (Kapur I.H.); CX 1489 at 13:5-2, 14:1, 14:15-25 (Cesan Dep)).

Complaint Counsel's Response to Finding No. 1.192:

Complaint counsel has no specific response.

1.193. Mr. Kapur telephoned Mr. Lauda and told him that Schering was considering a licensing opportunity for Upsher's sustained-release niacin product, that the opportunity would cost Schering approximately $60 million, and asked if Global Marketing would perform an

assessment of the product. (19 Tr. 4342-43 (Lauda)). Mr. Kapur told Mr. Lauda that he had a data package containing both commercial and clinical information on the product, which he would send to Mr. Lauda. (18 Tr. 4243 (Lauda)). Mr. Kapur did not tell Mr. Lauda that this licensing opportunity was connected to patent litigation, and at the time of this conversation with Mr. Kapur, Mr. Lauda did not know that Schering was in litigation with Upsher over the potassium chloride patents. (19 Tr. 4344 (Lauda); 8 Tr. 1627-28 (Lauda IH)).

Complaint Counsel's Response to Finding No.1.193:

The proposed finding is incomplete. Mr. Lauda admits that Mr. Kapur told him that the cost of the licensing opportunity was going to be $60 million. CX 151 at 86:13-87:13 (Lauda IH).

1.194. James Audibert, who is currently employed within the Schering Plough Research Institute, was serving in June of 1997 as the Senior Director of Global Marketing for Cardiovascular Products. (18 Tr. 4085, 4092 (Audibert)). Mr. Lauda asked Mr. Audibert to perform an evaluation of the Niacor-SR product opportunity for worldwide territories, excluding the United States, Canada, and Mexico ("worldwide Ex-NAFTA"). (19 Tr. 4344 (Lauda); 18 Tr. 4112 (Audibert)).

Complaint Counsel's Response to Finding No. 1.194:

The proposed finding is incomplete and misleading. Mr. Audibert stated that he was specifically asked to draft a "sales forecast" and not to conduct any due diligence on Niacor-SR beyond the papers given to him. *See* CPF 419.

In addition, prior to conducting this sales forecast, Mr. Audibert was informed

about the terms of the patent settlement with Upsher including payment for the Niacor-SR license. Mr. Wasserstein (a Schering in-house lawyer who participated in the settlement negotiations with Upsher) told Mr. Audibert what the terms of the settlement agreement with Upsher were prior to Mr. Audibert completing his review of Niacor-SR on June 17. CX 1532 at 17:13-18:22 (Wasserstein dep) (noting that he informed Mr. Audibert about the terms). Thus, Mr. Audibert's sales projections could have been influenced by his knowledge of the patent settlement deals terms.

1. Schering's Global Marketing Department

1.195. Mr. Lauda is the executive vice president in charge of Schering's global marketing department, a position he has held since 1996. (19 Tr. 4340 (Lauda)). Prior to serving in the global marketing department, Mr. Lauda was Schering's vice president of international marketing – the precursor to Schering's global marketing department. (19 Tr. 4339-40 (Lauda)). The changes that occurred as a result of the transformation of the international marketing department into the global marketing department included more direct responsibility for product acquisition and development. (19 Tr. 4340-41 (Lauda)).

Complaint Counsel's Response to Finding No.1.195:

The proposed finding is incomplete. Global Marketing is ordinarily not responsible for registering products with regulatory agencies. CPF 676 77 (describing Mr. Audibert's confusion when Global Marketing was tasked with "developing and registering" Niacor-SR).

1.196. The global marketing department employs more than 135 people. (19 Tr. 4342 (Lauda)). As the Executive Vice President of Global Marketing, Mr. Lauda reports directly to the CEO of Schering. (19 Tr. 4342 (Lauda)). The global marketing department serves three primary functions: (1) business development for pharmaceutical operations, including licensing, acquisitions and divestitures; (2) working with Schering's research organization through the development and registration process to develop the profiles of internally developed products; and (3) working with Schering's subsidiaries to prepare them to marketing products and to help them adjust to the marketplace once a product enters the market. (19 Tr. 4341 (Lauda); 18 Tr. 4091 (Audibert)). These functions include evaluation of pharmaceutical products for potential in-licensing. (18 Tr. 4091 (Audibert)).

Complaint Counsel's Response to Finding No.1.196:

The proposed finding is incomplete. Global Marketing's responsibilities do not include the registration of products with regulatory agencies. *See* CPRF 1.195.

2. Mr. Audibert's Qualifications in June 1997

a. Pharmacology Background

1.197. Mr. Audibert received his Bachelor of Science in Pharmacy from Northeastern University College of Pharmacy in 1974, and received his Master of Science in Pharmacology from Northeastern University College of Pharmacy in 1982. (18 Tr. 4081 (Audibert)). Between 1974 and 1976, Mr. Audibert worked as a pharmacist. (18 Tr. 4082 (Audibert)). As Complaint Counsel's rebuttal witness Mr. Egan explained:

[A] pharmacologist is a—is a person who is familiar with the science of the

application of pharmaceuticals for human indications. They are people that will be expert in analyzing a drug substance for its bioavailability, its administration, distribution, metabolism, excretion. He'll be able to evaluate a drug's duration in the body, how long it's going to be there, its local pharmacodynamic effect. It's a very broad experience that a pharmacologist might possess.

(33 Tr. 7879-80 (Egan)).

Complaint Counsel's Response to Finding No.1.197:

Complaint counsel has no specific response.

b. Expertise in the Research and Development of Sustained Release Pharmaceutical Products

1.198. From 1976 to 1980, Mr. Audibert worked for Dooner Laboratories and the company that acquired it, William H. Rorer. (18 Tr. 4082 (Audibert)). Dooner was a company that specialized in the use of sustained release technology to transform old compounds into new products which it would market. (18 Tr. 4082 (Audibert)).

Complaint Counsel's Response to Finding No.1.198:

Complaint counsel has no specific response.

1.199. Mr. Audibert's primary responsibilities at Dooner involved coordinating clinical studies of the company's products, and educating physicians and pharmacists about those products. (18 Tr. 4082-83 (Audibert)). These products included Slo-Phyllin and Slo-Bid, which were sustained release formulations of theophylline, a compound used for the treatment of asthma. (18 Tr. 4088 (Audibert)). Mr. Audibert's coordination of clinical studies included working with outside clinical investigators on protocol development, monitoring ongoing clinical

studies, and analyzing data and preparing final study reports. (18 Tr. 4083 (Audibert)). Upon study completion, Mr. Audibert would use the final study report to develop a dossier for submission to the FDA. (18 Tr. 4083 (Audibert)).

Complaint Counsel's Response to Finding No.1.199:

Complaint counsel has no specific response.

1.200. In 1980, Mr. Audibert went to work for Key Pharmaceuticals ("Key"), another company that specialized in the use of sustained release technology to develop new products from old compounds that were limited by issues related to side effects. (18 Tr. 4083-84 (Audibert)). Through the use of sustained release technology, Key developed the successful "Dur" franchise, including products like Theo-Dur which became the best selling asthma product in the United States. (18 Tr. 4084, 4088-89 (Audibert); SPX 557 at FTC 0006127). After Schering's acquisition of Key in 1986, the President and CEO of Key Pharmaceuticals went on to become the founder of Kos Pharmaceuticals, another company that utilized this same approach in developing new products, including a sustained release niacin product known as Niaspan. (18 Tr. 4100-01 (Audibert); SPX 557, at FTC 0006127; SPX 605, at Kos 0054).

Complaint Counsel's Response to Finding No.1.200:

Complaint counsel has no specific response.

1.201. While at Key between 1980 and 1987, Mr. Audibert spent three years in research and development, two years in sales, and two years in a hybrid position working in both sales and research. (18 Tr. 4084 (Audibert)). As with Dooner, Mr. Audibert's research and

development responsibilities at Key involved coordination of clinical studies, including working with outside clinical investigators on protocol development, monitoring ongoing clinical studies, and analyzing data and preparing final study reports. (18 Tr. 4086 (Audibert)). Some of these studies related to the FDA registration process, and others were phase IV post-approval studies done to enhance the profile of a product. (18 Tr. 4087 (Audibert)). Mr. Audibert also handled inquiries from physicians, pharmacists, and Key's sales force regarding company products. (18 Tr. 4086, 4088 (Audibert)).

Complaint Counsel's Response to Finding No.1.201:

The proposed finding is contradicted by other evidence. Mr. Audibert's job history at Key was mainly spent in sales and marketing. *See* Tr. at 18:4084 (Audibert) (describing his experience at Key). While at Key, Mr. Audibert did not interface with regulatory authorities. CPF 446. Further, Mr. Audibert has stated that he has not worked in the regulatory area since 1977, which predates his time at Key. CPF 449.

1.202. Among the sustained release products that Mr. Audibert was involved with at Key were Theo-Dur tablets, Theo-Dur Sprinkle, Nitro-Dur and K-Dur. (18 Tr. 4087 (Audibert)). Similar to Dooner's Slo-Phyllin and Slo-Bid, Key's Theo-Dur and Theo-Dur Sprinkle were sustained release formulations of theophylline used for the treatment of asthma. (18 Tr. 4088 (Audibert)). Because of his expertise in the area of sustained release formulations of theophylline, Mr. Audibert's responsibilities including representing Key as an expert on these products to various outside medical groups. (18 Tr. 4088 (Audibert)). Theo-Dur was very successful, and became the best selling asthma product in the United States. (18 Tr. 4089

(Audibert); SPX 557, at FTC 0006127).

Complaint Counsel's Response to Finding No.1.202:

Complaint counsel has no specific response.

1.203. While at Key, Mr. Audibert also worked on Nitro-Dur, a sustained release formulation of nitroglycerine used in the treatment of angina, and K-Dur, a sustained release potassium chloride product. (18 Tr. 4087 (Audibert)). Each of these products became market leaders, generating sales in the range of $200 to $300 million annually. (18 Tr. 4089 (Audibert)).

Complaint Counsel's Response to Finding No.1.203:

Complaint counsel has no specific response.

c. Expertise in the Area of Cholesterol Lowering Pharmaceutical Products

1.204. In mid-1986, Schering acquired Key and, in March 1987, Mr. Audibert moved to New Jersey to work for Schering's marketing department. (18 Tr. 4084 (Audibert)). At Schering, Mr. Audibert held a number of sales and marketing positions. (18 Tr. 4085 (Audibert)). In April 1995, Mr. Audibert went to work in Schering's global marketing department where he remained until, as a result of his knowledge of both the science and commercial aspects of Schering's pharmaceutical products, Mr. Audibert moved into his current position with the Schering Plough Research Institute September 2000. (18 Tr. 4085 (Audibert)).

Complaint Counsel's Response to Finding No.1.204:

The proposed finding is not relevant. While Mr. Audibert possessed some

knowledge about the cholesterol-lowering market, Mr. Audibert did not have the qualifications to perform the scientific review of Niacor-SR. *See* CPF 446-448 (describing Mr. Audibert's qualifications for conducting due diligence). In addition, Mr. Audibert committed numerous errors in his analysis of the package of information provided by Upsher to Schering on Niacor-SR. *See e.g.*, Tr. at 18:4197 (Audibert) (referencing his description of Niacor-SR in the commercial assessment: "[a]t the time I wrote this, this statement is incorrect in the sense that the initial registration program was with twice-a-day dosing"); *see generally* CPF 456-484A (describing various errors made by Mr. Audibert in reviewing Niacor-SR's patent status, administration and dosing schedule, and regulatory status).

1.205. In his position as Senior Director of Global Marketing, Mr. Audibert was the head of the cardiovascular and central nervous system ("CNS") business unit, and was in charge of cardiovascular/CNS products. (18 Tr. 4092 (Audibert)). The cardiovascular products Mr. Audibert was responsible for included cholesterol lowering products. (18 Tr. 4093 (Audibert)). In particular, Mr. Audibert's responsibilities included a cholesterol-lowering agent Schering had in development called ezetimibe. (18 Tr. 4093 (Audibert)). Ezetimibe, referred to in development as 58325, is a unique cholesterol absorption inhibitor that was in development at the time and for which Schering recently filed an application for regulatory approval with the FDA. (18 Tr. 4093-94, 4111 (Audibert)).

Complaint Counsel's Response to Finding No.1.205:

The proposed finding is not relevant. While Mr. Audibert possessed some

knowledge about the cholesterol-lowering market, Mr. Audibert did not have the qualifications to perform the scientific review of Niacor-SR, and he committed numerous errors in his analysis of the package of information provided by Upsher to Schering on Niacor-SR. *See* CPRF 1.204.

1.206. Ezetimibe is expected to become the biggest product in the history of Schering, with annual sales exceeding even the $3 billion level achieved by Schering's Claritin product. (18 Tr. 4093 (Audibert); 19 Tr. 4348-49 (Lauda)). In fact, Schering anticipates sales of the product to reach $6 or $7 billion annually. (15 Tr. 3439-40 (Russo)). Between 1995 and the evaluation of Niacor-SR in June 1997, Mr. Audibert was the individual within the global marketing department responsible for ezetimibe. (18 Tr. 4098 (Audibert)).

Complaint Counsel's Response to Finding No.1.206:

The proposed finding is not relevant. While Mr. Audibert possessed some knowledge about the cholesterol-lowering market, Mr. Audibert did not have the qualifications to perform the scientific review of Niacor-SR, and he committed numerous errors in his analysis of the package of information provided by Upsher to Schering on Niacor-SR. *See* CPRF 1.204.

In addition, when asked to approve the Schering/Upsher settlement agreement, the Schering Board was not informed about ezetemibe as a justification for the Niacor-SR license. *See* CX 338 at SP 12 00268–70 ("Niacor-SR" portion of Schering Board presentation on the Schering/Upsher settlement agreement).

1.207. By early-1997, Mr. Audibert was spending 35% to 40% of his time working on the ezetimibe product. (18 Tr. 4094 (Audibert)). This significant investment of time was required because, as the product was moving down the development path, Mr. Audibert began working with the research organization to identify the patient populations in which, and products against which, ezetimibe would be tested in clinical studies. (18 Tr. 4094 (Audibert)). As part of this process, Mr. Audibert was also conducting a detailed evaluation of the market for cholesterol lowering drugs. (18 Tr. 4094-95 (Audibert)).

Complaint Counsel's Response to Finding No.1.207:

The proposed finding is not relevant. While Mr. Audibert possessed some knowledge about the cholesterol-lowering market, Mr. Audibert did not have the qualifications to perform the scientific review of Niacor-SR, and he committed numerous errors in his analysis of the package of information provided by Upsher to Schering on Niacor-SR. *See* CPRF 1.204.

1.208. Mr. Audibert's detailed evaluation of the cholesterol lowering market included: (1) a review of secondary information and published literature regarding the market and products within the market; (2) conducting primary market research around the world, including interviewing physicians on what they perceived to be unmet needs and future trends in cholesterol management; (3) convening advisory panels to get input from experts in the cholesterol lowering area; (4) attending major cardiology meetings around the world dealing with current and future trends in cholesterol management, and the development of future cholesterol lowering products; and (5) traveling to subsidiaries around the world to meet with national

experts and local opinion leaders in cholesterol management. (18 Tr. 4095-96 (Audibert)).

Complaint Counsel's Response to Finding No.1.208:

The proposed finding is not relevant. While Mr. Audibert possessed some knowledge about the cholesterol-lowering market, Mr. Audibert did not have the qualifications to perform the scientific review of Niacor-SR on his own, and he committed numerous errors in his analysis of the package of information provided by Upsher to Schering on Niacor-SR. *See* CPRF 1.204.

1.209. As part of this process of evaluating the cholesterol lowering market, Mr. Audibert studied the profiles of the products that were already available for the treatment of cholesterol, as well as the anticipated profiles of future products, and evaluated what unmet needs existed within the market. (18 Tr. 4097-98 (Audibert)). This included studying the major cholesterol lowering products on the market in 1997, including the statins, the fibrates, the resins, and niacin. (18 Tr. 4098 (Audibert)).

Complaint Counsel's Response to Finding No.1.209:

The proposed finding is not relevant. While Mr. Audibert possessed some knowledge about the cholesterol-lowering market, Mr. Audibert did not have the qualifications to perform the scientific review of Niacor-SR, and he committed numerous errors in his analysis of the package of information provided by Upsher to Schering on Niacor-SR. *See* CPRF 1.204.

1.210. Mr. Audibert also conducted a detailed evaluation of the size of the cholesterol lowering market, which included: (1) examining the current size of the worldwide market by product and geographic territory; (2) predicting the future size of the cholesterol lowering market through conversations with opinions leaders, examination of cholesterol management treatment guidelines, estimation of the impact of future products on the market, and consideration of analyst reports published by the investment community. (18 Tr. 4096-97 (Audibert)).

Complaint Counsel's Response to Finding No.1.210:

The proposed finding is not relevant. While Mr. Audibert possessed some knowledge about the cholesterol-lowering market, Mr. Audibert did not have the qualifications to perform the scientific review of Niacor-SR, and he committed numerous errors in his analysis of the package of information provided by Upsher to Schering on Niacor-SR. *See* CPRF 1.204.

1.211. [redacted] For example, Dr. Hunninghake was a member of the National Cholesterol Education Program ("NCEP") that had been convened by the National Institutes of Health to develop guidelines for the treatment of high cholesterol. [redacted]; 21 Tr. 4964-65 (Freese)). [redacted].

Complaint Counsel's Response to Finding No.1.211:

The proposed finding is not relevant. While Mr. Audibert possessed some knowledge about the cholesterol-lowering market, Mr. Audibert did not have the qualifications to perform the scientific review of Niacor-SR, and he committed numerous errors in his analysis of the package of information provided by Upsher to Schering on Niacor-SR. *See* CPRF 1.204.

1.212. [redacted]

Complaint Counsel's Response to Finding No.1.212:

The proposed finding is not relevant. While Mr. Audibert possessed some knowledge about the cholesterol-lowering market, Mr. Audibert did not have the qualifications to perform the scientific review of Niacor-SR, and he committed numerous errors in his analysis of the package of information provided by Upsher to Schering on Niacor-SR. *See* CPRF 1.204.

[redacted]

1.213. [redacted]

Complaint Counsel's Response to Finding No.1.213:

The proposed finding is not relevant. While Mr. Audibert possessed some knowledge about the cholesterol-lowering market, Mr. Audibert did not have the qualifications to perform the scientific review of Niacor-SR, and he committed numerous errors in his analysis of the package of information provided by Upsher to Schering on Niacor-SR. *See* CPRF 1.204.

1.214. [redacted]

Complaint Counsel's Response to Finding No.1.214:

The proposed finding is not relevant. While Mr. Audibert possessed some knowledge about the cholesterol-lowering market, Mr. Audibert did not have the qualifications to perform the scientific review of Niacor-SR, and he committed numerous errors in his analysis of the package of information provided by Upsher to Schering on Niacor-SR. *See* CPRF 1.204.

1.215. [redacted]

Complaint Counsel's Response to Finding No.1.215:

The proposed finding is not relevant. While Mr. Audibert possessed some knowledge about the cholesterol-lowering market, Mr. Audibert did not have the

qualifications to perform the scientific review of Niacor-SR, and he committed numerous errors in his analysis of the package of information provided by Upsher to Schering on Niacor-SR. *See* CPRF 1.204.

1.216. During his work on ezetimibe, Mr. Audibert also learned about niacin. (18 Tr. 4098-99 (Audibert)). Mr. Audibert was fully aware of the available scientific knowledge regarding niacin, including: the fact that Niacin had been known for many years to have a positive effect on various lipid parameters that are important in cholesterol management, including lowering LDL, raising HDL, lowering triglycerides, and lowering Lp(a); the fact that niacin has been shown to be effective in long term morbidity studies; and the fact that niacin was incorporated into the NCEP treatment guidelines which recommend niacin as one of the agents for use in managing cholesterol. (18 Tr. 4098-99 (Audibert)). However, Mr. Audibert was also acutely aware of the fact that immediate release forms of niacin were limited by the side effect of flushing, and that sustained release niacin dietary supplements had been associated with substantial elevations in liver enzyme levels. (18 Tr. 4100 (Audibert)).

Complaint Counsel's Response to Finding No.1.216:

The proposed finding is not relevant. While Mr. Audibert possessed some knowledge about the cholesterol-lowering market, Mr. Audibert did not have the qualifications to perform the scientific review of Niacor-SR, and he committed numerous errors in his analysis of the package of information provided by Upsher to Schering on Niacor-SR. *See* CPRF 1.204.

d. Involvement in the Evaluation of Kos' Sustained Release Niacin Product in Spring 1997

1.217. In the spring of 1997, Mr. Audibert's responsibilities as the Senior Director of Global Marketing in charge of cardiovascular products, and his role as a member of Schering's Cardiovascular Licensing Group, led to his involvement in Schering's evaluation of a potential co-promotion opportunity for Niaspan, the sustained release niacin product developed by Kos Pharmaceuticals. (18 Tr. 4092, 4100-02 (Audibert)). Under a co-promotion arrangement, the two companies would jointly promote and market the product, and the two companies would both share the profits. (15 Tr. 3449-50 (Russo); 31 Tr. 7542 (Patel)).

Complaint Counsel's Response to Finding No.1.217:

The proposed finding is incomplete and misleading. Mr. Audibert had limited involvement in Schering's discussions with Kos regarding Niaspan. In fact, he only participated in one conference call with Kos in March 1997, and then dropped out of Schering's evaluation of Niaspan. Tr. at 15:3516-17 (Ray Russo) (confirming that Mr. Audibert only participated in one conference call which occurred in March 1997 (per CX 543)). In addition, when assessing Niacor-SR in June 1997, Mr. Audibert did not consult the Schering officials (e.g., Mr. Russo) involved in the full discussions with Kos regarding Niaspan. *See* CPF 425 (discussing Mr. Audibert's failure to consult Schering officials regarding Niaspan).

1.218. Following Schering's acquisition of Key in 1986, while Mr. Audibert went to work for Schering, the former President and CEO of Key, Michael Jaharis, founded Kos

Pharmaceuticals. (18 Tr. 4100-01 (Audibert); SPX 557, at FTC 0006127; SPX 605, at Kos 0054). Mr. Jaharis established Kos as a company that would employ sustained release technology in exactly the same way that it had been used at Key - to develop new products by overcoming known limitations of old compounds. (18 Tr. 4100-01 (Audibert); SPX 557, at FTC 0006127; SPX 605, at Kos 0054).

Complaint Counsel's Response to Finding No.1.218:

Complaint counsel has no specific response.

1.219. Kos selected niacin as the old compound it would transform through sustained release technology into a new and successful cholesterol lowering drug known as Niaspan. (SPX 605, at Kos 0054-55). The flushing side effect of immediate release niacin products is caused by spikes in the level of niacin in the blood when the drug is released into the system over a very short period of time. (16 Tr. 3627-28 (Horovitz)). By altering the release of niacin through a sustained release formulation, Kos hoped to minimize the flushing side effect that had limited the use of immediate release niacin products, without causing the significant elevations in liver enzymes associated with over-the-counter sustained release niacin products sold as dietary supplements. (SPX 605, at Kos 0076-77).

Complaint Counsel's Response to Finding No. 1.219:

Complaint counsel has no specific response.

1.220. In February 1997, Schering distributed to members of its Cardiovascular Licensing Group a confidential information package provided by Kos in connection with the

potential co-promotion of Niaspan by Schering. (18 Tr. 4102 (Audibert); SPX 924, at SP 002779). This package contained some overview information on Niaspan, a copy of its proposed labeling, and a published report of a clinical study conducted with Niaspan. (18 Tr. 4102 (Audibert); SPX 924, at SP 002779). The draft labeling included a chart reporting successful results from a study conducted with Niaspan in combination with a statin. (18 Tr. 4102-03 (Audibert); SPX 924, at SP 002792).

Complaint Counsel's Response to Finding No. 1.220:

Complaint counsel has no specific response.

1.221. [redacted] Mr. Russo was the Schering representative in charge of the U.S. territory in the negotiations with Kos regarding its Niaspan product, and Mr. Audibert was Mr. Russo's counterpart responsible for the territories outside the U.S. (18 Tr. 4109 (Audibert); 15 Tr. 3439, 3444 (Russo)).

Complaint Counsel's Response to Finding No.1.221:

The proposed finding is incomplete and misleading. Mr. Audibert had limited involvement in Schering's discussions with Kos regarding Niaspan. *See* CPRF 1.217.

1.222. As contemporaneous documents reflect, Schering was interested in Niaspan not only as a late stage product that could generate revenues in the near term, but also because it presented an opportunity for Schering to enter the cholesterol lowering market in advance of its

launch of ezetimibe. (18 Tr. 4108-11 (Audibert); 15 Tr. 3437-38 (Russo); SPX 21, at 002771). Marketing a sustained release niacin product had significant strategic value to Schering in that it would allow Schering to get to know the market and "earn its bumps and bruises" before its launch of ezetimibe. (18 Tr. 4108-11 (Audibert); SPX 21, at 002771). Because it was planning to launch the largest product in company history in a market in which it had no prior presence, it was important for Schering to first establish a presence in that market in order to build a knowledgeable sales force capable of maximizing the launch of ezetimibe. (18 Tr. 4108-11 (Audibert); 16 Tr. 3622-23, 3659-66 (Horovitz)). [redacted]

Complaint Counsel's Response to Finding No.1.222:

The proposed finding is not relevant. When asked to approve the Schering/Upsher settlement agreement, the Schering Board was not informed about ezetemibe as a justification for the Niacor-SR license. *See* CX 338 at SP 12 00268–70 ("Niacor-SR" portion of Schering Board presentation on the Schering/Upsher settlement agreement).

1.223. Mr. Audibert and Mr. Russo discussed the use of Niaspan to strategically bridge to ezetimibe, and that strategy is reflected in documents created during the discussions with Kos in the spring of 1997. (18 Tr. 4111 (Audibert); SPX 21; 15 Tr. 3437-38 (Russo); CX 576, at SP 020717). In fact, complaint counsel's fact witness from Kos, Mr. Patel, recorded this strategic value of Niaspan to Schering in notes of a meeting with Mr. Russo and others, and testified that

Schering representatives explained to him that this strategic value "was the very reason they wanted to talk to" Kos about Niaspan. (31 Tr. 7546-47 (Patel); ••••••••••••••••••••••••••••

Complaint Counsel's Response to Finding No.1.223:

The proposed finding is not relevant. *See* CPRF 1.222.

1.224. On March 13, 1997, Messrs. Audibert and Russo initiated a conference call with Kos to discuss Niaspan. (18 Tr. 4103-05 (Audibert); SPX 18, at SP 002776). During this conversation, Mr. Audibert initiated a discussion of Niaspan's side effect profile, including in particular, the success of its sustained release formulation in: (1) overcoming the flushing side effect of immediate release niacin, (2) without causing the significant elevations in liver enzymes reported with over-the-counter sustained release niacin formulations. (18 Tr. 4103-05 (Audibert); SPX 18, at SP 002776; 15 Tr. 3443-44 (Russo)).

Complaint Counsel's Response to Finding No.1.224:

The proposed finding is incomplete and misleading. Mr. Audibert had limited involvement in Schering's discussions with Kos regarding Niaspan. In fact, he only participated in one conference call with Kos in March 1997, and then dropped out of Schering's evaluation of Niaspan. Tr. at 15:3516-17 (Ray Russo) (confirming that Mr. Audibert only participated in one conference call which occurred in March 1997 (per CX 543)). In addition, when assessing Niacor-SR in June 1997, Mr. Audibert did not consult the Schering officials (e.g., Mr. Russo) involved in the full discussions with Kos regarding Niaspan. *See* CPF 425 (discussing Mr. Audibert's failure to consult Schering officials regarding Niaspan).

1.225. Kos advised Mr. Audibert that the rate of discontinuation due to flushing had been reduced to about 5% of patients. (18 Tr. 4103-05 (Audibert); SPX 18, at SP 002776). In addition, when Mr. Audibert raised the issue of liver enzyme elevations, the discussion turned to the well known study published by Dr. McKinney in the Journal of the American Medical Association. (18 Tr. 4103-05 (Audibert); SPX 18, at SP 002776). Kos advised Mr. Audibert that, in contrast to the McKinney study in which 50% of patients experienced liver enzyme elevations above five times the upper limit of normal, only about 1% of patients in clinical trials with Niaspan experienced elevations of three times the upper limit of normal. (18 Tr. 4103-05 (Audibert); SPX 18, at SP 002776). As compared to 1% of Niaspan patients with elevations above three times the upper limit of normal, Mr. Audibert's own review of the McKinney study revealed that 66% of patients in that study experienced liver enzyme elevations above three times the upper limit of normal. (18 Tr. 4104-05 (Audibert)).

Complaint Counsel's Response to Finding No.1.225:

The proposed finding is incomplete and misleading. Mr. Audibert had limited involvement in Schering's discussions with Kos regarding Niaspan. *See* CPRF 1.224.

1.226. During this conference call, Kos advised Mr. Audibert that it had filed an application for regulatory approval with the United States FDA, and that the FDA had completed its medical review of Niaspan and was discussing labeling with Kos. (18 Tr. 4105 (Audibert); SPX 18, at SP 002776). Because the FDA does not proceed to a discussion of labeling until it has determined a product is safe and effective, the fact that the FDA had completed its medical review and was discussing labeling for Niaspan indicated to Mr. Audibert that the FDA had

concluded that Niaspan's sustained release formulation was indeed safe and effective. (18 Tr. 4101-02, 4105-06 (Audibert)).

Complaint Counsel's Response to Finding No.1.226:

The proposed finding is incomplete and misleading. Mr. Audibert had limited involvement in Schering's discussions with Kos regarding Niaspan. *See* CPRF 1.224.

1.227. Commercial issues were also discussed during this conference call. First, Kos expressed an interest in focusing on co-promotion of the product in the United States, and indicated that promoting Niaspan outside the United States was not a priority for Kos. (18 Tr. 4106 (Audibert)). Second, Kos demanded that Niaspan be promoted by Schering in the "primary position." (18 Tr. 4106 (Audibert)). In other words, Kos wanted to have Niaspan promoted by Schering's sales representatives in the "primary position," meaning that it would be the first product a sales representative would discuss when visiting a doctor's office. (18 Tr. 4106 (Audibert)). Schering explained that it could not guarantee this because products such as Claritin would have to be detailed first during particular seasons, but Kos was very adamant that it wanted guaranteed primary positions and did not agree with Schering's view that secondary positioning would be sufficient. (18 Tr. 4106-07 (Audibert)). Mr. Audibert believed Kos was being totally irrational in their demands, and believed this would be very difficult for Schering to agree to. (18 Tr. 4106, 4111-12 (Audibert)). Mr. Audibert felt so strongly about this that, one year later, he expressly invoked these "unrealistic deal expectations" in a written recommendation to Mr. Lauda that Schering not pursue licensing of a different Kos product. (SPX 566, at SP 002986).

Complaint Counsel's Response to Finding No.1.227:

The proposed finding is contradicted by other evidence. [redacted]

1.228. On March 14, 1997, the day after his conference call with Kos, Mr. Audibert circulated a memorandum to Schering's European subsidiaries seeking feedback on their perceptions of the commercial potential for a sustained release niacin product in their countries. (18 Tr. 4107-08 (Audibert); CX 544, at FTC 0001405-1407). This type of memorandum is sometimes circulated when evaluating a product in international markets, and Mr. Audibert indicated that Schering's opportunity to market the product could begin by mid-1998. (18 Tr. 4107-08 (Audibert); CX 544, at FTC 0001405-1407; 16 Tr. 3789-91 (Horovitz)). Mr. Audibert explained that the product's sustained release formulation reduced the incidence of flushing seen with immediate release niacin without causing the "severe" liver toxicity caused by prior over-the-counter sustained release formulations. (CX 544, at FTC 0001405-1407). Mr. Audibert does not recall receiving any responses to this memorandum, but such was often the case where, as with the cholesterol lowering market, the subsidiaries had no experience in that therapeutic area. (18 Tr. 4108 (Audibert)). Mr. Russo recalls several responses from subsidiaries, some very favorable and others less favorable. (15 Tr. 3447 (Russo)).

Complaint Counsel's Response to Finding No.1.228:

The proposed finding is incomplete and misleading. The proposed finding refers to responses to CX 544, a questionnaire sent to Schering's overseas subsidiaries about

their interests in a sustained-release niacin product. Complaint counsel's first document request, specifically requested any responses to CX 544 in Schering's possession. *See* (Complaint Counsel's First Request for the Production of Documents and Things Specification 15 c.) Schering never produced any responses to CX 544.

The proposed finding also includes inadmissible hearsay. As complaint counsel did not receive any responses to the Schering questionnaire, the testimony cited to support the proposed finding cannot be used for the truth of the matter asserted. Mr. Russo's testimony of the substance of the responses from Schering's overseas subsidiaries is unsupported by any admissisble evidence and is unreliable. Furthermore, Mr. Audibert, the author of the survey, testified that he did not recall receiving any responses to the questionnaire. Tr. at 18:4107-08 (Audibert) (confirming this point). To the extent Mr. Russo's testimony can be credited that some subsidiaries gave unfavorable responses, this survey is inconsistent with Mr. Audibert's assumption in his commercial assessment of Niacor-SR that the product could be reimbursed in most major markets. CX 1044 at SP 16 00047 (Audibert's commercial assessment).

1.229. In late-March or early-April 1997, Mr. Audibert stopped participating as the international contact in the negotiations with Kos. (18 Tr. 4111-12 (Audibert)). Kos had indicated that it was focused on co-promotion of the product in the United States and that promoting Niaspan outside the United States was not a priority. (18 Tr. 4106 (Audibert)). Mr. Audibert terminated his involvement, in part, because he believed Kos' demands were "totally irrational" and he felt that it was unlikely that the parties would reach an agreement. (18 Tr.

4111-12 (Audibert)). Although Schering and Kos continued to discuss potential co-promotion of Niaspan in the United States, including a meeting held in Miami in April 1997, Mr. Audibert did not continue to be involved in those discussions other than through occasional conversations with Mr. Russo. (15 Tr. 3516-17 (Russo)).

Complaint Counsel's Response to Finding No.1.229:

The proposed finding is incomplete and therefore misleading. Prior to the April 9, 1997 meeting, Kos still considered a non-U.S. licensing arrangement as a possibility with Schering. Kos executives shared their plans for Niaspan in Europe with Schering. Schering's contemporaneous notes of the March 13, 1997 conference call reflect this. *See* SPX 18 at SP 002776-77 (Schering contact summary noting that Kos discussed plans to obtain European registration for Niaspan). While Kos focused its efforts on a U.S. launch first, it did not abandon its plans to launch Niaspan in Europe.

It was during the April 9, 1997 meeting that Schering suggested limiting the discussions to the United States, and Kos agreed. SPX 112 at SP 002748 (Schering contact report of April 9, 1997 meeting at Kos headquarters noting, "we suggested that . . . we concentrate on this territory first and leave ex-U.S. discussions for later. Bell did not have a problem with this.").

3. Mr. Audibert's Evaluation of the Niacor-SR Opportunity in June 1997

a. Mr. Lauda's Request That Mr. Audibert Perform an Evaluation of Niacor-SR

1.230. In June 1997, Mr. Lauda contacted Mr. Audibert regarding an evaluation of Upsher's Niacor-SR product. (19 Tr. 4344 (Lauda); 18 Tr. 4112 (Audibert)). Mr. Lauda did not know that this licensing opportunity was connected to patent litigation. (19 Tr. 4344, 4376-77 (Lauda); 8 Tr. 1627-28 (Lauda IH)). Mr. Lauda did not tell Mr. Audibert that this license opportunity had any connection with any patent litigation or settlement. (18 Tr. 4113 (Audibert)). Mr. Lauda asked Mr. Audibert to perform an assessment of Upsher's Niacor-SR product in territories outside the United States, Canada and Mexico ("worldwide Ex-NAFTA"). (18 Tr. 4112 (Audibert); 19 Tr. 4344 (Lauda)).

Complaint Counsel's Response to Finding No. 1.230:

The proposed finding is contradicted by other evidence. Mr. Audibert was informed about the terms of the patent settlement with Upsher that purportedly including payment for the Niacor-SR license. Mr. Wasserstein (a Schering in-house lawyer who participated in the settlement negotiations with Upsher) told Mr. Audibert what the terms of the patent settlement with Upsher were prior to completing Schering's review of Niacor-SR. CX 1532 at 17:13-18:22 (Wasserstein dep) (noting that he informed Mr. Audibert about the terms).

The proposed finding is incomplete and misleading. Mr. Audibert did not perform an "evaluation" of the Niacor-SR product, but rather conducted a limited "commercial assessment." Mr. Audibert described his assignment as "[g]enerat[ing] a

sales forecast." CX 1484 at 105:18–21 (Audibert dep); Tr. at 7:1367-68 (Levy) (describing Schering's analysis of the Niacor-SR as constituting only "about a third of the way through the preliminary evaluation" of full due diligence); CPF 417-419 (describing the limited scope of Mr. Audibert's "commercial assessment").

1.231. Mr. Lauda told Mr. Audibert that a packet of information about the product would be delivered, and that Mr. Kapur was available to answer any questions that he may have about the product. (19 Tr. 4404 (Lauda); 18 Tr. 4113 (Audibert)). Although Mr. Audibert does not recall Mr. Lauda specifying a deadline for this evaluation, he knew from past experiences with similar requests that Lauda usually wanted the assessment to be completed quickly. (18 Tr. 4112-13 (Audibert)).

Complaint Counsel's Response to Finding No. 1.231:

The proposed finding is incomplete. While Mr. Audibert was informed that Mr. Kapur was available to answer questions regarding Niacor-SR, Mr. Audibert never raised any such questions with Mr. Kapur, anyone else at Schering, or anyone at Upsher. CPF 424 (Mr. Audibert never spoke with anyone at Upsher regarding Niacor-SR during his review of the drug product); CPF 425 (Mr. Audibert never spoke with the individuals at Schering who had just completed an evaluation of another sustained-release niacin product). CX 1484 at 103:8-14 (Audibert dep) (noting that he had no conversations with Mr. Kapur regarding Niacor-SR).

1.232. Mr. Audibert began his review when he received the data package regarding Niacor-SR on June 12, 1997. (18 Tr. 4113 (Audibert); 19 Tr. 4344 (Lauda)). The package included results from the two phase III pivotal clinical trials conducted by Upsher to obtain registration of Niacor-SR, referred to by their protocol numbers 920115 and 900221. (18 Tr. 4113-15, 4171 (Audibert); CX 1042; 17 Tr. 3907-08 (Halvorsen)). In addition to the information regarding the Niacor-SR clinical trials, the package also included information regarding two draft protocols for phase III-B studies Upsher was planning to conduct once the NDA was filed. (18 Tr. 4113-15 (Audibert); SPX 71; SPX 72; 17 Tr. 4025 (Halvorsen)). Phase III-B studies are studies conducted not as part of the initial registration of a product, but to support subsequent labeling revisions. (18 Tr. 4114 (Audibert)). One protocol would evaluate the use of Niacor-SR in combination with a statin, and the other would evaluate Niacor-SR when administered as a single evening dose. (18 Tr. 4115 (Audibert); SPX 71; SPX 72).

Complaint Counsel's Response to Finding No. 1.232:

The proposed finding is contradicted by other the evidence. Mr. Audibert could not recall when he began his review of Niacor-SR or whether he worked on it on any specific day during the period he conducted his review. Tr. at 18:4161-62 (Audibert) (noting that "I don't remember which date" he was first assigned to work on Niacor-SR, but confirming that he did not start his work until after June 12, 1997); Tr. at 18:4164-65 (Audibert) ("I cannot remember specifically which days during that time period I worked on the product"); CPF 421-423 (discussing Mr. Audibert's inability to recall specifically when he worked on Niacor-SR, and Mr. Audibert's testimony that he may have worked a bit more than a day on his commercial assessment of Niacor-SR).

The proposed finding is incomplete and misleading. Mr. Audibert could not have received the "results" of Upsher's two phase III pivotal clinical trials, as the second trial was not yet complete. CX 1042 at SP 16 00079 (the "package" of information received from Upsher noting that the "projected" completion date for the second pivotal trial (Protocol 900221) was June 1997). In addition, the "phase III-B" studies discussed in the proposed findings were merely planned studies. Mr. Audibert never inquired with Upsher as to the status of these studies or whether they would ever be undertaken. *See* CPF 464 (discussing Mr. Audibert's failure to confirm or inquire about the status of these "draft" protocols).

b. Mr. Audibert's Evaluation of the Market Opportunity for Niacor-SR

1.233. Mr. Audibert conducted an evaluation of Niacor-SR using the same approach he had used in conducting prior assessments. (18 Tr. 4115 (Audibert)).

Complaint Counsel's Response to Finding No. 1.233:

The proposed finding is incomplete and misleading. Mr. Audibert did not perform an "evaluation" of the Niacor-SR product, but rather conducted a limited "commercial assessment." *See* CPRF 1.230. In addition, Mr. Audibert had not conducted "prior assessments" of drug products, but rather conducted limited "commercial assessments" of other drug products. His personal involvement in the review of those other drugs products did not include the customary due diligence steps for review of a pharmaceutical licensing opportunity. CPF 447 (discussing how Mr.

Audibert consulted other specialists at Schering for guidance on regulatory, clinical and toxicology issues raised in completing a commercial assessment); [redacted]; CPF 450-455 (noting Mr. Audibert's lack of experience regarding review of regulatory issues).

1.234. First, Mr. Audibert would conduct an evaluation of the particular therapeutic area in which the product would compete. (18 Tr. 4115-16 (Audibert)). In this case, Mr. Audibert was already intimately familiar with the cholesterol lowering market as a result of his detailed evaluation of that market in connection with ezetimibe. (18 Tr. 4094-98, 4115-16 (Audibert)).

Complaint Counsel's Response to Finding No. 1.234:

Complaint counsel has no specific response.

1.235. Second, Mr. Audibert would determine whether there existed "proof of principle" evidencing the successful use of this type of drug in the treatment of the particular conditions for which the product was intended. (18 Tr. 4116 (Audibert)). Mr. Audibert already knew that niacin had long been recognized as having a positive effect in the treatment of various lipid parameters and, in fact, had been incorporated into the treatment guidelines of the NIH's National Cholesterol Education Program. (18 Tr. 4098-4100, 4116 (Audibert)). In addition, Mr. Audibert knew from his discussions with Kos that the FDA was on the verge of approving a sustained release niacin product for the exact same indication that Niacor-SR was pursuing. (18 Tr. 4101-05, 4116 (Audibert); 11 Tr. 2454 (Audibert Dep.)).

Complaint Counsel's Response to Finding No. 1.235:

The proposed finding is incomplete and misleading. First, while Schering did know that niacin drugs had a recognized positive effect on lipid parameters, Schering also was well aware of the numerous adverse side-effects (including flushing and liver toxicity) that raised regulatory concerns and marketing concerns regarding niacin drugs. Schering's own panel of ten cholesterol-management experts reported to Schering in April 1997 that they "avoid use of sustained release preparations . . . because of diminished efficacy and concern regarding liver toxicity." CX 576 at SP 020709 (Decker report discussion of "conclusions and recommendations" at paragraphs 1 and 2); *see generally* CPF 596-619 (describing Schering's knowledge of the problems and side-effects associated with sustained-release niacin drugs).

Second, while Schering did learn from its discussions with Kos that the FDA was on the verge of approving Kos' sustained-release niacin drug, Schering also learned from its discussions with Kos that Kos had completed 14 pharmacokinetic studies and was in the process of patenting its dosing regimen for Niaspan. Through additional discussions with Kos, Schering also knew that "the most challenging aspect of [Niaspan's] development was niacin's pharmacokinetics" and that the 14 pharmacokinetic studies Kos had completed for regulatory filing came "at a cost of about $4 million." CX 1047 at SP 002748 (summary of April 1997 conference call held between Schering and Kos officials concerning the Niaspan product opportunity). Kos further indicated during a meeting with Schering that Niaspan's improved safety profile was "due to the release rate they provide and to the fact that the patient is introduced to the product through a slow

upward titration." CX 543 at SP 002776 (summary of meeting prepared by Schering licensing official); *see generally* CPF 612-613 (discussing what Schering learned from its meetings with Kos during the first half of 1997).

1.236. Third, Mr. Audibert would determine whether there was an unmet need in that particular therapeutic area which this type of product would fill. (18 Tr. 4116-17 (Audibert)). Based on his intimate familiarity with the cholesterol lowering market in June 1997, Mr. Audibert concluded that a sustained release niacin product that minimized the flushing associated with immediate release formulations without causing the high incidence of liver enzyme elevations associated with prior sustained release niacin formulations would fill such an unmet need, and therefore could be a commercially successful product in that market. (18 Tr. 4116-17 (Audibert)). Similarly, Dr. Horovitz testified that he had concluded that a market opportunity existed in June 1997 for a sustained release niacin product as both monotherapy and combination therapy, and that this conclusion is confirmed by the very positive reaction of the investment community to the initial public offering of Kos on the basis of Niaspan. (16 Tr. 3621-22, 3639-40 (Horovitz)).

Complaint Counsel's Response to Finding No. 1.236:

The proposed finding is incomplete and misleading. The proposed finding states that Mr. Audibert "concluded" certain things regarding "a sustained release niacin product." First, Mr. Audibert testified generally regarding a "sustained release niacin product," not specifically regarding Niacor-SR. Tr. at 18:4116-17 (Audibert). Second, his "conclusions" regarding "a sustained release niacin product" merely hypothesized that

"if one had a sustained release niacin that had a much better safety profile in the area of both flushing and itching as well as elevated liver enzymes, that product could be a commercially successful product in the marketplace" (emphasis added). *Id.*

c. Mr. Audibert's Evaluation of Niacor-SR's Product Profile

1.237. Having identified an unmet need in the market for this type of product, Mr. Audibert conducted an evaluation of Niacor-SR to determine whether its product profile satisfied that market opportunity. (18 Tr. 4117 (Audibert)). The 52-page data package provided by Upsher to Schering contained highly detailed summaries of the results of Niacor-SR's phase III pivotal trials, including all the information that Mr. Audibert required to conduct his evaluation of Niacor-SR's clinical profile.

Complaint Counsel's Response to Finding No. 1.237:

The proposed finding is incomplete and misleading. First, Mr. Audibert did not perform an "evaluation" of the Niacor-SR product, but rather conducted a limited "commercial assessment." *See* CPRF 1.230. Second, Mr. Audibert could not have received the "results" of Upsher's two phase III pivotal clinical trials, as the second trial was not yet complete at the time of Mr. Audibert's commercial assessment. CX 1042 at SP 16 00079 (the "package" of information received from Upsher noting that the "projected" completion date for the second pivotal trial (Protocol 900221) was June 1997).

The proposed finding is incomplete. While the "52-page data package" provided by Upsher to Schering did include the information referenced in the proposed finding,

that information was not reviewed by anyone at Schering with the requisite training or experience to evaluate that data. Mr. Audibert did not have the qualifications to do so. *See* CPF 446-448 (describing Mr. Audibert's general qualifications for conducting due diligence). In addition, Mr. Audibert committed numerous errors in his analysis of the package of information provided by Upsher. *See e.g.*, Tr. at 18:4197 (Audibert) (referencing his description of Niacor-SR in the commercial assessment: "[a]t the time I wrote this, this statement is incorrect in the sense that the initial registration program was with twice-a-day dosing"); *see generally* CPF 456-484A (describing various errors made by Mr. Audibert in reviewing Niacor-SR's patent status, administration and dosing schedule, and regulatory status).

In addition, this "52-page data package" was not reviewed by anyone in Schering's research and development department (SPRI). Schering Second Admission No. 335 (admitting that the "Schering-Plough Research Institute has never conducted a review of the safety or efficacy or Niacor-SR"); CX 1484 at 105:3-9 (Audibert dep) (confirming that he never spoke with anyone in Schering's research and development department (SPRI) during his evaluation, because he did not see a need to); [redacted] This was contrary to Schering's typical in-licensing practice, where in all cases a product has to have a "safety review" by SPRI. Tr. at 19:4387-88 (Lauda) (confirming this point and noting that "I don't know if [Mr. Audibert] actually had [a safety review] done"); *see generally* CPF 428-429 (discussing absence of research and development review for

Niacor-SR).

The proposed finding is not in evidence. The second line of the proposed finding provides no citation for this statement. There is no evidence to support the proposition that "summaries" provided by Upsher to Schering were "highly detailed summaries." There is no evidence to support the proposition that the "data package" "includ[ed] all the information that Mr. Audibert required." In contrast, complaint counsel's pharmaceutical industry expert described the data provided in this information package concerning liver toxicity as "scant." Tr. at 7:1317 (Levy) (further noting that this data suggested the Niacor-SR was hepatotoxic).

1.238. Reported results of efficacy included: average efficacy at each dose in altering LDL, HDL, TGs, Lp(a) and total cholesterol (CX 1042, at SP 16 00082-84, 00097-99); categorical efficacy at each dose, broken down by age, broken down by sex, and broken down by weight and sex (CX 1042, at SP 16 00084, 000109-110).

Complaint Counsel's Response to Finding No. 1.238:

The proposed finding is incomplete. While the "52-page data package" provided by Upsher to Schering did include the information referenced in the proposed finding, that information was not reviewed by anyone at Schering with the requisite training or experience to evaluate that data. Mr. Audibert did not have the qualifications to do so. *See* CPRF 1.237 (second paragraph). In addition, this "52-page data package" was not reviewed by anyone in Schering's research and development department (SPRI), contrary to Schering's typical in-licensing practice, where in all cases a product has to have a

"safety review" by SPRI. *See* CPRF 1.237 (third paragraph).

1.239. Reported results of patient demographics, disposition, dose reductions and exposure to study medication included: patient demographics broken at each dose by age, sex, weight, and race (CX 1042, at SP 00095); patient disposition at each dose broken down by category (CX 1042, at SP 00085, 00095); overall incidence of dose reductions at each dose, for every 3-week period, as well as average over the course of the entire study (CX 1042, at SP 00086); the extend of patients' exposure to study medication at each dose (CX 1042, at SP 16 00086).

Complaint Counsel's Response to Finding No. 1.239:

The proposed finding is incomplete. *See* CPRF 1.238 (discussing Mr. Audibert's lack of training and experience requisite to conduct due diligence, and the absence of any review of this data package by Schering's research and development department (SPRI)).

1.240. Reported results of adverse events, such as flushing, included: the incidence of adverse events at each dose, broken down by body group, and further broken down by specific type (CX 1042, at SP 16 00087); the overall incidence of flushing at each dose (CX 1042, at SP 16 00088); flushing categorized by severity at each dose (CX 1042, at SP 16 00088); the incidence of flushing at each dose, for every 3-week period, as well as average over the course of the entire study (CX 1042, at SP 16 00088); the total number of flushing occurrences, and the average number of occurrences per patient, at each dose (CX 1042, at SP 16 00089); the percentage of patients with flushing categorized by the number of occurrences of flushing for

each patient at each dose (CX 1042, at SP 00089); overall incidence of discontinuation due to adverse events at each dose (CX 1042, at SP 16 00090); the rate of discontinuation, broken down by adverse event, at each dose (CX 1042, at SP 16 00090).

Complaint Counsel's Response to Finding No. 1.240:

The proposed finding is incomplete. *See* CPRF 1.238 (discussing Mr. Audibert's lack of training and experience requisite to conduct due diligence, and the absence of any review of this data package by Schering's research and development department (SPRI)).

1.241. Reported results of adverse events related to liver enzyme elevations included: overall incidence of liver enzyme elevations of 1.5 times the upper limit of normal, broken down by ALT and AST, at each dose (CX 1042, at SP 16 00091); incidence of liver enzyme elevations, broken down by ALT and AST, at each dose, categorized by range of elevations above the upper limit of normal, including 1.5-2.0, 2.0-3.0, 3.0-5.0, above 5.0, and above 3.0 (CX 1042, at SP 16 00092); incidence of liver enzyme elevations above three times the upper limit of normal on single or successive occasions at each dose, broken down by ALT or AST or both ALT and AST, including what percentage of patients at each dose were reported as having other factors contributing to those elevations (CX 1042, at SP 16 00092); incidence of liver enzyme elevations above three times the upper limit of normal at each dose, broken down by dose of study medication taken at the time of the elevation (CX 1042, at SP 16 00093); resolution upon discontinuation of study medication of liver enzyme elevations above three times the upper limit of normal at each dose, including length of time for elevations to return to normal (CX 1042, at SP 16 00093); incidence of liver enzyme elevations above three times the upper limit of normal

at each dose, broken down by sex and by dose at time of elevation (CX 1042, at SP 16 00094).

Complaint Counsel's Response to Finding No. 1.241:

The proposed finding is incomplete. *See* CPRF 1.238 (discussing Mr. Audibert's lack of training and experience requisite to conduct due diligence, and the absence of any review of this data package by Schering's research and development department (SPRI)).

(1) Efficacy

1.242. The clinical data from Upsher's pivotal trials confirmed to Mr. Audibert that Niacor-SR was effective, and that it exceeded the regulatory hurdle of an average 15% reduction in LDL cholesterol. (18 Tr. 4123 (Audibert); CX 1042; CX 1484 at 119:6-25, 120:1-25, 121:1-25 (Audibert Dep.)). Of the three doses tested in the Niacor-SR pivotal trials, Niacor-SR achieved an average LDL reduction of greater than 15% at the 1500mg and 2000mg doses. (16 Tr. 3642-43 (Horovitz)). Although also effective in some patients, the 1000mg dose did not achieve an LDL reduction of 15% when averaged in patients taking that dose. (16 Tr. 3642-43 (Horovitz)). Because physician's would start patients off at doses of 1000mg and, in those patients in which the drug was effective, would not increase the dosage further (35 Tr. 8325 (Levy)), the fact that the 1000mg dose of Niacor-SR was effective in some patients means that fewer patients would ultimately proceed to higher doses. In addition to lowering LDL levels, Niacor-SR was also effective in raising HDL, lowering triglycerides and reducing Lp(a). (16 Tr. 3642-43 (Horovitz)). The results of the pivotal trials indicated that, as between the two doses, the 2000mg dose was only slightly more effective than the 1500mg dose. (16 Tr. 3642-43 (Horovitz)).

Complaint Counsel's Response to Finding No. 1.242:

The proposed finding is incomplete. *See* CPRF 1.238 (discussing Mr. Audibert's lack of training and experience requisite to conduct due diligence, and the absence of any review of this data package by Schering's research and development department (SPRI)).

1.243. Complaint counsel's licensing expert concedes that the efficacy of niacin in the treatment of high cholesterol was well recognized by the pharmaceutical industry, doctors, and cardiologists. ********** Complaint counsel's licensing expert also concedes that the efficacy of Niacor-SR is similar to the efficacy of Niaspan, and that, despite poor initial sales, Niaspan has rebounded to achieve annual sales of approximately $100 million in 2001. (7 Tr. 1315 (Levy); 9 Tr. 1899 (Levy); SPX 1205).

Complaint Counsel's Response to Finding No. 1.243:

The proposed finding is incomplete and misleading. While Dr. Levy testified that there were recognized benefits for niacin drugs (Tr. at 9:1763 (Levy)), he also testified that a major reason for niacin's trivial share of the worldwide cholesterol market is the array of intolerable side effects associated with niacin therapy that affect potential compliance. Tr. at 7:1313-14 (Levy); *see* CPF 277-279 (providing Dr. Levy's opinions on the side effects associated with niacin drugs).

(2) Flushing

1.244. The clinical data from Upsher's pivotal trials illustrated to Mr. Audibert that Niacor-SR had significantly reduced the incidence of flushing as compared to immediate release

niacin. (18 Tr. 4117-19 (Audibert); CX 1042, SP 16 00088-00089). As compared to immediate release niacin, Niacor-SR reduced the number of flushing occurrences more than four-fold. (18 Tr. 4118-19 (Audibert); CX 1042, at SP 16 00089; 16 Tr. 3645-46 (Horovitz)). Similarly, Dr. Horovitz performed an evaluation of Niacor-SR and concluded that Niacor-SR had significantly reduced the incidence of flushing as compared to immediate release niacin. (16 Tr. 3645-46 (Horovitz)). Complaint counsel's licensing expert concedes that the incidence and severity of flushing with Niacor-SR is very similar to that of Niaspan (9 Tr. 1898-1900 (Levy); SPX 220, at SP 002693; USX 535, at USL 11513), and that, despite poor initial sales, Niaspan has rebounded to achieve annual sales of approximately $100 million in 2001. (9 Tr. 1898-1900 (Levy); SPX 1205).

Complaint Counsel's Response to Finding No. 1.244:

The proposed finding is incomplete. *See* CPRF 1.238 (discussing Mr. Audibert's lack of training and experience requisite to conduct due diligence, and the absence of any review of this data package by Schering's research and development department (SPRI)).

The proposed finding is incomplete and misleading. While Dr. Levy stated that the incidence of flushing between Niacor-SR and Niaspan was comparable, he further explained: "To show you how bad the flushing is, Niaspan] still caused flushing in 88 percent of patients. So, that's better than 98 percent, but . . . it still had plenty of problems." Tr. at 7:1316 (Levy); CPF 278 (discussing how flushing affects patients and patient compliance).

(3) Liver Enzyme Elevations

1.245. The clinical data from Upsher's pivotal trials illustrated to Mr. Audibert that Niacor-SR caused a very low incidence of liver enzyme elevations. (18 Tr. 4119-20 (Audibert); CX 1484 at 82:20-83:4 (Audibert IH)). In evaluating this information, Mr. Audibert focused on the percentage of patients who experienced successive liver enzyme elevations above three time the upper limit of normal, which is the same criterion that clinicians and regulators use to evaluate cholesterol lowering drugs. (18 Tr. 4120 (Audibert); 16 Tr. 3632-35 (Horovitz)).

Complaint Counsel's Response to Finding No. 1.245:

The proposed finding is contrary to more reliable evidence. Mr. Audibert did not have a level of liver enzyme elevations in mind when he looked at Upsher's clinical data. According to his investigational hearing transcript (from September 21, 2000) as opposed to his trial testimony (nearly a year and half later on February 19, 2002), Mr. Audibert stated that he "did not have a specific number in mind" when looking at data for people who were "prematurely discontinued" from Upsher's clinical trial due to potential liver damage. CX 1483 at 74:6-12 (Audibert IH).

The proposed finding is incomplete. *See* CPRF 1.238 (discussing Mr. Audibert's lack of training and experience requisite to conduct due diligence, and the absence of any review of this data package by Schering's research and development department (SPRD)).

1.246. Mr. Audibert's evaluation of the results of the Niacor-SR pivotal trials revealed that only 4% of patients taking the highest doses of Niacor-SR experienced successive liver enzyme elevations above three times the upper limit of normal. (18 Tr. 4120-21 (Audibert); CX 1042, at SP 16 00092; 16 Tr. 3649 (Horovitz)). Mr. Audibert concluded that the incidence of

liver enzyme elevations in the Niacor-SR pivotal trials was consistent with that seen with cholesterol lowering drugs generally, and was substantially lower than the 66% incidence associated with prior sustained release niacin products. (18 Tr. 4104-05, 4121, 4124 (Audibert); 16 Tr. 3650-51 (Horovitz)). In his written commercial assessment, Mr. Audibert reported that the fact that some patients experienced liver enzyme elevations with Niacor-SR was consistent with the known side effect profile of the statins. (SPX 2, at SP 16 00044).

Complaint Counsel's Response to Finding No. 1.246:

The proposed finding is contrary to more reliable evidence. Mr. Audibert did not conclude that the incidence of liver enzymes was substantially lower than the 66% incidence associated with prior sustained release niacin product. He did not have a level of liver enzyme elevations in mind when he looked at Upsher's clinical data. *See* CPRF 1.245.

The proposed finding is incomplete. *See* CPRF 1.238 (discussing Mr. Audibert's lack of training and experience requisite to conduct due diligence, and the absence of any review of this data package by Schering's research and development department (SPRD)).

1.247. Mr. Audibert's evaluation of the results of the Niacor-SR pivotal trials also revealed that the liver enzyme elevations experienced in that small percentage of patients returned to normal when the drug was discontinued. (18 Tr. 4121-22 (Audibert); CX 1042, at SP 16 00093; 16 Tr. 3649-50 (Horovitz)). The reversibility of these liver enzyme elevations was consistent with what was known about niacin's profile generally, as well as the profile of all other cholesterol lowering drugs. (16 Tr. 3652 (Horovitz)). The fact that these elevations were

reversible was important to Mr. Audibert because it meant that, as with the elevations that occur with all cholesterol lowering drugs, physicians could simply manage patients' therapy through periodic monitoring of patients' liver enzyme levels. (18 Tr. 4122 (Audibert); 16 Tr. 3631-34 (Horovitz)). Dr. Levy conceded that this is exactly the same method used by physicians to address the liver enzyme elevations that are known to occur with statins, and that this procedure is mandated in the labeling for the statins. (9 Tr. 1812-13 (Levy)).

Complaint Counsel's Response to Finding No. 1.247:

The proposed finding is incomplete. *See* CPRF 1.238 (discussing Mr. Audibert's lack of training and experience requisite to conduct due diligence, and the absence of any review of this data package by Schering's research and development department (SPRI)).

The proposed finding is incomplete and misleading. Dr. Levy did not make the concession noted in the proposed finding (at the transcript pages cited nor at any time during this matter). He did not testify that through periodic monitoring of liver enzyme levels that physicians could address liver enzyme elevation levels for Niacor-SR as the "same method" used with the statins. In addition, he noted that with regard to the statins, only the "occasional patient may have a problem" with liver function studies. Tr. at 9:1812 (Levy).

1.248. Dr. Horovitz agrees with Mr. Audibert's conclusions regarding the liver enzyme elevations seen with Niacor-SR, and explained that they were in the same "ballpark" as those seen with other highly successful cholesterol lowering drugs. (16 Tr. 3651 (Horovitz)). For example, the market dominating statins are known to show successive liver enzyme elevations of

three times the upper limit of normal in as many as 5% of patients. (16 Tr. 3651 (Horovitz); 9 Tr. 1812-13 (Levy); SPX 1209). During cross-examination, Dr. Levy agreed that these levels of elevations do occur, but testified that because the statins have superior efficacy, certain levels of liver enzyme elevations that may be acceptable with the statins may not be acceptable for other classes of cholesterol lowering drugs like niacin or fibrates. (9 Tr. 1813-16 (Levy)).

Complaint Counsel's Response to Finding No. 1.248:

The proposed finding is incomplete and misleading. Dr. Levy testified regarding the statins that only the "occasional patient may have a problem" with liver function studies. Tr. at 9:1812 (Levy). He further testified that the type of potential liver toxicity that had been seen with niacin compounds was not merely a trivial elevation, it was "destructive liver disease." In comparison, the statins had been shown through use in millions of patients to have an exceedingly low incidence of serious liver problems. Tr. at 10:2142 (Levy).

1.249. Tricor, a product belonging to the fibrate class of cholesterol lowering drugs, is associated with elevations of three times the upper limit of normal in as many as 13% of patients and with successive elevations in more than 5% of patients. (16 Tr. 3651-52 (Horovitz); SPX 1208). Dr. Levy conceded that despite these liver enzyme elevations, Tricor achieved sales in the United States of more than $270 million between January and November of 2001. (9 Tr. 1821 (Levy); SPX 1205). Dr. Levy also conceded that, like the statins, physicians address these liver enzyme elevations by simply monitoring patients' liver enzyme levels, and that this procedure is mandated in Tricor's labeling. (9 Tr. 1819-20 (Levy)).

Complaint Counsel's Response to Finding No. 1.249:

The proposed finding is incomplete and misleading. Dr. Levy testified regarding the statins that only the "occasional patient may have a problem" with liver function studies. Tr. at 9:1812 (Levy). He further testified that the type of potential liver toxicity that had been seen with niacin compounds was not merely a trivial elevation, it was "destructive liver disease." In comparison, the statins had been shown through use in millions of patients to have an exceedingly low incidence of serious liver problems. Tr. at 10:2142 (Levy).

(4) Mr. Audibert's Conclusions Regarding the Profile of Niacor-SR

1.250. Based on his evaluation of the results of the pivotal trials, Mr. Audibert concluded that Niacor-SR was a safe and effective drug that satisfied the unmet need in the cholesterol lowering market that he identified in June 1997. (11 Tr. 4123-24 (Audibert Dep.)). Mr. Audibert had seen Niaspan as the "proof of concept," and he now concluded based on the results of Upsher's clinical trials that Upsher had also used sustained release technology to develop a safe and effective niacin product. (11 Tr. 2453-54 (Audibert Dep.); [redacted] Based on his review of the results of the Niacor-SR pivotal trials, Dr. Horovitz agrees with Mr. Audibert's conclusions. (16 Tr. 3658 (Horovitz)).

Complaint Counsel's Response to Finding No. 1.250:

The proposed finding is incomplete. *See* CPRF 1.238 (discussing Mr. Audibert's lack of training and experience requisite to conduct due diligence, and the absence of any review of this data package by Schering's research and development department (SPRI)).

(5) Dr. Levy's Criticism of Mr. Audibert's Conclusions Regarding the Clinical Profile of Niacor-SR

(a) Dr. Levy's Qualifications

1.251. Dr. Levy has held only two jobs in the pharmaceutical industry, one at Abbott and the other at Fujisawa. (9 Tr. 1866 (Levy)). His experience as an employee of a pharmaceutical company adds up to approximately 4 years, three of which were with Abbott in the early-1980's. (9 Tr. 1868 (Levy)). Dr. Levy admits that the only other position he ever held with a pharmaceutical company was with Fujisawa in the early-1990's, a company with annual sales of only $250 million. (9 Tr. 1868, 1931 (Levy)). By contrast, Mr. Audibert has been employed by pharmaceutical companies for approximately 20 years. (9 Tr. 1869 (Levy)).

Complaint Counsel's Response to Finding No. 1.251:

The proposed finding is contrary to the evidence and misleading. Dr. Levy has held multiple positions with various pharmaceutical companies over a period of more than two decades. His positions and responsibilities included the following:

- Abbott Laboratories (vice president of pharmaceutical research – involved in reviewing dozens of in-licensing opportunities);
- CoreTechs (president – consulting to the pharmaceutical industry, and assisting developing companies (including healthcare) in evaluating and developing their technologies);
- Erbamont Pharmaceutical company (consultant to Erbamont over five year period – responsible for overseeing worldwide research and development operations, including division in Italy);
- Ligand Pharmaceuticals (consultant to and served on board of directors – involved in Ligand review of numerous transactions over more than a decade including out-licensing and in-licensing of pharmaceutical research and products);

- LyphoMed/Fujisawa (consultant to this company for nearly a decade involved in LyphoMed transition from generic pharmaceutical company to branded company); and

- Fujisawa (president of Japanese pharmaceutical company's U.S. division – responsible for entire division's business including all business development and in-licensing activities). Tr. at 7:1293-1301 (Levy) (describing his positions and responsibilities with these companies).

In addition, Dr. Levy has received the following degrees and training: Yale University (B.A./B.S.), Columbia University (M.D.), University of Colorado (medical internship), Massachusetts General Hospital (medical internship), National Institutes of Health (two year research associate position in virology and immunology), Duke University (neurosurgery residency), Duke University (Ph.D. in immunology, and tenured professor). Tr. at 7:1287-90 (Levy).

Dr. Levy has published over 130 articles, including articles on clinical research, designing research projects, and assessing clinical data. Tr. at 7:1290-91 (Levy).

Dr. Levy has held positions on the boards of directors and scientific advisory boards of numerous pharmaceutical companies including: Zonagen Corporation, Targeted Genetics Corporation, and First Horizon Pharmaceutical Company. Tr. at 1302-03 (Levy).

1.252. When asked during cross-examination to explain his personal experience "transforming old, known compounds with undesirable side effects into new, sustained release formats," Dr. Levy identified his experience on the board of directors of a corporation that developed a product known as Vasomax. (9 Tr. 1863-66 (Levy)). In fact, Vasomax is not a

sustained release product at all but, quite the opposite, is an immediate release product - a fact that Dr. Levy was forced to concede when confronted with documentation regarding that drug. ********** Dr. Levy's difficulty in recalling the most simple detail about Vasomax relates, in part, to the fact that he did not even become a member of that company's board of directors until after that drug was licensed to Schering – at which point, according to Dr. Levy, it was already in phase III trials and just months from filing with the FDA. (7 Tr. 1386-87;**********
****

Complaint Counsel's Response to Finding No. 1.252:

Complaint counsel has no specific response.

1.253. In contrast to Dr. Levy's void of experience in this area, Mr. Audibert has had substantial experience working in the pharmaceutical industry developing successful new drugs from old compounds through the use of sustained release technology. (18 Tr. 4082-89 (Audibert)). In fact, Mr. Audibert's responsibilities have included his representation of Key Pharmaceuticals as an expert on such products at meetings with various outside medical groups. (18 Tr. 4088 (Audibert)).

Complaint Counsel's Response to Finding No. 1.253:

The proposed finding is incomplete. Mr. Audibert's own reference to himself as an "expert" is contrary to his role in the "meetings" discussed in this finding. For example, at one meeting held by Schering in Europe, various other Schering officials made presentations concerning cholesterol-lowering drugs. Mr. Audibert made no presentations, and merely wrote up a summary of the meeting and forwarded it to others

at Schering. SPX 231 at SP 002941-52 (summary of meeting of Schering advisory board). The individuals who made presentations on behalf of Schering at this meeting (primarily from Schering's research and development department (SPRI)) were not involved in the review of Niacor-SR. Schering Second Admission No. 335 (admitting that the "Schering-Plough Research Institute has never conducted a review of the safety or efficacy or Niacor-SR"); CX 1484 at 105:3-9 (Audibert dep) (confirming that he never spoke with anyone in Schering's research and development department (SPRI) during his evaluation, because he did not see a need to); [redacted]; *see* CPRF 1.238 (discussing SPRI absence from review of Niacor-SR as contrary to Schering's normal due diligence process).

The proposed finding is contrary to the evidence and misleading. Dr. Levy does not have "void of experience in this area." *See* CPRF 1.251 (discussing Dr. Levy's extensive background in the pharmaceutical industry, including serving as Abbott Laboratories' vice president of pharmaceutical research).

1.254. Dr. Levy is not an expert is the treatment of high cholesterol, or the drugs used to treat that condition. (9 Tr. 1857, 1861 (Levy); 35 Tr. 8303, 8409 (Levy)). Dr. Levy is not an expert in cholesterol metabolism. (9 Tr. 1857 (Levy)). Dr. Levy has never published any peer-reviewed scientific studies on lipid metabolism or drugs that affect it. (9 Tr. 1861 (Levy); 35 Tr. 8409 (Levy)). Dr. Levy is not a cardiologist, a lipidologist, or a state certified toxicologist. (35 Tr. 8409 (Levy)). Dr. Levy has not practiced medicine in 20 years, nor has he written a

prescription for cholesterol lowering medication in the last 20 years. (9 Tr. 1861 (Levy); 35 Tr. 8410-11 (Levy)). When he practiced medicine decades ago, he did not specialize in cholesterol diseases. (35 Tr. 8409 (Levy)). Dr. Levy cannot say what is generally accepted in the scientific community with respect to the effects of niacin on blood lipids. (35 Tr. 8412 (Levy)).

Complaint Counsel's Response to Finding No. 1.254:

The proposed finding is incomplete and misleading. While Dr. Levy does not have the specific credentials discussed in the proposed finding, Dr. Levy has extensive experience in the pharmaceutical industry, including the evaluating of dozens of drugs for in-licensing. *See* CPRF 1.251 (discussing Dr. Levy's extensive background in the pharmaceutical industry, including serving as Abbott Laboratories' vice president of pharmaceutical research).

1.255. During cross-examination, Dr. Levy conceded that he is not an expert on the state of knowledge in the pharmaceutical industry in 1997 regarding sustained release niacins, but he did claim to be an expert on what experts in that area had said about that topic prior to 1997: "one doesn't have to be an expert to be able to read the literature." (35 Tr. 8305-06, 8411 (Levy)). Dr. Levy testified that his literature review consisted simply of his review in the fall of 2001 of approximately 20 articles which, during cross-examination, he confessed had become an "amalgam" in his mind by the time of his trial testimony in 2002. (35 Tr. 8317-18 (Levy)). In fact, Dr. Levy simply had no familiarity with the literature he purported to have reviewed. (35 Tr. 8309-20 (Levy)). Moreover, during his direct testimony, Dr. Levy specifically discussed only one article which, on cross-examination, he admitted was not even published until 1998. (35 Tr.

8306 (Levy)).

Complaint Counsel's Response to Finding No. 1.255:

The proposed finding is incomplete and misleading. While Dr. Levy does not have the specific credentials discussed in the proposed finding, Dr. Levy has extensive experience in the pharmaceutical industry, including the evaluating of dozens of drugs for in-licensing. *See* CPRF 1.251 (discussing Dr. Levy's extensive background in the pharmaceutical industry, including serving as Abbott Laboratories' vice president of pharmaceutical research).

Concerning the "one article" discussed by Dr. Levy, he noted that this article also was relied upon by Schering's pharmaceutical expert Dr. Horovitz in his expert report. Tr. at 35:8264 (Levy). In addition, Dr. Levy specifically noted on direct examination that this article was published in 1998, and cited this study for the proposition that "the medical community had been quite negative on any of the sustained release forms of niacin, and they make the point that Niaspan was the exception to the rule . . . [and that] all the previous sustained release forms of niacin had failed in that regard." Tr. at 35:8264-65 (Levy).

1.256. Even based on his review of the literature, Dr. Levy was able to identify only one brand of sustained release niacin product available in 1997 -- Slo-Niacin – an Upsher product identified repeatedly in testimony in this case. (35 Tr. 8319-20, 8386 (Levy); 17 Tr. 3943 (Halvorsen); 14 Tr. 3172 (Brown)). Dr. Levy was also unable to recognize the names of numerous experts in the cholesterol lowering field, despite the fact that he was purporting to

summarize their opinions. (35 Tr. 8393-8406 (Levy)). In fact, Dr. Levy did not even know what the National Cholesterol Education Program ("NCEP") was, despite the fact that it is the organization charged by the National Institutes of Health with creating the guidelines used in the treatment of high cholesterol. (35 Tr. 8404-05 (Levy); SPX 605, at Kos 000076; SPX 608, at SP 16 00344, 347; SPX 924, at SP 002780; 21 Tr. 4964-95 (Preese)).

Complaint Counsel's Response to Finding No. 1.256:

The proposed finding is contrary to the evidence. Dr. Levy stated that he was unable to name sustained-release niacin products available in 1997, because "most of them didn't really have names, because they never made it to the marketplace." Tr. at 35:8319-20 (Levy).

1.257. Dr. Levy had no sales responsibility outside of North America in either of his two positions at pharmaceutical companies. (9 Tr. 1870 (Levy)). Dr. Levy never specifically focused on a licensing opportunity in Europe. (9 Tr. 1875 (Levy)). He has never personally taken an NDA filed in the United States and converted it into an application for European regulatory approval. (35 Tr. 8413 (Levy)). He could not say what type of pharmacokinetic study or data would have been required in connection with seeking approval for a sustained release formulation in Europe. (35 Tr. 8414 (Levy)).

Complaint Counsel's Response to Finding No. 1.257:

The proposed finding is incomplete and misleading. Dr. Levy served on the operating committee at Fujisawa (at the time he served as the president of Fujisawa's North American division) that had ultimate responsibility for global pharmaceutical sales.

Tr. at 9:1869 (Levy). Dr. Levy also had broad responsibilities with various pharmaceutical companies concerning the development and approval of pharmaceutical products in the United States and Europe. *See* CPRF 1.251 (discussing Dr. Levy's extensive background in the pharmaceutical industry, including serving as a consultant to Erbamont Pharmaceutical company over five year period where he was responsible for overseeing worldwide research and development operations including Erbamont's division in Italy).

1.258. In contrast to Dr. Levy who claims to be familiar with the opinions of experts, whose names he can't even recognize, through a literature review he conducted in the fall of 2001, Mr. Audibert was actually meeting with those very experts in 1997 as just one part of his detailed evaluation of the cholesterol lowering market for ezetimibe. (SPF 1.211-1.214). Moreover, while Dr. Levy did not even know what the NCEP was, [redacted]; 21 Tr. 4964-65 (Freese)). [redacted]

Complaint Counsel's Response to Finding No. 1.258:

Complaint counsel has no specific response.

(b) Dr. Horovitz's Qualifications

1.259. Dr. Horovitz received his B.S. in pharmacy and both an M.S. and Ph.D. in pharmacology from the University of Pittsburgh. (16 Tr. 3606 (Horovitz)). In 1967, after serving as a full-time member of the pharmacology department of the Squibb Institute, Dr. Horovitz became the director of that department where he formed the cardiovascular group. (16 Tr. 3606 (Horovitz)). Dr. Horovitz led the cardiovascular group in the discovery of the angiotensin converting enzyme inhibitors, a technology used to create Captopril for the treat high blood pressure and congestive heart failure. (16 Tr. 3606-07 (Horovitz)). Captopril became Squibb's first billion dollar drug, and only the second billion drug in the industry. (16 Tr. 3606-07 (Horovitz)). In recognition for this discovery, Dr. Horovitz and his team at Squibb received the American Heart Discoverer Award. (16 Tr. 3608-09 (Horovitz)).

Complaint Counsel's Response to Finding No. 1.259:

Complaint counsel has no specific response.

1.260. In 1972, Dr. Horovitz became the associate director of the Squibb Institute, which was the research and development arm of the Squibb Corporation. (16 Tr. 3607 (Horovitz)). Dr. Horovitz became vice president of research and development in 1979, and in 1981 became vice president of drug development. (16 Tr. 3607 (Horovitz)). In 1986 Dr. Horovitz assumed the position of vice president of planning and scientific liaison, in which he was tasked with bridging the communication gap between the research and business departments. (16 Tr. 3607 (Horovitz)).

Complaint Counsel's Response to Finding No. 1.260:

Complaint counsel has no specific response.

1.261. Following the merger of Bristol Myers and Squibb in 1989, Dr. Horovitz was appointed vice president of licensing, and later added the responsibility for business and commercial development. (16 Tr. 3607 (Horovitz)). Since his retirement in 1994, Dr. Horovitz has been serving as a consultant in the industry and serves on the board of directors of a number of biotechnology and pharmaceutical companies. (16 Tr. 3608 (Horovitz)).

Complaint Counsel's Response to Finding No. 1.261:

Complaint counsel has no specific response.

1.262. Dr. Horovitz has published over 60 articles or chapters in books and is a member of a number of professional associations, including the Licensing Executives Society and the Pharmacology Society. (16 Tr. 3608 (Horovitz)). He has held teaching positions at Rutgers Medical School, Rutgers Pharmacy School, the University of Pittsburgh Pharmacy School and Princeton University. (16 Tr. 3608 (Horovitz)).

Complaint Counsel's Response to Finding No. 1.262:

Complaint counsel has no specific response.

1.263. During his career, Dr. Horovitz has been involved with roughly 75 licensing or technology transactions. (16 Tr. 3609 (Horovitz)). In particular, Dr. Horovitz was involved in the in-licensing of a cholesterol-lowering drug, pravastatin or Pravachol, the second statin ever

discovered. (16 Tr. 3609 (Horovitz)).

Complaint Counsel's Response to Finding No. 1.263:

Complaint counsel has no specific response.

(c) Dr. Levy's Opinions Regarding Niacor-SR's Clinical Profile

1.264. Despite his lack of experience in the area, particularly as compared to Mr. Audibert, Dr. Levy questions Mr. Audibert's conclusion that Niacor-SR had a clinical profile that could be successful in the marketplace. As detailed above, Mr. Audibert concluded that Niacor-SR: (1) was effective in the treatment of high cholesterol; (2) significantly reduced flushing as compared to immediate release niacin; and (3) caused liver enzyme elevations in a small percentage of patients, as was the case with other cholesterol lowering drugs, but did not cause the substantial elevations of liver enzymes associated with sustained release niacins sold as dietary supplements. (18 Tr. 4117-20, 4123 (Audibert)).

Complaint Counsel's Response to Finding No. 1.264:

The proposed finding is contrary to the evidence and misleading. Dr. Levy does not have "lack of experience in this area." *See* CPRF 1.251 (discussing Dr. Levy's extensive background in the pharmaceutical industry, including serving as Abbott Laboratories' vice president of pharmaceutical research).

In addition, Mr. Audibert did not have the qualifications to conduct due diligence to reach the "conclusions" he purportedly made regarding Niacor-SR. *See* CPF 446-448 (describing Mr. Audibert's qualifications for conducting due diligence). In addition, Mr.

Audibert committed numerous errors in his analysis of the package of information provided by Upsher to Schering regarding Niacor-SR. *See e.g.*, Tr. at 18:4197 (Audibert) (referencing his description of Niacor-SR in the commercial assessment: "[a]t the time I wrote this, this statement is incorrect in the sense that the initial registration program was with twice-a-day dosing"); *see generally* CPF 456-484A (describing various errors made by Mr. Audibert in reviewing Niacor-SR's patent status, administration and dosing schedule, and regulatory status).

Moreover, in purportedly reaching these "conclusions" regarding Niacor-SR, Mr. Audibert did not consult anyone in Schering's research and development department (SPRI). Schering Second Admission No. 335 (admitting that the "Schering-Plough Research Institute has never conducted a review of the safety or efficacy or Niacor-SR"); CX 1484 at 105:3-9 (Audibert dep) (confirming that he never spoke with anyone in Schering's research and development department (SPRI) during his evaluation, because he did not see a need to); ********** ********** ********** This was contrary to Schering's typical in-licensing practice, where in all cases a product has to have a "safety review" by SPRI. Tr. at 19:4387-88 (Lauda) (confirming this point and noting that "I don't know if [Mr. Audibert] actually had [a safety review] done"); *see generally* CPF 428-429 (discussing absence of research and development review for Niacor-SR).

1.265. With regard to efficacy, Dr. Levy concedes that the efficacy of niacin in the

treatment of high cholesterol was well recognized by the pharmaceutical industry, doctors, and cardiologists, and that the efficacy of Niacor-SR is similar to the efficacy of Niaspan. (9 Tr. 1763, 1899 (Levy)). With regard to flushing, Dr. Levy concedes that the incidence and severity of flushing with Niacor-SR is also very similar to that of Niaspan. (9 Tr. 1898-1900 (Levy)). Dr. Levy recognizes, however, that with this similar efficacy and flushing profile, despite poor initial sales, Niaspan has rebounded to achieve annual sales of approximately $100 million in 2001. (7 Tr. 1315 (Levy); 9 Tr. 1898-1900 (Levy); SPX 1205).

Complaint Counsel's Response to Finding No. 1.265:

The proposed finding is incomplete and misleading. First, while Dr. Levy testified that there were recognized benefits for niacin drugs (Tr. at 9:1763 (Levy)), he also testified, however, that a major reason for niacin's trivial share of the worldwide cholesterol market is the array of intolerable side effects associated with niacin therapy that affect potential compliance. Tr. at 7:1313-14 (Levy); *see* CPF 277-279 (providing Dr. Levy's opinions on the side effects associated with niacin drugs).

Second, Dr. Levy stated that the incidence of flushing between Niacor-SR and Niaspan was comparable, but he further explained: "To show you how bad the flushing is, [Niaspan] still caused flushing in 88 percent of patients. So, that's better than 98 percent, but . . . it still had plenty of problems." Tr. at 7:1316 (Levy); CPF 278 (discussing how flushing affects patients and patient compliance).

1.266. Aside from its efficacy and flushing profile, Dr. Levy also disagrees with Mr. Audibert's conclusion that the liver enzyme elevations experienced with Niacor-SR were at a

level which would be acceptable in the marketplace. In his direct testimony, Dr. Levy asserted that the data he examined on Niacor-SR included "absolute and clear evidence that would suggest hepatotoxicity," although he later conceded: "I don't think anyone can say that an elevation of a couple of enzymes is evidence of liver toxicity." (7 Tr. 1317, 1774 (Levy); 9 Tr. 173 (Levy)).

Complaint Counsel's Response to Finding No. 1.266:

The proposed finding is incomplete and misleading. Dr. Levy testified consistently that the data presented to Schering regarding the potential for Niacor-SR to be toxic to the liver, "suggested" that the drug might be hepatotoxic. On direct examination he testified that "Niacor-SR in the scant data that I've seen, and for that matter Schering-Plough has seen, had absolute and clear evidence that would suggest hepatotoxicity." Tr. at 7:1317 (Levy). Later, during cross-examination when asked about this evidence which suggested hepatotoxicity, he states that "what I said in my report was that [this data] should have been followed up. I didn't say – I don't think anyone can say that an elevation of a couple of enzymes is evidence of liver toxicity." Tr. at 9:1773 (Levy).

1.267. During cross-examination regarding the criteria upon which he evaluated Niacor-SR's liver enzyme elevations, Dr. Levy conceded that he had not evaluated the level of liver enzyme elevations of three times the upper limit of normal, but had focused on liver enzyme elevations of 1.5 times the upper limit of normal. (9 Tr. 1809-10 (Levy)). Dr. Levy also conceded that in forming his opinions he had not considered the fact that the FDA had advised

Upsher that it was not even required to track liver enzyme elevations at levels below two times the upper limit of normal. (9 Tr. 1780-81 (Levy); SPX 267 at Upsher-Smith FTC 95037). As explained by Dr. Horovitz, 1.5 times the upper limit of normal is not a useful standard for evaluating liver enzyme elevations because it is far to sensitive and will capture mild fluctuation that are not drug related. (16 Tr. 3636-38 (Horovitz)).

Complaint Counsel's Response to Finding No. 1.267:

The proposed finding is incomplete and misleading. Dr. Levy relied on a 1.5 times upper limit of normal level for liver enzymes as a appropriate measure for due diligence review of a cholesterol lowering drug. He used this level because all previous attempts to develop a sustained-release niacin product resulted in liver toxicity, which could lead to liver damage. Due to these significant concerns, a physician would monitor liver enzyme levels and would be concerned about any level above the upper limit of normal, and certainly would be concerned about a level 1.5 times the upper limit of normal. This 1.5 level would be a signal of potential safety issues. Tr. at 10:2137-40 (Levy). This lower level serves as a screening test to allow a potential in-licensing party to determine whether it should investigate this issue further. Tr. at 10:2140-41; *see* CPRF 1.266 (further describing basis for Dr. Levy's reliance on the 1.5 times upper limit of normal level).

Contrary to Dr. Horovitz's assertion that the 1.5 times upper limit of normal standard is not useful for evaluating liver enzyme elevations, a consultant to Upsher specifically proposed to the FDA that the FDA adopt an even lower 1.2 level to evaluate potential liver toxicity for Niacor-SR. The following minutes of a meeting between

Upsher and the FDA from 1991 concerning Niacor-SR state the following:

> In the opinion of Dr. Kotke [consultant for Upsher from the Mayo Clinic], any value 1.2 times upper limit of normal (ULN) should be a signal to discontinue medication. Dr. Kotke feels that patients could become jaundiced if the medication is continued. The feeling of the FDA is that using 1.2 ULN as the cut-off could lead to a biased view of the actual degree of liver toxicity problems associated with niacin treatment. The FDA is willing to allow 1.5 times ULN (2 results 1 week apart) as a trigger to reduce dose; and 3.0 times ULN as a signal to stop medication. Patients who have any GI symptoms should report it to their physician immediately.

CX 1376 at Upsher-Smith FTC 127100 (summary of September 12, 1991 meeting between Upsher and the FDA regarding development of Niacor-SR).

In addition, Schering's own proposed finding 1.241specifically notes that the information package provided by Upsher to Schering on Niacor-SR (the information package that Mr. Audibert used in his commercial assessment) included data at the 1.5 upper limit of normal level. The proposed finding describes data on the "overall incidence of liver enzyme elevations of 1.5 times the upper limit of normal" and additional data breaking down the incidence of such elevations into groupings "including 1.5-2.0, 2.0-3.0, 3.0-5.0, above 5.0, and above 3.0." *See* Schering proposed finding 1.241 (emphasis added).

1.268. Although documents from Upsher's clinical trials confirm that the level the FDA considers clinically significant elevations to be those above three times the upper limit of normal on successive occasions, Dr. Levy could not recall what elevations were seen at this level with Niacor-SR. (9 Tr. 1780-81, 1809-10 (Levy)). Without considering the small percentage of

Niacor-SR patients with liver enzyme elevations of three times the upper limit of normal, Dr. Levy was simply not in a position to recognize, as Mr. Audibert and Dr. Horovitz both explained, that those elevations represented a dramatic improvement as compared to the 66% of patients with liver enzyme elevations in studies with sustained release niacin dietary supplements. (18 Tr. 4104-05, 4121, 4124 (Audibert); 16 Tr. 3651 (Horovitz)).

Complaint Counsel's Response to Finding No. 1.268:

The proposed finding is not supported by the evidence. As discussed in CPRF 1.267, Upsher's own consultant proposed a 1.2 upper limit of normal level to the FDA. CX 1376 at Upsher-Smith FTC 127100 (summary of September 12, 1991 meeting between Upsher and the FDA regarding development of Niacor-SR). In addition, Schering's own proposed finding 1.241specifically notes that the information package provided by Upsher to Schering on Niacor-SR (the information package that Mr. Audibert used in his commercial assessment) included data at the 1.5 upper limit of normal level. *See* CPRF 1.267 (last paragraph).

The proposed finding is contrary to more reliable evidence. Mr. Audibert did not have a level of liver enzyme elevations in mind when he looked at Upsher's clinical data. According to his investigational hearing transcript (from September 21, 2000) as opposed to his trial testimony (nearly a year and half later on February 19, 2002), Mr. Audibert stated that he "did not have a specific number in mind" when looking at data for people who were "prematurely discontinued" from Upsher's clinical trial due to potential liver damage. CX 1483 at 74:6-12 (Audibert (H).

1.269. In addition, without considering that only 4% of patients taking the highest doses of Niacor-SR experienced successive liver enzyme elevations above three times the upper limit of normal, Dr. Levy was not in a position to recognize, as Mr. Audibert and Dr. Horovitz both did, that those elevations are entirely consistent with those caused by all cholesterol lowering drugs. (18 Tr. 4120-21 (Audibert); 16 Tr. 3651 (Horovitz); CX 1042, at SP 16 00092). When confronted with the Physician's Desk Reference during cross-examination, for example, Dr. Levy was forced to concede that the market dominating statins are associated with successive liver enzyme elevations of three times the upper limit of normal in as many as 5% of patients. (9 Tr. 1811-12 (Levy); SPX 1208). Dr. Levy conceded that these elevations have not prevented the statins from becoming successful drugs because, as mandated in the labeling for the statins, physician's can simply manage patients' therapy through periodic monitoring of patients' liver enzyme levels. (9 Tr. 1812-13 (Levy)).

Complaint Counsel's Response to Finding No. 1.269:

The proposed finding is contrary to more reliable evidence. Mr. Audibert did not have a level of liver enzyme elevations in mind when he looked at Upsher's clinical data. According to his investigational hearing transcript (from September 21, 2000) as opposed to his trial testimony (nearly a year and half later on February 19, 2002), Mr. Audibert stated that he "did not have a specific number in mind" when looking at data for people who were "prematurely discontinued" from Upsher's clinical trial due to potential liver damage. CX 1483 at 74:6-12 (Audibert IH).

The proposed finding is incomplete and misleading. Dr. Levy testified regarding the statins that only the "occasional patient may have a problem" with liver function

studies. Tr. at 9:1812 (Levy). He further testified that the type of potential liver toxicity that had been seen with niacin compounds was not merely a trivial elevation, it was "destructive liver disease." In comparison, the statins had been shown through use in millions of patients to have an exceedingly low incidence of serious liver problems. Tr. at 10:2142 (Levy).

1.270. Similarly, when confronted with the Physician's Desk Reference during cross-examination, Dr. Levy was forced to concede that Tricor, a product belonging to the fibrate class of cholesterol lowering drugs, is associated with elevations of three times the upper limit of normal in as many as 13% of patients. (9 Tr. 1817-18 (Levy); SPX 1209). When confronted with this information during cross-examination, Dr. Levy confessed he had not been familiar with the Tricor brand of fibrates, despite the fact that it is a product marketed by his former employer, Abbott Laboratories. (9 Tr. 1819-21 (Levy)). Dr. Levy conceded that despite these liver enzyme elevations, Tricor achieved sales in the United States of more than $270 million between January and November of 2001. (9 Tr. 1821 (Levy); SPX 1205). Dr. Levy also conceded that, like the statins, physicians simply address these liver enzyme elevations by monitoring patients' liver enzyme levels, and that this procedure is mandated in Tricor's labeling. (9 Tr. 1819-20 (Levy)).

Complaint Counsel's Response to Finding No. 1.270:

The proposed finding is incomplete and misleading. Dr. Levy testified regarding the statins that only the "occasional patient may have a problem" with liver function studies. Tr. at 9:1812 (Levy). He further testified that the type of potential liver toxicity

that had been seen with niacin compounds was not merely a trivial elevation, it was "destructive liver disease." In comparison, the statins had been shown through use in millions of patients to have an exceedingly low incidence of serious liver problems. Tr. at 10:2142 (Levy).

1.271. Not only was Dr. Levy unable to make a comparison between the liver enzyme elevations seen with Niacor-SR and other cholesterol lowering drugs at the generally accepted level of three times the upper limit of normal, Dr. Levy was also unable to make a comparison at the level he choose to consider for Niacor-SR, because he did not know what percentage of patients taking other cholesterol lowering drugs had experienced liver enzyme elevations at 1.5 times the upper limit of normal. (9 Tr. 1783-84 (Levy)). During cross-examination, Dr. Levy conceded that in forming his opinions he had not considered the fact that the FDA had advised Upsher that it was not even required to track liver enzyme elevations at levels below two times the upper limit of normal. (9 Tr. 1780-81 (Levy); SPX 267, at Upsher-Smith FTC 95037). As explained by Dr. Horovitz, 1.5 times the upper limit of normal is not a useful standard for evaluating liver enzyme elevations because it is far to sensitive and will capture mild fluctuation that are not drug related. (16 Tr. 3636-38 (Horovitz)).

Complaint Counsel's Response to Finding No. 1.271:

The finding is incomplete and misleading. Contrary to Dr. Horovitz's assertion that the 1.5 times upper limit of normal standard is not useful for evaluating liver enzyme elevations, a consultant to Upsher specifically proposed to the FDA that the FDA adopt an even lower 1.2 level to evaluate potential liver toxicity for Niacor-SR. The following

minutes of a meeting between Upsher and the FDA from 1991 concerning Niacor-SR states the following:

> In the opinion of Dr. Kotke [consultant for Upsher from the Mayo Clinic], any value 1.2 times upper limit of normal (ULN) should be a signal to discontinue medication. Dr. Kotke feels that patients could become jaundiced if the medication is continued. The feeling of the FDA is that using 1.2 ULN as the cut-off could lead to a biased view of the actual degree of liver toxicity problems associated with niacin treatment. The FDA is willing to allow 1.5 times ULN (2 results 1 week apart) as a trigger to reduce dose; and 3.0 times ULN as a signal to stop medication. Patients who have any GI symptoms should report it to their physician immediately.

CX 1376 at Upsher-Smith FTC 127100 (summary of September 12, 1991 meeting between Upsher and the FDA regarding development of Niacor-SR).

In addition, Schering's own proposed finding 1.241specifically notes that the information package provided by Upsher to Schering on Niacor-SR (the information package that Mr. Audibert used in his commercial assessment) included data at the 1.5 upper limit of normal level. *See* CPRF 1.267 (last paragraph).

1.272. Having conceded that the FDA does not consider elevations of 1.5 times the upper limit of normal to be clinically significant and, in fact, had advised Upsher that it did not even need to track such mild elevations, Dr. Levy nevertheless concluded that the elevations of just 1.5 times the upper limit of normal should have prompted Schering to conduct a "detailed examination of the effects of Niacor-SR on the liver." (9 Tr. 1780-81, 1784-85 (Levy)). Based on his evaluation of that level of elevations, Dr. Levy initially testified that he "stands by" his opinion expressed in his expert report that such a detailed examination should have included, "at

the least," a liver biopsy of those patients with elevated enzyme levels. (9 Tr. 1745-86 (Levy)).

Complaint Counsel's Response to Finding No. 1.272:

The proposed finding is not supported by the evidence. Dr Levy did not concede that the FDA does not consider elevations of 1.5 times the upper limit of normal to be clinically significant. Dr. Levy recognized that the FDA used a 3 times the upper limit of normal level as a conservative measure of liver enzyme levels. However, he relied on a 1.5 times upper limit of normal level for liver enzymes as a appropriate measure for due diligence review of a cholesterol lowering drug. This lower level serves as a screening test to allow a potential in-licensing party to determine whether it should investigate this issue further. Tr. at 10:2140-41 (Levy); *see* CPRF 1.267 (further describing basis for Dr. Levy's reliance on the 1.5 times upper limit of normal level).

1.273. To perform such liver biopsies, Upsher would have been required to track down patients who had completed the study years earlier and re-dose those patients in an attempt to replicating those elevations, and then perform a surgical procedure to remove a piece of the patients' livers to determine whether that re-dosing had caused liver damage. (9 Tr. 1786-87, 1796-97 (Levy)). Dr. Levy testified at his deposition that it would have been "quite reasonable" for Schering to ask Upsher to do this. (9 Tr. 1786-87 (Levy)). Dr. Horovitz explained his experience with the clinical trials for one of the statins where a Japanese company had inquired about the possibility of taking liver biopsies of patients during the clinical trials, and the FDA considered that request "ridiculous." (16 Tr. 3708 (Horovitz)). During cross-examination, however, Dr. Levy admitted that he "probably overstated" the opinion expressed in his expert

report and deposition testimony regarding the requirement of liver biopsies. (9 Tr. 1790, 1793, 1798-99 (Levy)).

Complaint Counsel's Response to Finding No. 1.273:

The proposed finding is incomplete and misleading. Dr. Levy testified that conducting liver biopsies was one of the "multitude of things" that could have been done to further investigate whether the Niacor-SR liver function tests indicated that the drug was hepatotoxic. These other "things" include conducting repeat tests, examining whether the patient's liver enzyme levels returned to normal, or conducting other blood tests. A liver biopsy is the "ultimate test" to determine whether there was liver toxicity. Thus, if a patient had repeated tests showing elevated liver enzymes then a liver biopsy was in order. However, "I'm not saying that one jumps from a positive [liver function test] to a liver biopsy." Tr. at 9:1788-89 (Levy).

1.274. Dr. Levy has also asserted that Schering should have conducted a detailed examination of the histopathology results (abnormalities seen during microscopic examination of tissues and organs) from animal studies done prior to the clinical trials for Niacor-SR. (9 Tr. 1799-1800 (Levy)). During cross-examination, however, Dr. Levy admitted that he did not know whether such studies were even available for Schering to consider because he does not know whether animal studies were ever required for Niacor-SR. (9 Tr. 1800 (Levy)). Dr. Levy conceded that, although he would be "surprised" to find it to be the case, because niacin has been around for a long time, it is possible that the FDA did not require Upsher to perform such animal studies. (9 Tr. 1800 (Levy)). In fact, Upsher had performed a literature review of niacin in place

of animal toxicology studies for Niacor-SR. (CX 907).

Complaint Counsel's Response to Finding No. 1,274:

The proposed finding is not supported by the evidence. The document cited in the proposed finding (CX 907) does not indicate anything about the FDA's position on whether animal histopathology studies were required for approval of Niacor-SR. The document is merely an Upsher document labeled "USL Niacin Advisory Group" and provides a summary of certain literature concerning prior animal studies done with sustained-release niacin drugs. It is not clear from this document whether it was ever submitted to the FDA for review, and the document does not support the inference that the FDA would have accepted this literature review in place of actual animal studies.

In addition, Schering's own due diligence practice on other pharmaceutical licensing deals supports Dr. Levy's opinion that animal studies should be analyzed during due diligence. [redacted]

[redacted]

d. **Mr. Audibert's Commercial Assessment of the Niacor-SR Opportunity**

(1) **Niacor-SR Sales Projections and Profit & Loss Projection**

1.275. Having determined that Niacor-SR's product profile satisfied an unmet need in the marketplace, Mr. Audibert constructed a forecast of sales based on that product profile in that market. (18 Tr. 4124 (Audibert)). The process for constructing this sales forecast included: (1) an evaluation of the current and future size of the cholesterol lowering market; (2) an evaluation of how Niacor-SR would be positioned within that market; (3) an evaluation of the price at which the product would be sold; and (4) a determination of the market share that the product would obtain given that price and product position in a market that size. (18 Tr. 4124-27 (Audibert)).

Complaint Counsel's Response to Finding No. 1.275:

The proposed finding is incomplete. Mr. Audibert did not conduct a sales forecast or profit and loss projection consistent with Schering's practice on other licensing transactions. [redacted]; CX 689 at SP 018745 (Schering "finance manual" requiring financial review for any agreement where intellectual property rights were transferred to Schering); CX 1531 at 14:4-16 (Wasserstein IH) (discussing Schering's licensing

department's role as coordinator between different Schering departments, including the corporate finance group, so that "all the appropriate review was done"); *see generally* CPF 406-410 (describing customary pharmaceutical due diligence on financial and commercial assessments).

In addition, [redacted] *See* CPF 503-507 (describing Schering due diligence review of commercial and financial issues for its license with Zonagen); CPF 535-540 (describing Schering due diligence review of commercial and financial issues for its license with Cor Therapeutics); CPF 558-559 (describing Schering due diligence review of commercial and financial issues for its license with Atherogenics); CPF 568-569 (describing Schering due diligence review of commercial and financial issues for its license with British Biotech); CPF 577-578 (describing Schering due diligence review of commercial and financial issues for its license with ICN).

In contrast, before committing to pay $60 million for Niacor-SR, Mr. Audibert alone prepared one sales forecast and one profit and loss projection. CX 1044 (Mr. Audibert's eight-page "commercial assessment" of Niacor-SR). In addition, Mr. Audibert failed to consult any officials in Schering's European division – the individuals who would have been responsible for selling Niacor-SR in Europe in preparing these sales forecasts. *See* CPF 437-440 (describing the abbreviated nature of Mr. Audibert's commercial assessment, and his failure to take into consideration certain factors necessary

to evaluating a drug product for sale in Europe).

1.276. First, Mr. Audibert evaluated the current size of the market and made a projection of the future growth of that market for a period of ten years. (18 Tr. 4124-25 (Audibert)). Mr. Audibert had already been performing exactly this type of evaluation of the cholesterol lowering market as part of his work on ezetimibe. (18 Tr. 4096-97, 4124-25 (Audibert)).

Complaint Counsel's Response to Finding No. 1.276:

The proposed finding is incomplete. Mr. Audibert did not conduct a sales forecast or profit and loss projection consistent with Schering's practice on other licensing transactions. *See* CPRF 1.275.

1.277. Complaint Counsel's pharmaceutical licensing expert concedes that IMS data is "the most accepted and most widely used source of pharmaceutical sales data." (9 Tr. 1820 (Levy)). SPX 5 is a document, printed by Mr. Audibert during his evaluation of Niacor-SR, which contains the IMS data representing the current size of the cholesterol lowering market worldwide, excluding the U.S., Canada and Mexico ("worldwide Ex-NAFTA"), the territories in which the license to Niacor-SR was available. (SPX 5). The IMS data indicated that the size of the cholesterol lowering market in those territories in 1996 was $4 billion. (SPX 5).

Complaint Counsel's Response to Finding No. 1.277:

The proposed finding is incomplete. Mr. Audibert did not conduct a sales forecast or profit and loss projection consistent with Schering's practice on other licensing

transactions. *See* CPRF 1.275.

1.278. Mr. Audibert's handwritten notations on the IMS data reflect his calculation of prior growth in this market at a rate of 10%, 22% and 6% in the previous three years. (SPX 5). In addition, Mr. Audibert knew from his analysis of the market as part of his work on ezetimibe that analysts were projecting very strong growth in this market. (18 Tr. 4124-25 (Audibert)). As a result, Mr. Audibert estimated an average annual growth 15% in 1997, 1998 and 1999, and a lower growth rate of 10% thereafter. (18 Tr. 4127-29 (Audibert); SPX 2 at SP 16 000046). Dr. Levy concedes that, in fact, the market for cholesterol lowering drugs has grown considerably since 1997. (9 Tr. 1764 (Levy)).

Complaint Counsel's Response to Finding No. 1.278:

The proposed finding is incomplete. Mr. Audibert did not conduct a sales forecast or profit and loss projection consistent with Schering's practice on other licensing transactions. *See* CPRF 1.275.

1.279. Second, Mr. Audibert evaluated how Niacor-SR would be positioned within the cholesterol lowering market. (18 Tr. 4125 (Audibert)). As an initial matter, Mr. Audibert concluded that Niacor-SR would be marketed for the treatment of high cholesterol as monotherapy. (18 Tr. 4125-26 (Audibert)). In addition, on the basis of what he had learned (and reported to others at Schering just weeks earlier) from the European ezetimibe advisory panel regarding European physicians' frequent use of statins in combination with other cholesterol lowering drugs, Mr. Audibert concluded that Niacor-SR could also be positioned for use in

combination with statins. (18 Tr. 4125-26 (Audibert); ••••••••••••••••••••••••••••

Complaint Counsel's Response to Finding No. 1.279:

The proposed finding is incomplete. Mr. Audibert did not conduct a sales forecast or profit and loss projection consistent with Schering's practice on other licensing transactions. *See* CPRF 1.275.

In addition, Mr. Audibert's conclusion that "Niacor-SR could also be positioned for use in combination with statins" was flawed. As noted above in Schering's proposed finding 1.232, Mr. Audibert looked at two draft protocols for phase III-B studies Upsher was planning to conduct as part of the basis for his conclusion that Upsher's product could be used in combination with statins. However, the "phase III-B" studies discussed in the proposed findings were merely planned studies. Mr. Audibert never inquired with Upsher as to the status of these studies or whether they would ever be undertaken. CPF 464 (discussing Mr. Audibert's failure to confirm or inquire about the status of these "draft" protocols).

1.280. Third, Mr. Audibert conducted an evaluation of the price at which Niacor-SR could be marketed. (18 Tr. 4125-27 (Audibert)). In making this determination, Mr. Audibert knew that Niacor-SR's position against the "very potent" statins required that he be "realistic" in terms of pricing for Niacor-SR. (18 Tr. 4126 (Audibert)). As a result, he concluded that Niacor-SR would best be positioned as an inexpensive alternative to the statins and, as such, he selected a price of just half of atorvastatin, the generic name for Lipitor. (18 Tr. 4126 (Audibert)).

Complaint Counsel's Response to Finding No. 1.280:

The proposed finding is incomplete. Mr. Audibert did not conduct a sales forecast or profit and loss projection consistent with Schering's practice on other licensing transactions. *See* CPRF 1.275.

In addition, Mr. Audibert's evaluation of the price at which Niacor-SR could be marketed in Europe was flawed. In particular, he failed to take into consideration two parts of a European pricing evaluation that Schering's own European pricing expert used in his pricing evaluation in this matter. First, Mr. Audibert's evaluation of the European market failed to take into consideration the appropriate comparator drug for conducting a European pricing analysis. Tr. at 18:4285-86 (Furniss) (describing his use of a comparator drug to evaluate pricing issues for Niacor-SR). It was unclear what comparator drug Mr. Audibert chose in his analysis of pricing for Niacor-SR. Tr. at 18:4286-87 (Furniss) (noting that he could not tell what comparator Mr. Audibert had "in mind in making his assessment," but confirming that the only possible comparator mentioned in Mr. Audibert's assessment was a comparator drug that he (Schering's expert) did not consider to be a good comparator). Second, Mr. Audibert conducted no country-by-country European pricing analysis as part of this commercial assessment. CX 1484 at 151:11-18 (Audibert dep). Such a country-by-country analysis had been conducted by Schering's European pricing expert in every circumstance where he prepared a strategy for pricing for a pharmaceutical company, including for Schering. Tr. at 18:4272-75 (Furniss) (Schering's expert describing his use of a country-by-country pricing analysis methodology); *see generally* CPF 438-439 (describing these flaws in Mr.

Audibert's evaluation of European pricing issues).

1.281. Finally, Mr. Audibert projected what share of the market Niacor-SR could obtain at that price and with that positioning. (18 Tr. 4126-27 (Audibert)). Mr. Audibert concluded that Niacor-SR would compete as a low-priced, moderately effective product for the treatment of high cholesterol. (18 Tr. 4126-27 (Audibert)). From his experience in talking with cardiologists and health payers internationally, Mr. Audibert had learned that many countries with government funded health systems recognized the need to treat high cholesterol, but simply could not afford to treat significant portions of the population with the expensive statins. (18 Tr. 4126-27 (Audibert)). Mr. Audibert knew that a number of governments had openly stated that they would like to treat more patients, but that they simply could not afford to treat wide portions of the population with the statins given their pricing. (11 Tr. 2454-55 (Audibert Depo.)). For example, Mr. Audibert knew that patients in Italy could only obtain reimbursement for statins if they had experienced a heart attack or had a family history of heart disease. (11 Tr. 2454-55 (Audibert Depo.)). Mr. Audibert, therefore, saw a "real opportunity" to position Niacor-SR as a low-priced alternative to the stains, which would allow health authorities to treat larger portions of the population. (18 Tr. 4126-27, 4132 (Audibert)).

Complaint Counsel's Response to Finding No. 1.281:

The proposed finding is incomplete. Mr. Audibert did not conduct a sales forecast or profit and loss projection consistent with Schering's practice on other licensing transactions. *See* CPRF 1.275.

The proposed finding is contradicted by other evidence. In Europe, the market for

sustained-release niacin products was viewed by European pharmaceutical companies in mid-1997 as an "outdated" type of treatment for high cholesterol with limited market potential, particularly in light of the dominant position of the statins. CX 857 at USL09091 (letter from Italian pharmaceutical company, dated March 4, 1997, informing Upsher that it was not interested in licensing Niacor-SR because niacin is "viewed as a somewhat outdated treatment of hyperlipidaemia" in the Italian market that is "definitely dominated by statins"); CX 856 at USL 09086 (letter from German pharmaceutical company, dated April 9, 1997, informing Upsher that it was not interested in licensing Niacor-SR because niacin "drugs have been available in several European countries but most of them have been withdrawn in the meantime"); SPX 608 at SP 16 00391 (1996 Cardium Hyperlipidemia study received by Schering on June 11, 1997 explaining that "[n]iacin is not used for treatment in most European countries, particularly in France, Germany, and Spain, where it is available only as a component of multivitamin supplements"); **; *see* CPF 285 (describing views of European pharmaceutical companies concerning sustained-release niacin drugs).

1.282. Having identified this opportunity, Mr. Audibert still believed that Niacor-SR would only obtain an initial market share of .75%, rising for just two years to 1.5%, and then

decreasing thereafter to a 1% share. (18 Tr. 4127-29 (Audibert); SPX 2 at SP 16 00047). In estimating such a low market share, Mr. Audibert was taking into account that Schering would not be marketing Niacor-SR in Japan. (18 Tr. 4136-37 (Audibert)). Dr. Horovitz testified that, in his opinion, these market share projections were "very small and reasonable." (16 Tr. 3674-75 (Horovitz)). Dr. Levy conceded that a niacin drug which overcame the potentially problematic side effects could make "a lot" of money even if it got a small portion, such as 1 percent, of the cholesterol market. (9 Tr. 1765 (Levy)).

Complaint Counsel's Response to Finding No. 1.282:

The proposed finding is incomplete. Mr. Audibert did not conduct a sales forecast or profit and loss projection consistent with Schering's practice on other licensing transactions. *See* CPRF 1.275.

In addition, Dr. Levy's purported "concession" that a niacin drug which could overcome the potentially problematic side effects could make "a lot" of money is irrelevant. Dr. Levy's opinion concerning Niacor-SR was that this drug had significant problems with side effects. In particular, Niacor-SR did not succeed in overcoming the liver toxicity seen with previous attempts to develop a sustained-release niacin drug. Tr. at 7:1316-17 (Levy) (further noting that the data reviewed by Schering on Niacor-SR "had absolute and clear evidence that would suggest hepatotoxicity").

1.283. Having estimated the overall size of the market and a market share for this product over a ten year period, the rest was just a matter of multiplication. (18 Tr. 4127 (Audibert)). Mr. Audibert's formal written assessment for Niacor-SR, dated June 17, 1997,

includes tables illustrating Mr. Audibert's annual projections of market size and market share, from which he calculated annual dollar sales. (18 Tr. 4127-29 (Audibert)); SPX 2 at SP 16 00046-47). The sales projected for each of these years, in millions, were:

Sales ($)	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008
Millions	45	70	114	126	116	127	140	125	136	149

(SPX 2, at SP 16 00046-47).

Complaint Counsel's Response to Finding No. 1.283:

The proposed finding is incomplete. Mr. Audibert did not conduct a sales forecast or profit and loss projection consistent with Schering's practice on other licensing transactions. *See* CPRF 1.275.

The proposed finding is contradicted by other evidence. As seen with Schering's evaluation of other licensing opportunities, performing a sales projection is not simply a "matter of multiplication." For example, when Schering evaluated Kos' sustained-release niacin product earlier in 1997, it conducted three separate sales forecasts – a "base" analysis, a "downside analysis", and an "upside analysis – with two separate price assumptions. CX 550 at SP 002743-45. Each of the three separate sales forecasts also included eleven steps to reach a final sales forecast (which was then applied to two different price scenarios). These steps included the following inputs and calculations:

Total U.S. Population (in thousands)
% of Candidates for Rx
Total Patients Eligible (in thousands)
% of Patients Receiving Therapy

Patients Receiving Therapy
% of Patients Receiving Niacin
of Patients Receiving Niacin
% of Patients Receiving Niaspan
of Patients Receiving Niaspan
Sales (in thousands) per Price Scenario I
Sales (in thousands) per Price Scenario II

Id. These forecasts were conducted in part by Ray Russo of Schering's domestic marketing group. Mr. Russo testified that this detailed analysis was "not inconsistent with similar" analyses by Schering, and that this was how he "generally" conducted his sales forecasts. Tr. at 15:3473 (Ray Russo).

In contrast, Mr. Audibert's sales projections (according to proposed finding 1.283) were "just a matter of multiplication", multiplying the overall size of market against the market share.

1.284. On the basis of his sales projections, Mr. Audibert then prepared a written profit and loss analysis. (18 Tr. 4138-39 (Audibert); SPX 6). The annual profit and loss calculations were created by deducting from his sales forecasts, an estimated 10% cost of goods, as well as the cost of selling and promoting Niacor-SR, which Mr. Audibert estimated to peak at $22.8 million in the third year of sales. (SPX 6). Because Mr. Audibert did not know what royalty rate would be negotiated, his calculations represented the annual net profit before deducting the royalties to be paid to Upsher. (18 Tr. 4139 (Audibert)).

Complaint Counsel's Response to Finding No. 1.284:

The proposed finding is incomplete. Mr. Audibert did not conduct a sales forecast

or profit and loss projection consistent with Schering's practice on other licensing transactions. *See* CPRF 1.275.

1.285. Mr. Audibert's testimony regarding his assessment of the Niacor-SR licensing opportunity is credible.

Complaint Counsel's Response to Finding No. 1.285:

The proposed finding is not supported by the evidence. There is no citation provided for this proposed finding, and there is no support for this finding in the record.

In addition, Mr. Audibert's testimony is not credible as it is directly contrary to other testimony on key issues. For example, Mr. Audibert testified that he was not aware of the terms of the settlement agreement prior to conducting his commercial assessment. However, Mr. Wasserstein (a Schering in-house lawyer who participated in the settlement negotiations with Upsher) testified that he had told Mr. Audibert what the terms of the patent settlement with Upsher were prior to completing Schering's review of Niacor-SR. CX 1532 at 17:13-18:22 (Wasserstein dep) (noting that he informed Mr. Audibert about the terms).

1.286. Mr. Audibert's evaluation and sales predictions for Niacor-SR reflected his best business judgment of the sales that Schering could achieve with Niacor-SR. (18 Tr. 4129, 4225-26 (Audibert)). Mr. Audibert's sales projections were not influenced or determined by anything other than his best business judgment. (18 Tr. 4226 (Audibert)).

Complaint Counsel's Response to Finding No. 1.286:

The proposed finding is incomplete. Mr. Audibert did not conduct a sales forecast or profit and loss projection consistent with Schering's practice on other licensing transactions. *See* CPRF 1.275.

The proposed finding is contradicted by other evidence. Mr. Audibert was informed about the terms of the patent settlement with Upsher that purportedly including payment for the Niacor-SR license. Mr. Wasserstein (a Schering in-house lawyer who participated in the settlement negotiations with Upsher) told Mr. Audibert what the terms of the settlement agreement with Upsher were prior to completing Schering's review of Niacor-SR. CX 1532 at 17:13-18:22 (Wasserstein dep) (noting that he informed Mr. Audibert about the terms). Thus, Mr. Audibert's sales projections could have been influenced by his knowledge of the patent settlement deals terms.

(2) Assumptions Underlying the Niacor-SR Sales Projections

1.287. Following standard practice at Schering, each of the various conclusions Mr. Audibert reached which formed the basis for his sales projections were identified in Mr. Audibert's written assessment as "assumptions" upon which those projections were based. (18 Tr. 4129-30 (Audibert); SPX 2 at SP 16 00047). Dr. Horovitz testified that he conducted a detailed evaluation of Mr. Audibert's assumptions and concluded that each of the assumptions underlying Mr. Audibert's projections were reasonable and properly conservative. (16 Tr. 3612, 3675 (Horovitz)).

Complaint Counsel's Response to Finding No. 1.287:

The proposed finding is contradicted by other evidence. Mr. Audibert's conclusions" that formed the basis for his sales projections did not follow "standard practice" at Schering. [redacted]; CX 689 at SP 018745 (Schering "finance manual" requiring financial review for any agreement where intellectual property rights were transferred to Schering); CX 1531at 14:4-16 (Wasserstein IH) (discussing Schering's licensing department's role as coordinator between different Schering departments, including the corporate finance group, so that "all the appropriate review was done"); *see generally* CPF 406-410 (describing customary pharmaceutical due diligence on financial and commercial assessments).

In addition, [redacted] *See* CPF 503-507 (describing Schering due diligence review of commercial and financial issues for its license with Zonagen); CPF 535-540 (describing Schering due diligence review of commercial and financial issues for its license with Cor Therapeutics); CPF 558-559 (describing Schering due diligence review of commercial and financial issues for its license with Atherogenics); CPF 568-569 (describing Schering due diligence review of commercial and financial issues for its license with British Biotech); CPF 577-578

(describing Schering due diligence review of commercial and financial issues for its license with ICN).

In Schering's evaluation of Kos' sustained-release niacin product earlier in 1997, it conducted three separate sales forecasts – a "base" analysis, a "downside analysis", and an "upside analysis - - with two separate price assumptions. CX 550 at SP 002743-45. Each of the three separate sales forecasts also included eleven steps to reach a final sales forecast (which was then applied to two different price scenarios). *See* CPRF 1.283 (listing each of these eleven steps). These forecasts were conducted in part by Ray Russo of Schering's domestic marketing group. Mr. Russo testified that this detailed analysis was "not inconsistent with similar" analyses by Schering, and that this was how he "generally" conducted his sales forecasts. Tr. at 15:3473 (Ray Russo).

In contrast, before committing to pay $60 million for Niacor-SR, Mr. Audibert alone prepared one sales forecast and one profit and loss projection. CX 1044 (Mr. Audibert's eight-page "commercial assessment" of Niacor-SR). In addition, Mr. Audibert failed to consult any officials in Schering's European division – the individuals who would have been responsible for selling Niacor-SR in Europe – in preparing these sales forecasts. *See* CPF 437-440 (describing the abbreviated nature of Mr. Audibert's commercial assessment, and his failure to take into consideration certain factors necessary to evaluating a drug product for sale in Europe).

(a) Dossiers Approved in Late 1998

1.288. With respect to timing, Mr. Audibert projected that Niacor-SR would obtain

regulatory approval in late 1998, which would allow Schering to launch Niacor-SR in early 1999. (18 Tr. 4130-31 (Audibert)). The pivotal trials for Niacor-SR were already completed, and Upsher was preparing its U.S. NDA for filing in December 1997. (18 Tr. 4130-31 (Audibert); CX 1042 at SP 16 00079). Mr. Audibert knew that the two critical pieces of the NDA that would form the basis of Schering's overseas filing, the Integrated Summary of Efficacy and the Integrated Summary of Safety, would be available to Schering in October, 1997. (18 Tr. 4130-32 (Audibert); CX 1042 at 1600079). This would permit Schering to convert those materials into its overseas dossier for filing at the end of 1997. (18 Tr. 4130-32 (Audibert)). From that point, Mr. Audibert used Schering's standard assumption of a 12-month regulatory review time to arrive at late 1998 for approval. (18 Tr. 4130-31 (Audibert)). Dr. Horovitz concluded that Mr. Audibert's assumption of regulatory approval in late 1998 was reasonable. (16 Tr. 3667-69 (Horovitz)).

Complaint Counsel's Response to Finding No. 1.288:

The proposed finding is not supported by the evidence. First, the pivotal trials for Niacor-SR were not already completed at the time of Mr. Audibert's commercial assessment. CX 1042 at SP 16 00079 (the "package" of information received from Upsher noting that the "projected" completion date for the second pivotal trial (Protocol 900221) was June 1997).

Second, Mr. Audibert did not "know" that "two critical pieces" of the Upsher's NDA would be available in October 1997. He merely assumed this from Upsher's information package provided to Schering. Mr. Audibert never made any inquiries with Upsher concerning the availability of this information or any other information necessary for Schering to seek regulatory approval for Niacor-SR. *See* CPF 424 (noting that Mr.

Audibert never visited Upsher during his assessment, nor spoke with anyone at Upsher). In fact, Schering never received these "critical pieces" from Upsher. *See* CPF 703-710 (discussing failure of Upsher to provide Schering necessary clinical data on Niacor-SR).

In addition, the proposed finding is incomplete and misleading. While the proposed finding notes that Dr. Horovitz concluded that Mr. Audibert's regulatory approval assumption was reasonable, the proposed finding fails to note Schering's European pricing expert's opinion that the European approval process (which must be completed before a product can be marketed) would take at least 12 to 15 months, and between 15 to 24 months for major European markets such as France, Italy and Spain. Tr. at 18:4282-84 (Furniss). Thus, Mr. Audibert's assumptions for getting Niacor-SR to market in France, Italy and Spain were "optimistic." Tr. at 18:4285 (Furniss). In addition, even Dr. Horovitz testified that getting European regulatory approval is never certain. Tr. at 16:3712-13 (Horovitz) (also noting that Niacor-SR never received European regulatory approval).

(b) Reimbursement in Most Major Markets & Priced at Approximately 50% to Atorvastatin

1.289. Having concluded that Niacor-SR would be best positioned as a low-priced alternative to the statins, Mr. Audibert estimated that Niacor-SR would be priced at approximately 50% of the price of atorvastatin, the generic name for Lipitor. (18 Tr. 4135-36 (Audibert)).

Complaint Counsel's Response to Finding No. 1.289:

The proposed finding is incomplete and misleading. Mr. Audibert's evaluation of European pricing was flawed according to Schering's own European pricing expert (Mr. Furniss). First, Mr. Audibert's evaluation of the European market failed to take into consideration the appropriate comparator drug for conducting a European pricing analysis. Tr. at 18:4285-86 (Furniss) (describing his use of a comparator drug to evaluate pricing issues for Niacor-SR). It was unclear what comparator drug Mr. Audibert chose in his analysis of pricing for Niacor-SR. Mr. Furniss noted that he could not tell what comparator Mr. Audibert had "in mind in making his assessment," and further confirmed that the only possible comparator mentioned in Mr. Audibert's assessment was a comparator drug that he (Mr. Furniss) did not consider to be a good comparator). Tr. at 18:4286-87 (Furniss).

Second, Mr. Audibert conducted no country-by-country European pricing analysis as part of this commercial assessment. CX 1484 at 151:11-18 (Audibert dep). Such a country-by-country analysis had been conducted by Schering's European pricing expert in every circumstance where he prepared a strategy for pricing for a pharmaceutical company, including for Schering. Tr. at 18:4272-75 (Furniss) (Schering's expert describing his use of a country-by-country pricing analysis methodology).

1.290. Priced at a low level, Mr. Audibert anticipated that Niacor-SR would be reimbursed in most major markets. (18 Tr. 4132 (Audibert)). From his experience with ezetimibe, Mr. Audibert knew that a number of governments had openly stated that they would like to treat more patients, but that they simply could not afford to treat large portions of their

populations with the statins. (18 Tr. 4126-27 (Audibert); 11 Tr. 2454-55 (Audibert Dep.)). For example, Mr. Audibert knew that patients in Italy could only obtain reimbursement for statins if they had experienced a heart attack or had a family history of heart disease. (11 Tr. 2454-55 (Audibert Dep.)).

Complaint Counsel's Response to Finding No. 1.290:

The proposed finding is incomplete and misleading. Mr. Audibert's evaluation of European pricing was flawed according to Schering's own European pricing expert (Mr. Furniss) in two ways: (1) it failed to take into consideration the appropriate comparator drug for conducting a European pricing analysis, and (2) Mr. Audibert conducted no country-by-country European pricing analysis as part of this commercial assessment. *See* CPRF 1.289.

1.291. Because Mr. Audibert anticipated a low price for Niacor-SR, he believed that most major health authorities would be willing to reimburse an inexpensive alternative to the statins as a way to treat a larger portion of the population. (18 Tr. 4132 (Audibert)). Dr. Horovitz testified that, because overseas markets were seeking cheaper cholesterol lowering drugs at the time, positioning Niacor-SR as Mr. Audibert anticipated made reimbursed in most major markets a reasonable assumption. (16 Tr. 3669 (Horovitz)).

Complaint Counsel's Response to Finding No. 1.291:

The proposed finding is incomplete and misleading. Mr. Audibert's evaluation of European pricing was flawed according to Schering's own European pricing expert (Mr. Furniss) in two ways: (1) it failed to take into consideration the appropriate comparator

drug for conducting a European pricing analysis, and (2) Mr. Audibert conducted no country-by-country European pricing analysis as part of this commercial assessment. *See* CPRF 1.289.

1.292. Mr. Furniss, senior vice president of Cambridge Pharma Consultancy and former head of the Pharmaceutical Industry Branch of the United Kingdom Department of Health, testified on Schering's behalf as an expert in European pricing and reimbursement procedures for pharmaceutical products. (18 Tr. 4234-35, 4237 (Furniss)). Mr. Furniss evaluated the pricing and reimbursement status for comparator products to Niacor-SR, primarily fibrates, in the five major European markets of France, Germany, Italy, Spain and the United Kingdom. (18 Tr. 4239-40, 4264-65 (Furniss)). Based on this analysis, he testified that Mr. Audibert's pricing and reimbursement assumptions for Niacor-SR were reasonable and, in some countries, conservative in that higher prices may have actually been attained. (18 Tr. 4239-40 (Furniss)).

Complaint Counsel's Response to Finding No. 1.292:

The proposed finding is contradicted by other evidence. First, Mr. Furniss was unable to determine what comparator Mr. Audibert used in reaching his conclusions on European pricing. Tr. at 18:4286-87 (Furniss) (noting that he could not tell what comparator Mr. Audibert had "in mind in making his assessment," but confirming that the only possible comparator mentioned in Mr. Audibert's assessment was a comparator drug that he (Schering's expert) did not consider to be a good comparator). Second, contrary to Mr. Furniss' analysis, Mr. Audibert conducted no country-by-country

European pricing analysis as part of this commercial assessment. CX 1484 at 151:11-18 (Audibert dep). Such a country-by-country analysis had been conducted by Mr. Furniss in every circumstance where he prepared a strategy for pricing for a pharmaceutical company, including for Schering. Tr. at 18:4272-75 (Schering's expert describing his use of a country-by-country pricing analysis methodology).

In addition, Mr. Furniss' opinion is not reliable on whether Mr. Audibert's European pricing conclusion was reasonable. In reaching his opinions in this matter, Mr. Furniss merely reviewed the eight-page commercial assessment prepared by Mr. Audibert. Tr. at 18:4276-77 (Furniss) (confirming this was the only document he received from Schering's lawyers, and that he had not reviewed any other documents or testimony in this matter). When asked specifically about what comparator Mr. Audibert chose for his pricing analysis, Mr. Furniss responded "I can't tell you what he had in mind in making his assessment." Tr. at 18:4286-87 (Furniss) (further confirming he had never spoken with Mr. Audibert).

1.293. Mr. Furniss chose fibrates as the most likely comparators for Niacor-SR because, of the three classes of therapy used for management of hypercholesterolemia, the fibrates have a level of clinical performance most similar to that anticipated for Niacor-SR. (18 Tr. 4265 (Furniss)). In addition, the fibrates sometimes are prescribed in combination therapy with statins, as Niacor-SR would likely have been. (18 Tr. 4265 (Furniss)). Mr. Furniss considered, but ultimately rejected, statins and cholestyramine as comparator products. (18 Tr. 4265-66 (Furniss)). He did not use any sustained release niacin or nicotinic acid products with

hypercholesterolemia indications as comparators because he found no such products on the market in any of the five major European countries. (18 Tr. 4266-67 (Furniss)). He determined that niacin was available in these markets only within over-the-counter multi-vitamin products and testified that these multi-vitamin products would not have been used by the pricing authorities as comparators for pricing and reimbursement purposes. (18 Tr. 4267 (Furniss)).

Complaint Counsel's Response to Finding No. 1.293:

The proposed finding is not relevant. Mr. Furniss was unable to determine what comparator Mr. Audibert used in reaching his conclusions on European pricing. Tr. at 18:4286-87 (Furniss) (noting that he could not tell what comparator Mr. Audibert had "in mind in making his assessment," but confirming that the only possible comparator mentioned in Mr. Audibert's assessment was a comparator drug that he (Schering's expert) did not consider to be a good comparator).

1.294. Mr. Furniss explained that in the United Kingdom and Germany, reimbursement for newly launched pharmaceutical products is automatic, and generally, there are no pricing restrictions imposed on these new drugs. (18 Tr. 4249, 4260-61 (Furniss)). He testified that Niacor-SR would be reimbursed in these markets and could be marketed at a price equal to or higher than Audibert's estimate of 50% of the price of the Lipitor. (18 Tr. 4239, 4252-53, 4261-62 (Furniss)). Similarly, Mr. Furniss confirmed that Niacor-SR could achieve reimbursement in France, Italy and Spain (18 Tr. 4246-47, 4255, 4258 (Furniss)), and that it would be reasonable to assume, based on the pricing of fibrates such as gemfibrizol in these markets, that the product could have been priced at 50% of the price of Lipitor. (18 Tr. 4247-48, 4255-56, 4258-59

(Furniss)).

Complaint Counsel's Response to Finding No. 1.294:

The proposed finding is not relevant. Contrary to Mr. Furniss' analysis, Mr. Audibert conducted no country-by-country European pricing analysis as part of this commercial assessment. CX 1484 at 151:11-18 (Audibert dep). Such a country-by-country analysis had been conducted by Mr. Furniss in every circumstance where he prepared a strategy for pricing for a pharmaceutical company, including for Schering. Tr. at 18:4272-75 (Schering's expert describing his use of a country-by-country pricing analysis methodology).

In addition, Mr. Furniss' opinion is not reliable on whether Mr. Audibert's European pricing conclusion was reasonable. In reaching his opinions in this matter, Mr. Furniss merely reviewed the eight-page commercial assessment prepared by Mr. Audibert. Tr. at 18:4276-77 (Furniss) (confirming this was the only document he received from Schering's lawyers, and that he had not reviewed any other documents or testimony in this matter). When asked specifically about what comparator Mr. Audibert chose for his pricing analysis, Mr. Furniss responded "I can't tell you what he had in mind in making his assessment." Tr. at 18:4286-87 (Furniss) (further confirming he had never spoken with Mr. Audibert).

(c) Approved for Use as Monotherapy and in Combination With a Statin

1.295. Mr. Audibert anticipated Niacor-SR would be approved with the basic

indication for cholesterol lowering drugs, the treatment of high cholesterol as monotherapy. (18 Tr. 4129-30 (Audibert)). Of course, this was not simply an assumption, it was based on Mr. Audibert's evaluation of the results of Niacor-SR's pivotal trials. (18 Tr. 4129-30 (Audibert); 19 Tr. 4384-4385 (Lauda)). Based on the results of Niacor-SR's pivotal trials, Mr. Audibert concluded that Niacor-SR was a safe and effective form of niacin that exceeded the regulatory hurdle of a 15% average reduction in LDL, and that it would be approved for use as a cholesterol lowering agent in the relevant markets. (18 Tr. 4129-30 (Audibert)). Dr. Horovitz testified that although regulatory approval is never certain, he had concluded that this was a reasonable assumption for Niacor-SR. (16 Tr. 3670 (Horovitz)).

Complaint Counsel's Response to Finding No. 1.295:

The proposed finding is incomplete and misleading. First, Mr. Audibert did not perform an "evaluation" of the Niacor-SR product, but rather conducted a limited "commercial assessment." *See* CPRF 1.230. Second, Mr. Audibert could not have based any conclusions on the "results" of Upsher's two phase III pivotal clinical trials, as the second trial was not yet complete at the time of Mr. Audibert's commercial assessment. CX 1042 at SP 16 00079 (the "package" of information received from Upsher noting that the "projected" completion date for the second pivotal trial (Protocol 900221) was June 1997).

In addition, while Mr. Audibert may have "anticipated" that Niacor-SR would be approved for the treatment of high cholesterol as a monotherapy, he had no information from Upsher confirming this point. He never requested labeling on Niacor-SR (which would include indications for the drug) from Upsher. CX 1484 at 91:25–92:6 (Audibert

dep). In contrast, in evaluating another sustained-release niacin product (Kos' Niaspan) earlier in 1997, the Schering officials involved in due diligence for that product specifically noted that "due diligence" validation on labeling "need[s] to be reviewed and more completely understood before a deal could be made." CX 546 at SP 002770 (memorandum by Ray Russo of Schering marketing department, dated March 26, 1997). Schering's pharmaceutical expert (Dr. Horovitz) also would have reviewed draft labeling for Niacor-SR. He testified that if he had been in Schering's shoes evaluating Niacor-SR, he would have asked Upsher if it had labeling for Niacor-SR and reviewed such labeling had it been available. Tr. at 16:3750 (Horovitz) (also noting that he did not know whether anyone at Schering had reviewed Upsher's labeling for Niacor-SR).

1.296. Although Kos had advised Schering in April 1997 that the FDA had indicated that it was going to approve two additional "class labeling" indications for Niaspan on the basis of studies with niacin generally (and not on the basis of any studies conducted with Niaspan), Mr. Audibert assumed conservatively that Niacor-SR would not receive these additional indications. (SPX 22, at SP 002747; 16 Tr. 3758-60, 3796-3800 (Horovitz); CX 540 at SP 002804; 11 Tr. 2432-38 (Audibert Dep.)). Mr. Audibert elected to base his assessment on more conservative assumptions, despite the fact that it would have been reasonable to assume that, because regulatory bodies were approving "class labeling" for one sustained release niacin, they would also approve those same indications for another sustained release niacin. (16 Tr. 3758-60, 3796-3800 (Horovitz); 11 Tr. 2432-38 (Audibert Dep.)).

Complaint Counsel's Response to Finding No. 1.296:

The proposed finding is incomplete and misleading. Mr. Audibert's use of assumptions – and thus failure to request labeling from Upsher (*see* CPRF 1.295) – was contrary to Schering's practice in reviewing pharmaceutical products for in-licensing. In evaluating another sustained-release niacin product (Kos' Niaspan) earlier in 1997, the Schering officials involved in due diligence for that product specifically noted that "due diligence" validation on labeling "needs to be reviewed and more completely understood before a deal could be made." *See* CPRF 1.295.

The proposed finding is contradicted by other evidence. Schering cites its pharmaceutical industry expert (Dr. Horovitz) in support of Mr. Audibert's assumptions on "class labeling." However, Dr. Horovitz testified that if he had been in Schering's shoes evaluating Niacor-SR, he would have asked Upsher if it had labeling for Niacor-SR and reviewed such labeling had it been available. Tr. at 16:3750 (Horovitz) (also noting that he did not know whether anyone at Schering had reviewed Upsher's labeling for Niacor-SR).

1.297. With respect to its indication for the treatment of high cholesterol, Mr. Audibert also concluded that Niacor-SR would be approved for use in combination with statins. (18 Tr. 4132-4135 (Audibert)). Mr. Audibert was aware of numerous publications regarding the use of niacin in combination with a statin, as well as the fact that the NCEP had incorporated this combination into its treatment guidelines. (18 Tr. 4133-34 (Audibert); CX 1042 at SP 16 00073-74). Mr. Audibert had also recently learned from the European Advisory Panel that European

physicians often used statins in combination with other cholesterol lowering drugs. (18 Tr. 4125-26, 4302-04 (Audibert); ••••••••••••••••••••••••••••

Complaint Counsel's Response to Finding No. 1.297:

The proposed finding is incomplete and misleading. In performing his commercial assessment of Niacor-SR, Mr. Audibert based his assumption that Niacor-SR was a product that could be used in combination therapy with a statin on two draft protocols concerning planned clinical studies by Upsher. Tr. at 18:4134-4135 (Audibert). However, the two "draft" protocol studies that Mr. Audibert received at the time of his commercial assessment (SPX 4 and SPX 71) had not been conducted at the time that Mr. Audibert did his assessment. Tr. at 18:4171-4172, 4173-4174 (Audibert). In addition, these protocol synopses did not indicate when these studies were to be started. Tr. at 18:4172-74 (Audibert); SPX 71; SPX 4. Mr. Audibert did not know when the studies were going to be started and he did not contact Upsher to confirm when the described studies would be started, if at all. Tr. at 18:4173-75 (Audibert). While he was working on his commercial assessment of Niacor-SR, Mr. Audibert did not show the two draft protocol synopses to anyone in Schering's research and development group (SPRD). Tr. at 18:4176 (Audibert).

1.298. Included in the materials provided by Upsher was a protocol for a study Upsher would be conducting which would test Niacor-SR in combination with a statin, and Mr. Audibert also knew that Niaspan had already conducted a similar study of Niaspan in combination with a statin. (18 Tr. 4102-03, 4132-35 (Audibert); SPX 72). Mr. Audibert believed Upsher's study

would be sufficient for approval of this combination. (18 Tr. 4132-35 (Audibert)). Dr. Horovitz testified that he also believed Niacor-SR would receive approval on the basis of the study Upsher would be conducting and, even if that approval were slightly delayed, he believed physicians would have continued their practice of prescribing combination therapy anyway. (16 Tr. 3760 (Horovitz)).

Complaint Counsel's Response to Finding No. 1.298:

The proposed finding is incomplete and misleading. Mr. Audibert's assumption that Upsher's studies would be sufficient for approval of a combination product was based on planned studies by Upsher, for which Mr. Audibert's made no inquiries regarding their status. *See* CPRF 1.297.

(d) Similar Products Enter the Market in Late 2002

1.299. Because Mr. Audibert assumed that Schering would not be able to block potential competitors with Upsher's patents for Niacor-SR, Mr. Audibert assumed that entry of similar competitive products into the international market would occur. (18 Tr. 4133-34 (Audibert)). In estimating that Kos or another unidentified company would make such an enter in 2002, Mr. Audibert made what he believed to be a conservative assumption. (11 Tr. 2458 (Audibert Dep.)).

Complaint Counsel's Response to Finding No. 1.299:

The finding is incomplete and contradicted by other evidence. Mr. Audibert's purported "assumptions" concerning Upsher's patent status contradict his written commercial assessment which described Niacor-SR as "a patented sustained-release

niacin product." SPX 2 at SP 1600044 (Audibert's June 17, 1997 "commercial assessment" of Niacor-SR). His description of Niacor-SR's patent status in his commercial assessment, however, was wrong. Niacor-SR had no patent protection in Europe at the time of Mr. Audibert's commercial assessment of Niacor-SR. CX 1484 at 123:5-124:22 (Audibert dep) (discussing patent status of Niacor-SR in Europe); CX 1042 at SP 16 00063-64 (Upsher information package reviewed by Mr. Audibert noting Upsher's two patents for Niacor-SR had not issued in Europe). In addition, Mr. Audibert was not given any information about the patent cross licensing agreement entered into by Kos and Upsher earlier in 1997 before he did his commercial assessment of Niacor-SR. Tr. at 18:4207-08 (Audibert).

In addition, Schering did not have any patent counsel review Niacor-SR before entering into the settlement agreement with Upsher. Schering Second Admissions No. 310. Mr. Audibert did not conduct any due diligence regarding the patent status of Niacor-SR, nor was he aware of anyone at Schering who conducted any such analysis. CX 1484 at 89:2-10 (Audibert dep). [redacted]

1.300. In June 1997, Kos was the only company that Mr. Audibert knew to be developing a sustained release niacin product. (11 Tr. 2458 (Audibert Dep.)). Mr. Audibert

knew from his involvement in the negotiations with Kos that Niaspan was near approval in the United States, however, he also knew from those discussions that Kos was focusing on launching Niaspan in the U.S. market and was not interested in pursuing international markets in the near term. (18 Tr. 4133-34 (Audibert)).

Complaint Counsel's Response to Finding No. 1.300:

The proposed finding is incomplete and misleading. Mr. Audibert had limited involvement in Schering's discussions with Kos regarding Niaspan. In fact, he only participated in one conference call with Kos in March 1997, and then dropped out of Schering's evaluation of Niaspan. Tr. at 15:3516-17 (Ray Russo) (confirming that Mr. Audibert only participated in one conference call which occurred in March 1997 (per CX 543)). In addition, when assessing Niacor-SR in June 1997, Mr. Audibert did not consult the Schering officials (e.g., Mr. Russo) involved in the full discussions with Kos regarding Niaspan. *See* CPF 425 (discussing Mr. Audibert's failure to consult Schering officials regarding Niaspan).

The proposed finding is also contradicted by other evidence. In March 1997, Mr. Audibert sent a survey to several of Schering's European subsidiaries inquiring about their interest in a Kos' Niaspan product. In that survey, Mr. Audibert represented that Kos could be on the market in Europe by the end of 1998, directly contradicting the proposed finding. CX 782 at Schering-Plough White Paper Exhibits 0000189. In addition, a Schering prepared contact report regarding its meeting with Kos on April 9, 1997, specifically discusses Kos' plans for seeking approval for Niaspan in Europe. That document states that Kos "plan[s] to use a [contract research organization] for handling

the submission in the EU (expect this process to be about 18 months behind the U.S.) and have not thought about possibilities elsewhere." CX 1047 at SP 002748.

In addition, while Schering knew from its discussions with Kos that Kos was near approval with the FDA in the United States, Schering also learned from its discussions with Kos that Kos had completed 14 pharmacokinetic studies and was in the process of patenting its dosing regimen for Niaspan. Through additional discussions with Kos, Schering also knew that "the most challenging aspect of [Niaspan's] development was niacin's pharmacokinetics" and that the 14 pharmacokinetic studies Kos had completed for regulatory filing came "at a cost of about $4 million." *See generally* CPF 612-613 (discussing what Schering learned from its meetings with Kos during the first half of 1997).

1.301. Complaint counsel's fact witness, the director of licensing for Kos in 1997, confirmed that Kos was focusing on the U.S. market in 1997. (31 Tr. 7508, 7558 (Patel)). In fact, the March 1997 prospectus for Kos' initial public offering expressly stated that Kos did not intend to market Niaspan outside the United States, and eventually intended to license the marketing rights to an international partner: "To date, the Company has had no material discussions concerning such possible arrangements with other companies." (SPX 605 at Kos 0073). In a document dated November 1997, another of complaint counsel's fact witnesses, Mr. Egan, confirmed that during Searle's discussions with Kos in which Searle expressed its desire to pursue both the U.S. and international rights to Niaspan, Kos stated its desire to "delink" those discussions and pursue only the U.S. rights at that time. (33 Tr. 7979-80 (Egan)); CX 524 at

Pharmacia 00038).

Complaint Counsel's Response to Finding No. 1.301:

Complaint counsel has no specific response.

1.302. Based on his knowledge about Kos's focus on the U.S. market, Mr. Audibert assumed that Kos or another competitor would enter the international market with a similar product in 2002, just 3 years after the launch of Niacor-SR. (18 Tr. 4133 (Audibert)). Dr. Horovitz concluded that Mr. Audibert's assumption that similar products with similar labeling would enter the market in 2002 was reasonable. (16 Tr. 3670-71 (Horovitz)). As we now know, Mr. Audibert's assumption was accurate. (16 Tr. 3673 (Horovitz); 18 Tr. 4266 (Furniss)).

Complaint Counsel's Response to Finding No. 1.302:

The proposed finding is incomplete and misleading. Mr. Audibert had limited involvement in Schering's discussions with Kos regarding Niaspan. In fact, he only participated in one conference call with Kos in March 1997, and then dropped out of Schering's evaluation of Niaspan. Tr. at 15:3516-17 (Ray Russo) (confirming that Mr. Audibert only participated in one conference call which occurred in March 1997 (per CX 543)). In addition, when assessing Niacor-SR in June 1997, Mr. Audibert did not consult the Schering officials involved in the full discussions with Kos regarding Niaspan. *See* CPF 425 (discussing Mr. Audibert's failure to consult Schering officials regarding Niaspan).

1.303. As a result of his projection of entry by a competitive product in 2002, Mr.

Audibert projected a decline in Niacor-SR's market share. (11 Tr. 2457-58 (Audibert Dep.)). Mr. Audibert believed this to be a conservative assumption because he believed entry by a competitor would increase the total market share for all sustained release niacin products. (11 Tr. 2458-59 (Audibert Dep.)). Dr. Horovitz testified that the increased physician awareness that often occurs when a second product enters the market and two companies promote those similar products made this assumption "very conservative." (16 Tr. 3670-72 (Horovitz)).

Complaint Counsel's Response to Finding No. 1.303:

Complaint counsel has no specific response.

(e) Side Effect Profile Doesn't Significantly Change

1.304. Mr. Audibert assumed that the side effect profile of Niacor-SR would not significantly change as compared to the data from the pivotal trials with Niacor-SR, because he saw no reason to believe it would change. (18 Tr. 4136 (Audibert)). Dr. Horovitz agrees that this assumption was also reasonable. (16 Tr. 3674 (Horovitz)).

Complaint Counsel's Response to Finding No. 1.304:

The proposed finding is incomplete and misleading. Mr. Audibert's assumption that the side effect profile from Upsher's pivotal trials was flawed. He could not make this assumption, because he had not even received the full results from both of Upsher's pivotal trials. The results of Upsher's second pivotal trial were not complete at the time Mr. Audibert received the information package from Upsher on these trials. CX 1042 at SP 16 00079 (the "package" of information received from Upsher noting that the "projected" completion date for the second pivotal trial (Protocol 900221) was June 1997).

1.305. Each of Mr. Audibert's assumptions that formed the basis for his commecial assessment of Niacor-SR was reasonable when he made that assessment in June 1997.

Complaint Counsel's Response to Finding No. 1.305:

The proposed finding is not supported by the evidence. There is no evidence cited for this proposition. In addition, Mr. Audibert's commercial assessment contained numerous flawed assumptions. *See generally* CPF 456-484 (describing flaws in Mr. Audibert's evaluation of Upsher's patent status, the administration and dosing schedule for Niacor-SR, use of niacin in combination with a statin, the anticipated date of Niacor-SR entry in the European market, and the regulatory status of Niacor-SR).

(3) Mr. Audibert's Written Commercial Assessment of the Niacor-SR Opportunity

1.306. Following his evaluation of the Niacor-SR opportunity, Mr. Audibert prepared a written commercial assessment, as well as a written profit and loss projection on the basis of the sales he had projected in his commercial assessment. (SPX 2; SPX 6). Mr. Audibert provided a copy of each of these documents to Mr. Lauda. (18 Tr. 4138-40 (Audibert); 19 Tr. 4345-46 (Lauda)).

Complaint Counsel's Response to Finding No. 1.306:

The proposed finding is incomplete and misleading. Mr. Audibert did not

perform an "evaluation" of the Niacor-SR product, but merely conducted a limited "commercial assessment." Mr. Audibert described his assignment as "[g]enerating a sales forecast." CX 1484 at 105:18-21 (Audibert dep); Tr. at 7:1367-68 (Levy) (describing Schering's analysis of the Niacor-SR as constituting only "about a third of the way through the preliminary evaluation" of full due diligence); CPF 417-419 (describing the limited scope of Mr. Audibert's "commercial assessment").

1.307. In his assessment, Mr. Audibert provided background information regarding the cholesterol lowering market, including the competitor products in that market. (SPX 2 at SP 16 00040-45). Mr. Audibert explained the current state of knowledge regarding niacin as an effective cholesterol lowering agent, as well as the difficulties that had hampered prior immediate release niacins (flushing) and sustained release niacins (association with hepatotoxicity). (SPX 2 at SP 16 00040-45). Mr. Audibert detailed the current size of the cholesterol lowering market, recent growth experienced in that market, and provided an assessment of why the growth of that market was expected to continue. (SPX 2 at SP 16 00040-45). Mr. Audibert identified his conclusion that a product opportunity existed for Niacor-SR, and on the basis of his conclusions, he provided a summary of his sales projections for Niacor-SR, which were detailed . (SPX 2 at SP 16 00040-45).

Complaint Counsel's Response to Finding No. 1.307:

The proposed finding is incomplete. Mr. Audibert's commercial assessment did not provide a complete explanation of the current state of knowledge regarding niacin, and failed to report problems concerning niacin drugs that were well-known to Schering

at the time of Mr. Audibert's commercial assessment. In particular, Mr. Audibert failed to note Schering's survey in April 1997 of ten cholesterol-management experts who evaluated a potential joint marketing opportunity concerning Kos' sustained-release niacin preparation. Those experts reported to Schering the following concerning sustained-release niacin drugs: (1) general practitioners "avoid use of sustained release preparations . . . because of diminished efficacy and concern regarding hepatotoxicity"; (2) "niacin and, particularly sustained release niacin, has such a bad reputation among primary care physicians" that successful marketing of Niaspan will require "compelling data" and strong support from lipid specialists; and that (3) data from clinical studies of a sustained release niacin product "will be scrutinized very carefully" as a result of "niacin's history, and, especially, the safety issue with sustained release niacin." CX 576 at SP 020709, 15, 17 (April 1997 Decker Research Associates report entitled "A Qualitative Evaluation of the Opportunity for Niaspan in Multiple Lipid Disorders"). *See generally* CPF 598-609 (discussing the Decker report in detail and how it indicated that Niacor-SR was not a straightforward licensing opportunity).

Mr. Audibert's commercial assessment also failed to note a memorandum prepared by Martin Driscoll (Schering's vice president of marketing and sales for its Key division) recommending discontinuation of discussions with Kos for the "principal reason" that the product did not "represent a large-enough opportunity in the marketplace . . .". CX 558 at SP 002719. Mr. Driscoll's memorandum was prepared on June 9, 1997, just eight days before Mr. Audibert completed his commercial assessment of Niacor-SR. In reaching this recommendation on Niaspan, Mr. Driscoll noted that "immediate-release

niacin products cause flushing in most patients [and as a result] patient compliance is greatly impacted" and that "long-term use of the immediate-release niacin can lead to hepatotoxicity." CX 558 at SP 002719 (Driscoll memorandum recommending discontinuation of discussions with Kos). Mr. Driscoll also noted that the "current market dynamics of the 'statin' category" was another "important factor" that would impact Niaspan's acceptance in the marketplace. He observed that because of the apparent potency and benign side-effect profile of statins like Pfizer's Lipitor, "Niaspan's market opportunity is narrowing even prior to its introduction [and that i]ndeed, the use of other classes of cholesterol-lowering agents such as niacin, gemfibrozil, and cholestyramine has declined since the introduction of Lipitor." CX 558 at SP 002720 (Driscoll memorandum recommending discontinuation of discussions with Kos).

1.308. Mr. Audibert attached to his assessment two tables which contained his detailed financial projections of both the future growth of the cholesterol lowering market and his sales projections for Niacor-SR in that market. (SPX 2 at SP 16 00046-47).

Complaint Counsel's Response to Finding No. 1.308:

The proposed finding is incomplete and misleading. Mr. Audibert's financial projections were not "detailed" and were not consistent with Schering's practice in performing financial evaluation of in-licensing opportunities. [redacted]

[redacted]; CX 689 at SP 018745 (Schering "finance manual" requiring financial review for any agreement where intellectual property rights were transferred to Schering); CX 1531at 14:4-16 (Wasserstein III) (discussing Schering's licensing department's role as coordinator between different Schering departments, including the corporate finance group, so that "all the appropriate review was done"); *see generally* CPF 406-410 (describing customary pharmaceutical due diligence on financial and commercial assessments).

In addition, [redacted] *See* CPF 503-507 (describing Schering due diligence review of commercial and financial issues for its license with Zonagen); CPF 535-540 (describing Schering due diligence review of commercial and financial issues for its license with Cor Therapeutics); CPF 558-559 (describing Schering due diligence review of commercial and financial issues for its license with Atherogenics); CPF 568-569 (describing Schering due diligence review of commercial and financial issues for its license with British Biotech); CPF 577-578 (describing Schering due diligence review of commercial and financial issues for its license with ICN).

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 OF FACT RELATING TO THE SETTLEMENT WITH UPSHER-SMITH

VOLUME II

[PUBLIC VERSION]

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May 14, 2002

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(4) Mr. Audibert's Sales Projections for Niacor-SR Were Consistent With Other Projections for Sustained Release Niacins

(a) Market Analysts' 1997 Niaspan Sales Projections

1.309. In March 1997, Kos proceeded with an Initial Public Offering ("IPO") on the basis of projected sales of its primary product, Niaspan, a sustained release niacin. (31 Tr. 7544 (Patel); 33 Tr. 7982 (Egan); 28 Tr. 6982 (Kerr)). Kos raised over $62 million by selling 29% of its stock to the public in this IPO. (31 Tr. 7545 (Patel); USX 21 at Kos 0052; 10 Tr. 2070 (Levy)). The market capitalization of Kos as of March 1997 was approximately $200 million. (10 Tr. 2070 (Levy)). Between March and September 1997, Kos' stock and market capitalization were rising and, by the summer of 1997, Kos had a market capitalization of over $500 million. (31 Tr. 7574 (Patel); 10 Tr. 2070 (Levy)).

Complaint Counsel's Response to Finding No. 1.309:

The proposed finding is incomplete. Kos raised capital through its IPO based on the extensive development it undertook for its sustained-release niacin drug, Niaspan. Kos' IPO registration statement (which was provided as part of a February 1997 "confidential disclosure" to Schering) specifically discussed known problems and risks associated with sustained-release niacin drugs, including a "high incidence" of liver toxicity. It stated that: "In order to remedy the side effects associated with [immediate-release] niacin, several manufacturers have developed sustained-release ("SR") preparations of niacin, typically administered twice a day. Such SR preparations have not been approved by the FDA for treatment of lipid disorders, and their administration frequently has been associated with a high incidence of liver toxicity." CX 540 at SP

002781. The IPO registration statement gave additional detail on specifics of Kos' product development, which Kos represented as providing for Niaspan's improved safety and side effects profile. Kos' registration statement reports that its sustained-release formulation of niacin "reduces the intolerable side effects and frequent safety problems characteristic of currently available niacin formulations [and that] Kos believes that it is the unique controlled-release nature of its Niaspan formulation in conjunction with Niaspan's specific dosing regimen that minimizes adverse events while maintaining niacin's positive effect on lipids." CX 540 at SP 02781.

1.310. Around the time of the IPO in the spring of 1997, several market analysts published projected U.S. sales for Niaspan reaching between $220 million and $250 million in the third year of sales. (10 Tr. 2072 (Levy); SPX 226; 28 Tr. 6872-73 (Kerr); USX 535 at USL 11514; ••••••••••••••••••••••••••• In addition, after Kos had established itself in the domestic market, stock analysts projected Niaspan could go on to achieve a "few hundred million in sales overseas." (28 Tr. 6874 (Kerr)).

Complaint Counsel's Response to Finding No. 1.310:

The proposed finding is contradicted by other evidence. The projected sales for Niaspan were exaggerated by both Kos and its investment bankers. First, these sales projections were exaggerated according to Schering's own sales estimates for Niaspan. As discussed below in Schering's proposed finding 1.316, Schering estimated third year sales of Niaspan at $101 million (as compared to the between "$220 and $250 million" estimated by the market analysts). In addition, as expressly stated in Schering's proposed

finding 1.314, "Schering did not agree with market analysts' public projections of Niaspan sales of $250 million." Second, according to complaint counsel's expert Dr. Levy, "it is not atypical for a startup company doing an IPO to grossly overstate its potential earnings. That's how they pump up their stock price. And it's not atypical for investment bankers to comport with that behavior." Tr. at 9:1856 (Levy).

The proposed finding is incomplete and misleading. The financial market referenced in the proposed finding refers to analysts whose objectives were to underwrite the initial public offering of Kos' stock and to promote the company to achieve high stock value. Dillon, Read & Co., Cowen & Company, Salomon Brothers Inc., are identified on the front page of Kos' initial public offering prospectus as the underwriters of the Kos IPO. USX 21 at AAA 0000052. Also noted on the first page of the prospectus is the interest that these firms have in the company; all three underwriters were offered substantial shares of the company. The underwriters are required by the SEC to disclose this interest, and consequently, their incentive to strongly support and promote the company. Upsher, however, chose not to include this point in its finding.

In addition, the proposed finding on Kos' capitalization and outside analysts projections is not relevant to this proceeding. There is no evidence that Schering valued Niaspan, or even Niacor-SR on the basis of outside analysts projections. In fact, Schering conducted its own due diligence and completed projections to evaluate the Niaspan opportunity. CX 548 (Niaspan financial analysis prepared by Ray Russo and Toni DeMola of Schering, dated April 17, 1997); CX 549 (additional Niaspan financial analysis prepared by Ray Russo and Toni DeMola, dated April, 1997); CX 550 (Niaspan

sales forecasts prepared by Ray Russo and Toni DeMola, indicating "base," "downside," and "upside" sales forecast); Tr. at 15:3472, 3476-77 (Ray Russo) at 3472 (confirming that he completed sales projections for Niaspan); 3476-77(acknowledging that sales projections were completed for Niacor-SR).

1.311. In May 1997, during the course of its negotiations with Schering, Kos quoted Schering what it characterized as "conservative" projections for sales of Niaspan that had been published by stock analysts. (SPX 230 at SP 002721). Those projections forecasted $175 million in U.S. sales in just the second year after launch, increasing further to $200 million in the third year. (SPX 230 at SP 002721). •• •• •• In fact, documents from one partner with whom Kos negotiated indicated that projections for peak year sales were as high as $400 million. (CX 524 at Pharmacia 0000037).

Complaint Counsel's Response to Finding No. 1.311:

The proposed finding is incomplete and misleading. The projected sales for Niaspan were exaggerated by both Kos and its investment bankers. *See* CPRF 1.310.

(b) Mr. Russo's Conservative Sales Projections for Niaspan in April 1997

1.312. In April 1997, Mr. Russo was Schering's senior director of marketing in charge of the negotiations with Kos regarding a potential co-promotion of Niaspan in the United States.

(15 Tr. 3439, 3482 (Russo)). As part of Schering's evaluation, Mr. Russo and another Schering representative prepared a range of forecasts of potential U.S. Niaspan sales, with peak year sales in the more optimistic "upside" scenarios exceeding $350 million. (15 Tr. 3455-56 (Russo); CX 550 at SP 002745).

Complaint Counsel's Response to Finding No. 1.312:

The proposed finding is incomplete and misleading. Mr. Russo had three separate sales projections conducted for Niaspan, which were then applied against two separate pricing scenarios. The proposed finding only reports the highest projected figure. The full projections completed by Mr. Russo were:

	Price Scenario I	Price Scenario II
"Downside"	$64,691	$101,284
"Base"	$123,840	$193,265
"Upside"	$227,328	$354,770

CX 550 at SP 002743-45.

1.313. Mr. Russo, exercising his best business judgment, forecasted as his "base case scenario II" what he thought was the most realistic projection of Niaspan sales in the United States. (15 Tr. 3459, 3461-63, 3472 (Russo); CX 550 at SP 002743; CX 551, at SP 002731). Under this scenario, Mr. Russo projected that Schering could achieve $134 million in sales in 2002, rising thereafter to $193 million. (15 Tr. 3461, 3529 (Russo); CX 550 at SP 002743).

Complaint Counsel's Response to Finding No. 1.313:

The proposed finding is incomplete and misleading. Despite Mr. Russo's forecasts, Schering decided not to proceed with discussions with Kos regarding Niaspan. The recommendation to discontinue discussions with Kos was made by Mr. Russo's boss, Martin Driscoll (Schering's vice president of marketing and sales for its Key division). Mr. Driscoll made this recommendation for the "principal reason" that the product did not "represent a large-enough opportunity in the marketplace . . .". Mr. Driscoll's memorandum was prepared on June 9, 1997, just eight days before Mr. Audibert completed his commercial assessment of Niacor-SR. In reaching this recommendation on Niaspan, Mr. Driscoll noted that the "current market dynamics of the 'statin' category" was another "important factor" that would impact Niaspan's acceptance in the marketplace. He observed that because of the apparent potency and benign side-effect profile of statins like Pfizer's Lipitor, "Niaspan's market opportunity is narrowing even prior to its introduction [and that i]ndeed, the use of other classes of cholesterol-lowering agents such as niacin, gemfibrozil, and cholestyramine has declined since the introduction of Lipitor." CX 558 at SP 002720 (Driscoll memorandum recommending discontinuation of discussions with Kos).

1.314. Eventually, in June 1997, Mr. Driscoll sent a memorandum to Mr. Cesan recommending that Schering terminate negotiations with Kos, part of which indicated that Schering did not agree with market analysts' public projections of Niaspan sales of $250 million. (15 Tr. 3527-30 (Russo); CX 558). That written recommendation adopted Mr. Russo's "base

case scenario II" projection of Niaspan sales of $134 million in 2002. (15 Tr. 3527-30 (Russo); CX 558). As indicated in that recommendation, however, because Schering would be splitting revenues with Kos, Schering's projected revenues would be $67 million, exactly half of the sales figure projected by Mr. Russo. (15 Tr. 3527-30 (Russo); CX 558; CX 550).

Complaint Counsel's Response to Finding No. 1.314:

The proposed finding is incomplete and misleading. Mr. Driscoll recommended terminating negotiations with Kos for several reasons, including that the "current market dynamics of the 'statin' category" was another "important factor" that would impact Niaspan's acceptance in the marketplace. *See* CPRF 1.313 (discussing Mr. Driscoll's rationale for discontinuing negotiations).

1.315. In 1997, according to complaint counsel's pharmaceutical licensing expert, U.S. sales represented "roughly" half of worldwide sales of cholesterol lowering drugs. (9 Tr. 1914-15 (Levy)). According to the documents available to Schering in June 1997, the market for cholesterol lowering drugs outside the U.S., Canada and Mexico ("worldwide Ex-NAFTA") was larger than the U.S. market for cholesterol lowering drugs. (SPX 5 at SP 16 00447; CX 1042 at SP 16 00112).

Complaint Counsel's Response to Finding No. 1.315:

Complaint counsel has no specific response.

1.316. Mr. Russo's "base case" projections for U.S. sales of Niaspan in April 1997 compare to Mr. Audibert's Ex-NAFTA projections for Niacor-SR in June 1997 as follows:

Sales ($)	1997	1998	1999	2000	2001	2002	2003	2004	2005
Niaspan (U.S. Only)	7	48	101	106	126	133	140	152	174

Sales ($)	1999	2000	2001	2002	2003	2004	2005	2006	2007
Niacor-SR (Ex-NAFTA)	45	70	114	126	116	127	140	125	136

(CX 550 at SP 002743; SPX 2 at SP 16 00046-47).

Complaint Counsel's Response to Finding No. 1.316:

The proposed finding is incomplete and misleading. The proposed finding only reports the higher of the two "base case" projections performed by Mr. Russo. It does not include the two "downside" forecasts done for Mr. Russo that were substantially lower than Mr. Audibert's projections for Niacor-SR, as follows:

Sales ($ millions)	1997	1998	1999	2000	2001	2002	2003	2004	2005
Niaspan (Price Scenario I)	.5	11	21	33	42	44	47	51	64
Niaspan (Price Scenario II)	.7	17	32	52	66	69	74	80	84

CX 550 at SP 002744.

1.317. Dr. Kerr explained that Schering's projections for Niaspan and Niacor-SR were very similar, and that both were more conservative than market analyst projections for Niaspan at the time. (28 Tr. 6927 (Kerr)). This supported Dr. Kerr's conclusion that Mr. Audibert's sales projections for Niacor-SR were reasonable. (28 Tr. 6927 (Kerr)).

Complaint Counsel's Response to Finding No. 1.317:

The proposed finding is not relevant. The fact that Dr. Kerr found Schering's projections for Niaspan and Niacor-SR to be conservative relative to market analysts' projections is irrelevant, considering that Schering itself did not agree with the market analysts' projections. *See* CPRF 1.314.

(c) Upsher's Internal Projections for Niacor-SR

1.318. Various Upsher employees testified that Upsher believed Niacor-SR could achieve annual sales of $100 million to as much as $250 million in the United States market alone. (21 Tr. 5011 (Kralovec); 21 Tr. 4978 (Freese)). Upsher felt that achieving those sales depended upon a significant marketing effort, including active promotion by 100 or even 200 outside sales representatives. (21 Tr. 5012 (Kralovec)). In the mid-1990s, Upsher did not have a sales force, but intended to use Niacor-SR as the basis for development of a sales force, at a cost of approximately $15 to $20 million. (21 Tr. 5012-13 (Kralovec)). Upsher's documents reflect that it was projecting annual sales for Niacor-SR of anywhere from $226 million to as much as $498 million. (USX 1563; USX 1564 at USL 10045).

Complaint Counsel's Response to Finding No. 1.318:

The proposed finding is contradicted by other evidence. Upsher's sales projections for Niacor-SR as of July 1997 merely ranged between $5-7 million. CX 930 at USL 13191 (sales projections prepared by Upsher marketing official Denise Dolan).

The proposed finding is not relevant and incomplete. Upsher's marketing strategy for Niacor-SR included retaining an outside side force to market Niacor-SR. Upsher's

July 1997 sales projections assumed that "USL will hire or retain a detail force to market Niacor-SR successfully." CX 930 at USL 13192 (sales projections prepared by Upsher marketing official Denise Dolan); *see also* CX 929 at USL 13140 (memorandum prepared by Denise Dolan in March 1997 stating that as part of its "promotional strategies" for Niacor-SR, Upsher expected that "[t]his promotion may be beyond the scope of telephone selling and will entail the employment of an outside detail force.")

1.319. By 1997, however, Upsher's marketing force had grown to just 20 telephone salespeople, 8 national account representatives, 4 marketing representatives, and some service support in charge of direct mail programs and other marketing initiatives. (20 Tr. 4619 (Dritsas)). Upsher did not have a field sales force or detail force in 1997. (20 Tr. 4619-20 (Dritsas)). Upsher's total sales were approximately $35 million in 1996. (20 Tr. 4620 (Dritsas)). In fact, unlike most pharmaceutical companies, Upsher could not afford to purchase new IMS data and had to rely on outdated data when making projections. (20 Tr. 4708-09 (Dritsas)).

Complaint Counsel's Response to Finding No. 1.319:

The proposed finding is not relevant. Upsher's marketing strategy for Niacor-SR included retaining an outside side force to market Niacor-SR. Upsher's July 1997 sales projections assumed that "USL will hire or retain a detail force to market Niacor-SR successfully." CX 930 at USL 13192 (sales projections prepared by Upsher marketing official Denise Dolan); *see also* CX 929 at USL 13140 (memorandum prepared by Denise Dolan in March 1997 stating that as part of its "promotional strategies" for Niacor-SR, Upsher expected that "[t]his promotion may be beyond the scope of telephone selling and

will entail the employment of an outside detail force.")

1.320. In late-1996, as a result of not having built a field or detail sales force, Upsher projected sales of Niacor-SR, based on its limited ability to market the product, of $10 million in the first year and $20 million in the second year. (23 Tr. 5528-29; 5535-36 (Troup); CX 322; CX 234). Schering, on the other hand, could put thousands of salespeople behind the product. (23 Tr. 5528-29, 5536 (Troup)).

Complaint Counsel's Response to Finding No. 1.320:

The proposed finding is contradicted by other evidence. Upsher's sales projections for Niacor-SR as of July 1997 merely ranged between $5-7 million. CX 930 at USL 13191 (sales projections prepared by Upsher marketing official Denise Dolan).

In addition, Mr. Troup's statement that Schering could "put thousands of salespeople behind the product" is irrelevant. Upsher's sales projections assumed that "USL will hire or retain a detail force to market Niacor-SR successfully." CX 930 at USL 13192; *see also* CX 929 at USL 13140 (memorandum prepared by Upsher marketing official Denise Dolan in March 1997 stating that as part of its "promotional strategies" for Niacor-SR, Upsher expected that "[t]his promotion may be beyond the scope of telephone selling and will entail the employment of an outside detail force.")

4. The Strategic Value that Niacor-SR Offered to Schering in June 1997

1.321. Because Schering was planning to launch the largest product in company history in a market in which it had no presence, it was important for Schering to first establish a presence

in that market in order to build a knowledgeable sales force capable of maximizing the launch of ezetimibe. (18 Tr. 4108-11 (Audibert); 16 Tr. 3622-23, 3659-66 (Horovitz); 19 Tr. 4348-49 (Lauda); 15 Tr. 3437-38 (Russo)). Promoting a sustained release niacin product had significant strategic value to Schering in that it would allow Schering to get to know the market and "earn its bumps and bruises" before its launch of ezetimibe. (18 Tr. 4108-11 (Audibert); 15 Tr. 3437-38 (Russo); SPX 21 at 002771).

Complaint Counsel's Response to Finding No. 1.321:

The proposed finding is not relevant. The Schering Board of Directors never heard this "strategic value" justification before approving the settlement agreement between Schering and Upsher. *See* CX 338 at SP 12 00268-71 (Schering Board presentation document on Niacor-SR). However, the Schering Board was informed of the need for Upsher to receive "a guaranteed income stream" to replace Upsher's projected Klor-Con profits. *See* CX 338 at SP 12 00270 (Schering Board of Directors briefing document for the Schering/Upsher Agreement).

The proposed finding is also inconsistent with Schering's proposed finding 1.133, which represents that Schering's "superior field force, particularly in the area of cardiovascular medicine," as one of its "unique advantages."

1.322. During Schering's discussions with Kos regarding Niaspan just a few months earlier, Schering had identified a strategic value to Schering from promoting a sustained release niacin product in advance of its launch of ezetimibe. (18 Tr. 4108-11 (Audibert); 15 Tr. 3437-38 (Russo)). Schering's strategic interest in Niaspan is reflected in documents created during the

course of those negotiations in the spring of 1997, as well as the testimony of the parties involved in those negotiations. (SPX 21 at 002771; 18 Tr. 4108-11 (Audibert); 15 Tr. 3437-38 (Russo); 31 Tr. 7546-47 (Patel)). In fact, Mr. Patel of Kos testified that Schering explained to him that this strategic value "was the very reason [Schering] wanted to talk to" Kos about Niaspan. (31 Tr. 7546-47 (Patel)).

Complaint Counsel's Response to Finding No. 1.322:

The proposed finding is not relevant. *See* CPRF 1.321 (noting that Schering's Board was never told this "strategic value" justification before entering into the settlement agreement, while it was informed of the need for Upsher to receive "a guaranteed income stream" to replace Upsher's projected Klor-Con profits).

1.323. At the time of his assessment, Mr. Audibert saw Niacor-SR as a sustained release niacin product that would also offer this strategic value to Schering. (CX 1484 at 148:1-25 (Audibert IH)). Mr. Lauda testified that he too saw Niacor-SR as an appealing opportunity, in part, because of this significant strategic benefit. (19 Tr. 4348-49 (Lauda)). In fact, Schering's interest in using Niacor-SR as a lead-in to ezetimibe is reflected in contemporaneous documents created in June 1997 in advance of the presentation of the Niacor-SR opportunity to Schering's board of directors for approval. (16 Tr. 3623, 3663-66 (Horovitz); SPX 235 at SP 16 00003).

Complaint Counsel's Response to Finding No. 1.323:

The proposed finding is not relevant. *See* CPRF 1.321 (noting that Schering's Board was never told this "strategic value" justification before entering into the settlement agreement, while it was informed of the need for Upsher to receive "a

guaranteed income stream" to replace Upsher's projected Klor-Con profits).

In addition, the proposed finding is incomplete and misleading. This "ezetemibe" rationale is not mentioned in any of the documents generated by Mr. Audibert during his commercial assessment. It is only discussed in one document, dated June 23, 1997. Dr. Horovitz was the only witness who testified concerning that document (SPX 235), and he thought it came from Upsher. Tr. at 16:3871-72 (Horovitz).

1.324. Dr. Horovitz testified that determining the strategic value of a licensing transaction to a party is crucial in assessing the value of that transaction to the party, and is absolutely a consideration of a company evaluating a potential licensing transaction. (16 Tr. 3665 (Horovitz)). In evaluating a licensing opportunity, Schering always considers strategic value. (19 Tr. 4362, 4374- 75 (Lauda)). Dr. Horovitz explained that Schering had a significant incentive to enter the huge cholesterol lowering market in advance of its launch of ezetimibe, and that one of the best ways to achieve this was to acquire a product to sell in that market "so that your company from the top down learns about this field, learns how to sell in this field." (16 Tr. 3660 (Horovitz)).

Complaint Counsel's Response to Finding No. 1.324:

The proposed finding is not relevant. *See* CPRF 1.321 (noting that Schering's Board was never told this "strategic value" justification before entering into the settlement agreement, while it was informed of the need for Upsher to receive "a guaranteed income stream" to replace Upsher's projected Klor-Con profits).

1.325. Dr. Horovitz identified evidence, including contemporaneous documentary evidence, which confirmed that Schering had pursued this strategy with Niaspan in the spring of 1997. (16 Tr. 3660-63 (Horovitz); SPX 21 at 002771). Dr. Horovitz also identified evidence, including contemporaneous documentary evidence, which confirmed that Schering was pursuing this strategy with Niacor-SR in June 1997. (16 Tr. 3623, 3663-66 (Horovitz); SPX 235 at SP 16 00003). The uncontradicted testimony of Schering's executives confirms the documentary evidence: Schering acted on a strategic interest in pursuing Niacor-SR as part of its preparation for the launch of ezetimibe. (19 Tr. 4348-49 (Lauda); CX 1484 at 148:1-25 (Audibert IH)). Dr. Horovitz testified that this evidence supports his opinion regarding the value of the Niacor-SR license to Schering. (16 Tr. 3664-65 (Horovitz)).

Complaint Counsel's Response to Finding No. 1.325:

The proposed finding is not relevant. *See* CPRF 1.321 (noting that Schering's Board was never told this "strategic value" justification before entering into the settlement agreement, while it was informed of the need for Upsher to receive "a guaranteed income stream" to replace Upsher's projected Klor-Con profits).

5. Schering's Determination that the Value of Niacor-SR to Schering in June 1997 Exceeded $60 Million

a. Schering's Decision that Niacor-SR Was Worth More than $60 Million to Schering

1.326. Following Mr. Audibert's evaluation, Messrs. Lauda and Audibert met to discuss the written assessment and profit and loss statement, including the projected sales that Schering could expect from Niacor-SR, its projected market share, and assumptions underlying

those projections. (19 Tr. 4345-46 (Lauda); SPX 2; SPX 6; 18 Tr. 4138-40 (Audibert)).

Complaint Counsel's Response to Finding No. 1,326:

The proposed finding is incomplete and misleading. Mr. Audibert did not perform an "evaluation" of the Niacor-SR product, but rather conducted a limited "commercial assessment." Mr. Audibert described his assignment as "[g]enerating a sales forecast." CX 1484 at 105:18–21 (Audibert dep); Tr. at 7:1367-68 (Levy) (describing Schering's analysis of the Niacor-SR as constituting only "about a third of the way through the preliminary evaluation" of full due diligence); CPF 417-419 (describing the limited scope of Mr. Audibert's "commercial assessment").

1,327. Mr. Lauda concluded that Schering could promote Niacor-SR and "easily garner" the market share that Mr. Audibert projected because: (1) Schering knew the market for cholesterol lowering drugs very well; (2) the use of niacin as an effective treatment for high cholesterol was established and well recognized; (3) Schering was very familiar with the use of sustained release technology in the development of successful products in the past; and (4) the results of the Niacor-SR pivotal trials confirmed that Niacor-SR would be approved. (19 Tr. 4347-49 (Lauda)). Dr. Horovitz performed his own detailed evaluation of these sales projections, including the assumptions underlying them, and concluded that they were reasonable and properly conservative. (16 Tr. 3612, 3675 (Horovitz)). Dr. Kerr performed a sensitivity analysis and determined that the Niacor-SR sales projections were conservative and easily justified the license fees paid. (26 Tr. 6285-6294 (Kerr)).

Complaint Counsel's Response to Finding No. 1.327:

The proposed finding is incomplete, misleading, and contradicted by other evidence. Mr. Lauda's purported conclusions were contrary to other information known to Schering at the time. Primarily, Schering knew from its own market research that sustained-release niacin drugs faced significant development and marketing obstacles. *See* CPF 596-619 (discussing problems concerning sustained-release niacin known to Schering at the time of the settlement agreement). Mr. Lauda also was not familiar with what Schering had learned about sustained-release niacin products from Schering's discussion with Kos.

Dr. Horovitz reached his conclusions without understanding what information Schering knew at the time of the settlement agreement about sustained-release drugs in general and Niacor-SR in particular. In fact, Dr. Horovitz identified several aspects of Schering's review of Niacor-SR that were contrary to his experience with due diligence and how he would have reviewed Niacor-SR had he been in Schering's shoes.

- First, contrary to Mr. Audibert's review, Dr. Horovitz would have at least asked Upsher if there were any "outstanding issues" with the FDA. He also confirmed that in his experience with in-licensing late stage drugs (like Niacor-SR), he was unaware of any licensing deal in which such an inquiry was not made. Tr. at 16:3721-22 (Horovitz).

- Second, contrary to Mr. Audibert's review, Dr. Horovitz testified that if he had been in Schering's shoes evaluating Niacor-SR, he would have asked Upsher if it had labeling for Niacor-SR and reviewed such labeling had it been available. Tr. at 16:3750 (Horovitz) (also noting that he did not know whether anyone at Schering had reviewed Upsher's labeling for Niacor-SR).

- [redacted]

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- Fourth, contrary to Mr. Audibert's review, Dr. Horovitz, if he were in Schering's shoes and was going to license Niacor-SR, would like to have reviewed the FDA correspondence regarding Upsher's pharmacokinetic studies. Tr. at 16:3744 (Horovitz) (specifically noting he would have liked to review CX 1383 (discussed below) concerning Upsher's communications with the FDA).

- Finally, contrary to Mr. Lauda's purported conclusion that Niacor-SR would be approved, Dr. Horovitz testified that getting European regulatory approval is never certain. Tr. at 16:3712-13 (Horovitz) (also noting that Niacor-SR never received European regulatory approval).

Likewise, Dr. Kerr reached his conclusions without understanding what information Schering knew at the time of the settlement agreement about sustained-release drugs in general and Niacor-SR in particular. He also identified aspects of Schering's review of Niacor-SR that were contrary to his own conclusion. In particular, while Mr. Audibert was not aware of the patent cross-license between Kos and Upsher, Dr. Kerr confirmed that the cross license agreement could have affected the value of Schering's license for Niacor-SR. Tr. at 27:6610 (Kerr).

1.328. Using these financial projections and the terms of the license agreement, including the royalty payments to Upsher called for under the agreement, Schering performed its standard calculation of the economic value for this transaction which confirmed that Niacor-SR presented an economic value to Schering of between $225 to $265 million, and an internal rate of return of 43%. (SPX 26 at SP 16 00275). Dr. Horovitz testified that based on his experience with in-licensing transactions in the pharmaceutical industry, an internal rate of return of 35% is something to be "very happy with." (16 Tr. 3616-18 (Horovitz)). None of complaint counsel's

witnesses challenged the validity of Schering's calculation that Mr. Audibert's financial projections for Niacor-SR represented an economic value to Schering of between $225 to $265 million, and an return on its investment of 43%. (SPX 26, at SP 16 00275). Dr. Horovitz performed his own "conservative" calculations and concluded that Schering could have paid as much as $100 million and still obtained a 35% internal rate of return and an economic value of $205 million. (16 Tr. 3617-18 (Horovitz)).

Complaint Counsel's Response to Finding No. 1.328:

The proposed finding is not relevant. Complaint counsel does not challenge Mr. Audibert's arithmetic; however, the commercial assessment conducted by Mr. Audibert contained numerous fundamental flaws. CPF 456 484A (detailing the numerous flaws in Mr. Audibert's assessment).

Many of these flaws were recognized by Schering's own experts – Dr. Horovitz in particular – as contrary to his own experience in the pharmaceutical industry and contrary to how he would have conducted review of Niacor-SR. *See* CPRF 1.327 (noting several areas of Mr. Audibert's review that Dr. Horovitz did not agree with). Schering's European pricing expert also testified that Mr. Audibert did not conduct his European pricing analysis consistent with the expert's practice (including his evaluation of pricing issues in this matter). *See* CPRF 1.280 (discussing Mr. Audibert's failure to identify a comparator drug in Europe, and to review the European market on a country-by-country basis).

1.329. In addition to the economic value he saw for the product, Mr. Lauda also concluded that Niacor-SR presented "a major strategic fit for us as a precursor to launching ezetimibe." (19 Tr. 4348 (Lauda)). Based on both the economic and strategic values, Mr. Lauda concluded that the value of the Niacor-SR licensing opportunity to Schering in a "conservative format" was much more than $60 million. (19 Tr. 4345-47 (Lauda); 8 Tr. 1634-36 (Lauda Dep.)). Based on his own detailed evaluation of the Niacor-SR opportunity in June 1997, Dr. Horovitz concluded that the significant economic and strategic values of that opportunity to Schering exceeded $60 million. (16 Tr. 3618, 3698-3700 (Horovitz)). Dr. Horovitz reached this conclusion without having examined the supply agreement that permitted Schering the option to purchase supplies from Upsher at its cost of goods, and believes that this improves Schering's margin and renders the agreement "even better for Schering." (16 Tr. 3606-07 (Horovitz); CX 348).

Complaint Counsel's Response to Finding No. 1.329:

The proposed finding is not relevant. *See* CPRF 1.321 (noting that Schering's Board was never told this "strategic value" justification before entering into the settlement agreement, while it was informed of the need for Upsher to receive "a guaranteed income stream" to replace Upsher's projected Klor-Con profits).

The proposed finding is incomplete. Mr. Lauda's purported conclusions were contrary to other information known to Schering at the time. Primarily, Schering knew from its own market research that sustained-release niacin drugs faced significant development and marketing obstacles. *See* CPF 596-619 (discussing problems concerning sustained-release niacin known to Schering at the time of the settlement

agreement).

In addition, Dr. Horovitz reached his conclusions without understanding what information Schering knew at the time of the settlement agreement about sustained-release drugs in general and Niacor-SR in particular. In fact, Dr. Horovitz identified several aspects of Schering's review of Niacor-SR that were contrary to his experience with due diligence and how he would have reviewed Niacor-SR had he been in Schering's shoes. *See* CPRF 1.327.

1.330. Having concluded that the Niacor-SR opportunity presented a value to Schering in excess of $60 million, Mr. Lauda advised Mr. Kapur of his conclusion and later provided him a copy of Mr. Audibert's written assessment and profit and loss projections. (19 Tr. 4349 (Lauda); SPX 2; SPX 6). Mr. Lauda understood that this information would be used by Mr. Kapur to negotiate a license agreement for Niacor-SR. (19 Tr. 4349 (Lauda)).

Complaint Counsel's Response to Finding No. 1.330:

The proposed finding is incomplete. Mr. Lauda was informed before instructing Mr. Audibert to conduct his commercial assessment about the terms of the patent settlement with Upsher (including the $60 million payment). CPF 242. Mr. Wasserstein (a Schering in-house lawyer who participated in the settlement negotiations with Upsher) also had told Mr. Audibert what the terms of the patent settlement with Upsher were prior to completing Schering's review of Niacor-SR. CX 1532 at 17:13-18:22 (Wasserstein dep) (noting that he informed Mr. Audibert about the terms)

b. Dr. Levy's Criticism of Schering's Decision that Niacor-SR Was Worth More than $60 Million to Schering in June 1997

1.331. Dr. Levy testified that he had concluded that the $60 million license fee called for in the Niacor-SR license agreement "was not for Niacor-SR," because the payment terms of the Niacor-SR license agreement were "grossly excessive." (7 Tr. 1306-07, 1320 (Levy); CX 1597). Dr. Levy identified license fees, milestone payments, and royalty payments as the three main types of consideration contained in licensing arrangements. (7 Tr. 1321 (Levy)). Dr. Levy ignored the Niacor-SR license provisions relating to two of these three categories – milestone and royalty payments – stating simply that they were in-line with what he would expect for a product like Niacor-SR. (7 Tr. 1329 (Levy)). "It's just the license fee that was grossly out of line." (7 Tr. 1337 (Levy)).

Complaint Counsel's Response to Finding No. 1.331:

The proposed finding is incomplete and misleading. As the proposed finding itself notes, rather than ignore them, Dr. Levy discussed the milestone and royalty payments for Niacor-SR that were included in the settlement agreement. Based on his analysis of those payment terms, and his knowledge of other licensing deals, he concluded that the milestone and royalty payments included in the settlement agreement for Niacor-SR were in line with similar deals. CPF 306, 307; Tr. at 7:1329, 1337 (Levy).

1.332. With respect to the third category, however, Dr. Levy testified that the $60 million license fee was "grossly excessive" on the basis of just two factors: (a) Schering's evaluation of Niacor-SR ranks it as a "minor" drug and, as such, its economic value does not

justify the license fees paid; and (b) Dr. Levy's belief that the $60 million license fee was larger than any previous license fee in the history of the pharmaceutical industry. (7 Tr. 1329-30 (Levy)).

Complaint Counsel's Response to Finding No. 1.332:

The proposed finding is incomplete and misleading. Dr. Levy's analysis of the propriety of the $60 million dollar licensing fee was extensive and detailed, relying on many more than "just two factors." Dr. Levy examined niacin and the general hyperlipidemia market (CPF 265-86), the same documents used by Schering in its analysis of the Niacor-SR opportunity (Tr. at 7:1342, 1367-76), Schering's records of over 33 other Schering deals (Tr. at 7:1334-35), other payments by pharmaceutical companies up until the date of the Schering agreement (Tr. at 7:1330-31), and Schering's actions after the money was paid to Upsher (CPF 664-693).

In addition, in reaching his conclusion that the $60 million payment was grossly excessive, he also testified that this payment was the largest such payment in Schering's history, a fact which remains uncontested by the respondents. *See* CPF 314-323 (discussing Dr. Levy's review of the terms of over 30 Schering licensing agreements).

(1) Dr. Levy's Criticism of the Payment of $60 Million for a Product With the Economic Value of Niacor-SR

1.333. One of the two "factors" Dr. Levy relied upon to conclude that the Niacor-SR license fees were "grossly excessive" was that those license fees were not justified by the size of Schering's projections. (7 Tr. 1330-31, 1333-34 (Levy)). Dr. Levy explained that Schering's

projections of peak annual sales of $140 million a year would rank Niacor-SR as approximately the 305th largest drug in the world. (7 Tr. 1330-31, 1333-34 (Levy); CX 1603). On the basis of his classification of Niacor-SR as a "minor" drug, Dr. Levy concluded that the license fees were excessive. (7 Tr. 1330-31, 1333-34 (Levy)).

Complaint Counsel's Response to Finding No. 1.333:

The proposed finding is incomplete and misleading. Dr. Levy extensively analyzed several different issues before concluding that Niacor-SR was a minor drug and that it was not worth the $60 million given to Upsher. *See* CPRF 1.332.

1.334. According to, Professor Bresnahan, complaint counsel's own economic expert, complaint counsel cannot meet their burden of proving the existence of a payment for delay if, at the time of the license agreement, Schering's executives made a stand-alone determination that "it was getting as much in return for these products as it was paying." (5 Tr. 964-66 (Bresnahan)). In particular, Professor Bresnahan testified that complaint counsel have failed to meet this burden if Schering exercised its business judgement and concluded that "the net present value of the licenses exceeded $100 million." (5 Tr. 964-66 (Bresnahan)). Professor Bresnahan testified, however, that although he believes the Niacor-SR license agreement had some value to Schering, he does not know what that value was and did not perform a Net Present Value or any other type of quantitative analysis to make that determination. (5 Tr. 950-51 (Bresnahan)). Professor Bresnahan testified that he relied upon Dr. Levy for a quantitative evaluation of the value of Niacor-SR. (4 Tr. 577-78 (Bresnahan)).

Complaint Counsel's Response to Finding No. 1.334:

The proposed finding is incomplete and misleading. Schering never determined whether the products licensed under the settlement payment stood on their own two feet. Schering never conducted due diligence on these drugs, and in particular, the level of its review of Niacor-SR was "lower" than its review on other deals. *See* CPF 417-425 (discussing the limited scope and duration of Schering's review of Niacor-SR); CPF 426-445 (discussing absence of Schering's review of key issues including the patent status and regulatory status of Niacor-SR).

1.335. As complaint counsel's sole licensing expert, Dr. Levy's analysis of the economic value of Schering's projections for Niacor-SR simply ended with his determination that Niacor-SR was a "minor" drug. (10 Tr. 2059, 2064 (Levy)). Nowhere in Dr. Levy's testimony is there any type of financial analysis of whether Schering stood to gain an acceptable or even a substantial return on its investment, because Dr. Levy did not perform any type of financial analysis for Niacor-SR. (10 Tr. 2057-59, 2064 (Levy)). Dr. Levy testified that, although it is a very simple calculation that he himself has used in the past, he simply did not perform a Net Present Value analysis for Niacor-SR. (10 Tr. 2057-59, 2064 (Levy)). In fact, Dr. Levy admits that he did not perform any type of quantitative analysis of the value of Niacor-SR. (10 Tr. 2064 (Levy)).

Complaint Counsel's Response to Finding No. 1.335:

The proposed finding is incomplete and misleading. Dr. Levy reached his conclusion that the $60 million non-contingent payment made by Schering to Upsher

cannot reasonably be considered to have been a license fee for Niacor-SR and the five generic products licensed under the settlement agreement on three grounds. Tr. at 7:1307, 1338-39 (Levy). First, the $60 million non-contingent fee was grossly excessive for Niacor-SR and the other licensed products, and greatly surpassed the non-contingent fees paid by Schering in other unrelated pharmaceutical transactions. In fact, it was the largest such payment by Schering in its history. Tr. at 7:1307, 1336, [redacted] (Levy) [redacted]; CPF 287-372. Second, the due diligence conducted by Schering for Niacor-SR – over only a five day period – was strikingly superficial relative to industry standards on due diligence and Schering's own due diligence practices. Tr. at 7:1307, 1341 (Levy); CPF 373-663. Third, after the settlement agreement was executed, neither Schering nor Upsher undertook behavior consistent with parties who had just entered into a licensing transaction, never mind a transaction for which Schering committed to pay $60 million. Tr. at 7:1307 (Levy); CPF 664-721.

Second, the NPV methodology of evaluating discounted cash flows is not a reliable method for valuing pharmaceutical licensing products still under development. The two key variables in conducting a NPV evaluation are the discount rate and expected sales revenues. These two variables are unkowns when evaluating a pharmaceutical product that is still under development. Tr. at 10:2156-57 (Levy). In contrast, NPV evaluation has utility for other endeavors where these two variables are known. For example, NPV is useful if you are deciding to build a plant, where you are presently out-sourcing manufacturing. In that example, by using NPV you can determine what the change in cash flow will be resulting from building the new plant. Tr. at 10:2155-56

(Levy). The deposition testimony of other experts in this matter illustrates the difficulty in applying NPV to a pharmaceutical product under development such as Niacor-SR. In applying NPV to Niacor-SR, these experts' cash flow estimates differed greatly and the discount rates ranged from about 13% to 30%. Tr. at 10:2157-58 (Levy).

In addition, the testimony of respondents' experts provides support for the unreliable nature of NPV analysis. Dr. Kerr's testimony on NPV analysis provides support for Dr. Levy's opinion that NPV analysis is not useful for a pharmaceutical product under development. In particular, Dr. Kerr testified about a range of discount rates that could be used for evaluating Niacor-SR. He noted that he used a discount rate of 25%, but that Schering generally used a discount rate of 13%. He then added that "when doing this kind of valuation, I would think that a discount rate in the 20 – 18 to 20, maybe 22 percent range was what I would use looking at it from outside." Tr. at 26:6285 (Kerr). The unreliable nature of NPV analysis is further demonstrated by the results of Dr. Kerr's NPV analysis (which found a NPV of $110.8 million) as compared to substantially higher estimate presented to Schering's board of directors (which found "economic value" of $225-255 million). Tr. at 26:6286 (Kerr) (discussing his NPV figure); CX 338 at SP 12 00275 (presentation to Schering board on Niacor-SR). In addition, Dr. Horovitz testified that he used a 10% discount rate. Tr. at 16:3615 (Horovitz). Based on the testimony of these two experts for respondents, therefore, the discount rate that could be applied to Niacor-SR would range from between 10% to 25%, which supports Dr. Levy's opinion that such analysis is not useful since the discount rate to be used for evaluating a pharmaceutical product under development is an "unknown."

1.336. Dr. Levy testified that Net Present Value, while useful in other industries or contexts, is simply not useful in valuing pharmaceutical products because of the uncertainty in those valuations: "So, you can do all the calculations you want, but its still [garbage in, garbage out], and nobody is going to rely on it." (10 Tr. 2157 (Levy)). To the contrary, as complaint counsel's own rebuttal witness confirmed, Net Present Value calculations are a standard tool used in the pharmaceutical industry when evaluating a licensing transaction. (32 Tr. 7973 (Egan)). Dr. Horovitz testified that he too used Net Present Value calculations throughout his career in the pharmaceutical industry to evaluate licensing transactions. (16 Tr. 3613-18 (Horovitz)). In fact, Schering's evaluation of licensing transactions typically involves such a calculation. (19 Tr. 4361-62 (Lauda)).

Complaint Counsel's Response to Finding No. 1.336:

The proposed finding is incomplete and not relevant. Dr. Levy did not categorically state that NPV analysis is not useful. He testified that NPV is not a reliable method for valuing pharmaceutical products still under development. The two key variables in conducting an NPV evaluation are the discount rate and expected sales revenues. These two variables are unkowns when evaluating a pharmaceutical product that is still under development. Tr. at 10:2156-57 (Levy). *See* CPRF 1.135 (further describing Dr. Levy's testimony regarding NPV's lack of utility in evaluating pharmaceutical products under development).

In addition, the citation to Mr. Egan's testimony is not relevant. Mr. Egan's employer, Searle, rejected Niacor-SR based on Searle's perception that Niacor-SR, as presented by Upsher at a meeting with Searle, "had a toxicity profile that suggested that it

was not going to be a successful drug." Tr. at 33:7886 (Egan). From the Upsher presentation (CX 886), Searle did not believe that Niacor-SR "had a profile that was registerable or a profile that would have been commercially successful." Tr. at 33:7894 (Egan) (explaining why Niacor-SR would not meet Searle's needs for a "bridge" product).

1.337. None of complaint counsel's witnesses challenged the validity of Schering's calculation that Mr. Audibert's financial projections for Niacor-SR represented an economic value to Schering of between $225 to $265 million, and an return on its investment of 43%. (SPX 26 at SP 16 00275).

Complaint Counsel's Response to Finding No. 1.337:

The proposed finding is not relevant. Complaint counsel has not challenged the arithmetic involved in this economic value calculation; however, the commercial assessment conducted by Mr. Audibert that led to the "economic value" calculation contained numerous fundamental flaws. CPF 456–484A (detailing the numerous flaws in Mr. Audibert's assessment).

Many of these flaws were recognized by Schering's own experts – Dr. Horovitz in particular – as contrary to his own experience in the pharmaceutical industry and contrary to how he would have conducted a review of Niacor-SR. *See* CPRF 1.327 (noting several areas of Mr. Audibert's review that Dr. Horovitz did not agree with). Schering's European pricing expert also testified that Mr. Audibert did not conduct his European pricing analysis consistent with the expert's practice (including his evaluation of pricing

issues in this matter). *See* CPRF 1.280 (discussing Mr. Audibert's failure to identify a comparator drug in Europe, and to review the European market on a country-by-country basis).

(2) Dr. Levy's Comparison of the Payment Terms of the Niacor-SR License Agreement to Other Schering Deals

1.338. The second of the two "factors" Dr. Levy relied upon to conclude that the Niacor-SR license fees were "grossly excessive" was his belief that the $60 million up-front payment was larger than any previous license fee in the history of the pharmaceutical industry. (7 Tr. 1329-30 (Levy)). ********** ********** ********** ********** In discussing his up-front-payments-only analysis, Dr. Levy stated: "It's just the license fee that was grossly out of line." (7 Tr. 1337 (Levy)).

Complaint Counsel's Response to Finding No. 1.338:

The proposed finding is incomplete and misleading. Dr. Levy reached his conclusion that the $60 million non-contingent payment made by Schering to Upsher cannot reasonably be considered to have been a license fee for Niacor-SR and the five generic products licensed under the settlement agreement on three grounds. *See* CPRF 1.335 (first paragraph). In addition, Dr. Levy did not simply ignore the other payments. As Schering's proposed finding 1.331 notes, Dr. Levy discussed the milestone and royalty payments for Niacor-SR that were included in the settlement agreement. Based on his

analysis of those payment terms, and his knowledge of other licensing deals, he concluded that the milestone and royalty payments included in the settlement agreement for Niacor-SR were in line with similar deals. CPF 306, 307; Tr. at 7:1329, 1337 (Levy).

1.339. Unlike Dr. Levy, when Schering is analyzing the amount and structure of payments for a licensing opportunity, it performs internal assessments to determine the level of interest in the opportunity, and considers a number of factors. (19 Tr. 4374-75 (Lauda)). Specifically, in evaluating a deal, Schering considers five factors: (1) economic value; (2) degree of risk; (3) research resources required; (4) strategic fit of the product; and (5) total investment required to bring the product to approvability. (19 Tr. 4362 (Lauda)). Any comparison of the payment terms of various deals requires more than an isolated consideration of the up-front license fees.

Complaint Counsel's Response to Finding No. 1.339:

The proposed finding is not relevant. Schering did not evaluate each of these factors for Niacor-SR before committing to pay $60 million under the settlement agreement. In particular, Schering did not conduct sufficient due diligence to properly assess the economic value of Niacor-SR (CPF 419), the degree of risk involved with Niacor-SR (CPF 428-36), the research resources required to bring Niacor-SR to the market (CPRF 1.327), and the total investment needed to bring Niacor-SR to FDA approvability. CPF 456-484A.

(a) Up-Front Payments Are Directly Linked to How Future Profits Will Be Split

1.340. In performing his up-front-payments-only analysis, Dr. Levy simply ignored any provisions relating to how the parties agreed to split future revenues generated from the product. (7 Tr. 1337, ••••••••••••••••••••••••••••••••• But in discussing how deal terms are negotiated, Complaint Counsel's own rebuttal witness explained that up-front payments are very much linked to how the parties agree to split future profits:

> Typically a big pharma player will use up-fronts to buy down the upside. In other words, if a guy wants a relatively big up-front, for whatever reason, you know, he wants to go to the stock market and say, look, they're willing to pay $20 million, usually *you only pop up an up-front in that neighborhood when you have absolutely won the point on what split of values you want* and you've done that bigger deal. So, typically, if you're in a negotiation with a biotech, *you put in big up-front payments if you have a very favorable split of the revenues going forward.*

(33 Tr. 7983 (Egan)).

Complaint Counsel's Response to Finding No. 1.340:

The proposed finding is incomplete and misleading. Prior to the cited portion of the transcript above, Mr. Egan had testified Kos wanted upfront payments in the range of $10-20 million "that wouldn't make the product look cheap." Tr. at 33:7982 (Egan). This level of payment is in stark contrast to the $60 million upfront payment Schering agreed to pay Upsher. In addition, the portion of the transcript cited in the proposed finding is consistent with Dr. Levy's conclusion that $60 million was grossly excessive for a sustained-release niacin product. Mr. Egan characterized a $20 million payment as "big" for such a product.

1.341. [redacted]

Complaint Counsel's Response to Finding No. 1.341:

The proposed finding is incomplete. First, Dr. Levy did consider all payment terms of the various Schering licensing agreements he reviewed, as the proposed finding itself points out. Second, Schering (like all pharmaceutical companies) recognizes the distinction between non-contingent and contingent payments. The key distinction is that contingent payments are conditional upon some element of performance by a party. Tr. at 7:1321 (Levy). [redacted]

[redacted]

(b) Up-Front Payments Are Directly Linked to Risk

1.342. As noted by Mr. Egan, Complaint Counsel's rebuttal witness, there is risk

involved in making a large up-front payment (33 Tr. 7983 (Egan)), which is why Schering considers risk in evaluating licensing transactions (19 Tr. 4361-62 (Lauda)), another factor that Dr. Levy's up-front-payments-only analysis simply ignores. [redacted]

Complaint Counsel's Response to Finding No. 1.342:

The proposed finding is incomplete and misleading. An opportunity's perceived risk is assessed during due diligence, when a company learns all it can about a product before negotiating acquisition terms. Tr. at 16:3714-15 (Horovitz). Schering's due diligence process fulfills this risk assessment function for Schering. CPF 485-580. In reviewing Niacor-SR, Schering did not conduct due diligence consistent with its practice on other licensing deals. Thus, Schering had not assessed the actual level of risk involved since it only conducted a strikingly superficial review. CPRF 1.327, CPF 417-25.

1.343. [redacted]

Complaint Counsel's Response to Finding No. 1.343:

The proposed finding is contradicted by the evidence. In reviewing Niacor-SR, Schering did not conduct due diligence consistent with its practice on other licensing deals. Thus, Schering had not assessed the actual level of risk involved since it only conducted a strikingly superficial review. CPRF 1.327, CPF 417-25.

(c) Evaluation of Payment Terms of Licensing Transactions Must Consider Total Investment, Not Simply Up-Front Payments

1.344. In evaluating a licensing opportunity, Schering always analyzes the total investment required to bring a product "to a state of registration." (19 Tr. 4365-66, 4444 (Lauda); SPX 2266 (demonstrative)). This "Total Investment Pre-Approval" includes not only up-front non-contingent payments, but also: (1) research and development expenditures required

to bring a product to the approvable stage; and (2) payments that are contingent upon pre-approval events, such as successful completion of phase II studies. (19 Tr. 4365-66 (Lauda)).

Complaint Counsel's Response to Finding No. 1,344:

The proposed finding is incomplete. While Schering may consider total investment when considering a licensing transactions, Schering (like all pharmaceutical companies) recognizes the distinction between non-contingent and contingent payments. The key distinction is that contingent payments are conditional upon some element of performance by a party. Tr. at 7:1321 (Levy). [redacted]

[redacted]

1.345. Schering is not alone in considering the total investment required to bring a product up to the point of approvability (35 Tr. 8335, 8373 (Levy)), the Windhover database, upon which Dr. Levy himself relies (35 Tr. 8340 (Levy)), categorizes deals by total precommercialization payments, as follows: "Total deal value is defined as the sum of all precommercialization payments, including upfront licensing fees, equity purchases, milestones, scheduled R&D payments, and loans." (35 Tr. 8373 (Levy)). Of course, with the results of the Phase III clinical trials already in Schering's hands, Niacor-SR was much further along in development than most of the other Schering deals analyzed by Dr. Levy. [redacted]; 16 Tr. 3766 (Horovitz)).

Complaint Counsel's Response to Finding No. 1.345:

The proposed finding is incomplete. While Schering may consider total investment when considering a licensing transactions, Schering (like all pharmaceutical

companies) recognizes the distinction between non-contingent and contingent payments.

[redacted] *See* CPRF 1.344.

The proposed finding also is misleading. While Dr. Levy testified that he has relied on the Windhover database, he never stated that he agreed with that database's use of the term "total deal value." The cited definition for "total deal value" was read in to the record by Dr. Levy in response to the following question from Schering's counsel: "I'm asking you to read what it states underneath that heading." Tr. at 35:8373 (Levy).

1.346. Schering always includes its own anticipated research and development expenditures in estimating total investment when evaluating a licensing opportunity. (19 Tr. 4365-67 (Lauda)). Although Dr. Levy's analysis simply ignored these expenditures, Dr. Levy acknowledged that companies often invest $100-$200 million on research and development to bring a product to market. [redacted] For example, Dr. Horovitz described his in-licensing of the cholesterol drug, pravastatin, while at Bristol Myers Squibb in the mid-1980's, which involved an up-front payment of as much as $50 million and additional anticipated R&D costs of $50-$100 million. (16 Tr. 3688-91 (Horovitz)). [redacted]

[redacted]

Complaint Counsel's Response to Finding No. 1.346:

The proposed finding is incomplete. The proposed finding states that Schering always includes its own anticipated research and development expenditures when evaluating a licensing opportunity. However, when evaluating Niacor-SR, Schering simply assumed that such expenditures would be minimal without any evaluation of the issue. [redacted] *See* CPF 365-369.

In addition, while Schering may consider total investment – including anticipated research and development expenditures – when considering a licensing transactions, Schering (like all pharmaceutical companies) recognizes the distinction between non-contingent and contingent payments. [redacted] *See* CPRF 1.344.

1.347. Dr. Levy's entire explanation as to why he ignored research and development expenses was: "What a company spends on R&D to develop in-licensed products is one of its operating expenses . . . one presumes they had a budget to do that. It's – it's no more relevant to this slide [comparing up-front payments] than their human resources budget." (10 Tr. 2153 (Levy)). On cross-examination, Dr. Levy explained: "I don't think that when a company is

deciding how much of an up-front payment it's going to make that's a – that's a parameter that it considers." (10 Tr. 2178 (Levy)). To the contrary, Mr. Lauda explained that Schering considers five factors, including research and development, when deciding how much to pay up-front, and how much to pay in total. (19 Tr. 4374-75, 4362 (Lauda)).

Complaint Counsel's Response to Finding No. 1.347:

The proposed finding is incomplete. Dr. Levy explained in detail that while Schering may consider total investment – including anticipated research and development expenditures -- when considering a licensing transaction, Schering (like all pharmaceutical companies) recognizes the distinction between non-contingent and contingent payments. [redacted] *See* CPRF 1.344.

1.348. And when questioned about the opportunity cost of having R&D resources tied up on a project, Dr. Levy simply replied that they could "expand their research budget if they have an opportunity," although he conceded that this too costs money. (10 Tr. 2179 (Levy)). In identifying the flaws in Dr. Levy's theory, Dr. Horovitz explained: "I don't know if Dr. Levy understands that for most deals, the up-front payment is an R&D expense. It comes out of the R&D budget . . . and the reason for that is it's an opportunity cost." (16 Tr. 3687-88 (Horovitz)). Mr. Lauda testified that Schering considers the R&D commitment when evaluating a deal, because: "[I]f we have to use some of those resources in a licensed project, we are going

to have to discontinue something else." (19 Tr. 4364-67 (Lauda)). Moreover, Dr. Levy was forced to admit that pharmaceutical companies often out-source R&D expenditures (<u>i.e.</u>, make a <u>payment</u> to an outside company to do that work) (10 Tr. 2178-79 (Levy)), [redacted]

<u>Complaint Counsel's Response to Finding No. 1.348:</u>

The proposed finding is incomplete. Dr. Levy explained in detail that while Schering may consider total investment – including anticipated research and development expenditures – when considering a licensing transactions, Schering (like all pharmaceutical companies) recognizes the distinction between non-contingent and contingent payments. [redacted] *See* CPRF 1.344. [redacted]

1.349. Dr. Horovitz testified that Dr Levy's method of comparing deals, based on up-front payments to the exclusion of all other terms, like research and development, is just "completely wrong." (16 Tr. 3685-87 (Horovitz)). [redacted]

[redacted]

Complaint Counsel's Response to Finding No. 1.349:

The proposed finding is incomplete. Dr. Levy explained in detail that while Schering may consider total investment when considering a licensing transaction, Schering (like all pharmaceutical companies) recognizes the distinction between non-contingent and contingent payments. [redacted]

See CPRF 1.344.

(d) Evaluation of Up-Front Payments Must Include Consideration of Economic Value

1.350. Schering also regularly considers economic value when considering an in-licensing opportunity. (19 Tr. 4361-63 (Lauda)). The economic value is the estimated economic return Schering expects to realize on a project. (19 Tr. 4362 (Lauda)). Economic value is determined by preparing an assessment of the underlying asset, license rights, sales projections, and expected profitability, and applying financial calculations to determine the present economic value of the transaction to Schering. (19 Tr. 4362-63 (Lauda)). The fundamental determination made with this calculation is how much profit Schering expects from the transaction. (19 Tr. 4362 (Lauda)).

Complaint Counsel's Response to Finding No. 1.350:

The proposed finding is not relevant. Schering did not conduct a sales forecast or profit and loss projection consistent with Schering's practice on other licensing transactions. [redacted]; CX 689 at SP 018744 (Schering "finance manual" requiring financial review for any agreement where intellectual property rights were transferred to Schering); CX 1531at 14:4-16 (Wasserstein IH) (discussing Schering's licensing department's role as coordinator between different Schering departments, including the corporate finance group, so that "all the appropriate review was done"); *see generally* CPF 406-410 (describing customary pharmaceutical due diligence on financial and commercial assessments).

In addition,[redacted] *See* CPF 503-507 (describing Schering due diligence review of commercial and financial issues for its license with Zonagen); CPF 535-540 (describing Schering due diligence review of commercial and financial issues for its license with Cor Therapeutics); CPF 558-559 (describing Schering due diligence review of commercial and financial issues for its license with Atherogenics); CPF 568-569 (describing Schering due diligence review of

commercial and financial issues for its license with British Biotech); CPF 577-578 (describing Schering due diligence review of commercial and financial issues for its license with ICN).

In contrast, before committing to pay $60 million for Niacor-SR, Mr. Audibert alone prepared one sales forecast and one profit and loss projection. CX 1044 (Mr. Audibert's eight-page "commercial assessment" of Niacor-SR). In addition, Mr. Audibert failed to consult any officials in Schering's European division – the individuals who would have been responsible for selling Niacor-SR in Europe – in preparing these sales forecasts. *See* CPF 437-440 (describing the abbreviated nature of Mr. Audibert's commercial assessment, and his failure to take into consideration certain factors necessary to evaluating a drug product for sale in Europe).

The proposed finding is incomplete. Schering did not complete more than a superficial assessment of the Niacor-SR project before paying Upsher $60 million dollars. CPRF 1.339. This assessment did not include a due diligence assessment of Niacor-SR, the patent status of Niacor-SR in Europe, or a country-by-country pricing analysis for Europe (which puts any sales, profitability, or financial calculations into question). CPF 426-42.

1.351. Dr. Levy's up-front-payments-only analysis simply ignored economic value. If Dr. Levy had considered economic value in connection with his analysis of up-front payments,

[redacted]

[redacted]

Complaint Counsel's Response to Finding No. 1.351:

The proposed finding is not relevant. Schering did not conduct a sales forecast or profit and loss projection consistent with Schering's practice on other licensing transactions. [redacted] *See* CPRF 1.350.

[redacted]

	Non-Contingent Fees	Other Licensing Compensation	Other Licensing Compensation as a Percentage of Non-Contingent Fees
Upsher (Niacor-SR)	$ 60 M	$ 10 M	17%
Zonagen (Vasomax)	[redacted]	[redacted]	[redacted]
Centocor (Remicade)	[redacted]	[redacted]	[redacted]
COR (Integrelin)	[redacted]	[redacted]	[redacted]
ICN (Ribavarin)	[redacted]	[redacted]	[redacted]
Neurogen (Dopamine)	[redacted]	[redacted]	[redacted]
Chugai (Maxacalatol)	[redacted]	[redacted]	[redacted]
British BioTech (Marimastat)	[redacted]	[redacted]	[redacted]
AtheroGenics (AGI-1067)	[redacted]	[redacted]	[redacted]

[redacted]; and SPX 2266 (Schering demonstrative which provides the total investment pre-approval for these deals). The notable exception to this standard practice is Niacor-SR. Schering offers no rationale as to why, in this case, it abandoned its standard licensing practices, adopting instead a compensation structure in which non-contingent payments made up the dominant component.

1.352. In comparing these two deal, Dr. Levy's simplistic analysis literally consisted of his observation that $60 million is "larger" than [redacted] Unlike Dr. Levy's analysis, the economic value analysis performed by Schering and others in the pharmaceutical industry accounts for things like how future profits will be split by the parties. [redacted]

[redacted] the Upsher license (Schering to pay-out 10%-15% of revenues) (SPX 92 at SP 00195). [redacted] When evaluated in this fashion, the comparison becomes entirely unremarkable: [redacted]

Complaint Counsel's Response to Finding No. 1.352:

The proposed finding is incomplete and misleading. [redacted]

1.353. Moreover, Dr. Levy's characterization of the Centocor deal as involving a "billion dollar drug" is [redacted] Schering's peak year sales projections for Niacor-SR. (SPX 26, at SP 12 00273).

Complaint Counsel's Response to Finding No. 1.353:

The proposed finding is incomplete and misleading. [redacted]

1.354. A comparison of the Niacor-SR license and the Centocor deal is as follows:

[redacted]

Complaint Counsel's Response to Finding No. 1.354:

The proposed finding is incomplete and misleading. [redacted] Schering did not conduct a sales forecast or profit and loss projection for Niacor-SR consistent with Schering's practice on other licensing transactions. *See* CPRF 1.350.

1.355. The economic value is an equally useful tool for evaluating all of the other Schering deals addressed by Dr. Levy.

[redacted] Again, when viewed in any context other than Dr. Levy's self-crafted up-front-payment-only model, the Upsher deal is simply unremarkable.

Complaint Counsel's Response to Finding No. 1.355:

The proposed finding is incomplete and misleading. The values assigned to the other deals were derived after extensive due diligence into the other products. Schering did not conduct a sales forecast or profit and loss projection for Niacor-SR consistent

with Schering's practice on other licensing transactions. *See* CPRF 1.350.

In addition, the proposed finding ignores Schering's use of contingent payments in every deal Schering has done other than its settlement agreement with Upsher. *See* CPRF 1.351

[redacted]

(e) Dr. Levy's Flawed Understanding of Why Large Up-Front Payments are Made

1.356. In explaining his "expert" understanding of the circumstances that lead to large up-front payments, Dr. Levy testified as follows: "The only time when license fees rise above a fairly – a very low level is when there is considerable competitive activity for this – for this product and when the product has enormous upside potential." (7 Tr. 1326 (Levy)). [redacted]

Rather, Schering made those large up-front payments because "that's what it took to get the deal done." (19 Tr. 4374 (Lauda)).

Complaint Counsel's Response to Finding No. 1.356:

The proposed finding is incomplete and misleading. [redacted]

[redacted]

In addition, Dr. Levy's testimony discussed license fees remaining at "modest level[s] compared to the overall size of the deal." Tr. at 7:1326 (Levy). [redacted]

[redacted]

[redacted]

[redacted]

c. Dr. Levy's Criticism of the Volume of Due Diligence Performed for Niacor-SR

1.357. Dr. Levy testified that he concluded that the $60 million license fee called for in the Niacor-SR license agreement "was not for Niacor-SR" because the level of due diligence performed by Schering was in his view "strikingly superficial." (7 Tr. 1341-42 (Levy); CX 1597). In fact, Dr. Levy testified that his minimum due diligence requirement was a stand alone criterion, i.e., even if the $60 million was perfectly in line with the value of Niacor-SR, the alleged lack of due diligence conducted by Schering would – by itself – lead him to conclude that the $60 million "was not for Niacor-SR." (10 Tr. 2133-34 (Levy)).

Complaint Counsel's Response to Finding No. 1.357:

Complaint counsel has no specific response.

(1) Dr. Levy's Second Guessing of Schering's Due Diligence is Inconsistent with Professor Bresnahan's Testimony

1.358. Although complaint counsel use Dr. Levy's conclusion that the payment "was not for Niacor-SR" to support Professor Bresnahan's conclusion that the payment was for delay, Dr. Levy appears to be at odds with Professor Bresnahan on the propriety of second guessing the due diligence performed by Schering. (4 Tr. 577-78, 607 (Bresnahan); CX 1577). Professor Bresnahan specifically testified that the analysis of whether there was a payment for delay does not impose a minimum due diligence requirement and that if Schering's conclusion about the value of Niacor-SR was based on its business judgment, the agreement would not contain a payment for delay. (5 Tr. 967-68 (Bresnahan)).

Complaint Counsel's Response to Finding No. 1.358:

The proposed finding is incomplete and misleading. Dr. Bresnahan's comments on "business judgement" referred to a rational objective economic decision to trade monetary payment for like value, not a spurious subjective assessment of "worth." *See* Tr. at 5:967 (Bresnahan) ("The business people can come to beliefs through either sober business judgements or by other mechanisms. If it were based on sober business judgement, the value, then I would say yes . . . then there's no payment for delay . . . [i]f it were honestly held but come to by some other way, then I just don't know. It's outside my purview").

(2) Due Diligence is the Level of Diligence That is Due, Which is Dependent on the Specific Product Being Evaluated

1.359. During the course of his career in the pharmaceutical industry, Dr. Horovitz has been involved with roughly 75 licensing or technology transfers. (16 Tr. 3609 (Horovitz)). Dr. Horovitz explained that due diligence, by its very definition, is the diligence that is due for a specific licensing opportunity, and therefore the diligence that is due will necessarily vary from opportunity to opportunity. (16 Tr. 3678 (Horovitz)). This has been true throughout Dr. Horovitz's career. (16 Tr. 3683-84 (Horovitz)). A variety of factors can influence the amount of due diligence that is required for a particular opportunity, including the stage of development the product is in and whether the product is a new chemical entity or an old, known compound. (16 Tr. 3678 (Horovitz)). Further, a due diligence review may also be greatly facilitated where the individual conducting the review has preexisting knowledge of the market or product being evaluated. (16 Tr. 3678-79 (Horovitz)).

Complaint Counsel's Response to Finding No. 1.359:

The proposed finding is incomplete and misleading. While Dr. Horovitz may have testified that due diligence can vary depending on the transaction, he identified several aspects of Schering's review of Niacor-SR that were contrary to his experience with due diligence and how he would have reviewed Niacor-SR had he been in Schering's shoes.

First, contrary to Mr. Audibert's review, Dr. Horovitz would have at least asked Upsher if there were any "outstanding issues" with the FDA. He also confirmed that in his experience with in-licensing late stage drugs (like Niacor-SR), he was unaware

of any licensing deal in which such an inquiry was not made. Tr. at 16:3721-22 (Horovitz).

- Second, contrary to Mr. Audibert's review, Dr. Horovitz testified that if he had been in Schering's shoes evaluating Niacor-SR, he would have asked Upsher if it had labeling for Niacor-SR and reviewed such labeling had it been available. Tr. at 16:3750 (Horovitz) (also noting that he did not know whether anyone at Schering had reviewed Upsher's labeling for Niacor-SR).

- [redacted]

- Fourth, contrary to Mr. Audibert's review, Dr. Horovitz, if he were in Schering's shoes and was going to license Niacor-SR, would have liked to review the FDA correspondence regarding Upsher's pharmacokinetic studies. Tr. at 16:3744 (Horovitz) (specifically noting he would have liked to review CX 1383 (discussed below) concerning Upsher's communications with the FDA).

- Finally, contrary to Mr. Lauda's purported conclusion that Niacor-SR would be approved, Dr. Horovitz testified that getting European regulatory approval is never certain. Tr. at 16:3712-13 (Horovitz) (also noting that Niacor-SR never received European regulatory approval).

1.360. As has been the case with Dr. Horovitz's experience with pharmaceutical licensing transactions, the amount of due diligence that Schering performs in evaluating a licensing opportunity depends on the nature of the opportunity. (15 Tr. 3432-33 (Russo); [redacted]; 7 Tr. 1409-10 (Driscoll IH)). Schering does not use any standard approach in evaluating a licensing opportunity. (15 Tr. 3432-33 (Russo)). Generally, the higher the risk involved with a particular product, the more involved Schering's review process will be. (15 Tr. 3432-33 (Russo)).

<u>Complaint Counsel's Response to Finding No. 1.360:</u>

The proposed finding is incomplete and misleading. While Dr. Horovitz may

have testified that due diligence can vary depending on the transaction, he identified several aspects of Schering's review of Niacor-SR that were contrary to his experience with due diligence and how he would have reviewed Niacor-SR had he been in Schering's shoes. *See* CPRF 1.359.

Mr. Russo's testimony is contrary to his experience and the documents he created while evaluating Kos' Niaspan product. In a March 1997 memorandum prepared by Mr. Russo, he specifically discussed the need for "due diligence validation" on patent status, finalized labeling, manufacturing capabilities, and product liability. He further wrote that these issues "need to be reviewed and more completely understood before a deal could be made. . . . We would of course subject any deal to this criteria." CX 546 at SP 002770.

In addition, a review of Schering's due diligence on five licensing deals shows

[redacted] The chart below (from CPF 486) illustrates the due diligence conducted on these other deals in comparison to the extremely abbreviated review conducted on Niacor-SR:

	Upsher-Smith's "Niacor-SR"	AtheroGenics' "AGI-1067"	British Biotech's "Marimastat"	Zonagen's "Vasomax"	COR Therapeutics' "Integrelin"	ICN's "Ribavarin" (Infliximab)
Research & Development Review		•	•	•	•	•
Regulatory Review		•	•	•	•	•
Intellectual Property Review		•	•	•	•	•
Financial Review	√	•	•	•	•	•
Commercial Assessment	√	•	•	•	•	•
Manufacturing Assessment		•	•	•	•	•
Time Spent on Due Diligence	no more than 5 days	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Up Front Payments	$60 million	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

1.361. First, Schering performs more due diligence for a product that is in an early stage of development as opposed to a late stage product for which Phase III data is already available. (15 Tr. 3432-33 (Russo)). This is because there is often less risk and more known about a drug that is further along in development, whereas a drug in an early stage of development is more of an "unknown" and typically requires a more cautious approach. (15 Tr. 3433 (Russo); 16 Tr. 3681-82 (Horovitz)).

Complaint Counsel's Response to Finding No. 1.361:

The proposed finding is not relevant. While more may be known about a late stage drug, Schering only undertook cursory due diligence on Niacor-SR which failed to evaluate nearly all issues normally reviewed by Schering before licensing a drug. In

reviewing Niacor-SR, Schering did not evaluate its regulatory status, patent status, manufacturing issues, or conduct a safety review of the drug. *See* CPRF 1.360 (describing Schering's due diligence on other drugs in comparison to Niacor-SR).

1.362. Second, Schering performs more due diligence for a product that involves a new chemical entity as opposed to a product that involves an old, known compound. (15 Tr. 3532-33 (Russo); 18 Tr. 4138 (Audibert); ••••••••••••••••••••••••••••••. A new chemical entity requires significantly more due diligence than an old known compound because the lack of experience or familiarity with a new chemical entity means they are simply less predictable than old drugs. (18 Tr. 4138 (Audibert); 16 Tr. 3678-81 (Horovitz)). In contrast, evaluating a known compound can be much more straightforward when the data you evaluate serves to confirm your expectations for the product. (16 Tr. 3680-81 (Horovitz); 18 Tr. 4138 (Audibert); •••. In fact, the March 1997 prospectus from Kos' initial public offering explained Kos' strategy in focusing on reformulations of known drugs, as with Niaspan: "Kos believes that developing proprietary products based on currently approved drugs, rather than new chemical entities ("NCEs"), may reduce regulatory and development risks . . ." (SPX 605 at Kos 0073).

Complaint Counsel's Response to Finding No. 1.362:

The proposed finding is not relevant. While more may be generally known about an old chemical compound, Schering only undertook cursory due diligence on Niacor-SR, which failed to evaluate nearly all issues normally reviewed by Schering before licensing any drug. In reviewing Niacor-SR, Schering did not evaluate its regulatory status, patent status, manufacturing issues, or conduct a safety review of the drug. *See* CPRF 1.360

(describing Schering's due diligence on other drugs in comparison to Niacor-SR).

1.363. Third, a product that does not already have an established "proof of principle" presents a greater risk and, therefore, more due diligence will be performed by Schering as compared to a product for which the efficacy in treating the targeted disease is already well established.[redacted]; 15 Tr. 3432-33 (Russo)). Because having "proof of principle" means a drug is already known to be effective in treating that particular disease, there is less risk that the product will not prove to be efficacious and, therefore, Schering considers this to be a very important factor in assessing risk. (19 Tr. 4363 (Lauda); 18 Tr. 4116-17 (Audibert)).

Complaint Counsel's Response to Finding No. 1.363:

The proposed finding is not relevant. While more may be known about a drug with an established "proof of principle," Schering only undertook cursory due diligence on Niacor-SR, which failed to evaluate nearly all issues normally reviewed by Schering before licensing any drug. In reviewing Niacor-SR, Schering did not evaluate its regulatory status, patent status, manufacturing issues, or conduct a safety review of the drug. *See* CPRF 1.360 (describing Schering's due diligence on other drugs in comparison to Niacor-SR).

(3) Schering Performed the Level of Due Diligence Required for Niacor-SR

1.364. Unlike other products Schering has evaluated, Niacor-SR was a very "straightforward" product in a market with which Schering was intimately familiar. [redacted]; 18 Tr. 4093-98, [redacted], 4137 (Audibert)). [redacted]

[redacted]

Complaint Counsel's Response to Finding No. 1.364:

The proposed finding is contradicted by other evidence. The Niacor-SR licensing opportunity was not straightforward. First, sustained-release niacin drugs were known to have adverse side-effects that would impact on the development and marketing of any such drug. CPF 588-595 (describing known problems with these drugs). Second, Schering was well aware of these problems based on its own review of Niaspan and market research conducted on sustained-release niacin drugs. CPF 596-619. Third, other potential licensors of Niacor-SR did not find this drug to be straightforward based on the concerns they raised when meeting with Upsher, and the fact that most companies evaluating the drug sought additional time and/or additional information from Upsher as part of their evaluation. CPF 620-652. Fourth, the FDA in its correspondence with Upsher concerning Niacor-SR noted concerns about the status of Upsher's pharmacokinetic study and questions about the fileability of Upsher's NDA. CPF 653-659.

1.365. Niacor-SR was a "straightforward product." ••••••••••••••••••••••••••, 4384–85 (Lauda); 18 Tr. 4137 (Audibert); 8 Tr. 1637 (Lauda Dep.)). First, Niacor-SR was a late stage Phase III product, and Schering was able to conduct its evaluation on the basis of the results of the Phase III pivotal trials. (18 Tr. 4113-14 (Audibert); ••••••••••••••••••••••••••••; 16 Tr. 3682, 3717 (Horovitz); CX 1042). Second, Niacor-SR's active ingredient, niacin, is an old and well-known compound with an established product profile. (18 Tr. 4137-38 (Audibert); ••••••••••••••••••••••••••••••; 16 Tr. 3681 (Horovitz)). Third, Niacor-SR had "proof of principle" in that niacin has long been known to be effective in the treatment of high cholesterol, the exact indication targeted for Niacor-SR. (18 Tr. 4116-17 (Audibert); ••••••••••••••••••••••••••••••. In fact, as a result of niacin's known efficacy profile, the FDA had advised Upsher during the development of Niacor-SR that "there is no question that niacin is effective," and that "efficacy was considered almost a non-issue." (CX 1376 at Upsher-Smith FTC 127098; CX 1371).

Complaint Counsel's Response to Finding No. 1.365:

The proposed finding is contradicted by other evidence. The Niacor-SR licensing opportunity was not straightforward. *See* CPRF 1.364.

In addition, Schering did not have the "results" of Upsher's two pivotal trials, so it could not have concluded from that information that Niacor-SR was straightforward. CX 1042 at SP 16 00079 (the "package" of information received from Upsher noting that the "projected" completion date for the second pivotal trial (Protocol 900221) was June 1997).

The statement in the proposed finding concerning what the FDA had advised Upsher is not relevant. During its evaluation of Niacor-SR, Schering did not review any

information that would have indicated whether the FDA had identified potential problems with Niacor-SR. Tr. at 18:4178 (Audibert) (confirming that the information he was provided during his commercial assessment did not tell him whether there were any problems identified by the FDA); Tr. at 18: 4190 (Audibert) (indicating he did not review any of Upsher's FDA files during his evaluation of Niacor-SR).

If Schering had evaluated such correspondence, it would have learned that the FDA expressed concerns about the status of Upsher's pharmacokinetic study and questions about the fileability of Upsher's NDA. CPF 470-81 (discussing several pieces of correspondence detailing issues and concerns raised by the FDA prior to June 1997); CX 1382 at Upsher-Smith FTC 107436 (Upsher's minutes from February 5, 1997 meeting with FDA, reporting that "[d]ue to the known pharmacokinetic issues outstanding for Niacor-SR, the FDA should not file the NDA without the requested pharmacokinetic study results"); CX 1383 at Upsher-Smith FTC 107457 (fax from FDA's division of metabolic and endocrine drug products to Upsher regulatory affairs specialist cautioning "that approval of Niacor-SR as a controlled-release product is dependent on the results of the submitted [pharmacokinetic] study, and not merely on its completion.").

1.366. On the basis of these considerations, Dr. Horovitz testified that in evaluating a drug like Niacor-SR, he would expect that a knowledgeable person could perform the requisite due diligence more quickly than would be the case with other licensing evaluations. (16 Tr. 3682 (Horovitz)). As it turns out, in addition to the fact that Niacor-SR was a "straightforward"

product, Mr. Audibert was uniquely qualified to evaluate this exact product in June 1997.

Complaint Counsel's Response to Finding No. 1.366:

The proposed finding is contradicted by other evidence. Dr. Horovitz identified several aspects of Schering's review of Niacor-SR that were contrary to his experience with due diligence and how he would have reviewed Niacor-SR had he been in Schering's shoes. *See* CPRF 1.359.

The proposed finding is contradicted by other evidence. Mr. Audibert did not have "unique qualifications" to evaluate Niacor-SR on his own. Mr. Audibert did not have the training or experience necessary to conduct due diligence on Niacor-SR. In particular, he had not worked in the regulatory area since 1977, and was not familiar with FDA requirements or procedures regarding the approval of drugs. CPF 446-455B.

1.367. First, Mr. Audibert was already familiar with cholesterol lowering drugs -- including niacin – as a result of his detailed evaluation of the cholesterol lowering market as part of his work on Schering's blockbuster pipeline drug, ezetimibe. (18 Tr. 4095-4100 (Audibert)).

Complaint Counsel's Response to Finding No. 1.367:

The proposed finding is incomplete and misleading. Mr. Audibert's "familiarity" with cholesterol-lowering drugs was from his experience as a sales and marketing executive, not as a research scientist. *See* CPF 446-55B; Tr. at 18:4082-85, 4092-95 (Audibert) (describing his work experience).

The proposed finding is not relevant. While Mr. Audibert possessed some knowledge about the cholesterol-lowering market, Mr. Audibert did not have the

qualifications to perform the scientific review of Niacor-SR, and he committed numerous errors in his analysis of the package of information provided by Upsher to Schering on Niacor-SR. *See* CPRF 1.204.

1.368. Second, as a result of his work on ezetimibe, Mr. Audibert was already intimately familiar with, and had been spending about a third of his professional time studying, the cholesterol lowering market. (18 Tr. 4092-4101, ••••••••••••••• (Audibert); 16 Tr. 3679-80 (Horovitz)).

Complaint Counsel's Response to Finding No. 1.368:

The proposed finding is incomplete and misleading. *See* CPRF 1.367 (describing the majority of Audibert's work experience as being in the sales and marketing field).

The proposed finding is not relevant. While Mr. Audibert possessed some knowledge about the cholesterol-lowering market, Mr. Audibert did not have the qualifications to perform the scientific review of Niacor-SR, and he committed numerous errors in his analysis of the package of information provided by Upsher to Schering on Niacor-SR. *See* CPRF 1.204.

1.369. Third, Niacor-SR was a known drug reformulated using sustained release technology to overcome a known side effect, a method of development with which Mr. Audibert had gained substantial expertise throughout his career. (18 Tr. 4082-89 (Audibert)); 16 Tr. 3679-80 (Horovitz)).

Complaint Counsel's Response to Finding No. 1.369:

The proposed finding is not relevant. Sustained release drugs are not interchangeable. Each must be individually evaluated, even if the same drug compound is being used with different sustained release technologies. CPRF 1.363 (discussing differences between sustained-release technologies). In addition, while Mr. Audibert possessed some knowledge about the cholesterol-lowering market, Mr. Audibert did not have the qualifications to perform the scientific review of Niacor-SR, and he committed numerous errors in his analysis of the package of information provided by Upsher to Schering on Niacor-SR. *See* CPRF 1.204.

1.370. Fourth, Mr. Audibert was an educated pharmacologist with substantial experience throughout his career in overseeing and evaluating clinical trials. (18 Tr. 4081-89 (Audibert); 16 Tr. 3679-80 (Horovitz)).

Complaint Counsel's Response to Finding No. 1.370:

The proposed finding is incomplete and misleading. Although Mr. Audibert did receive a pharmacology degree, he has never been employed as a pharmacologist. Most of his career has been in sales and marketing. *See* CPRF 1.367 (describing Mr. Audibert's work experience).

1.371. Fifth, Mr. Audibert knew from his evaluation of Niaspan just months earlier that the FDA was on the verge of approving another sustained release niacin, and the results of the pivotal trials for Niacor-SR confirmed that Upsher had similarly succeeded in developing a safe

and effective sustained release niacin. (11 Tr. 2453-54 (Audibert Dep.); [redacted]; 16 Tr. 3679-80 (Horovitz)).

<u>Complaint Counsel's Response to Finding No. 1.371</u>:

The proposed finding is incomplete and misleading. Mr. Audibert had limited involvement in Schering's discussions with Kos regarding Niaspan. In fact, he only participated in one conference call with Kos in March 1997, and then dropped out of Schering's evaluation of Niaspan. Tr. at 15:3516-17 (Ray Russo) (confirming that Mr. Audibert only participated in one conference call which occurred in March 1997 (per CX 543)). In addition, when assessing Niacor-SR in June 1997, Mr. Audibert did not consult the Schering officials (e.g., Mr. Russo) involved in the full discussions with Kos regarding Niaspan. *See* CPF 425 (discussing Mr. Audibert's failure to consult Schering officials regarding Niaspan).

1.372. As a result of the convergence of Mr. Audibert's particular expertise and Niacor-SR's "straightforward" profile, the level of due diligence that Schering had to perform in evaluating Niacor-SR was expectedly less than the level of due diligence required for other products Schering has evaluated. [redacted] Other departments were available to Mr. Audibert had he seen a need to consult them, but he saw no need to do so in the case of Niacor-SR. (18 Tr. 4138 (Audibert); 8 Tr. 1641, 1643, 1652 (Lauda Dep.)). Niacor-SR was unlike any other product evaluation in which Mr. Audibert had previously been involved. (18 Tr. 4138 (Audibert)). For example, although Mr. Audibert frequently consults people outside global marketing in conducting an evaluation, virtually every other product which Mr. Audibert has

evaluated involved a new chemical entity, unlike Niacor-SR. (18 Tr. 4138 (Audibert)).

Complaint Counsel's Response to Finding No. 1.372:

The proposed finding is contradicted by other evidence. The testimony of Dr. Horovitz identifies several aspects of Schering's review of Niacor-SR that were contrary to his experience with due diligence. He further testified that he would have conducted further review in several areas that were not explored by Mr. Audibert. *See* CPRF 1.359.

1.373. Based on Mr. Audibert's evaluation of Niacor-SR, Schering did not believe that additional due diligence was required: "We felt we had the answers to the questions." ••••••• ••••••••••••••••••; 18 Tr. 4137 (Audibert)). Mr. Lauda testified that Mr. Audibert's sales projections, which were reviewed and approved by Mr. Lauda, represented Schering's best estimate of what Schering could achieve in the marketplace with Niacor-SR. •••••••••••• ••••••••••••

Complaint Counsel's Response to Finding No. 1.373:

The proposed finding is contradicted by other evidence. The testimony of Dr. Horovitz identifies several aspects of Schering's review of Niacor-SR that were contrary to his experience with due diligence. He further testified that he would have conducted further review in several areas that were not explored by Mr. Audibert. *See* CPRF 1.359.

In addition, Schering did not conduct a sales forecast or profit and loss projection for Niacor-SR consistent with Schering's practice on other licensing transactions. *See* CPRF 1.350.

(4) Dr. Levy's Criticism of the "Volume" of Due Diligence Performed for Niacor-SR

1.374. Dr. Levy testified to his opinion that the level of due diligence performed by Schering for Niacor-SR was in his view "strikingly superficial." (7 Tr. 1341-42 (Levy); CX 1597). In explaining how he reached this conclusion, Dr. Levy testified that he had put himself in Schering's position in June 1997 to "try to ascertain what I might have done had I seen what they saw." (7 Tr. 1342 (Levy)). This statement reveals an obvious and fundamental flaw in Dr. Levy's analysis in that it ignores the possibility that what Dr. Levy may have needed to see in terms of due diligence might bear little relation to what Mr. Audibert would have wanted to see. (16 Tr. 3678-79 (Horovitz)). Conservatively stated, Dr. Levy's qualifications to evaluate Niacor-SR are not remotely comparable to Mr. Audibert's in this context: as illustrated above, *Mr. Audibert was uniquely qualified to evaluate this exact product at that exact moment in time.* (SPF 1.366-1.373.)

Complaint Counsel's Response to Finding No. 1.374:

The proposed finding is incomplete and misleading. Mr. Audibert was not "uniquely qualified" to evaluate Niacor-SR. *See* CPRF 1.366-367. In comparison, Dr. Levy was submitted in this case "as an expert in the field of pharmaceutical licensing and pharmaceutical valuation." Tr. at 7:1304-05 (Levy). His qualifications as an expert in those fields provided him with the necessary expertise to offer opinions regarding the level of due diligence needed for a review of the safety and efficacy of Niacor-SR as it relates to the pharmaceutical licensing evaluation process.

Dr. Levy has held multiple positions with various pharmaceutical companies over

a period of more than two decades that qualifies him to offer his opinions in this matter.

His positions and responsibilities included the following:

- Abbott Laboratories (vice president of pharmaceutical research – involved in reviewing dozens of in-licensing opportunities);

- CoreTechs (president – consulting to the pharmaceutical industry, and assisting developing companies (including healthcare) in evaluating and developing their technologies);

  Erbamont Pharmaceutical company (consultant to Erbamont over five year period – responsible for overseeing worldwide research and development operations, including division in Italy);

- Ligand Pharmaceuticals (consultant to and served on board of directors – involved in Ligand review of numerous transactions over more than a decade including out-licensing and in-licensing of pharmaceutical research and products);

- LyphoMed/Fujisawa (consultant to this company for nearly a decade – involved in LyphoMed transition from generic pharmaceutical company to branded company); and

- Fujisawa (president of Japanese pharmaceutical company's U.S. division – responsible for entire division's business including all business development and in-licensing activities). Tr. at 7:1293-1301 (Levy) (describing his positions and responsibilities with these companies).

In addition, Dr. Levy has received the following degrees and training: Yale University (B.A./B.S.), Columbia University (M.D.), University of Colorado (medical internship), Massachusetts General Hospital (medical internship), National Institutes of Health (two year research associate position in virology and immunology), Duke University (neurosurgery residency), Duke University (Ph.D. in immunology, and tenured professor). Tr. at 7:1287-90 (Levy).

Dr. Levy has published over 130 articles, including articles on clinical research, designing research projects, and assessing clinical data. Tr. at 7:1290-91 (Levy).

Dr. Levy has held positions on the boards of directors and scientific advisory boards of numerous pharmaceutical companies including: Zonagen Corporation, Targeted Genetics Corporation, and First Horizon Pharmaceutical Company. Tr. at 7:1302-03 (Levy).

In addition, Dr. Levy's opinions regarding Schering's due diligence were not based solely on his own industry experience, but also his detailed review of Schering's due diligence on several transactions. *See, e.g.*, CPF 487-549 (discussing Schering's due diligence on two licensing transactions, and Dr. Levy's evaluation of the due diligence conducted).

1.375. In further support of his testimony that the due diligence performed for Niacor-SR was "strikingly superficial," Dr. Levy set out to prove that Schering's evaluation of pharmaceutical licensing opportunities always involves a much larger volume of due diligence (*i.e.*, more people, more time and more paper) than was the case for Niacor-SR. [*7 Tr.*] 1375-78, ••••••••••••••••••••••••• The method of proof utilized by Dr. Levy was to compare the volume of due diligence for Niacor-SR to the volume of due diligence from just two other Schering evaluations. (7 Tr. 1376-78,••••••••••••••••• 1886–87 (Levy)). This represents the second obvious and fundamental flaw in Dr. Levy's analysis: comparing the due diligence performed for Niacor-SR to the level of due diligence performed in two other hand-picked Schering deals does not establish a comparison of Niacor-SR to every other Schering deal. In fact, in selecting his two yardsticks, Dr. Levy concedes that he simply selected these comparators from a "list," and that he did not review "in toto" all 33 license evaluations for which Schering produced documents to

Complaint Counsel. [redacted]

Complaint Counsel's Response to Finding No. 1.375:

The proposed finding is incomplete and misleading. Nowhere in Dr. Levy's testimony does he state that he "set out" to prove anything, let alone that Schering's due diligence "always" involves a large "volume" of due diligence. Rather, Dr. Levy undertook an analysis of Schering's due diligence reviews of other drugs to evaluate whether Schering's review of Niacor-SR was consistent with Schering's own practices. His conclusion was that Schering's due diligence on other deals further indicates that the due diligence undertaken by Schering for Niacor-SR was superficial. Tr. at 7:1376-77 (Levy).

In particular, he chose to review the due diligence for those two drugs because they were comparable to Niacor-SR (*i.e.*, drugs that were licensed around the same time as Niacor-SR and were both late-stage development drugs). The due diligence conducted by Schering on those two drugs illustrates that Schering normally undertakes extensive due diligence review of potential in-licensing candidate drugs. These two drugs were Vasomax (licensed by Schering from Zonagen in 1997) and [redacted] Tr. at 7:1377-78 (Levy) (describing basis for determining what transactions were comparable to Niacor-SR, and discussing comparability of Zonagen transaction); [redacted]

The proposed finding is also misleading in appearing to criticize Dr. Levy's for not reviewing the due diligence from all 33 Schering transactions. Dr. Levy was not able

to review documentation from all of those transactions, because at the request of Schering's counsel, complaint counsel agreed to limit the scope of Schering's production of such due diligence documents. Based on the documents that were produced, Dr. Levy identified the two deals he believed were most comparable to Niacor-SR.

1.376. In testifying that he disagrees with Dr. Levy's ultimate conclusion that the due diligence performed by Schering for Niacor-SR was "superficial," Dr. Horovitz explained that the level of due diligence can only be considered in the context of a particular opportunity. (16 Tr. 3699 (Horovitz)). During his decades of experience in the pharmaceutical industry, including as the former vice president of licensing for Bristol Myers Squibb, Dr. Horovitz has been involved in roughly 75 pharmaceutical licensing or technology transactions. (16 Tr. 3607-09 (Horovitz)). On the basis of his experience, Dr. Horovitz explained why he does not believe that the type of comparison performed by Dr. Levy is useful: due diligence, by its very definition, will necessarily vary from opportunity to opportunity. (16 Tr. 3677-78, 3682-83 (Horovitz)). It can vary not only by the characteristics of the product involved, but also by the experience of the individual conducting the review and the strategic interests of the company evaluating the product. (16 Tr. 3678-79 (Horovitz)). In fact, Dr. Horovitz explained that every licensing evaluation in which he has been involved during his career required various levels of due diligence, with one lasting nearly a year and another lasting just 10 days. (16 Tr. 3683-84 (Horovitz)).

Complaint Counsel's Response to Finding No. 1.376:

The proposed finding is contradicted by other evidence. The testimony of Dr.

Horovitz identifies several aspects of Schering's review of Niacor-SR that were contrary to his experience with due diligence. He further testified that he would have conducted further review in several areas that were not explored by Mr. Audibert. *See* CPRF 1.359.

1.377. Dr. Levy testified that he utilized three criteria in selecting the Schering licensing evaluations that were sufficiently "analogous" to use as yardsticks: (1) the evaluation involved a pharmaceutical product as opposed to a development agreement; (2) the evaluation took place at "roughly" the same time as the Niacor-SR evaluation; and (3) the product evaluated was a "late stage product." (7 Tr. 1376-78 (Levy)). Dr. Levy's application of this test led to his trial testimony in which he measured the volume of due diligence performed for Niacor-SR against that performed for: (1) Cor Therapeutics' Integrelin product; and (2) Zonagen's Vasomax product. [(7 Tr.] 1377-78, ********** Moreover, Dr. Levy also claimed that Vasomax is particularly similar to Niacor-SR because it too is a sustained release product. (9 Tr. 1864-66 (Levy)). Of course, neither of these are cholesterol lowering drugs. (10 Tr. 2180-81 (Levy)).

Complaint Counsel's Response to Finding No. 1.377:

The proposed finding is incomplete and misleading. Dr. Levy undertook an analysis of Schering's due diligence reviews of other drugs to evaluate whether Schering's review of Niacor-SR was consistent with Schering's own practices. His conclusion was that Schering's due diligence on other deals further indicates that the due diligence undertaken by Schering for Niacor-SR was superficial. Tr. at 7:1376-77 (Levy).

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[redacted] *See* CPF 511-516 (describing Zonagen deal), CPF 547-549 (describing Cor Therapeutics deal).

[redacted]

In contrast, in reviewing Niacor-SR, Mr. Audibert simply reviewed an information package from Upsher containing summary data and two "draft" protocols. Mr. Audibert never requested any additional information from Upsher, never spoke with

anyone at Upsher during his review of Niacor-SR, and never conducted a site visit to Upsher. CPF 420-425 (describing scope of Mr. Audibert's review).

1.378. As an initial matter, there is serious reason to question the accuracy of Dr. Levy's application of even his own criteria. [redacted]

Complaint Counsel's Response to Finding No. 1.378:

The proposed finding is incomplete and misleading. [redacted]

1.379. [redacted]

[redacted]

[redacted] This is in contrast to Niacor-SR which, unlike Integrelin, was simply a reformulation of a compound with an established efficacy profile, and for which the "definitive" Phase III clinical data was available and confirmed unequivocally that Niacor-SR was effective in the indication for which it was intended. [redacted]; 18 Tr. 4099, 4123 (Audibert); CX 1042; 16 Tr. 3642-43 (Horovitz)).

Complaint Counsel's Response to Finding No. 1.379:

The proposed finding is contradicted by other evidence. The clinical data for both of Niacor-SR's pivotal trials was not available at the time Schering reviewed the information package provided to Schering. CX 1042 at SP 16 00079 (the "package" of information received from Upsher noting that the "projected" completion date for the second pivotal trial (Protocol 900221) was June 1997). In addition, the data provided was far from "definitive." Even more than one year after the settlement agreement, when Upsher confirmed that it had "suspended all research on Niacor-SR," Upsher informed Schering that "[s]everal of the studies are *not* in final form, and are not suitable for submission to a regulatory agency." CX 1111 at USL 13275 (letter from Upsher chief financial officer to Schering dated October 6, 1998) (emphasis in original document).

1.380. [redacted]

[redacted]

[redacted].

Complaint Counsel's Response to Finding No. 1.380:

The proposed finding is not relevant. Whether [redacted] has no bearing on Dr. Levy's testimony that Schering's due diligence on this deal and other licensing transactions supported the conclusion that Schering's review of Niacor-SR was strikingly superficial.

[redacted] In contrast, Schering did not conduct any research and development review of Niacor-SR before entering the settlement agreement. Tr. at

7:1369 (Levy); Schering Second Admission No. 335 (admitting that the "Schering-Plough Research Institute has never conducted a review of the safety or efficacy or Niacor-SR"); CX 1484 at 105:3-9 (Audibert dep) (confirming that he never spoke with anyone in Schering's research and development department (SPRI) during his evaluation); [redacted] This was contrary to Schering's typical in-licensing practice, where in all cases a product has to have a "safety review" by SPRI. Tr. at 19:4387-88 (Lauda) (confirming this point and noting that "I don't know if [Mr. Audibert] actually had [a safety review] done").

1.381. [redacted]

Complaint Counsel's Response to Finding No. 1.381:

The proposed finding is incomplete. [redacted]

1.382. As it turned out, despite its due diligence evaluation of all of these issues, Schering's hopes could not have been more misplaced. The FDA raised safety concerns regarding the results of the toxicology studies which suggested the possibility that Vasomax might cause cancer, and the FDA ultimately placed the application on hold and expressly prohibited Zonagen from proceeding with its clinical development. (9 Tr. 1941-1942, [redacted] (Levy); [redacted] Today, as a result, Zonagen's stock has dropped to roughly 10 percent of its value at the time Schering mistakenly entered into that deal, and roughly the same time that Zonagen generated $70 million in an initial public offering. (9 Tr. 1939, 1943 (Levy)). Dr. Levy testified that he thinks there is still a chance that Zonagen can recover (9 Tr. 1939 (Levy)), – perhaps like Kos has since recovered from the initial failure of Niaspan which cut into its 1997 market capitalization of $500 million. (31 Tr. 7574 (Patel)).

Complaint Counsel's Response to Finding No. 1.382:

The proposed finding is incomplete. These types of events are exactly why pharmaceutical deal payments are heavily weighted towards contingent payments. *See* CPRF 1.362-363 (explaining the preference for structuring more control over payments into pharmaceutical agreements).

1.383. Aside from his general criticism of the volume of due diligence performed for Niacor-SR, Dr. Levy identified two specific aspects of due diligence that he believes should have raised concerns for Schering: (1) dietary supplement forms of sustained release niacin had been associated with liver toxicity; and (2) the FDA had requested that Upsher perform an additional 17-day, single-dose pharmacokinetic study in 30 patients. (7 Tr. 1317, 1388 (Levy)); 17 Tr. 4001-4003 (Halvorsen); SPX 0331).

Complaint Counsel's Response to Finding No. 1.383:

The proposed finding is incomplete and misleading. Dr. Levy undertook an analysis of Schering's due diligence reviews of other drugs to evaluate whether Schering's review of Niacor-SR was consistent with Schering's own practices. He did not simply make a "general criticism of the volume" of due diligence for Niacor-SR. His conclusion was that Schering's due diligence on other deals further indicates that the due diligence undertaken by Schering for Niacor-SR was superficial. Tr. at 7:1376-77 (Levy).

1.384. First, as discussed previously, the liver toxicity issue was specifically evaluated by Schering, and complaint counsel have no evidence that contradicts Schering's conclusion that Niacor-SR was a dramatic improvement as compared to over-the-counter sustained release niacin products, and was consistent with other successful cholesterol lowering drugs. (SPF 1.245-1.250, 1.264-1.274).

Complaint Counsel's Response to Finding No. 1.384:

The proposed finding is contradicted by other evidence. Schering's own panel of cholesterol-lowering experts in evaluating another sustained-release niacin drug reported

to Schering in April 1997 that practitioners "tend to avoid" using niacin for cholesterol management, "because of diminished efficacy and concern regarding hepatotoxicity." CX 576 at SP 020709 (Decker report discussion of "conclusions and recommendations" at paragraphs 1 and 2) (emphasis added). In addition, based on Dr. Levy's review of the information package provided to Schering by Upsher, Niacor-SR "had absolute and clear evidence that would suggest hepatotoxicity." Tr. at 7:1317 (Levy).

This concern regarding liver toxicity was confirmed by the draft labeling Upsher prepared (but which was never provided to Schering or requested by Schering), which stated that dose-related hepatotoxicity existed for Niacor-SR above 2 grams. USX 308 at Upsher-Smith FTC 110474 (Niacor-SR draft package insert as of July 1997).

1.385. Second, Dr. Levy described the requirement of a pharmacokinetic study as follows: "Doing a pharmacokinetic study in Schering-Plough is like falling of a log. I mean they do them routinely." (7 Tr. 1388 (Levy)). Not surprisingly, Mr. Lauda testified that the PK study was, at best, a very minor issue that would not even have "caused a blip on the radar." (19 Tr. 4516-4517, 4421 (Lauda)). Moreover, at the time of the license agreement for Niacor-SR, Upsher had already built the PK study into the December 1997 NDA filing timetable upon which Schering relied. (16 Tr. at 3728, 3793-3794 (Horovitz)). In fact, Dr. Levy admitted that he could not say what type of pharmacokinetic study would have been required in connection with seeking approval for a sustained release formulation in Europe. (35 Tr. 8414 (Levy)).

Complaint Counsel's Response to Finding No. 1.385:

The proposed finding is incomplete. While conducting a pharmacokinetic study

may not have been difficult, the FDA expressed concerns regarding Upsher's attempts to conduct such a study. In particular, in correspondence from Upsher's files, the FDA expressed concerns about how the status of Upsher's pharmacokinetic study the fileability of Upsher's NDA. CPF 470-81 (discussing several pieces of correspondence detailing issues and concerns raised by the FDA prior to June 1997); CX 1382 at Upsher-Smith FTC 107436 (Upsher's minutes from February 5, 1997 meeting with FDA, reporting that "[d]ue to the known pharmacokinetic issues outstanding for Niacor-SR, the FDA should not file the NDA without the requested pharmacokinetic study results"); CX 1383 at Upsher-Smith FTC 107457 (fax from FDA's division of metabolic and endocrine drug products to Upsher regulatory affairs specialist cautioning "that approval of Niacor-SR as a controlled-release product is dependent on the results of the submitted [pharmacokinetic] study, and not merely on its completion.").

In addition, Kos' experience with conducting pharmacokinetic studies for its sustained-release niacin drug indicated that the FDA conducted substantial review of these studies. Prior to approving Niaspan, the FDA required that Kos conduct numerous pharmacokinetic and clinical studies, despite the fact that the active ingredient was widely available. CX 1047 at SP 002748 (Schering summary of meeting with Kos in April 1997, noting that Kos had conducted 14 pharmacokinetic studies at a cost of about $4 million); Tr. at 31:7498 (Patel) ("[o]ur formulation of Niaspan was developed as an NDA development and filing, which involved a number of lengthy pharmacokinetic and clinical studies.")

d. Professor Bresnahan's "Revealed Preference" Test

1.386. Professor Bresnahan testified that he applied a "revealed preference" to prove that the $60 million payment was not for the Niacor license. Professor Bresnahan testified that Schering's decision not to pay Kos for the right to co-market Niaspan revealed that Schering would not pay $60 million for a license for any sustained-release niacin product. (24 Tr. 582, 596-98 (Bresnahan); CX 1578).

Complaint Counsel's Response to Finding No. 1.386:

The proposed finding is incomplete. Professor Bresnahan applied the revealed preference test to conclude that the $60 million payment to Upsher was for delay. The revealed preference test is a basic economic idea and is applied in two ways. First, a company's choice of one opportunity over another indicates that it is better off making that choice over other options. Alternately, a company's rejection of an opportunity indicates that a company is not better off making that choice over other options.

In applying this test to the present facts, Professor Bresnahan first determined whether the Niaspan co-promotion arrangement and the Niacor-SR license were comparable opportunities for Schering. He concluded that they were because both concerned the same product type (*i.e.*, a sustained-release niacin drug). Then he compared key characteristics important to Schering such as: therapeutic efficacy, dosing regimen, side effect profile, licensed area, detailing priority and regulatory approval status. In comparing these criteria, Niaspan was at least equivalent to, and in some areas, superior to Niacor-SR. CPF 735-768 (explaining how Niaspan was at least equal to, and in some areas, superior to Niacor-SR).

Schering rejected the Niaspan opportunity despite its offering an equal or superior opportunity to Schering in comparison to the Niacor-SR opportunity. Under the revealed preference test, Schering's rejection of Niaspan revealed that it was not willing to pay an upfront payment for a sustained-release niacin product. As Schering was unwilling to pay any upfront money for Niaspan, it follows that Schering would not be willing to pay for an equal or worse opportunity, Niacor-SR. Thus, Schering's $60 million non-contingent payment to Upsher was not for Niacor-SR, but rather was for delay. CPF 774-777 (discussing Professor Bresnahan's conclusion under the revealed preference test).

1.387. As previously demonstrated, Professor Bresnahan's "revealed preference" reveals unmistakably (1) that Schering was interested in sustained release niacin products wholly independent of any settlement agreement; and (2) that Schering believed a sustained release niacin product would garner significant sales in the marketplace. (SPF 1.83-1.160, 1.312-1.317.)

Complaint Counsel's Response to Finding No. 1.387:

The proposed finding is incomplete. *See* CPRF 1.386; CPF 747-777 (explaining Professor Bresnahan's conclusion that Schering's rejection of Niaspan indicates that the payment to Upsher was for delay).

1.388. Moreover, Schering's decision to discontinue discussions with Kos with respect to a potential co-marketing arrangement was made for reasons that did not apply to its license transaction with Upsher-Smith.

Complaint Counsel's Response to Finding No. 1.388:

The proposed finding contradicted by other evidence. Schering rejected the Niaspan opportunity for several reasons. These reasons included Schering's evaluation of Kos' ability to make certain claims regarding a sustained-release niacin drug, and its general evaluation of the market for sustained-release niacin drugs. In particular, Martin Driscoll (Schering's vice president of marketing and sales for its Key division) recommending discontinuation of discussions with Kos for the "principal reason" that the product did not "represent a large-enough opportunity in the marketplace . . .". CX 558 at SP 002719. Mr. Driscoll's memorandum was prepared on June 9, 1997, just eight days before Mr. Audibert completed his commercial assessment of Niacor-SR. In reaching this recommendation on Niaspan, Mr. Driscoll noted that "immediate-release niacin products cause flushing in most patients [and as a result] patient compliance is greatly impacted" and that "long-term use of the immediate-release niacin can lead to hepatotoxicity." CX 558 at SP 002719 (Driscoll memorandum recommending discontinuation of discussions with Kos). Mr. Driscoll also noted that the "current market dynamics of the 'statin' category" was another "important factor" that would impact Niaspan's acceptance in the marketplace. He observed that because of the apparent potency and benign side-effect profile of statins like Pfizer's Lipitor, "Niaspan's market opportunity is narrowing even prior to its introduction [and that i]ndeed, the use of other classes of cholesterol-lowering agents such as niacin, gemfibrozil, and cholestyramine has declined since the

introduction of Lipitor." CX 558 at SP 002720 (Driscoll memorandum recommending discontinuation of discussions with Kos).

(1) Schering's Decision to Discontinue Negotiations with Kos Reveals Nothing Relevant to its Interest in Niacor-SR

1.389. Professor Bresnahan concedes that the inference that one should draw from the outcome of Schering's negotiations with Kos depends on the particular circumstances of that deal (Bresnahan 1109), consideration of which illustrate that Schering's reasons for discontinuing the Niaspan negotiations related to factors not present in the Niacor license transaction.

Complaint Counsel's Response to Finding No. 1.389:

The proposed finding is incomplete and contradicted by other evidence. *See* CPRF 1.388 (discussing Schering rejection of the Niaspan opportunity for several reasons including Schering's evaluation of Kos' ability to make certain claims regarding a sustained-release niacin drug, and its general evaluation of the market for sustained-release niacin drugs).

1.390. First, Schering was to receive at most half the profits from sales of Niaspan. As Professor Bresnahan conceded, this meant that the projected Net Present Value of Schering's interest in Niaspan profits was $127 million. (6 Tr. 1115-16 (Bresnahan); CX 558; 25 Tr. 3529-30 (Russo)). On the other hand, Schering was to receive all of the Niacor-SR sales after deducting a small royalty. (7 Tr. 1329 (Levy); SPX 92 at SP 00195). As Professor Bresnahan conceded, the projected Net Present Value of Schering's interest in the Niacor-SR sales was

$225-$265 million. (6 Tr. 1117 (Bresnahan); [redacted]; SPX 26 at SP 16 00275). Thus, as Professor Bresnahan admits, the Kos negotiations merely reveal Schering's preference to receive all, rather than half, the profits from the niacin product at issue. (6 Tr. 1118-19 (Bresnahan)).

Complaint Counsel's Response to Finding No. 1.390:

The proposed finding is incomplete. *See* CPRF 1.386; CPF 747-777 (explaining Professor Bresnahan's conclusion that Schering's rejection of Niaspan indicates that the payment to Upsher was for delay).

1.391. Second, Kos' demands from a co-promotion arrangement were high. Kos insisted that under any arrangement Schering would have to guarantee a significant number of primary details for Niaspan. (31 Tr. 7531, 7554 (Patel); CX 769). A primary detail is a sales call in which the salesperson gives priority to a particular product, either by mentioning it first or mentioning it most frequently. (31 Tr. 7554 (Patel); 15 Tr. 3450 (Russo)). Kos also wanted guarantees with respect to the level of sales call activity, demanding specific numbers of specific types of calls throughout the launch period. (15 Tr. 3451 (Russo)). This presented a problem, because Schering had other products, such as Claritin, that would have to be detailed first during particular seasons. (18 Tr. 4106-07 (Audibert)).

Complaint Counsel's Response to Finding No. 1.391:

The proposed finding is not relevant and contradicted by other evidence. [redacted]

[redacted]

1.392. Third, Kos wanted to retain most of the control over how the product was marketed. (6 Tr. 1112 (Bresnahan)). Fourth, Kos insisted on booking sales or making Schering pay money in order to book sales. (31 Tr. 7556 (Patel)). And fifth, and very importantly, the Kos people were proving to be very difficult to work with. (6 Tr. 1122 (Bresnahan)). They treated Schering representatives with "great disrespect," (7 Tr. 1411 (Driscoll IH)), calling Schering's written proposal "practically insulting." (SPX 230). This did not bode well for a potential partnership, (*id.*), and was an "important factor" in Schering's decision to terminate discussions. (7 Tr. 1423 (Driscoll Dep.)).

Complaint Counsel's Response to Finding No. 1.392:

The proposed finding is not relevant and contradicted by other evidence. [redacted]

Finally, as far as Kos treating Schering with "great disrepect," after the negotiations on Niaspan, the same people from Schering and Kos participated in discussions for other

product opportunities. Tr. at 31:7611 (Patel) (confirming this point).

1.393. The "preference" that emerges from Professor Bresnahan's "revealed preference" test is one not to enter into a 50/50 co-marketing arrangement with a partner who is difficult to work with and has unreasonable expectations. In fact, this preference was confirmed one year later when Mr. Audibert expressly invoked these "unrealistic deal expectations" in a written recommendation to Mr. Lauda that Schering not pursue licensing of a totally separate Kos product. (SPX 566 at SP 002986). None of these factors was present in the Niacor license.

Complaint Counsel's Response to Finding No. 1.393:

The proposed finding is incomplete. *See* CPRF 1.386; CPF 747-777 (explaining Professor Bresnahan's conclusion that Schering's rejection of Niaspan indicates that the payment to Upsher was for delay).

(2) Searle, Another Major Company Interested in Niaspan, Also found Kos Unreasonable to Deal With

1.394. Searle, another company with whom Kos was negotiating, reached a similar conclusion. Like Schering, Searle had a strategic interest in Niaspan. Mr. Egan, one of Complaint Counsel's rebuttal witnesses, explained that it had a potential blockbuster cardiovascular product in its pipeline, and that it was interested in acquiring rights to a sustained release niacin product so that its sales force could form relationships with cardiologists. (33 Tr. 7894 (Egan)). Searle found Niaspan to be an attractive product, (31 Tr. 7576-77 (Patel)), and believed that Kos' formulation, which promised improved compliance as compared with existing

niacin formulations, had some commercial promise. (33 Tr. at 7917 (Egan)).

Complaint Counsel's Response to Finding No. 1.394:

The proposed finding is include and misleading. The proposed finding fails to discuss that Searle (Mr. Egan's employer) was one of the 49 companies that turned down Niacor-SR, which is consistent with Professor Bresnahan's conclusions under the revealed preference test. At Upsher's meeting with Searle, Upsher presented a package of information on Niacor-SR. CX 886 (package of presentation slides including summaries of clinical data on Niacor-SR prepared by Upsher). Following the meeting, the Searle employees conferred about the Upsher presentation and decided that Niacor-SR "was not a licensing candidate, that [they] had no interest in further pursuing the product." Tr. at 33:7886 (Egan). This decision was based on Searle's perception that Niacor-SR, as presented by Upsher at the meeting, "had a toxicity profile that suggested that it was not going to be a successful drug." Tr. at 33:7886 (Egan). From the Upsher presentation (CX 886), Searle did not believe that Niacor-SR "had a profile that was registerable or a profile that would have been commercially successful." Tr. at 33:7894 (Egan) (explaining why Niacor-SR would not meet Searle's needs for a "bridge" product). *See generally* CPF 627-633 (discussing Searle's review and rejection of Niacor-SR).

1.395. But Searle, like Schering, found Kos' demands to be unreasonable. Searle viewed Niaspan as a reformulation of an existing, well-established product. (*Id.* at 7995-96). From Searle's perspective, much of the value from the product would depend upon sales and marketing efforts. (*Id.*) Kos expected Searle to contribute most of the marketing effort, using its

established sales force. (*Id.* at 7985). Yet Kos wanted a "ridiculous" percentage of the profits, as well as an up-front payment in the $10 to $20 million range. (*Id.*) Searle rejected the co-promotion opportunity, concluding, like Schering, that the promotional effort sought by Kos was not worthwhile given the profit split that Kos was seeking. (*Id.* at 7988).

Complaint Counsel's Response to Finding No. 1.395:

The proposed finding is incomplete. Kos and Searle negotiated on a number of niacin opportunities within and outside of the United States. Kos never expected to received an upfront payment of $60 million for its product in any market. In addition, Searle rejected Upsher's Niacor-SR product having determined that that product "had a toxicity profile that suggested that it was not going to be a successful drug" (*see* CPRF 1.394) – before even exploring deal terms with Upsher. Searle's rejection of Niacor-SR based on that drug's safety profile is consistent with Professor Bresnahan's conclusions under the revealed preference test.

e. Professor Bresnahan's "Market Test" for Niacor-SR

1.396. Professor Bresnahan testified that he applied a "market test" to prove that the $60 million was a payment for delay, and not for Niacor-SR. Professor Bresnahan explained that because no other company had made Upsher-Smith an offer that included a substantial non-contingent payment for the licenses, the "market test of the $60 million payment is failed." (4 Tr. 601-02 (Bresnahan)). However, Professor Bresnahan has never before applied this "market test" it in the context of pharmaceutical licensing, and he did not understand, when he applied it, how Schering normally goes about deciding what to pay for a license. (6 Tr. 1125 (Bresnahan)).

Complaint Counsel's Response to Finding No. 1.396:

The proposed finding is incomplete and misleading. While Professor Bresnahan had not previously applied his "market test" to the pharmaceutical industry, market tests are used by economists to reveal the value of assets in the marketplace by examining offers and transactions in the marketplace. Professor Bresnahan performed that test in relation to Niacor-SR by examining Upsher's efforts to market the Niacor-SR license to numerous European companies. Tr. at 4:598-99 (Bresnahan).

(1) Schering Values Licensing Opportunities Internally, Not Based on What Others in the Market Value It At

1.397. When applying his "market test," Professor Bresnahan had no idea whether Schering customarily knew or cared what other companies were bidding for a product. As Mr. Lauda explained, there is never a "market price" for a licensing opportunity. Schering generally does not know what other companies are bidding, and Schering's determination of how large a bid to make is driven by the company's own internal assessments. (19 Tr. 4374-75 (Lauda)).

Complaint Counsel's Response to Finding No. 1.397:

The proposed finding is not relevant. The proposed finding misconstrues the market test. The market test does not assume that there will always be multiple bidders on any single transaction. The market test is used to reveal the value of assets in the marketplace where there are multiple parties being offered a license. *See* CPF 778-780 (explaining the market test and how Professor Bresnahan applied it to the Niacor-SR example). It is not disputed that Upsher approached more than 40 companies in Europe

concerning a potential license for Niacor-SR. Thus, the market test can be applied to Niacor-SR where multiple parties were offered this licensing opportunity to determine whether this license had value in the marketplace.

In applying the market test to Niacor-SR, Professor Bresnahan found that none of the companies to which Upsher offered the Niacor-SR European rights responded with an offer of a non-contingent payment. Thus, according to the market test, Niacor-SR was not highly valued enough in the marketplace to justify a non-contingent payment, and therefore, the $60 million non-contingent payment made by Schering to Upsher was not for Niacor-SR. *See* CPF 781-783 (summarizing Professor Bresnahan's conclusion under the market test).

In addition, the proposed finding is contradicted by other evidence. [redacted]

1.398. [redacted]

[redacted] Yet those deals would also fail Professor Bresnahan's "market test" because, in both cases, there were no other bidders (19 Tr. 4374 (Lauda)). In reality, Schering made a large up-front payment because "that's what it took to get the deal done." (19 Tr. 4374 (Lauda)). The fact that the ICN and Centocor deals would also fail Professor Bresnahan's "market test" is consistent with the fact that the amount at which other companies value a product has no bearing on Schering's own analysis, and illustrates that the "market test" is unreliable.

Complaint Counsel's Response to Finding No. 1.398:

The proposed finding is not relevant. The proposed finding misconstrues the market test as this test does not assume that there will always be multiple bidders on any single transaction. *See* CPRF 1.397 (explaining market test and its application to the Niacor-SR licensing rights).

1.399. Complaint Counsel's own rebuttal witness, Mr. Egan, testified that one company may value a licensing opportunity differently from another. (33 Tr. 7964 (Egan)). These differences in valuation are attributable to varying subjective criteria. (*Id*). They are also attributable to companies' varying commercial needs. (*Id*). And it is not uncommon in the industry for several companies to decline a licensing opportunity that later develops into a successful product for another company. (*Id*. at 7965). Thus, one cannot infer from the fact that several companies decline to offer large payments for a license that the license is not worth a large payment.

Complaint Counsel's Response to Finding No. 1.399:

The proposed finding is incomplete and misleading. Mr. Egan did testify that companies may decline licensing opportunities for subjective reasons and may value opportunities differently. However, Mr. Egan did not testify to the concluding sentence of the proposed finding which asserts that "one cannot infer from the fact that several companies decline to offer large payments for a license that the license is not worth a large payment." The proposed finding provides no citation for that conclusion. In addition, Professor's Bresnahan's application of the market test did not merely examine "several companies" who declined licensing opportunities. He reviewed the record concerning 49 companies who did not offer any payment for Niacor-SR in reaching his conclusions under the market test. *See* CPF 780-783.

The proposed finding also fails to discuss that Searle (Mr. Egan's employer) was one of the 49 companies that turned down Niacor-SR. At Upsher's meeting with Searle, Upsher presented a package of information on Niacor-SR. CX 886 (package of presentation slides including summaries of clinical data on Niacor-SR prepared by Upsher). Following the meeting, the Searle employees conferred about the Upsher presentation and decided that Niacor-SR "was not a licensing candidate, that [they] had no interest in further pursuing the product." Tr. at 33:7886 (Egan). This decision was based on Searle's perception that Niacor-SR, as presented by Upsher at the meeting, "had a toxicity profile that suggested that it was not going to be a successful drug." Tr. at 33:7886 (Egan). From the Upsher presentation (CX 886), Searle did not believe that Niacor-SR "had a profile that was registerable or a profile that would have been

commercially successful." Tr. at 33:7894 (Egan) (explaining why Niacor-SR would not meet Searle's needs for a "bridge" product). *See generally* CPF 627-633 (discussing Searle's review and rejection of Niacor-SR).

(2) The Market Test Fails to Account for the Market Valuation of Niaspan

1.400. Professor Bresnahan, in applying his "market test," ignored the reaction of a real-world market to Kos' sustained-release product. Professor Bresnahan did not know what Kos' market capitalization was at the time, but he agreed that if it were in the neighborhood of $500 million, and if Kos was essentially a one-product company, that would mean that the market valued Niaspan at somewhere in the range of $500 million. (6 Tr. 1129 (Bresnahan)). In fact, by the summer of 1997, Kos had a market capitalization of over $500 million. (31 Tr. 7574 (Patel)). Kos' market capitalization was primarily based on the promise of Kos' only real product, Niaspan. (33 Tr. 7982 (Egan); SPX 224 at 8; 38 Tr. 6892 (Kerr)). Thus, we have real-world proof of how the market valued Niaspan, which Professor Bresnahan regards as a product comparable to Niacor-SR. (4 Tr. 596 (Bresnahan)). At the time Schering entered into the agreement with Upsher-Smith, the market valued Niaspan at $500 million. (31 Tr. 7574 (Patel)).

Complaint Counsel's Response to Finding No. 1.400:

The proposed finding is incomplete and misleading. The projected sales for Niaspan (and thus its market capitalization based on share prices) were exaggerated by both Kos and its investment bankers. First, these sales projections were exaggerated according to Schering's own sales estimates for Niaspan. As discussed above in

Schering's proposed finding 1.316, Schering estimated third year sales of Niaspan at $101 million (as compared to the between "$220 and $250 million" estimated by the market analysts). In addition, as expressly stated in Schering's proposed finding 1.314, "Schering did not agree with market analysts' public projections of Niaspan sales of $250 million." Second, according to complaint counsel's expert Dr. Levy, "it is not atypical for a startup company doing an IPO to grossly overstate its potential earnings. That's how they pump up their stock price. And it's not atypical for investment bankers to comport with that behavior." Tr. at 9:1856 (Levy).

(3) Niacor-SR Generated Serious Interest From Several Companies, But Before They Could Make an Offer, Schering Licensed the Product

1.401. During the 30 days preceding Schering's license of Niacor-SR, Upsher had received expressions of interest from a number of European companies. (17 Tr. 3970-3973 (Halvorsen)). In fact, just 2 weeks before Niacor-SR was licensed to Schering, Upsher's representatives traveled to Europe for the sole purpose of meeting with four companies who were interested in Niacor-SR. (17 Tr. 3970-3973 (Halvorsen)). Those meetings took place following execution of a confidentiality agreement. (17 Tr. 3974 (Halvorsen)). Complaint counsel's rebuttal witness, Mr. Egan, testified that companies only hold meetings following execution of a confidentiality agreement when "you're really serious about hearing what they have to say." (33 Tr. 7863-64 (Egan)).

Complaint Counsel's Response to Finding No. 1.401:

The proposed finding is incomplete and misleading. The four companies that

Upsher met with in Europe who expressed interest in Niacor-SR never offered any payments for the Niacor-SR product. One of those companies (Esteve) specifically rejected the Niacor-SR opportunity, explained that the "reason behind our decision has been mainly a marketing one," noting the "enormous, expensive, and risky promotional effort" that Esteve expected would need to be mounted to "'re-introduce'" a niacin product into the European cholesterol management market. CX 869 at USL11968 (letter from Esteve to Upsher dated September 29, 1997). The remaining three companies, while expressing some interest, all voiced concerns regarding safety and/or requested additional time and information to evaluated Niacor-SR. *See* CPF 635 (noting Servier's concern over the elevation of liver function tests); CPF 639 (noting that Lacer need to review the clinical data for Niacor-SR, and requested Upsher to provide information on statin/niacin combination studies); CPF 646 (noting that Pierre Fabre "asked intelligent perceptive questions on the incidence of elevation" in liver function tests).

1.402. At the conclusions of the June meetings in Europe, those companies indicated that they would review Niacor-SR and contact Upsher, but not within the following month. (17 Tr. 3974 (Halvorsen)). For example, the company that expressed the highest level of interest in Niacor-SR was Pierre Fabre (17 Tr. 3973 (Halvorsen)), with Upsher's internal meeting minutes reflecting its view that Pierre Fabre was "moderately to highly interested in Niacor-SR." (USX 544 at USL 11811). At the conclusion of its meeting with Upsher in Paris, France on June 3, 1997, Pierre Fabre advised Upsher that it would "get back to Upsher-Smith by the end of June concerning a 'go/no go' decision." (USX 544 at USL 11811). Of course, just two weeks later, Niacor-SR was taken off the block by Schering.

Complaint Counsel's Response to Finding No. 1.402:

The proposed finding is incomplete and misleading. As noted in the proposed finding, Upsher's internal minutes of its meeting with Pierre Fabre noted that company's interest in Niacor-SR. However, the full statement concerning that interest is as follows: "Pierre Fabre demonstrated an interest in niacin therapy but are concerned about high upfront and milestone payments. Overall, we believe Pierre Fabre is moderately to highly interested in Niacor-SR, if we can negotiate an acceptable deal." CX 881 at USL 11826 (emphasis added on language left out of proposed finding). In addition, during Pierre Fabre's meeting with Upsher, the discussion included questions about whether Upsher would be able to patent its evening dosing schedule in Europe. The Upsher memorandum further indicates that the Pierre Fabre representatives "asked intelligent perceptive questions on the incidence of elevation" in liver function tests and "expressed concern over the high incidence [of liver function elevations] at the 2000 mg dose." CX 881 at USL11825.

B. Schering's And Upsher's Post-Deal Conduct And Independent Decisions Not To Pursue Niacor-SR

1. Schering's Internal Preparations And Communications With Upsher Regarding Availability Of Niacor-SR Data

1.403. Shortly after Schering's Board of Directors approved the Niacor-SR license (CX 340), Schering began to get the Niacor-SR project organized. On July 2, 1997, Mr. Kapur informed Mr. Cesan that global marketing would take responsibility for Niacor-SR, while

Warrick would oversee development of the generic products licensed from Upsher. (SPX 8). At the same time, Mr. Kapur notified Mr. Lauda that the Niacor-SR deal had been approved and that global marketing was to take the lead in supervising Schering's international registration and marketing of Niacor-SR. (SPX 7; 19 Tr. 4350 (Lauda)). Mr. Lauda assigned Mr. Audibert as project leader for the Niacor-SR project (19 Tr. 4350, 4352-53; 18 Tr. 4140, 4145-46 (Audibert); 8 Tr. 1669 (Audibert IH)) and instructed him to assign someone to begin planning Schering's development program for the product (SPX 8; 19 Tr. 4353-54; 18 Tr. 4147).

Complaint Counsel's Response to Finding 1.403:

The proposed finding is not supported by the evidence. First, the assignment of Global Marketing personnel to handle the international registration for Niacor-SR was a departure from the regular procedures at Schering because Global Marketing, where Mr. Audibert and Mr. Lauda worked in 1997, was not responsible for registering products. CPF 676; CX 1483 at 122:22-124:13 (Audibert IH).

Moreover, the proposed finding is contrary to more reliable evidence. When Mr. Audibert was asked about his responsibilities for overseeing the Niacor-SR project, he testified that he was neither aware of his department's responsibility for registering Niacor-SR in Europe nor of his specific designation as the project leader:

Q. Did you have an understanding that global marketing was fully responsible for developing and registering Niacor-SR?.

A. I don't – I don't remember what I thought when I saw this.

Q. Well, now, do you recall that you had – that global marketing was fully responsible for developing and registering Niacor-SR?

A. Global marketing is not responsible for registering products, so as I read it

today, this is what's confusing.

Q. You just don't understand what this means?

A. That's correct.

Q. Did you have a designated project leader, to your knowledge, for the Niacor-SR?

A. I'm not sure of whether he meant me, but I'm not sure there was a designated project leader.

Q. I'm not sure I understood your answer. Do you know if there was any designated project leader in global marketing for this product?

A. Well, I don't know what Mr. Kapur means by the term "designated project leader."

Q. Okay. Did you consider yourself a designated project leader for Niacor-SR?

A. I guess de facto.

CX 1483 at 123:8-124:71 (Audibert IH) (referencing CX 1087). *See* CPF 677-678 (indicating that Mr. Audibert did not feel he was responsible for the development and registration work on Niacor-SR, never met with Upsher, and never did any work on the international registration of Niacor-SR).

1.404. Schering also contacted Upsher regarding Niacor-SR and other matters soon after the Schering Board approved the Upsher license agreement. (SPX 255; SPX 9). On June 30, 1997, Schering's in-house counsel for licensing, Paul Thompson, sent Upsher a draft of a more detailed Amendment Agreement that expanded on such issues as the supply and delivery of Niacor-SR and other licensed products. (SPX 255; 21 Tr. 5050-51 (Kralovec)). On July 16,

1997, Mr. Kapur wrote to Mr. Troup regarding Schering's intention to schedule a visit to inspect Upsher's facility that manufactured cholestyramine, one of the generic products Schering had licensed from Upsher. (SPX 9). In the same letter, Mr. Kapur informed Mr. Troup that Mr. Audibert had been given the name of Mark Halvorsen of Upsher as a contact to schedule a meeting regarding the Niacor-SR submission. (SPX 9).

Complaint Counsel's Response to Finding No. 1.404:

The proposed finding is incomplete and not supported by the evidence. While the parties did exchange some correspondence and made several contacts with each other, the parties' post-deal conduct does not indicate a serious interest on the part of either party to develop and market Niacor-SR. For example, Mr. Lauda, who was Mr. Audibert's direct supervisor at the time, testified that although Schering's Global Marketing unit had purportedly been charged with responsibility for shepherding the $60 million Niacor-SR product through to European registration and marketing, he personally "never had a discussion with anybody from Upsher-Smith on any subject." Tr. at 19:4379 (Lauda). *See also* CPF 682-688 (regarding the parties' limited communication during the course of the first few months after the execution of the settlement and the parties' failure to meet and coordinate resolutions to development problems with Niacor-SR); CPF 664-670 (concerning the aggressive development and regulatory schedule assumed by Schering's commercial assessment for Niacor-SR).

1.405. Mr. Halvorsen, the director of clinical and regulatory affairs at Upsher, had responsibility for the clinical development of Niacor-SR. (17 Tr. 3899 (Halvorsen)). Mr.

Audibert testified that he had a number of conversations with Mr. Halvorsen to discuss a potential site visit by Schering clinical and regulatory personnel and other issues. (18 Tr. 4148; 8 Tr. 1684 (Audibert IH)). Likewise, Mr. Halvorsen testified that he communicated with Mr. Audibert several times via facsimile and telephone. (17 Tr. 3976-77). In offering his opinion that the parties' did not show serious interest in Niacor-SR after executing the license agreement, Dr. Levy testified that he saw "almost no communications between the parties." (9 Tr. 1824-52 (Levy); 7 Tr. 1382 (Levy)). Yet Dr. Levy was forced to concede that he did not even know who Mr. Halvorsen was, and had not read his deposition. (9 Tr. 1825 (Levy)).

Complaint Counsel's Response to Finding No 1.405:

The proposed finding is incomplete, mischaracterizes Dr. Levy's testimony, and are not supported by the evidence. Dr. Levy testified that the parties' post-deal conduct was specifically lacking in that the parties failed to meet and coordinate resolutions to problems in the development of Niacor-SR. Tr. at 7:1389, at 9:1823 (Levy). Mr. Audibert and Mr. Halvorsen both testified that they conversed with one another, but respondents offered no documentary evidence of communication between them aside from SPX 241, a faxed note from Mr. Audibert to Mr. Halvorsen, dated August 14, 1997. This was nearly two months after the execution of the Schering/Upsher settlement agreement, yet it was also only two months prior to the date that Schering claims it assumed that it would be ready to file its European dossiers in order to enter the market by late 1997. Additionally, the only meeting Mr. Audibert attempted to schedule with Mr. Halvorsen never even occurred. Tr. at 18:4142-43, 4155-56 (Audibert). *See* CPF 682-688 (regarding the parties' surprisingly limited communication during the course of

the first few months after the execution of the settlement and the parties' failure to meet and coordinate resolutions to development problems with Niacor-SR); CPF 664-670 (concerning the aggressive development and regulatory schedule assumed by Schering's commercial assessment for Niacor-SR).

1.406. As the Niacor-SR project leader, Mr. Audibert was to be responsible for coordinating the efforts of Schering's regulatory and clinical people to ensure that the dossier for international filing was assembled and filed. (18 Tr. 4140). Schering planned to follow its frequent practice of using the NDA as the basis of its filings for regulatory approval in Europe. (18 Tr. 4140-41; 8 Tr. 1665 (Audibert IH)). This would permit Schering to prepare and file the dossiers with only minimal expenses. (19 Tr. 4405-06 (Lauda)). Schering could begin the process of converting Upsher's work to European filings when it received from Upsher the two major components of the NDA, the integrated summary of safety ("ISS") and the integrated summary of efficacy ("ISE"), which summarize the safety and efficacy data from all the clinical studies of the product. (18 Tr. 4141). Based on information provided by Upsher, Schering expected to receive the ISS and ISE for Niacor-SR from Upsher in October 1997. (19 Tr. 4141, 4151-52).

Complaint Counsel's Response to Finding No. 1.406:

The proposed finding is incomplete and contradicted by other evidence. First, Mr. Audibert himself testified that he was neither aware of his designation or responsibilities as project leader for Niacor-SR, nor did he carry out activities related to the international registration of Niacor-SR. Second, the assignment of duties involving regulatory affairs

runs counter to Schering's normal business practices, wherein Global Marketing does not take responsibility for such projects. *See* CPRF 1.403. Third, no evidence was offered by respondents that Schering ever formed an internal project team. CPF 671-681 (concerning Schering's failure to form a project team). Fourth, the finding implies that Schering aimed to minimize additional expenditures by using Upsher's completed NDA to file for regulatory approval in Europe. However, during Schering's review of Niacor-SR, it failed to even examine whether it would face additional research expenditures. CPF 693 (regarding Schering's failure to assess potential additional research required to file for regulatory approval of Niacor-SR in Europe) [redacted]
Finally, the proposed finding claims that Schering anticipated receiving the critical portions of Upsher's NDA in October 1997, but it does not explain how Schering intended to meet the schedule dictated by the aggressive product development plan offered to the Board of Directors. CX 338 at SP 12 00273 (Schering Board presentation for Niacor-SR, outlining assumptions behind anticipated sales). *See* CPF 664-670, 689-693 (concerning Schering's failure to undertake necessary steps toward meeting the aggressive schedule for launching Niacor-SR in Europe).

1.407. In preparation for receiving the ISS and ISE, Mr. Audibert took several steps to notify and prepare the Schering people who were going to be involved in the process of converting Upsher's documents to European filings. (18 Tr. 4142; 19 Tr. 4351 (Lauda); 16 Tr.

3696-97 (Horovitz)). For example, he obtained the protocols for Upsher's clinical studies (CX 1092; 18 Tr. 4150) and forwarded these protocols to Dr. Veltri, vice president of clinical research for cardiovascular at Schering (SPX 243). Mr. Audibert wanted Dr. Veltri to familiarize himself with the overall study design in preparation for reviewing the ISS and ISE later on. (18 Tr. 4150-51). He also wanted to put Dr. Veltri on notice that someone in Dr. Veltri's group should be ready to review Upsher's clinical study results in connection with the process of preparing the European filings. (SPX 243; 18 Tr. 4151).

Complaint Counsel's Response to Finding No. 1.407:

The proposed finding is incomplete and contradicted by the evidence. First, when Mr. Audibert was asked about his responsibilities for overseeing the Niacor-SR project, he testified that he was neither aware of his department's responsibility for registering Niacor-SR in Europe nor of his specific designation as the project leader. *See* CPRF 1.403. Second, Schering did not establish a project team for Niacor-SR. CPF 674. *See* CPF 671-681 (describing that project teams in the pharmaceutical industry are usually formed before the execution of an in-licensing agreement, but that it is certainly unusual for such activities to be initiated a full two months after the execution of the agreement; elaborating on evidence cited by respondents above to indicate that Mr. Audibert's memoranda never affected any action on Niacor-SR within Schering).

1.408. Mr. Audibert also provided information concerning Niacor-SR to Michael Perelman, a director in Schering's worldwide regulatory affairs department, who would be working with the head of Schering's European regulatory group, Dr. Jean-Pierre Osselaere, to put

together the Niacor-SR filings for Europe. (SPX 244; 18 Tr. 4149, 4152).

Complaint Counsel's Response to Finding No. 1.408:

The proposed finding is incomplete and contradicted by the evidence. Mr. Audibert testified that he was neither aware of his department's responsibility for registering Niacor-SR in Europe nor of his specific designation as the project leader, and Schering never established a project team for Niacor-SR. *See* CPRF 1.407.

1.409. In addition, Mr. Audibert contacted Dr. Bill Carlock, who worked for Schering's technical operations group that would be responsible for manufacturing Niacor-SR, if Schering decided to take on the manufacturing responsibilities itself. (SPX 245; 18 Tr. 4153). Mr. Audibert provided Dr. Carlock with a draft manufacturing agreement for Niacor-SR. (SPX 245; 18 Tr. 4153).

Complaint Counsel's Response to Finding No. 1.409:

The proposed finding is incomplete and contradicted by the evidence. Mr. Audibert testified that he was neither aware of his department's responsibility for registering Niacor-SR in Europe nor of his specific designation as the project leader, and Schering never established a project team for Niacor-SR. *See* CPRF 1.407.

1.410. Mr. Audibert also attempted to arrange, through Mark Halvorsen, a visit by Dr. Osselaere and someone from Schering's clinical research group to Upsher in order to review Upsher's data and discuss regulatory filing strategies. (SPX 241; 18 Tr. 4142, 4149-50). On August 21, 1997, Mr. Audibert updated Mr. Kapur on the Niacor-SR project, explaining that his

efforts to arrange this trip to Upsher had been unsuccessful because of Upsher's delays in compiling the relevant clinical data and regulatory documents. (SPX 11; 18 Tr. 4154-55). The meeting between Upsher and Dr. Osselaere ultimately did not occur because Upsher did not have adequate information available regarding the Niacor-SR dossier to make the visit worthwhile in September 1997, when Dr. Osselaere could have made the trip from Europe. (18 Tr. 4142-43, 4156).

Complaint Counsel's Response to Finding No. 1.410:

The proposed finding is incomplete and contradicted by the evidence. Mr. Audibert testified that he was neither aware of his department's responsibility for registering Niacor-SR in Europe nor of his specific designation as the project leader, and Schering never established a project team for Niacor-SR. *See* CPRF 1.407.

1.411. Despite these delays, Schering continued to communicate with Upsher regarding its desire to obtain the Niacor-SR data. (SPX 10; SPX 12). On October 21, 1997, Mr. Kapur wrote to Mr. Troup, asking whether the Niacor-SR clinical data that Schering had expected by mid-October was available and attempting once again to set up a meeting for Schering to review the information at Upsher's offices. (SPX 12 at SP 05 00014; 18 Tr. 4156). A November 7, 1997 memo from Mr. Kapur to Mr. Audibert indicates that Mr. Troup had agreed that Upsher would send Schering the Niacor-SR registration information in segments so that Schering would not have to wait until the full ISS and ISE were completed. (SPX 12 at SP 05 00013; 18 Tr. 4156). Mr. Lauda testified that this note reflected Mr. Kapur's awareness that global marketing was pushing hard to get the data. (19 Tr. 4356). Mr. Lauda perceived Upsher's willingness to

send the relevant information in segments as a sign of progress on the Niacor-SR project. (19 Tr. 4356).

Complaint Counsel's Response to Finding No. 1.411:

The proposed finding is incomplete and misleading, and is not supported by the evidence. Mr. Audibert contacted Mr. Kapur on August 21, 1997 indicating that there had been delays in the compilation of Upsher's data on Niacor-SR. This was already two months after the settlement agreement had been signed (CX 348 at USL 03183, dated June 17, 1997) and only two months before Schering originally anticipated that it would receive the completed ISS and ISE data from Upsher. SPX 11 (memorandum from Mr. Audibert to Mr. Kapur dated August 21, 1997). The finding claims that "Schering continued to communicate with Upsher" in order to obtain this data. However, the next documented evidence of Schering's purported "continued" efforts to obtain the data from Upsher did not come until October 21, 1997 – an additional two months following Mr. Audibert's report to Mr. Kapur. SPX 12 at SP 05 00014 (memorandum from Mr. Kapur to Mr. Troup inquiring about the availability of clinical data). While Mr. Lauda testified that global marketing was pushing hard to get data from Upsher, Mr. Audibert's testified that Schering "waited for the information, and it actually never came." Tr. at 18: 4156-57. Finally, Schering made no additional requests to get the data subsequent to October 1997, nor did it ever receive the full data packages. *See* CPF 703-710 (concerning Upsher's failure to provide data to Schering, and Schering's lack of serious efforts to obtain the data).

1.412. Schering's licensing expert, Dr. Horovitz, testified that based on his review of the evidence, the actions taken by Schering internally, as well as its communications with Upsher prior to October 1997, were consistent with Schering's original plan of preparing its overseas filing once it received the ISS and ISE. (16 Tr. 3697-98 (Horovitz)). At that point, Schering's difficulties stemmed from the fact that Upsher experienced delays and could not provide the information that Schering needed to prepare its filings. (16 Tr. 3697-98). Dr. Horovitz, Mr. Lauda, and Mr. Audibert all testified that delays in compiling information for regulatory submissions are common in the pharmaceutical industry. (16 Tr. 3697-98 (Horovitz); 18 Tr. 4143 (Audibert); 19 Tr. 4356 (Lauda)).

Complaint Counsel's Response to Finding No. 1.412:

The proposed finding is incomplete. The delays experienced by Upsher could have been anticipated by Schering, however, Schering conducted no due diligence on the regulatory status of Niacor-SR and thus was not aware that these delays were likely. CPF 430-433 (discussing Schering's failure to conduct due diligence on the regulatory status of Niacor-SR).

2. Upsher's Internal Development Efforts On Niacor-SR

1.413. A significant amount of work remains after the patients have completed treatment in the clinical studies. (17 Tr. 3912 (Halvorsen)). All the data from the trials must be compiled into a database and verified for accuracy and patients must be tested for any conditions that may have affected the results. (17 Tr. 3912). When the database is completed and "locked,"

statisticians create programming to organize and retrieve the results, the data tables are audited, and the clinical study report is prepared. (17 Tr. 3912-13). By merging all the clinical study reports, the final integrated reports are created for filing with the NDA. (17 Tr. 3913-14). The "ISS" or integrated safety summary summarizes all the safety information in the clinical trials. (17 Tr. 3913-14). The "ISE" or integrated summary of efficacy compiles all of the efficacy data. (17 Tr. 3914). Finally, the package insert is created, briefly summarizing everything a company knows about its drug. (17 Tr. 3914-15). These post-patient activities consume a substantial amount of time. (17 Tr. 3915).

Complaint Counsel's Response to Finding No. 1.413:

Complaint counsel has no specific response.

1.414. Beginning in July 1996, the entire clinical department at Upsher was involved in Niacor's post-patient work. (17 Tr. 3915-16). Upsher was not capable of performing all the work itself, however, and hired three contract research organizations, ClinTrials Research, NovaTech Sciences, and CSR Consultants, to help in compiling the data, performing the statistical analyses, and writing the final study reports. (17 Tr. 3915-16). Between May 1995 and approximately March 1998, Upsher participated in weekly teleconferences, recorded in minutes by ClinTrials, in an attempt to ensure all these contract groups remained on schedule. (17 Tr. 3916, 3924).

Complaint Counsel's Response to Finding No. 1.414:

Complaint counsel has no specific response.

1.415. The FDA's approval of Kos' sustained-release product Niaspan prompted Upsher to reexamine its Niacor-SR NDA strategy. (17 Tr. 3986; USX 1190). Mr. Halvorsen had some information on Niaspan, including safety and efficacy information, and he felt that Niaspan and Niacor-SR were virtually the same in those areas. (17 Tr. 3947-48, 3952). However, Upsher learned after June 1997 that Niaspan had been approved with two indications for reducing the risk of recurrent heart attack and regression of atherosclerosis. (17 Tr. 4017-18). Mr. Halvorsen testified that Upsher believed at the time, incorrectly, that Kos had performed studies designed to achieve these indications for Niaspan and that Niacor-SR would not have been able to get these indications approved by the FDA because it had not performed such studies. (17 Tr. 3951-52, 3954, 3957-58, 4017-18; CX 1090).

Complaint Counsel's Response to Finding No. 1.415:

Complaint counsel has no specific response.

1.416. After Niaspan's approval, Upsher contemplated three alternatives: (1) going forward with the Niacor-SR NDA as planned, with no additional studies, at a cost of $1 to $2 million; (2) modifying the Niacor-SR NDA with additional "outcome" studies to match Kos' indications, which, alone, would cost $3 to $4 million; and (3) preparing an ANDA to Kos' product rather than an NDA. (SPX 1238, Halvorsen Dep. 196:11 – 198:11; 17 Tr. 3955, 3957; CX 1090). According to Mr. Halvorsen, completing the original NDA, with no additional studies, would have been the cheapest alternative for Upsher. (17 Tr. 3957).

Complaint Counsel's Response to Finding No. 1.416:

The proposed finding is not relevant. Upsher never informed Schering that it was

considering these changes in strategy at the time they occurred. In fact, Upsher did not inform Schering that it had ceased work on Niacor-SR until September 1998. Upsher's failure to inform Schering about these significant changes in strategies indicates that the parties were not serious about developing and marketing Niacor-SR. *See* CPF 694-702 (concerning Upsher's failure to inform Schering about critical changes in the development strategy for Niacor-SR); CPF 711-716 (describing how Upsher failed to notify Schering of its inability to overcome critical regulatory and developmental hurdles, and providing evidence regarding Upsher's post-hoc justifications for its decision not to complete work on Niacor-SR).

1.417. By August 1997, however, Upsher had decided to continue its pursuit of an NDA. (17 Tr. 3986-87; USX 1192). An October 24, 1997 fax reported that conference calls between Upsher and its contract research organization were ongoing, and Mr. Halvorsen testified that Upsher and these outside researchers communicated daily. (17 Tr. 3987; USX 1216). As of November 7, 1997, the Niacor-SR NDA project was an active project on which Upsher was expending resources. (17 Tr. 3961).

Complaint Counsel's Response to Finding No. 1.417:

The proposed finding is not relevant. Upsher never informed Schering that it was considering these changes in strategy at the time they occurred. *See* CPRF 1.416.

1.418. At the same time, Upsher investigated the feasibility of bringing Niacor-SR to market through an ANDA based on Kos' Niaspan. (17 Tr. 3955). Upsher's parallel path strategy

of proceeding with its NDA while investigating an ANDA option continued for two or three months, with two teams working on the two alternatives. (17 Tr. 3955-56).

Complaint Counsel's Response to Finding No. 1.418:

The proposed finding is not relevant. Upsher never informed Schering that it was considering these changes in strategy at the time they occurred. *See* CPRF 1.416.

3. Kos' Stock Plunge Preceded Upsher's And Schering's Decisions Not To Pursue Niacor-SR Projects

1.419. In November 1997, Kos announced its first quarterly results for Niaspan sales in the United States, which were considerably below what everyone had expected. (18 Tr. 4156 (Audibert); 19 Tr. 4433 (Lauda); 7 Tr. 1404 (Driscoll III); 17 Tr. 3956 (Halvorsen); 18 Tr. 5480 (Troup)). Kos' sales of Niaspan throughout the next several years were much lower than Schering had predicted during its own negotiations with Kos in April 1997. Mr. Russo's "base case" projections for U.S. sales of Niaspan in April 1997 compare to Niaspan's actual U.S. sales as follows:

Sales ($)	1997	1998	1999	2000	2001
Russo	7	48	101	106	126
Actual	1.8	16.3	37.9	64.0	95.3[1]

(CX 550 at SP 002743; SPX 1205.)

Complaint Counsel's Response to Finding No. 1.419:

The proposed finding is contradicted by other evidence. Schering did not expect

[1] Sales from January to November, 2001.

that Kos would earn sales levels as projected by certain market analysts. These sales projections were exaggerated according to Schering's own sales estimates for Niaspan. As discussed below in Schering's proposed finding 1.316, Schering estimated third year sales of Niaspan at $101 million (as compared to the between "$220 and $250 million" estimated by the market analysts). In addition, as expressly stated in Schering's proposed finding 1.314, "Schering did not agree with market analysts' public projections of Niaspan sales of $250 million."

In addition, the proposed finding is not relevant to this proceeding. There is no evidence that Schering valued Niaspan, or even Niacor-SR on the basis of outside analysts projections. In fact, Schering conducted its own due diligence and completed projections to evaluate the Niaspan opportunity. CX 548 (Niaspan financial analysis prepared by Ray Russo and Toni DeMola of Schering, dated April 17, 1997); CX 549 (additional Niaspan financial analysis prepared by Ray Russo and Toni DeMola, dated April, 1997); CX 550 (Niaspan sales forecasts prepared by Ray Russo and Toni DeMola, indicating "base," "downside," and "upside" sales forecast); Tr. at 15:3472, 3476-77 (Ray Russo) at 3472 (confirming that he completed sales projections for Niaspan), 3476-77 (acknowledging that sales projections were completed for Niacor-SR).

1.420. The first published figures regarding Niaspan sales in November 1997 were a major disappointment to investors, and stock price, which had peaked around $44 per share, plummeted to $5 per share. (18 Tr. 5480 (Troup)). Complaint counsel's expert Dr. Levy conceded that Niaspan did not do as well as the investment community had expected when it was

launched (9 Tr. 1856) and that Kos' stock price fell "pretty precipitously after the launch" (9 Tr. 1854). ON November 11, 1997, Kos' stock fell from $30.94 to $16.56. (USX 1027; 27 Tr. 6867 (Kerr); 10 Tr. 2055-78 (Levy)).

Complaint Counsel's Response to Finding No. 1.420:

The proposed finding is not relevant and contradicted by other evidence. Schering did not expect that Kos would earn sales levels as projected by certain market analysts, and there is no evidence that Schering valued Niaspan, or even Niacor-SR on the basis of outside analysts projections. *See* CPRF 1.419.

In addition, the citation to Dr. Levy's testimony is incomplete. He also testified that "it is not atypical for a startup company doing an IPO to grossly overstate its potential earnings. That's how they pump up their stock price. And it's not atypical for investment bankers to comport with that behavior." Tr. at 9:1856 (Levy).

1.421. Within a few weeks after Kos released the sales information for Niaspan, Upsher had pulled back on its ANDA project because in order to successfully go forward with a generic product, the branded product must attain a certain level of sales. (17 Tr. 3956, 3964 (Halvorsen)). An NDA was equally unpromising, as Niacor-SR was a very similar product to Niaspan, which failed to achieve a large following. (17 Tr. 3964). In December 1997, Upsher put its Niacor-SR development project "on hold status, pending evaluation of Kos marketing success." (SPX 302 at USL 16165).

Complaint Counsel's Response to Finding No. 1.421:

The proposed finding is incomplete and contradicted by other evidence. Upsher's

decision to alter its plans for Niacor-SR is documented in minutes from August 14, 1997 and October 21, 1997 meetings indicating that Upsher's changes in strategy were not precipitated by the publication of Kos' sales in November 1997. CX 963 at USL 12583, 12581 (Upsher internal Niacor-SR meeting minutes discussing possibility of changes in marketing strategy in August 1997; later, noting in October 1997 that an "[a]lternate strategy for an ANDA approval has been identified" and that "[t]he NDA will [be] continued with minimal activity while the ANDA strategy is formulated and evaluated"); Tr. at 7:1392-93 (Levy) (describing these documents); CPF 695. *See* CPF 694-702 (regarding Upsher's failure to notify Schering of changes in its Niacor-SR development strategy).

In addition, the proposed finding is not relevant. Upsher never informed Schering that it was considering these changes in strategy at the time they occurred. *See* CPRF 1.416.

1.422. Although Upsher decided not to go forward with its NDA in the United States, a December 16, 1997 fax reports that Mr. Halvorsen informed the Niacor-SR team that there was a possibility that the project would proceed in Europe through Schering. (USX 1226; 17 Tr. 3987-88). While January 15, 1998 meeting minutes indicate that the Niacor-SR project was on hold with "only minimal activity" to continue in most departments (CX 962 at USL 13253; 17 Tr. 4051), Mr. Halvorsen testified that Upsher's clinical department proceeded "full forward" at that point with efforts to complete the study reports. (17 Tr. 4051). The January 15, 1998 meeting minutes indicate that this continuing work represented "a significant amount of resource hours"

for Upsher. (CX 962 at USL 13252, USL 13253; 17 Tr. 4051). Upsher continued to communicate with its contract research organizations in efforts to compile the integrated summary of safety and the draft clinical tables in January 1998. (17 Tr. 3988-89; USX 1235).

Complaint Counsel's Response to Finding No. 1.422:

The proposed finding is incomplete and contradicted by other evidence. Upsher's decision to alter its plans for Niacor-SR is documented in minutes from August 14, 1997 and October 21, 1997 meetings – indicating that Upsher's changes in strategy were not precipitated by the publication of Kos' sales in November 1997. CX 963 at USL 12583, 12581 (Upsher internal Niacor-SR meeting minutes discussing possibility of changes in marketing strategy in August 1997; later, noting in October 1997 that an "[a]lternate strategy for an ANDA approval has been identified" and that "[t]he NDA will [be] continued with minimal activity while the ANDA strategy is formulated and evaluated"); Tr. at 7:1392-93 (Levy) (describing these documents); CPF 695. *See* CPF 694-702 (regarding Upsher's failure to notify Schering of changes in its Niacor-SR development strategy).

In addition, contrary to the proposed finding that efforts were undertake to complete clinical work, when Upsher confirmed with Schering in October 1998 that it had "suspended all research on Niacor-SR," Upsher informed Schering that "[s]everal of the studies are *not* in final form, and are not suitable for submission to a regulatory agency." CX 1111 at USL 13275 (letter from Upsher chief financial officer to Schering dated October 6, 1998) (emphasis in original document).

1.423. For some time after Schering learned that Kos' product had done poorly in the marketplace, it still asked Upsher to send the Niacor-SR ISS and ISE. (18 Tr. 4144 (Audibert)). Mr. Kapur's secretary sent a confidentiality agreement to Upsher's Vickie O'Neill on April 20, 1998, asking that "complete information with regard to Niacor" be sent to Mr. Lauda. (SPX 251). Sometime prior to September 26, 1998, Mr. Audibert told Mr. Lauda that he suspected that Upsher was not progressing and was going to abandon the Niacor-SR project. (19 Tr. 4377 (Lauda)). Mr. Lauda asked Mr. Audibert to have a direct conversation with Upsher, along with Mr. Kapur, to determine Upsher's progress and plans. (19 Tr. 4377).

Complaint Counsel's Response to Finding No. 1.423:

The proposed finding is incomplete and is not supported by the evidence. When describing Schering's activities following the announcement of Kos' sales, Mr. Audibert claimed that "there had been discussions with Upsher-Smith [and w]e still awaited the arrival of the clinical studies, the ISS/ISE." Tr. at 18:4144 (Audibert). Mr. Audibert did not testify to any particular efforts made by Schering in the wake of Kos' declining stock price. Tr. 18:4144 (Audibert). In fact, during this time period, there are only three documented contacts between Schering and Upsher regarding the data Schering had expected in October 1997: an October 21, 1997 fax from Mr. Kapur to Mr. Troup (SPX 12 at SP 0500014), a facsimile sent from Mr. Kapur to Mr. Audibert on November 7, 1997 (SPX 12 at SP 0500013) and the April 1998 confidentiality agreement sent by Mr. Kapur (SPX 13). Schering did not offer any other evidence of its efforts to obtain the data during the time between Kos' stock drop and September 1998 – nearly one year after Schering had originally anticipated that it would receive the information from Upsher.

1.424. Niaspan's performance in the marketplace was relevant to the Niacor-SR project because it provided a real world opportunity to test the market. (18 Tr. 4144 (Audibert)). By September 1998, the whole industry and analysts who had widely touted Kos before the launch knew that Kos was in fact doing very poorly, and Schering no longer believed that Niacor-SR would do as well as it had originally predicted. (19 Tr. 4433-34 (Lauda); 18 Tr. 4143-44 (Audibert)). Products sometime fail unexpectedly in the pharmaceutical industry. (33 Tr. 7966 (Egan)).

Complaint Counsel's Response to Finding No. 1.424:

The proposed finding is contradicted by other evidence. Schering did not expect that Kos would earn sales levels as projected by certain market analysts. These sales projections were exaggerated according to Schering's own sales estimates for Niaspan. As discussed below in Schering's proposed finding 1.316, Schering estimated third year sales of Niaspan at $101 million (as compared to the between "$220 and $250 million" estimated by the market analysts). In addition, as expressly stated in Schering's proposed finding 1.314, "Schering did not agree with market analysts' public projections of Niaspan sales of $250 million."

In addition, the proposed finding is not relevant to this proceeding. There is no evidence that Schering valued Niaspan, or even Niacor-SR on the basis of outside analysts projections. In fact, Schering conducted its own due diligence and completed projections to evaluate the Niaspan opportunity. CX 548 (Niaspan financial analysis prepared by Ray Russo and Toni DeMola of Schering, dated April 17, 1997); CX 549 (additional Niaspan financial analysis prepared by Ray Russo and Toni DeMola, dated

April, 1997); CX 550 (Niaspan sales forecasts prepared by Ray Russo and Toni DeMola, indicating "base," "downside," and "upside" sales forecast); Tr. at 15:3472, 3476-77 (Ray Russo) at 3472 (confirming that he completed sales projections for Niaspan); 3476-77 (acknowledging that sales projections were completed for Niacor-SR).

1.425. A subsequent discussion between Mr. Audibert, Mr. Kapur and Mr. Troup regarding Niacor-SR is summarized in a September 25, 1998 memo from Mr. Audibert to Mr. Lauda. (SPX 15). During this discussion, Mr. Troup stated that Upsher was not going forward with its NDA. (SPX 15; 18 Tr. 4159 (Audibert)). Mr. Audibert's memo indicates that this raised some real issues in his mind about the potential commercial viability of Niacor-SR from his perspective. (SPX 15; 18 Tr. 4159). He noted that "in August 1998, after being in the market one year, Niaspan's new Rx share for the month is only 1.1 percent" and that, "judging by the response of the investment community, the prognosis of Niaspan is poor." (SPX 15). He also stated that Upsher's decision not to pursue its NDA would result in delay and a greater demand on Schering's resources if it proceeded with its European filings. (SPX 15).

Complaint Counsel's Response to Finding No. 1.424:

The proposed finding is incomplete and contradicted by other evidence. The proposed finding represents that Mr. Audibert used Niaspan sales of "only 1.1 percent" as a justification for not proceeding with Niacor-SR. However, that sales level was consistent with (and exceeded in individual years) his own projections of sales for Niacor-SR in his commercial assessment. That assessment projected that Niacor-SR would achieve the following sales levels in Europe:

Year	'99	'00	'01	'02	'03	'04	'05	'06	'07	'08
Market Share %	.75	1.0	1.5	1.5	1.25	1.25	1.25	1.0	1.0	1.0

CX 1044 at SP 16 0047.

1.426. On October 6, 1998, Mr. Kralovec confirmed in a letter to Mr. Kapur that Upsher had suspended all research on Niacor-SR. (CX 1111; Tr. 19 Tr. 5058-59 (Kralovec); 4428-29 (Lauda)). Upsher cited the poor performance of Kos' Niaspan as one factor in its decision (21 Tr. 5061-62), as well as the fact that the FDA had requested that Upsher conduct an additional PK study, which would have delayed Upsher's NDA and resulted in the product coming to market two or three years behind the launch of Niaspan. (19 Tr. 4429 (Lauda); CX 1111).

Complaint Counsel's Response to Finding No. 1.426:

The proposed finding is incomplete and misleading, and is contradicted by the evidence. Mr. Kralovec's letter to Mr. Kapur states the following: "Per your request to Ian Troup last week, I am writing to confirm that Upsher-Smith Laboratories, Inc. has suspended all research on Niacor-SR. There were multiple reasons for this decision. First and foremost, an additional multiple-dose pharmacokinetic study was required prior to submitting an NDA. In light of Niaspan's FDA approval, Upsher-Smith's NDA would have been two to three years behind the launch of Niaspan." CX 1111 at USL13275 (emphasis added). The letter further explains that, secondarily, Kos' "less successful" marketing efforts for Niaspan "have reinforced our decision not to invest any additional resources in Niacor-SR." CX 1111 at USL 13275. Thus, according to contemporaneous

documentation, Upsher's primary rationale for suspending its work on Niacor-SR was related to additional clinical work required by the FDA.

In addition, the cited document indicates that "[s]everal of the studies are *not* in final form, and are not suitable for submission to a regulatory agency. Should [Schering] decide to proceed to obtain approval in your agreed upon area, we will address what resources would be necessary to get the remaining studies into suitable form." CX 1111 at USL 13275. Thus, nearly a year after Schering had anticipated receipt of complete ISS and ISE data, Upsher indicated that the data was still incomplete.

1.427. During the third quarter of 1998, Schering made an independent decision that it would not pursue the Niacor-SR project by itself. (19 Tr. 4352, 4377 (Lauda)). Although the decision to discontinue the Niacor-SR project was made after the meeting between Mr. Audibert, Mr. Kapur and Mr. Troup, Mr. Lauda testified that Schering had been considering whether to proceed with the project even before that meeting. (19 Tr. 4377-78 (Lauda)).

Complaint Counsel's Response to Finding No. 1.427:

The proposed finding is incomplete and misleading. In making the decision to abandon the Niacor-SR project, no one at Schering created any paper record of this decision or the reasons for abandoning the project. Nor did Mr. Lauda recall informing anyone above himself in Schering's corporate organization that he was not moving forward with Niacor-SR at that time. Tr. at 19:4377-79 (Lauda). Furthermore, Mr. Lauda was unable to recall exactly who made the decision to abandon the deal, although he claims that the decision was made "largely" by Mr. Audibert (Tr. at 19:4378 (Lauda)),

who testified that he did not even know he had been appointed project leader or what responsibilities he had regarding Niacor-SR. CPRF 1.403.

1.428. Schering abandoned its efforts to bring Niacor-SR to market for several reasons. (18 Tr. 4144; 19 Tr. 4352-53 (Lauda)). The Kos product continued to do poorly in the marketplace, telling Schering that marketing a sustained release niacin product was going to be more difficult than anticipated. (18 Tr. 4144-45 (Audibert)). Schering did not think Niacor-SR was going to reach the shares it originally had projected and, in light of Kos' sales, doubted that Niacor-SR product would be commercially viable. (19 Tr. 4352 (Lauda)). In addition, Niaspan's poor performance in the United States had implications for Niacor-SR sales in Europe, because many European physicians read the United States literature, attend United States meetings, and follow what happens to products the United States market. (18 Tr. 4145 (Audibert)). If Niaspan had been more successful in the United States, it would have made Schering's job promoting Niacor-SR easier in Europe. (18 Tr. 4145 (Audibert)). Moreover, the fact that Upsher had abandoned its pursuit of the NDA before it was ready to be filed meant that Schering would have to devote more of its own resources to putting together its international dossier than had originally been anticipated. (18 Tr. 4145 (Audibert)). Finally, even if Schering had gone forward with the work to prepare the dossier, the entry of Niacor-SR in Europe would have been much later than originally anticipated. (18 Tr. 4145 (Audibert)). As a result, Schering decided not to pursue Niacor-SR further. (19 Tr. 4407 (Lauda)).

Complaint Counsel's Response to Finding No. 1.428:

The proposed finding is incomplete and misleading. In making the decision to

abandon the Niacor-SR project, no one at Schering created any paper record of this decision or the reasons for abandoning the project. Nor did Mr. Lauda recall informing anyone above himself in Schering's corporate organization that he was not moving forward with Niacor-SR at that time. Tr. at 19:4377-79 (Lauda).

IV. 180 DAY EXCLUSIVITY

A. Schering and Upsher Did Not Engage in "Concerted Activity" to Manipulate the 180-Day Exclusivity Trigger Date

1. Legal Framework of 180-day Exclusivity

1.429. FDA approval is required for any new drug—branded or generic—to be legally marketed in the United States. (10 Tr. 2206 (Joel Hoffman); 28 Tr. 6965 (Safir)). A branded drug, also known as a pioneer or innovator drug, is typically the first drug product containing the particular active ingredient to be reviewed and approved by the FDA. (10 Tr. 2206-07 (JOEL Hoffman); 28 Tr. 6965 (Safir)). A generic drug is a drug product containing the same active ingredient but not necessarily the same inactive ingredients as the branded drug. (10 Tr. 2207 (JOEL Hoffman); 28 Tr. 6965 (Safir)).

Complaint Counsel's Response to Finding No. 1429:

Complaint counsel has no specific response.

1.430. The manufacturer of a branded drug is required to submit to the FDA a new drug application ("NDA") containing a showing that the drug is safe, and substantial evidence that the drug is effective for its intended uses, as well as complete information on the

manufacturing processes that will be used. (10 Tr. 2207 (JOEL Hoffman); 28 Tr. 6965 (Safir)). NDAs are handled by a unit of the FDA called the Center for Drug Evaluation and Research. (10 Tr. 2209 (JOEL Hoffman); 28 Tr. 6965 (Safir)).

Complaint Counsel's Response to Finding No.1.430:

Complaint counsel has no specific response.

1.431. Congress enacted the Hatch-Waxman Act, and changed the process for the FDA to approve generic drugs. (10 Tr. 2207-08 (JOEL Hoffman); 28 Tr. 6965 (Safir)). Congress had two separate and distinct goals in enacting the Hatch-Waxman Act. (10 Tr. 2212 (JOEL Hoffman); 28 Tr. 6965 (Safir)). The first was the goal of expediting the availability of generic drugs to the public. (10 Tr. 2212 (JOEL Hoffman); 28 Tr. 6965 (Safir)). The second goal was to provide affirmative incentives for brand name manufacturers to innovate. (10 Tr. 2212-13 (JOEL Hoffman); 28 Tr. 6965 (Safir)).

Complaint Counsel's Response to Finding No. 1.431:

Complaint counsel has no specific response.

1.432. Under the Hatch-Waxman Act, a generic drug manufacturer must show that its generic product is bioequivalent to the branded product containing the same active ingredient, along with evidence of its own manufacturing processes for approval. (10 Tr. 2208 (JOEL Hoffman); 28 Tr. 6965 (Safir)).

Complaint Counsel's Response to Finding No. 1.432:

Complaint counsel has no specific response.

1.433. A generic drug submission to the FDA is called an abbreviated new drug application, or an ANDA. (10 Tr. 2209 (JOEL Hoffman); 28 Tr. 6965 (Safir)). The FDA's Office of Generic Drugs is responsible for reviewing and approving ANDAs. (10 Tr. 2209 (JOEL Hoffman); 28 Tr. 6965 (Safir)).

Complaint Counsel's Response to Finding No. 1.433:

Complaint counsel has no specific response.

1.434. There are two stages of approval of an ANDA, tentative approval and final approval. (10 Tr. 2210-11 (JOEL Hoffman); 28 Tr. 6965 (Safir)). A generic manufacturer will receive tentative approval if it meets the FDA regulatory requirements for approval, but is statutorily barred from being approved. (10 Tr. 2211 (JOEL Hoffman); 28 Tr. 6965 (Safir)). Statutory bars from approval could include, for example, an exclusivity period held by another manufacturer or product labeling problems. (10 Tr. 2212 (JOEL Hoffman); 28 Tr. 6965 (Safir)). A tentative approval does not permit the generic applicant to market the drug. (10 Tr. 2211 (JOEL Hoffman); 28 Tr. 6965 (Safir)).

Complaint Counsel's Response to Finding No. 1.434:

Complaint counsel has no specific response.

1.435. To receive final approval, the drug's ANDA must meet all the FDA's regulatory requirements for approval, including the bioequivalence requirement and a showing of a satisfactory manufacturing process, and there must be no statutory barrier to the FDA's issuance

of final approval. (10 Tr. 2211 (JOEL Hoffman); 28 Tr. 6965 (Safir)). Final approval allows a generic product to be legally marketed in the United States. (10 Tr. 2213 (JOEL Hoffman); 28 Tr. 6965 (Safir)).

Complaint Counsel's Response to Finding No. 1.435:

Complaint counsel has no specific response.

1.436. A generic drug manufacturer must include one of four certifications with its ANDA filing. (10 Tr. 2215-16 (JOEL Hoffman); 28 Tr. 6965 (Safir)). One possible certification is a Paragraph III certification, which certifies that the generic will enter the market when the brand product's patent expires. (10 Tr. 2216 (JOEL Hoffman); 28 Tr. 6965 (Safir)).

Complaint Counsel's Response to Finding No. 1.436

The second sentence of this proposed finding is not supported by the cited testimony. Mr. Hoffman did not testify that a paragraph III certification "certifies that a generic will enter the market when the brand product's patent expires." Mr. Hoffman testified that "[a] paragraph III certification is simply a certification of the expiration dates of unexpired patents that are listed for that innovator drug in the Orange Book." (Tr. 10: 2216 (Hoffman)). Mr. Hoffman also testified that "If the certification filed was a paragraph III certification, FDA is prohibited by the statute from approving – from approving the ANDA until the last of the listed expiration dates has come and gone." (Tr. 10:2217 (Hoffman)). The citation to Mr. Safir's testimony is simply his general agreement with Mr. Hoffman's testimony of his summary of the factual background related to the history of 180-day exclusivity, and thus does not independently support the finding.

1.437. Another certification is a Paragraph IV certification, which certifies that in the opinion of the generic applicant, the patent on the brand name product is either invalid or not infringed by the generic applicant's product. (10 Tr. 2216 (JOEL Hoffman); 28 Tr. 6965 (Safir)). When an ANDA filer includes a Paragraph IV certification, the ANDA filer is required to notify both the patent holder and the brand name manufacturer (which may or may not be the same entity) of the filing. (10 Tr. 2217 2217 (JOEL Hoffman); 28 Tr. 6965 (Safir); 8 Tr. 1574 (Rosenthal)).

Complaint Counsel's Response to Finding No. 1.437:

Complaint counsel has no specific response.

1.438. When the patent holder/brand name manufacturer receives notice of the Paragraph IV certification, it may file an infringement suit against the ANDA applicant. (10 Tr. 2218 (JOEL Hoffman); 28 Tr. 6965 (Safir)). If an infringement suit is filed within a 45-day window, the FDA is not permitted to approve the ANDA until one of three events has occurred: (1) the patent expires; (2) the patent is judicially determined to be invalid or noninfringed; or (3) a 30-month period, which can be lengthened of shortened by the court, has elapsed. (10 Tr. 2218 (JOEL Hoffman); 28 Tr. 6965 (Safir); 8 Tr. 1575-76 (Rosenthal)).

Complaint Counsel's Response to Finding No. 1.438:

Complaint counsel has no specific response.

1.439. If no suit is brought by the patent holder/branded manufacturer within the 45-

day window, the FDA is legally permitted to approve the generic product. (10 Tr. 2218 (Hoffman); 28 Tr. 6965 (Safir)). The patent holder/branded manufacturer is not precluded from bringing a suit after the 45-day period, and therefore the generic manufacturer who markets his product after approval still subjects himself to the risk of an infringement suit and damages. (10 Tr. 2218-19 (JOEL Hoffman); 28 Tr. 6965 (Safir)).

Complaint Counsel's Response to Finding No. 1.439:

Complaint counsel has no specific response.

1.440. The Hatch-Waxman Act and its implementing FDA regulations provide that under certain circumstances, the first ANDA applicant who has filed a Paragraph IV certification is entitled to market its generic product free from competition from other generic products for 180 days. (10 Tr. 2219-20 (JOEL Hoffman); 28 Tr. 6965 (Safir)). The FDA is prohibited from approving any subsequent ANDAs for that drug until the 180-day period has elapsed. (10 Tr. 2219-20 (JOEL Hoffman); 28 Tr. 6965 (Safir)). The generic manufacturer's market exclusivity does not prohibit the patent holder/branded manufacturer from licensing another manufacturer to produce or distribute the brand name product. (10 Tr. 2221 (JOEL Hoffman); 28 Tr. 6965 (Safir)).

Complaint Counsel's Response to Finding No. 1.440:

Complaint counsel has no specific response.

1.441. The 180-day exclusivity period will begin to run at the commencement of commercial marketing of the generic product by the first ANDA filer, or from the date of a decision by a court holding the relevant patent to be invalid or not infringed. (10 Tr. 2220 (JOEL Hoffman); 28 Tr. 6965 (Safir)).

Complaint Counsel's Response to Finding No. 1.441:

Complaint counsel has no specific response.

1.442. As of June 17, 1997, FDA regulations provided that to be eligible for a 180-day exclusivity period, a first Paragraph IV ANDA filer was required to have been sued by the holder of the listed patent and to have already successfully defended that patent infringement action. *See* 21 C.F.R. § 314.107(c)(1)(1998). (SPX 1220 at ¶ 6; 10 Tr. 2223, 2248 (JOEL Hoffman); SPX 1277). This requirement is commonly referred to as the "successful defense" requirement. (SPX 1277 at ¶ 6).

Complaint Counsel's Response to Finding No. 1.442:

Complaint counsel has no specific response.

1.443. FDA revoked this regulation in 1998 as a result of Courts of Appeals decisions in two cases. *See Mova Pharm Corp. v. Shalala*, 140 F.3d 1060, 1069 (D.C. Cir. April 14, 1998); *Granutec, Inc. v. Shalala*, 139 F.3d 889 (table), 1998 WL 153410 (4th Cir. April 3, 1998). (SPX 1221; SPX 183; SPX 1277 at ¶ 7; 10 Tr. 2247, 2334-35 (JOEL Hoffman)).

Complaint Counsel's Response to Finding No. 1.443:

Complaint counsel has no specific response, except to note that FDA revoked the successful defense regulation on November 5, 1998, effective November 10, 1998. 63 C.F.R. 59710, 59712 (November 5, 1998).

1.444. Prior to the decisions in *Mova*, FDA's regulation and policies were clear – the FDA had consistently stated that a settler was not entitled to 180-day exclusivity. (SPX 1277 at ¶ 11). *See Mova Pharm. Corp. v. Shalala,* 955 F. Supp. 128 (D.D.C. 1997), *aff'd,* 140 F.3d 1060, 1069 (D.C. Cir. 1998). (SPX 208; SPX 1221). In order for the first filer of a Paragraph IV ANDA to obtain exclusivity, the applicant had to be sued and the patent had to have already been found to be either invalid or not infringed. *See* 21 C.F.R. § 314.107(c)(1)(1998). (SPX 206; SPX 1277 at ¶ 11).

Complaint Counsel's Response to Finding No. 1.444:

The proposed finding is incomplete and misleading, and is irrelevant. While what the FDA's regulations stated regarding entitlement to 180-day exclusivity were clear prior to the *Mova* district court and court of appeals decisions (and also long after those decisions, since the FDA did not formally withdraw its successful defense regulation until November 5, 1998, almost seven months after the Court of Appeals decisions in *Mova* and *Granutec*, holding that regulation to be unlawful. *See* 63 Fed. Reg. 59710 (November 5, 1998)), the legality of that regulation – which is relevant – was not clear, given the earlier decision by the federal District Court for the District of Columbia in *Inwood Laboratories, Inc. v. Young*, 723 F. Supp. 1523 (D.D.C. 1989), *appeal dismissed,*

judgment vacated and remanded, 43 F.3d 712, No. 89-5209, 1989 WL 513201 (D.C. Cir. Nov. 13, 1989). While the 1989 *Inwood* decision had been vacated, its reasoning – that it was improper for the FDA to add a requirement for 180-day exclusivity to what in the Hatch-Waxman Act was "clear on its face" – remained valid, and the decision was cited, and its reasoning was adopted, by the District Court in *Mova* in enjoining the FDA on January 23, 1997, from applying the successful defense regulation in that case. (*See Mova Pharmaceutical Corp. v. Shalala*, 955 F. Supp. 128, 130 (D.D.C. 1997); CPF 905-906).

1.445. In a 1988 FDA guidance letter, the Agency explained that a settlement signed by a federal judge entering final judgment and including a finding that the patent is invalid or not infringed constitutes a "decision of a court" within the meaning of the statute. (SPX 199; SPX 1277 at ¶ 11). Under such circumstances, the settling ANDA applicant would be entitled to 180-day exclusivity. *See* Letter to NDA and ANDA Holders and Applicants from C. Peck, Director, CDER (July 29, 1988). (SPX 199; SPX 1277 at ¶ 11). However, the guidance letter stated that a settlement under which the ANDA applicant accepts a license from the pioneer under the patent would not entitle the ANDA applicant to 180-day exclusivity because such a settlement is not a decision of a court finding the patent invalid or not infringed, as a license is not necessary to market a non-infringing product. (SPX 199; SPX 1277).

Complaint Counsel's Response to Finding No. 1.445:

The proposed finding is incomplete and misleading, and is irrelevant. While what the FDA's guidance letter, dated 7/29/88, stated regarding an ANDA submitter's

entitlement to 180-day exclusivity is clear, the legality of FDA's position – which is relevant – was not clear, given the decision by the federal District Court for the District of Columbia in *Inwood Laboratories, Inc. v. Young*, 723 F. Supp. 1523 (D.D.C. 1989), *appeal dismissed, judgment vacated and remanded*, 43 F.3d 712, No. 89-5209, 1989 WL 513201 (D.C. Cir. Nov. 13, 1989). *Inwood* held that it was improper for the FDA to add a requirement for 180-day exclusivity – being sued for patent infringement - to what in the Hatch-Waxman Act was "clear on its face." While the *Inwood* decision had been vacated, its reasoning remained valid, and the decision was cited, and its reasoning adopted, by the District Court in *Mova* in enjoining the FDA from applying the successful defense regulation in that case. (*See Mova Pharmaceutical Corp. v. Shalala*, 955 F. Supp. 128, 130 (D.D.C. 1997); CPF 905-906).

1.446. Similarly, although FDA's regulations did not discuss settlements specifically, settlements were addressed in the 1989 preamble to FDA's proposed rule. (SPX 1277 at ¶ 11). FDA stated that for purposes of determining the date on which a decision of a court holding a patent invalid or not infringed, the agency would use, among others, "the date of a settlement order or consent decree . . . which enters final judgment and includes a finding that the patent is invalid or not infringed." *See Abbreviated New Drug Application Regulations; Proposed Rule*, 54 Fed. Reg. 28872, 28895 (July 10, 1989); *see also 180-Day Generic Drug Exclusivity for Abbreviated New Drug Applications*, 64 Fed. Reg. 42873, 42880 (Aug. 6, 1999) (SPX 1277 at ¶ 11) (SPX 202). A settlement that did not include a finding of invalidity or non-infringement would not have resulted in exclusivity. (SPX 1277 at ¶ 11).

Complaint Counsel's Response to Finding No. 1.446:

The proposed finding is incomplete and misleading, and is irrelevant. Schering is correct that the final regulation adopted by the FDA (*i.e.*, the "successful defense" regulation) did not discuss an ANDA submitter's entitlement to 180-day exclusivity in the case of a settlement. *See* 59 Fed. Reg. 50338, 50350-56, 50367-68 (October 3, 1994). Moreover, both the discussion of settlements in the preamble to the 1989 proposed rule quoted by Schering in this proposed finding, and the discussion of settlements in the 1999 proposed FDA regulation, related to the "court decision trigger" date for the running of 180-day exclusivity, and not to an ANDA submitter's eligibility for, or entitlement to, 180-day exclusivity under the Act. *See* 54 Fed. Reg. 28872, 28894-95 (July 10, 1989); 64 Fed. Reg. 42873, 42880 (Aug. 6, 1999); Schering's Proposed Finding 1.464, below. Thus, the Federal Register citations in Schering's proposed finding are irrelevant to the issue of a settling first ANDA submitter's entitlement to 180-day exclusivity. Furthermore, even if FDA's interpretation of the Hatch-Waxman Act was that a settling first filer was not entitled to exclusivity because it did not meet the "successful defense" requirement, the rationale of the *Inwood* and *Mova* district court decisions, essentially holding that requirement to be invalid, *a fortiorari* would compel the same entitlement to exclusivity for a settling ANDA submitter. CPF 905-906; Tr. 10:2227 (Joel Hoffman) ("[T]he reasoning [of the district court in *Mova*] didn't depend on anything relating to the particular litigants or their – or their procedural posture."). Moreover, the FDA was aware of the legal inconsistency of its successful defense regulation with the *Inwood* decision when it adopted the regulation. CPF 905.

1.447. In January 1997, the U.S. District Court for the District of Columbia decided *Mova Pharm. Corp. v. Shalala,* 955 F. Supp. 128 (D.D.C. 1997). (SPX 208) (SPX 1277 at ¶ 7). In the *Mova* case, the first Paragraph IV ANDA applicant, Mova, had been sued by the patent holder and was actively defending a patent infringement suit when FDA approved the ANDA of a subsequent Paragraph IV applicant, Mylan, who had not been sued. (SPX 1277 at ¶ 7; 10 Tr. 2326, 2328-30 (JOEL Hoffman)) (USX 767). FDA approved Mylan's ANDA because Mova had not yet successfully defended the patent infringement suit brought by the pioneer. (SPX 1277).

Complaint Counsel's Response to Finding No. 1.447:

Complaint counsel has no specific response.

1.448. The district court in *Mova* granted a preliminary injunction barring application of FDA's successful defense regulation on the ground that the successful defense requirement likely was inconsistent with the language providing for 180-day exclusivity in the Hatch-Waxman Act. (SPX 208; SPX 1277). The Court did not broadly enjoin future application of FDA's successful defense regulation, but rather, limited its injunction to the parties then before it. (SPX 208; SPX 1277 at ¶ 7).

Complaint Counsel's Response to Finding No. 1.448:

This proposed finding is incomplete and misleading. While the District Court in *Mova* only granted the injunction request before it, which related to the FDA's application of the successful defense requirement in the specific circumstances there at issue, the reasoning of the District Court had application to all situations involving the FDA's application of the requirement. Tr. at 10:2226-28 (Joel Hoffman). The broader

application of the *Mova* decision was particularly apparent given that the decision was rendered by the federal District Court for the District of Columbia, where FDA could be sued by any plaintiff with standing, who likely could expect to obtain the same result as in the *Mova* case. Tr. at 10:2228 (Joel Hoffman); CPF 907; Tr. 28:7002 (Safir).

1.449. Mylan, the second ANDA filer, appealed the *Mova* decision and FDA continued to take the position that its regulation was valid. (SPX 1277 at ¶ 7). The FDA supported Mylan's position on appeal. (SPX 1277 at ¶ 7).

Complaint Counsel's Response to Finding No. 1.449:

This proposed finding is incomplete and misleading. Because it recognized the potential application of the *Mova* District Court decision to its ability to apply the successful defense regulation to future exclusivity determinations, the FDA acquiesced in the decision pending reversal of *Mova* on appeal. CPF 907, 909.

1.450. From the date of the district court's decision in *Mova* until May 21, 1997, FDA gave no public indication that it would do anything other than continue to enforce the "successful defense" regulation as written, and to support its validity. (SPX 1277 at ¶ 8). Prior to June 17, 1997, the only suggestion that FDA might change its policies in response to the *Mova* decision occurred at a May 21, 1997 public meeting. (SPX 1277 at ¶ 8).

Complaint Counsel's Response to Finding No. 1.450:

This proposed finding is misleading. The announcement by FDA of its acquiescence in the *Mova* District Court decision, pending reversal on appeal, was not a

"suggestion" that FDA "might" change its policies regarding the successful defense requirement in response to the decision. It was an announcement that, at that time, the FDA in fact was changing its policies in that regard unless and until *Mova* was reversed on appeal. CPF 909.

1.451. On May 21, 1997, a single FDA attorney indicated at a public meeting that, for the time being, the Agency would abide by *Mova* in future exclusivity determinations while continuing to disagree with the decision. (SPX 1277 at ¶ 8). Although this statement was reported in the trade press, it was highly qualified:

> [FDA is] unhappy with the outcome of the [*Mova*] case. We do not think it's consistent with the intent of the statute . . . Right now we are acquiescing to the Mova court decision, but for those of you who think you know that that may mean . . . please don't go running out of here and say you know the answer . . .."

Geneva Seeks Six-Month Exclusivity on Ranitidine Form 1; Novopharm Expects Marketing Plans to Proceed, The Pink Sheet, Vol. 59, Issue 21 (May 26, 1997). (CX 601; SPX 1277 at ¶ 8; 10 Tr. 2287 (JOEL Hoffman)).

Complaint Counsel's Response to Finding No. 1.451:

This proposed finding is misleading. The use of the term "a single FDA attorney" suggests that the person announcing the FDA's acquiescence *pendente lite* in the *Mova* District Court decision perhaps was unauthorized or unqualified to make such an announcement on behalf of the FDA. In fact, the FDA official making the announcement was the FDA's Associate Chief Counsel for Drugs, the FDA's chief legal advisor on

Hatch-Waxman Act issues. CPF 909. The FDA's Associate Chief Counsel for Drugs did not "indicate" that the FDA would be abiding by the *Mova* decision, she announced that the FDA would be doing so. CPF 909.

1.452. Other than this brief reference in the trade press, there was no public information about FDA's acquiescence to the *Mova* decision, or the significance of that acquiescence, until June 23, 1997, when the trade press obtained copies of June 17, 1997 letters FDA sent to generic applicants for ranitidine. *See Novopharm Seeks Preliminary Injunction Against FDA Ranitidine Decision; Generics Likely to Reach Market Aug. 19, Except for Exclusivity Winner Genpharm*, The Pink Sheet, Vol. 59, Issue 25 (June 23, 1997). (CX605; SPX 1277). FDA did not make these letters public at the time they were sent. (SPX 1277 at ¶ 9). They were only released to the press by some of the recipients some time after they received them. (SPX 1277 at ¶ 9).

Complaint Counsel's Response to Finding No. 1.452:

This proposed finding is incomplete and misleading. The FDA's action of, in fact, acquiescing in the *Mova* decision regarding the ANDA applicants for ranitidine was made public as early as June 17, 1997, the date the first ranitidine letters were sent by the FDA, when Granutec filed a lawsuit appealing the FDA's action. CPF 912. The FDA's sending of these letters also necessarily must have been made public fairly quickly, since they were reported in the trade press only six days later, in the June 23, 1997, edition of "The Pink Sheet." CX 605; CPF 912.

1.453. Thus, as of June 17, 1997, FDA was on record as disagreeing with the District Court's decision in *Mova*, relatively few people knew that FDA would be abiding by the *Mova* decision in other exclusivity determinations, and the sole public statement to that effect was highly qualified and had been made by a low level FDA official. (SPX 1277 at ¶ 8-9).

Complaint Counsel's Response to Finding No. 1.453:

This proposed finding is not supported by the evidence, and is contradicted by other, more reliable, evidence. First, there is no evidentiary support cited, or contained in the record, other than the bald conclusion of Schering's expert, for finding that, as of June 17, 1997, "relatively few people knew that FDA would be abiding by the *Mova* decision in other exclusivity determinations." This conclusion is not credible given: 1) the importance of the January 1997 *Mova* district court decision to the FDA and members of the pharmaceutical industry, in view of its being issued by the federal District Court for the District of Columbia (CPF 907); 2) the fact that the D.C. District Court's decision in *Mova* was reported in a widely read pharmaceutical industry trade publication on January 20, 1997 (CPF 908); 3) the public announcement at a pharmaceutical industry trade association meeting on May 21, 1997, by the FDA's Associate Chief Counsel for Drugs, the FDA's chief legal advisor on Hatch-Waxman Act issues, of the FDA's decision to acquiesce in the *Mova* District Court decision (CPF 909); 4) the prominent reporting of FDA's announcement of its acquiescence in *Mova* in the pharmaceutical trade press on May 26, 1997 (CPF 909); and 5) the filing of a court appeal on June 17, 1997, in response to the FDA's acquiescence in practice in the *Mova* decision regarding the ranitidine ANDAs (CPRF 1.452). In addition, the characterization of the person announcing the

FDA's acquiescence in *Mova* as "a low level FDA official" is misleading. (CPRF 1.451).

1.454. Therefore, on June 17, 1997, it was reasonable and even prudent to believe that by settling, Upsher would not be entitled to exclusivity. Rather, on June 17, 1997, it was reasonable and even prudent to believe that Upsher would be entitled to exclusivity only if it litigated and successfully defended the patent suit brought by Schering. (SPX 1277 at ¶ 9; 28 Tr. 6965-66 (Safir); 10 Tr. 2322-23 (JOEL Hoffman)).

Complaint Counsel's Response to Finding No. 1.454:

This proposed finding is not supported by the evidence, and is contradicted by other evidence. The citation to Joel Hoffman's testimony at Tr. at 10:2322-23 does not support this finding. Mr. Hoffman's testimony there responds to an inquiry by Upsher's counsel as to Upsher's entitlement to 180-day exclusivity in June of 1997 if it settled its litigation with Schering. Mr. Hoffman's response was that he would have told Upsher "something to th[e] effect" that he "had no idea one way or the other . . . whether [180-day exclusivity] would apply." Mr. Hoffman explained that this essentially was because the legality of the FDA's successful defense regulation had been brought into serious question by the *Mova* District Court decision. Mr. Safir's testimony on the cited pages simply states his agreement with Mr. Hoffman's testimony regarding the factual background and history of the 180-day exclusivity provisions of the Hatch-Waxman Act, and his agreement with Mr. Hoffman's opinion that there was substantial uncertainty about Upsher-Smith's entitlement to that exclusivity on June 17, 1997, if it settled with Schering, and on January 23, 1998, having by then settled with Schering. Thus, neither

Mr. Hoffman's nor Mr. Safir's testimony supports the proposition that Upsher would be entitled to exclusivity only if it litigated and successfully defended against Schering. The entire thrust of Mr. Hoffman's testimony, with which Mr. Safir agrees, is that there was substantial uncertainty at that time – June 17, 1997 – and that there were several factors, including the *Mova* District Court decision, indicating that Upsher might indeed be entitled to 180-day exclusivity then, even if it did not litigate and successfully defend. CPF 905-910.

1.455. On July 3, 1997, the United States District Court for the Eastern District of North Carolina held that FDA's "successful defense" regulation was valid and binding upon FDA. (SPX 1277 at ¶ 10). Because the ANDA applicant to whom FDA had awarded exclusivity had not successfully defended the patent suit brought by the pioneer, as required by FDA's regulations, the applicant was not entitled to exclusivity, and the Court ordered FDA to approve a competitor's ANDA. *Granutec, Inc. v. Shalala*, 1997 WL 1403894 (E.D.N.C. July 3, 1997). (SPX 178; SPX 1277 at ¶ 10).

Complaint Counsel's Response to Finding No. 1.455:

Complaint counsel has no specific response.

1.456. In November 1997, following the *Granutec* district court decision, FDA announced that it would no longer acquiesce to the District Court's holding in *Mova*, and instead would apply the "successful defense" requirement as set forth in 21 C.F.R. § 314.107(c) (1998). *See Policy on 180-Day Marketing Exclusivity for Drugs Marketed Under Abbreviated New Drug*

Applications; Clarification, 62 Fed. Reg. 63268 (Nov. 28, 1997). (CX 607; SPX 1277 at ¶ 10; 10 Tr. 2246-47 (JOEL Hoffman)).

Complaint Counsel's Response to Finding No. 1.456:

Complaint counsel has no specific response.

1.457. In April 1998, the U.S. Court of Appeals for the D.C. Circuit decided the *Mova* case. *Mova Pharm. Corp. v. Shalala,* 140 F.3d 1060 (D.C. Cir. 1998). (SPX 1221; SPX 1277 at ¶ 7). The Court of Appeals rejected FDA's argument that the "successful defense" requirement was necessary to prevent first Paragraph IV applicants who are either not sued or who lose their patent infringement suits from benefitting from the 180-day exclusivity period. (SPX 1277 at ¶ 12). The Court of Appeals held that FDA could have effectively addressed the problem of first Paragraph IV applicants who lose their suits through either a "wait-and-see" approach or a "win-first" approach. (SPX 1277 at ¶ 12). FDA opted for the "win-first" approach, under which the 180-day exclusivity provisions do not have any effect on subsequent applicants *until* the first Paragraph IV applicant wins its patent suit. (SPX 1277 at ¶ 12). The Court of Appeals concluded that this "win-first" approach, as set forth in 21 C.F.R. § 314.107(c)(1)(1998), was overbroad and inconsistent with the text and structure of the statute. *Mova Pharm. Corp. v. Shalala,* 140 F.3d 1060, 1069 (D.C. Cir. 1998). (SPX 1221; SPX 1277 at ¶ 12).

Complaint Counsel's Response to Finding No. 1.457:

Complaint counsel has no specific response.

1.458. While the *Mova* Court of Appeals acknowledged that the statute, as written, could produce bizarre results in certain situations, *e.g.*, where the first Paragraph IV applicant is either never sued and never goes to market or loses its patent suit, it held that FDA's "win-first" solution to the problem was overbroad and inconsistent with Congressional intent. (SPX 1221 at 1069-1074; SPX 1277 at ¶ 12). FDA erred in adopting such a broad rule where a more narrow solution could have corrected the statutory anomaly. (SPX 1221 at 1071, 1074; SPX 1277). Therefore, the Court affirmed the District Court's order invalidating the successful defense requirement of 21 C.F.R. § 314.107(c)(1)(1998) (SPX 1277 at ¶ 12).

Complaint Counsel's Response to Finding No. 1.458:

Complaint counsel has no specific response.

1.459. The *Mova* case did not involve the settlement of litigation, and the Court of Appeals did not address exclusivity in the context of a settlement. (SPX 1277 at ¶ 12).

Complaint Counsel's Response to Finding No. 1.459:

This proposed finding is incomplete and misleading. As discussed in CPRF 1.446, above, the rationale of the *Mova* decision (like the earlier, but vacated, *Inwood* decision) would preclude the FDA's adding any requirement to the Hatch-Waxman Act's facially clear enumeration of the requirements for eligibility for 180-day exclusivity. Thus, if an ANDA applicant need not be sued, and need not successfully defend in a lawsuit, in order to qualify for exclusivity, the FDA likewise could not add a non-statutory requirement to the statute's clear provisions, and require that the ANDA filer not settle the litigation (in which it was not required to be engaged in the first instance) in

order to qualify for exclusivity under the statute.

1.460. The same month as the D.C. Circuit's decision in *Mova*, the United States Court of Appeals for the Fourth Circuit issued an unpublished opinion in *Granutec, Inc. v. Shalala,* 139 F.3d 889 (table), 1998 WL 153410 (4th Cir. April 3, 1998). (SPX 183; SPX 1277 at ¶ 13). In that case, the court concluded that the first applicant to submit a Paragraph IV ANDA, Genpharm, was entitled to 180-day exclusivity, and declared FDA's "successful defense" requirement invalid. (SPX 1277 at ¶ 13).

Complaint Counsel's Response to Finding No. 1.460:

Complaint counsel has no specific response.

1.461. After the Court of Appeals' decisions in *Mova* and *Granutec*, FDA began the process of drafting a new regulation to replace the overbroad "successful defense" regulation that had been rejected by the Courts of Appeals for the D.C. and Fourth Circuits. (SPX 1277 at ¶ 14).

Complaint Counsel's Response to Finding No. 1.461:

Complaint counsel has no specific response.

1.462. In the meantime, FDA took the position that the right to exclusivity was not dependent upon the first filer being sued and successfully defending the lawsuit, and therefore routinely granted exclusivity to the first Paragraph IV filer. (SPX 1277 at ¶ 14). Consistent with this position, the Agency granted exclusivity to first filing generic applicants who had entered into agreements with pioneers without examining the terms of the agreements. (SPX 1277 at ¶ 14).

Complaint Counsel's Response to Finding No. 1.462:

Complaint counsel has no specific response.

1.463. In August 1999, FDA issued proposed regulations addressing various issues raised by the *Mova* and *Granutec* decisions, including applicability of 180-day exclusivity in situations where the pioneer has entered into a settlement agreement with the first generic applicant to submit a Paragraph IV ANDA. *See 180-Day Generic Exclusivity for Abbreviated New Drug Applications,* 64 Fed. Reg. 42873, 42874, 42880 (Aug. 6, 1999). (SPX 202) (SPX 1277 at ¶ 15). In the preamble, FDA explained that settlements that effectively block approval of later filed ANDAs and do not result in the sale of the first filer's ANDA product raise significant policy concerns. (SPX 202; SPX 1277 at ¶ 15).

Complaint Counsel's Response to Finding No. 1.463:

This proposed finding is incomplete and misleading, and is irrelevant. There is no evidence that this proposed regulation has been adopted by the FDA (and in fact it has not been finally adopted by FDA), or that the policies and positions contained therein have been implemented by the FDA. Moreover, this regulation was only first proposed in August of 1999, long after the relevant time period regarding Respondents' challenged actions, and well after the FDA notified Upsher in January 1999 of its entitlement to 180-day exclusivity (CX 611; CPF 926). In fact, Upsher was not concerned about this regulation, believing that, even if it was adopted by the FDA, it would not be applied retroactively to Upsher. CX 190 at Upsher-Smith-FTC-138948 ("Upsher-Smith has six months exclusivity beginning on the first day Upsher-Smith introduces product into

interstate commerce. This exclusivity relates to being the first to file an ANDA product against a product with a patent. . . . In August 1999, the FDA submitted a proposal which requests that the current six month exclusivity period be modified. It is unlikely that this proposal will be retroactive and thus not impact Upsher Smith's current plans."). The proposed regulation, and this proposed finding, therefore are irrelevant to this proceeding. *See also* Tr. at 10: 2306 (Joel Hoffman) (". . . in other documents being issued by FDA over the last couple of years, FDA has indicated a disinclination – this is expressly stated – that it is not inclined to apply these kinds of new [statutory] interpretations retrospectively; that is, to prior – to prior settlements, prior awards of exclusivity.").

1.464. While the proposed regulations did not directly address the issue of whether such settlements may render a first filer *ineligible* for exclusivity, they did include a trigger mechanism that would limit any undue blocking effect on later filed ANDAs resulting from settlements. (SPX 1277 at ¶ 15). Under this trigger proposal, parties could still enter into settlement agreements, but "their effect on generic competition would be limited by the [proposed] requirement that, within 180 days of the first *tentative* approval of a subsequent ANDA, the first ANDA applicant begin commercially marketing its own product or obtain a favorable court decision." (SPX 202 at 42880; SPX 1277 at ¶ 15) (emphasis added). If neither of these events occurs during this period, the first Paragraph IV filer will lose its eligibility for exclusivity and subsequent ANDAs will be eligible for immediate approval. (SPX 202 at 42877; SPX 1277 at ¶ 15).

Complaint Counsel's Response to Finding No. 1.464:

This proposed finding is incomplete and misleading, and is irrelevant. First, as Schering admits in the proposed finding, the proposed regulation did not even relate to the eligibility of a settling first ANDA filer for 180-day exclusivity, but only to the possible triggering of a settling first ANDA filer's exclusivity by FDA's granting tentative approval to a subsequent filer's ANDA. Thus, insofar as this proposed regulation has any relevance, it clearly contemplates a settling first ANDA filer as having exclusivity, and proposes a mechanism to trigger that exclusivity, so as to avoid a blocking effect on subsequent ANDA filers. More importantly, there is no evidence cited or in the record that this proposed regulation has been adopted by the FDA (and in fact it has not been adopted), or that any of the policies or positions therein that are referred to in this finding in fact have been implemented in practice by the FDA. Moreover, this regulation was only first proposed in August of 1999, long after the relevant time period regarding Respondents' challenged actions, and long after the FDA had notified Upsher of its entitlement to exclusivity. Upsher was aware of this proposed regulation, and did not believe that it would apply retroactively to Upsher's exclusivity. CPRF 1.463. The proposed regulation, and this proposed finding, therefore are irrelevant to this proceeding.

1.465. FDA's preamble makes the point that the proposed regulations "address the most challenging issue with respect to 180-day exclusivity: settlement and licensing agreements between innovator and generic drug companies. . . . The proposed regulations, by applying the triggering period, would reduce the delay in market entry of generic drug products that can result

from such agreements." (SPX 202 at 42880; SPX 1277 at ¶ 15).

Complaint Counsel's Response to Finding No. 1.465:

This proposed finding is incomplete and misleading, and is irrelevant. There is no evidence cited or in the record that this proposed regulation has been adopted by the FDA (and in fact it has not been adopted), or that any of the policies or positions therein that are referred to in this finding in fact have been implemented in practice by the FDA. Moreover, this regulation was only first proposed in August of 1999, long after the relevant time period regarding Respondents' challenged actions, and Upsher believed that it would have no effect on their entitlement to exclusivity. *See* CPRF 1.463. The proposed regulation, and this proposed finding, therefore are irrelevant to this proceeding.

1.466. In February 2001, in response to a Citizen Petition filed by Teva Pharmaceuticals, FDA modified its position on the impact of settlement agreements upon eligibility for exclusivity. (SPX 1277 at ¶ 16) (CX 613). There, FDA concluded that a settlement between the pioneer and the first filer under which the first filer is no longer participating in litigation intended to prove that its product will not infringe the listed patent effectively changes the Paragraph IV certification to a Paragraph III certification. (CX 613; SPX 1277 at ¶ 16; 28 Tr. 6968 (Safir); 10 Tr. 2310(JOEL Hoffman)). As a result, the Agency concluded that the first filer was no longer eligible for exclusivity. *See* Letter to Teva Pharmaceuticals responding to Citizen Petition, Docket No. 00P-1446 (Feb. 6, 2001). (CX 613; SPX 1277 at ¶ 16; 28 Tr. 6968 (Safir)).

Complaint Counsel's Response to Finding No. 1.466:

This proposed finding is incomplete and misleading. The FDA's position in its

response to the Teva Petition was overruled by the federal District Court for the Northern District of West Virginia in *Mylan Pharmaceuticals, Inc. v. Thompson,* Civ. Action No. 1:01CV23 2001 WL 1654781 (N.D.W.V. April 18, 2001), which found the FDA's position to be "unreasonable" in four different respects. (Tr. at 28:7026-31 (Safir); Tr. at 10:2293-94 (Joel Hoffman). While the appeal of this decision was dismissed, the district court's decision was not vacated. CX 1696; CX 1697; Tr. 28:7031-33 (Safir).

1.467. FDA now views a first filer who enters into a settlement pursuant to which it abandons its challenge to the listed patent and declines to bring its FDA-approved ANDA product to market the same way it views a first filer who litigated and lost, *i.e,* as not entitled to exclusivity. (SPX 1277 at ¶ 16; 28 Tr. 6967 (Safir)). As explained in FDA's response to the Teva Citizen Petition, FDA's current view is that an ANDA applicant that loses the patent litigation is no longer considered eligible for exclusivity:

> Only an application containing a paragraph IV certification may be eligible for exclusivity. FDA regulations contain a provision at 21 C.F.R. § 314.94(a)(12)(viii) stating that an applicant may amend its certification, and if it does so, the application will no longer be considered to contain the previous certification. Under certain circumstances, an ANDA applicant is required to amend its patent certification if the patent is determined to be infringed or if the applicant discovers the submitted certification is no longer correct. If an applicant changes from a paragraph IV certification to a paragraph III certification, the ANDA will no longer be eligible for exclusivity.

FDA's Response to Teva's Citizen Petition at 4. (CX 613). *See also Mylan v. Henney*, 94 F. Supp. 2d 36, 56-58 (D.D.C. 2000) (rejecting argument that change from paragraph IV to paragraph III did not require loss of exclusivity). (SPX 1277 at ¶ 17; 28 Tr. 6967-68 (Safir)).

Complaint Counsel's Response to Finding No. 1.467:

This proposed finding is incomplete and misleading, not supported by the evidence, and irrelevant. While the FDA's position regarding a settling first ANDA filer, as stated in its February 6, 2001, response to the Teva petition (CX 613) is self-explanatory, there is no evidence in the record as to what FDA's policy or position is on the matters addressed in that response since it was held to be unreasonable and enjoined in *Mylan v. Thompson*, and the appeal of that decision was dismissed without the lower court decision being vacated. In the absence of any evidence as to the FDA's position on these issues subsequent to the district court's finding its position to be unreasonable, FDA's earlier response to the Teva petition does not support the proposed finding's assertion regarding how the "FDA now views a first filer who enters into a settlement pursuant to which it abandons its challenge to the listed patent and declines to bring its FDA-approved ANDA product to market" (emphasis added), or that "FDA's current view is that an ANDA applicant that loses the patent litigation is no longer considered eligible for exclusivity." (emphasis added). Moreover, the FDA has expressed its disinclination to apply new statutory interpretations retrospectively to the subjects of prior awards of exclusivity under the Hatch-Waxman Act. *See* Tr. at 2306 (Joel Hoffman). In addition, Schering neglects to point out that the decision in *Mylan v. Henney* that it cites: 1) was found by the court in *Mylan v. Thompson* (at pp. 22-23) to be distinguishable from the

situation the FDA was addressing in its response to the Teva petition, and therefore of no support whatsoever for the FDA's position; and 2) that *Mylan v. Henney* was vacated on appeal, and remanded with instructions to dismiss. *Pharmachemie B.V. v. Barr Laboratories, Inc.*, 276 F.3d 627 (D.C. Cir., 2002). Finally, what the FDA might or might not have considered doing at some time is irrelevant, given that the FDA in informed Upsher of its entitlement to 180-day exclusivity in January 1999, FDA never changed its position regarding Upsher's entitlement to exclusivity, and Upsher in fact enjoyed a 180-day period of exclusivity beginning with its commencement of marketing of Klor-Con 20 on September 1, 2001 and ending on February 28, 2002. *See* CPF 923-928.

1.468. As indicated by the Teva Citizen Petition, FDA now takes the view that an ANDA filer that settles and agrees to take a license from the patent holder and to market only in the future also changes its certification. (SPX 1277 at ¶ 18; 28 Tr. 6966-67 (Safir)). Such a settling ANDA filer, like a ANDA filer that litigates and loses, is, in FDA's view, no longer eligible for exclusivity. *See* FDA's Response to Teva's Citizen Petition, at 4. (CX 613; SPX 1277 at ¶ 18).

Complaint Counsel's Response to Finding No. 1.468:

This proposed finding is incomplete and misleading, and not supported by the evidence. The cited evidence does not support a finding regarding the FDA's current position on the issues, or its willingness to retroactively apply its new interpretations regarding Hatch-Waxman Act exclusivity to previous determinations. *See* CPRF 1.467.

1.469. Although FDA's decision on Teva's Citizen Petition was overruled by a district court in *Mylan Pharm, Inc. v. Thompson,* Civ. No. 1:01CV23 (N.D. W. Va. April 18, 2001), FDA appealed the case to the Court of Appeals for the Fourth Circuit. (CX 1695; SPX 1277 at ¶ 19). FDA maintains that a settlement pursuant to which the first filer abandons its challenge to the listed patent and declines to bring its FDA-approved ANDA product to market may result in a loss of entitlement to exclusivity. *See Brief of Federal Defendants-Appellees in Mylan Pharm., Inc. v. Thompson,* No. 01-1554 (4th Cir. July 25, 2001). (SPX 204; SPX 1277 at ¶ 17; 28 Tr. 6969 (Safir)).

Complaint Counsel's Response to Finding No. 1.469:

This proposed finding is incomplete and misleading, and not supported by the evidence. The cited evidence does not support a finding regarding the FDA's current position on the issues. *See* CPRF 1.467.

1.470. As stated in FDA's brief in the Court of Appeals in *Mylan v. Thompson*:

> The facts here are only a slight variation on the scenario in [C.F.R. § 314.94(a)(12)(viii)]. Mylan did not lose the litigation but settled before the court issued a judgment. The effect of the settlement and losing the patent litigation are essentially the same: the patent litigation ended without opening the door to approval of competing ANDAs. Thus, Mylan, like the ANDA applicant in [C.F.R. § 314.94(a)(12)(viii)], should be considered to have amended its certification.

Brief of Federal Defendants-Appellants in Mylan Pharm., Inc. v. Thompson, No. 01-1554 (4th

Cir. July 25, 2001), at 50. (SPX 204; SPX 1277 at ¶ 17).

Complaint Counsel's Response to Finding No. 1.470:

This proposed finding is irrelevant. The cited evidence does not support a finding regarding the FDA's current position on the issues, and the FDA's position on appeal, which did not result in reversal of the district court decision, is irrelevant to the present proceeding. *See* CPRF 1.467.

1.471. As FDA explained in its brief before the Fourth Circuit, the effect of such a settlement and losing the patent litigation are essentially the same. Accordingly, like applicants who lose their patent cases, applicants entering into such settlements should be considered to have changed their Paragraph IV certifications to Paragraph III certifications, thus rendering them ineligible for 180-day exclusivity. (SPX 204 at 46, 50; SPX 1277 at ¶ 17). FDA pointed out that the Hatch-Waxman amendments do not specifically address application of 180-day exclusivity in the event that the patent litigation is settled without a court decision, and thus urged the Court to defer to the Agency's reasonable interpretation, which allows market access to other generic manufacturers, consistent with the principles that guide construction of the Hatch-Waxman amendments. (SPX 204 at 48-50; SPX 1277 at ¶ 17).

Complaint Counsel's Response to Finding No. 1.471:

This proposed finding is irrelevant. The cited evidence does not support a finding regarding the FDA's current position on the issues, and the FDA's position on appeal of *Mylan v. Thompson*, which did not result in reversal of the district court decision, is irrelevant to the present proceeding. *See* CPRF 1.467.

1.472. FDA's position on the Teva Citizen Petition and in the ensuing litigation, *Mylan Pharm., Inc. v. Thompson*, No. 01-1554, provides a basis for concluding that Upsher was not entitled to exclusivity. (SPX 1277 at ¶ 18; 28 Tr. 6968 (Safir)). In 1995, Upsher sought FDA approval to manufacture and distribute a generic version of Schering's K-Dur 20, an extended release potassium chloride tablet product. (SPX 1277 at ¶ 18). Upsher's ANDA was the first to contain a Paragraph IV certification for one of the patents listed by Schering in the Orange book. (SPX 1277 at ¶ 18). Thereafter, Schering brought a patent infringement action against Upsher, which was settled on June 17, 1997. (SPX 1277 at ¶ 18).

Complaint Counsel's Response to Finding No. 1.472:

The first sentence of this proposed finding is not supported by the evidence, and is contradicted by more reliable evidence. The FDA's position on the Teva petition was found to be unreasonable for four separate reasons, and application of that position was enjoined by the federal District Court in *Mylan Pharmaceuticals, Inc. v. Thompson*, 2001 WL 1654781 (N.D.W.V. April 18, 2001); Tr. at 28:7027-31 (Safir). No other court has reached a decision contrary to the District Court in *Mylan v. Thompson*. Tr. at 28:7035 (Safir). Thus, the FDA's discredited position on the Teva petition provides no basis for concluding that Upsher was not entitled to exclusivity. It is also clear that the FDA viewed Upsher as entitled to exclusivity, and that Upsher, in fact, enjoyed its 180-day exclusivity period. *See* CPF 923-928. Moreover, there is considerable evidence that Upsher was viewed by the FDA and by Upsher itself as having exclusivity, and that it, in fact, had such exclusivity. CPF 923-927; CX 190 at Upsher-Smith-FTC-138948 ("Upsher-Smith has six months exclusivity beginning on the first day Upsher-Smith

introduces product into interstate commerce. This exclusivity relates to being the first to file an ANDA product against a product with a patent."). And the FDA has expressed its disinclination to apply new statutory interpretations retrospectively to the subjects of prior awards of exclusivity under the Hatch-Waxman Act. *See* Tr. at 10:2306 (Joel Hoffman).

1.473. Pursuant to the settlement agreement, the parties agreed to a dismissal of the litigation with prejudice; Schering agreed to grant Upsher a license under its patent allowing Upsher's generic potassium chloride table on the market in September 2001, five years before expiration of Schering's patent; Upsher agreed not to market its generic until that time; and Schering licensed six Upsher products in exchange for sixty million dollars. (SPX 92)

Complaint Counsel's Response to Finding No. 1.473:

The proposed finding is contrary to more reliable evidence. Schering did not license six Upsher products in exchange for sixty million dollars. Three categories of evidence prove that, in fact, Schering paid Upsher $60 million to delay Upsher's entry into the K-Dur 20 market: (1) the circumstances of the negotiations and the Schering/Upsher Agreement itself; (2) an analysis of the license for Niacor-SR; and (3) the economic incentives of branded monopolies and potential generic entrants:

(1) First, the text of the Schering/Upsher Agreement and the circumstances of the negotiations indicates payment for delay. The Schering/Upsher Agreement itself indicates that the license and supply agreement was not a separate agreement for value independent of the settlement agreement, but in fact that the $60 million and the agreement to settle the patent infringement suit were inextricably intertwined. CPF 176

(paragraph 11 of the Schering/Upsher Agreement explicitly states $60 million is for paragraphs 1-10 of the Schering/Upsher Agreement, which includes the settlement of the litigation, Upsher's agreement to delay entry until 2001, and its agreement not to help any other challengers to the '743 patent); CPF 178 (Mr. Hoffman concedes that the agreement on its face indicates some money paid for settlement); CPF 179 (paragraph 3 allows Upsher to come to market immediately if a court strikes down the Agreement (and thus Schering's requirement to pay the $60 million)); CPF 181 (paragraph 3 allows Upsher to come to market if Schering licenses another generic to enter); CPF 180 (paragraph 10 ("*force majeure*" clause) obligates Schering to pay $60 million to Upsher even if some unforeseen event causes the license to be worthless). This contemporaneous documentary evidence is more reliable than the self-serving, post-hoc testimony cited in the proposed finding.

There is also reliable evidence that Mr. Troup asked for money from Schering repeatedly in order to agree to settle the Schering/Upsher patent infringement suit. CPF 190, 200, 204 (Mr. Troup demands for $60-70 million to settle the lawsuit at the May 21 meeting); CPF 191, 206, 209 (Mr. Troup stresses his need for cash at the May 28 and June 3 meetings); CPF 192, 194, 200, 206 (Mr. Troup repeats his demand for money to settle the lawsuit at the June 12 meeting); CPF 196, 200 (Mr. Troup stressed a need for an income stream and up-front payments as part of a settlement at the June 16 meeting); CPF 201 (Mr. Troup repeats his need for revenue as part of a settlement at the June 17 meeting).

Mr. Troup based these requested requests for money from Schering to settle the

lawsuit not on the value of Niacor, but instead on Upsher's forgone revenues for not entering the market and the revenue impact its product would have on Schering's K-Dur 20 monopoly if Upsher entered the market. CPF 200-02 (discussing Mr. Troup repeatedly sought to replace revenues lost by not being on the market); CPF 204, 212-13 (discussing Mr. Troup requesting $60-70 million to end the litigation and basing that figure on a percentage of the harm that Upsher's product would do to Schering's monopoly); CPF 206-07 (discussing Mr. Kapur and Mr. Wasserstein's testimony that Mr. Troup wanted to replace the revenue Upsher was losing by delaying entry); CPF 214-18 (discussing money requested to settle the lawsuit based on Upsher's lost revenues from not entering the generic K-Dur 20 market).

(2) Second, the $60 million non-contingent payment made by Schering to Upsher cannot reasonably be considered to have been a license fee for Niacor-SR and the five generic products licensed under the settlement agreement. Tr. at 7:1307, 1338-39 (Levy); Tr. at 4:577 (Bresnahan). The $60 million non-contingent fee was grossly excessive for Niacor-SR and the other licensed products, CPF 287-372, Schering's due diligence was strikingly superficial relative to industry standards, CPF 373-663, Schering's and Upsher's post-license behavior does not comport with parties' who had just entered into a typical licensing deal, CPF 664-721, Schering had previously rejected an equal or better product, CPF 722-777, and no other company had offered Upsher any money for Niacor-SR, let alone $60 million, CPF 778-808.

(3) Third, economic theory proves Schering paid Upsher $60 million to delay Upsher's entry into the K-Dur 20 market. There is always an incentive for the

monopolist to pay the entrant to delay its entry and for the entrant to agree to delay its entry, which harms consumers. CPF 1150 – 1157. A monopolist and potential entrants have those incentives to delay entry even with it is uncertain. CPF 1161 – 1165. Uncertain competition provides the same benefits qualitatively as certain entry, so delaying uncertain entry harms consumers. CPF 1166 – 1172. Applying the criteria to these settlements, Schering was a monopolist and Upsher and AHP were threats to that monopoly. Therefore, the parties had the incentives to delay uncertain entry. CPF 1173 – 1184 (applying economic theory to facts of this case and explaining how Schering, as a monopolist, had the incentive to pay Upsher to delay its entry and how Upsher, as a potential entrant, had the incentive to accept money to delay its entry). Schering paid Upsher net consideration for delay. CPF 1185 – 1206 (explaining Schering's and Upsher's incentives to agreement to payment for delay, the actions of each which led to payment for delay, and that the $60 million was not for Niacor-SR).

1.474. FDA granted final approval of Upsher's ANDA in November 1998. *See* Letter from D. Sporn to Upsher-Smith Laboratories, Inc. (Nov. 20, 1998). (SPX 1277 at ¶ 18; CX 59). Thereafter, on January 28, 1999, FDA advised Upsher that it was eligible for 180-day exclusivity. FDA's January 1999 letter stated that, "[t]he Agency expects that you will begin commercial marketing of this drug product in a prompt manner." *See* Letter from D. Sporn to Upsher-Smith Laboratories, Inc. (Jan. 28, 1999). (SPX 1277 at ¶ 18; CX 611; 10 Tr. 2308 (JOEL Hoffman)). As of this time, FDA knew that Schering's lawsuit against Upsher-Smith had been dismissed, but it did not know whether Upsher-Smith had won, lost, or what the terms of any

settlement were. (28 Tr. 7015 (Safir); CX 611).

Complaint Counsel's Response to Finding No. 1.474:

Complaint counsel has no specific response.

1.475. Subsequently, in May 1999, FDA advised ESI Lederle, Inc. ("ESI") that its ANDA for generic K-Dur 20 was tentatively approved, and that the ANDA would be eligible for final approval after the conclusion of the first Paragraph IV filer's (*i.e.*, Upsher's) 180-day exclusivity period. *See* Letter from D. Sporn to ESI Lederle, Inc. (May 11, 1999); CX 612; SPX 1277 at ¶18).

Complaint Counsel's Response to Finding No. 1.475:

Complaint counsel has no specific response.

1.476. Though the above-described correspondence indicates that FDA concluded that Upsher was eligible for 180-day exclusivity, Upsher's eligibility for exclusivity would have been subject to challenge at FDA and in the courts, based upon the reasoning subsequently adopted by FDA in its decision on Teva's Citizen Petition and in its brief in the *Mylan* case. (SPX 1277 at ¶ 19; 28 Tr. 6966-67 (Safir)). Specifically, because Upsher was no longer participating in litigation intended to prove that its product will not infringe Schering's patent and, until permitted to do so under a license from Schering, declined to bring its approved ANDA product to market, FDA would have applied the same reasoning as applied to Mylan's settlement and concluded that Upsher was ineligible for exclusivity. (SPX 1277 at ¶ 19; 28 Tr. 6969-70 (Safir)).

Complaint Counsel's Response to Finding No. 1.476:

The proposed finding is not supported by the evidence. *See* CPRF 1.466, 1.467, 1.472. Moreover, the FDA knew that Upsher-Smith was not pursuing its litigation with Schering when it notified Upsher of its final ANDA approval on November 20, 1998 (CX 59 at Upsher-Smith FTC - 087345)("You also have notified the Agency that on July 24, 1997, the New Jersey court issued a Stipulation and Order of Dismissal officially terminating the litigation with Key Pharmaceuticals, Inc."), and when it notified Upsher of its entitlement to 180-day exclusivity on January 28, 1999. CX 611 at USL07067 ("You also have notified the Agency that on July 24, 1997, the New Jersey court issued a Stipulation and Order of Dismissal terminating the litigation with Key Pharmaceuticals, Inc."). Tr. 28:7014-15 (Safir). Moreover, the FDA has expressed its disinclination to apply new statutory interpretations retrospectively to the subjects of prior awards of exclusivity under the Hatch-Waxman Act. *See* Tr. at 10:2306 (Joel Hoffman). The evidence therefore does not support the view that the FDA would look favorably on an after-the-fact challenge to Upsher's exclusivity based on a party raising facts that were known to the FDA at the time it awarded exclusivity to Upsher.

1.477. Though the District Court for the Northern District of West Virginia rejected FDA's position, FDA appealed. (SPX 1277 at ¶ 19). Moreover, another District Court could well reach a different conclusion. (SPX 1277 at ¶ 19). Notably, there have been other instances in which District Courts have reached differing conclusions on the validity of challenged FDA regulations. *Compare Mova Pharm. Corp. v. Shalala,* 955 F. Supp. 128 (D.D.C. 1997) *with*

Granutec, Inc. v. Shalala, 1997 WL 1403894 (E.D.N.C. July 3, 1997) *and Inwood Labs, Inc., v. Young,* 723 F. Supp. 1523 (D.D.C. 1989), *vacated as moot,* 43 F.3d 712 (D.C. Cir. 1989) *with Mylan Pharms., Inc. v. Sullivan,* Civ. No. 89-0036-C(K) (N.D.W.Va. May 5, 1989). (SPX 208; SPX 178; CX 1714; SPX 1277 at ¶ 19). Thus, Upsher's entitlement to exclusivity was far from certain. (SPX 1277 at ¶ 19).

Complaint Counsel's Response to Finding No. 1.477:

The second and the last sentences of this proposed finding are not supported by the evidence cited. That district courts have reached contrary conclusions on certain FDA positions provides no basis for concluding that a district court would reach a decision contrary to that reached by the District Court in *Mylan v. Thompson*, holding the FDA's position in response to the Teva petition to be unreasonable. Schering provides no evidence as to why the decision of the District Court in *Mylan v. Thompson* was wrong or inconsistent with any other precedent. In fact, no other court has reached a contrary result. CPRF 1.472. Therefore, such an inference from this evidence is mere speculation as to what theoretically could occur, without any support for the proposition that it had any reasonable or substantial likelihood of occurring. While Upsher's entitlement to exclusivity was uncertain on the dates of the Schering/Upsher settlement agreement and the Schering/AHP agreement in principle, as of June 1, 1998, Upsher's entitlement to exclusivity no longer was uncertain. CPF 924. Upsher's entitlement to exclusivity was confirmed by the FDA's letter of January 28, 1999 to Upsher (CX 611; CPF 926), the FDA's Orange Book listing (CX 1653 at FTC 0022684-688; CPF 926-927), and the FDA's granting of tentative approval to AHP's 20 mEq potassium chloride product on

May 11, 1999, with final approval subject to the running of Upsher's 180-day exclusivity (CX 612; CPF 928).

1.478. No one challenged Upsher-Smith's eligibility for exclusivity. (28 Tr. 6970-71, 7017 (Safir)).

Complaint Counsel's Response to Finding No.:

Complaint counsel has no specific response.

2. The opinions of Complaint Counsel's Expert Joel Hoffman regarding 180-day exclusivity.

1.479. The opinions of complaint counsel's FDA law expert, Mr. Joel Hoffman, are not credible. Mr. Hoffman's testimony ignored information related to the FDA's current position concerning the eligibility for 180-day exclusivity of ANDA filers that settle patent lawsuits. (10 Tr. 2304-07 (JOEL Hoffman); 11 Tr. 2378-79 (JOEL Hoffman)).

Complaint Counsel's Response to Finding No. 1.479:

This proposed finding is not supported by the evidence cited, and is contradicted by other evidence, including the opinion of Schering's own expert witness regarding Mr. Hoffman's credibility. First, Mr. Hoffman's opinions did not ignore information "related to FDA's current position concerning the eligibility for 180-day exclusivity of ANDA filers that settle patent lawsuits." As discussed above (CPRF 1.467), and fatal to Schering's assertions that Mr. Hoffman ignored the FDA's current positions on settlements, there is no evidence in the record relating to the FDA's position on this issue,

either currently or at any time after its appeal attempting to overturn the district court decision in *Mylan v. Thompson* was dismissed. Second, Mr. Hoffman in fact explained in his testimony why the FDA's earlier position on settlements in its response to the Teva petition, and in its appeal of the district court's decision in *Mylan v. Thompson*, were not relevant to his opinions and did not need to be specifically addressed in them (Tr. at 10:2378-79 (Joel Hoffman) ("I didn't specifically mention it [FDA's position in its response to the Teva petition and in its appeal brief] because . . . there was an underlying premise; namely that FDA could interpret the statute in this general way to deny exclusivity to a first filer. I addressed that general point and the fact that FDA's underlying rationale was rejected by the District Court, and there was no need to spell out the logical implications of that for the specific settlement point.")). Third, Schering challenges the credibility of Mr. Hoffman's opinions, even as its own expert on FDA and Hatch-Waxman Act matters - Peter Safir - has stated his substantial concurrence with most of Mr. Hoffman's conclusions. SPX-1277 at ¶ 24 ("In general, I am in substantial agreement with much of Mr. Hoffman's Expert Report and his February 6, 2002 testimony in this matter. As an initial matter, I agree with the statutory framework provided by Mr, Hoffman at pp. 2206-27 of his February 6, 2002 testimony, and therefore have not repeated that background in my testimony." "With respect to Mr. Hoffman's analyses of the four questions posed to him by Complaint Counsel, I agree with his opinions on the first and second questions . . . but disagree somewhat with his opinions on the third and fourth questions."). Finally, Schering itself cites and relies upon Mr. Hoffman's testimony as an expert witness in this proceeding as support for virtually every

one of its proposed findings relating to the Hatch-Waxman Act and 180-day exclusivity, which is bizarrely inconsistent with Schering's assertion that "the opinions of complaint counsel's FDA law expert, Mr. Joel Hoffman, are not credible." Given Mr. Hoffman's credentials as an expert in this area, to which Respondents raised no objections, and given the deference to, and agreement with, Mr. Hoffman by Schering's own expert witness in this area, as well as Schering's numerous citations to Mr. Hoffman's testimony in many of its own proposed findings, Schering's assertion of Mr. Hoffman's lack of credibility itself has no credible basis.

1.480. Mr. Hoffman's reading of FDA regulations was inconsistent with the plain language of the regulation, and FDA's interpretation of the regulation. (10 Tr. 2291-304 (JOEL Hoffman); CX 613; SPX 1277 at ¶ 24, 26). Mr. Hoffman testified that FDA's current position is that a first ANDA filer who loses the patent litigation is entitled to 180-day exclusivity. (10 Tr. 2291-304 (JOEL Hoffman); SPX 1277 at ¶ 26). This is incorrect. (CX 613; SPX 1277 at ¶ 24, 26). Mr. Hoffman's testimony on this point was evasive and not credible. (10 Tr. 2291-304 (JOEL Hoffman)). Mr. Hoffman said that FDA's current position is that a first filer who settles a patent case agreeing to stay off the market for some period of time is nonetheless entitled to exclusivity. (10 Tr. 2302-06 (JOEL Hoffman)). This is also incorrect. (CX 613; SPX 204; SPX 1277 at ¶ 25, 26).

Complaint Counsel's Response to Finding No. 1.480:

This proposed finding is not supported by the evidence and is misleading. It also is irrelevant. Contrary to this proposed finding, Mr. Hoffman did not testify either "that

the FDA's current position is that a first ANDA filer who loses the patent litigation is entitled to 180-day exclusivity," or that "FDA's current position is that a first filer who settles a patent case agreeing to stay off the market for some period of time is nonetheless entitled to exclusivity." Rather, Mr. Hoffman's testimony was that he could not say what the FDA's current position was:

"Q: . . . isn't it a fact that [the] position of FDA was rejected in a court suit but that FDA's position remains the same today?

A: I have no idea whether FDA's position remains the same after its – after its -- its statement to that effect was overruled in the court suits." Tr. at 10:2303-04 (Joel Hoffman).

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"Q: And sir, you don't represent, do you, that your [expert] report necessarily reflects the opinions, the current opinions, of FDA regulators, do you sir?

A: Oh, I would - would never suggest that anything I wrote represented the current opinions of FDA regulators, particularly on a subject where those opinions seem somewhat subject to change." Tr. at 10:2353-54 (Joel Hoffman).

A fair reading of Mr. Hoffman's testimony makes clear that what he said in his testimony was that he believed that a first ANDA filer with a paragraph IV certification who either lost or settled its patent litigation nevertheless would be entitled to exclusivity "as the law stands today" (emphasis added) (*i.e.*, after two U.S. Courts of Appeals had clearly held that the FDA's successful defense requirement was an improper and unlawful addition by FDA to the facially clear requirements for 180-day exclusivity specified in the

statute, and after another federal District Court had held the FDA's position regarding a settling first ANDA filer's loss of entitlement to exclusivity to be unreasonable). Schering attempts to discredit Mr. Hoffman's testimony as being inconsistent with current FDA regulations and policy. However, Schering has not even presented evidence as to the FDA's current position on these issues. *See* CPRF 1.467. The evidence Schering cites only demonstrates that Mr. Hoffman's views as to the current state of the law, as interpreted by the courts, are inconsistent with the positions that the FDA took regarding the Teva petition, and that subsequently were found to be improper and unreasonable by a federal district court. The cited testimony and evidence do not support a finding that Mr. Hoffman's opinions were incorrect, and certainly provide no support whatsoever for asserting that his testimony is not credible or is evasive. Finally, it is irrelevant to this proceeding what the FDA's current position is on the eligibility for 180-day exclusivity of a settling first ANDA filer. What is relevant is the state of the law on this question, as interpreted by the courts, at the times of the actions at issue in this proceeding.

1.481. Moreover, Mr. Hoffman suggests that Schering and Upsher-Smith were aware of the FDA's position on 180-day exclusivity at the time of the their settlement in June 1997. Mr. Hoffman concedes that he does not know if Upsher was present at or heard about the conference at which the FDA announced its decision to acquiesce to the *Mova* district court decision. (11 Tr. 2358-59 (JOEL Hoffman)). Mr. Hoffman also concedes that Upsher was not copied on the June 17, 1997 letter sent to certain ANDA applicants by the FDA. (11 Tr. 2357 (JOEL Hoffman); CX 602; CX 595). He has no idea whether Upsher ever saw the letter. (11 Tr. 2357

(JOEL Hoffman)). Mr. Hoffman admits that he does not know whether Upsher actually received or reviewed the issue of the Pink Sheet in which that letter was reported. (11 Tr. 2358 (JOEL Hoffman); CX 605).

Complaint Counsel's Response to Finding No. 1.481:

The first sentence of this proposed finding is not supported by the evidence. Schering cites no testimony of Mr. Hoffman where he suggests that Schering and Upsher were aware of the FDA's position on 180-day exclusivity at the time of their settlement agreement in June of 1997. In fact, nowhere in his testimony does Mr. Hoffman state or "suggest" any such thing. Mr. Hoffman's testimony does provide evidence to the effect that there was information available and disseminated to the public and the pharmaceutical industry concerning the state of the law regarding 180-day exclusivity under the Hatch-Waxman Act at various times prior and up to the June 17, 1997, settlement agreement. *See* CPF 905-910.

1.482. Finally, Mr. Hoffman's opinions related to Upsher-Smith's eligibility for 180-day exclusivity are inconsistent with complaint counsel's positions in the case. (10 Tr. 2285-88 (JOEL Hoffman);11 Tr. 2367 (JOEL Hoffman)).

Complaint Counsel's Response to Finding No. 1.482:

The proposed finding is not consistent with the evidence. Schering's Counsel is attempting in this proposed finding to base an alleged inconsistency between Mr. Hoffman's opinions and Complaint Counsel's allegations on a comparison of "apples and oranges." Mr. Hoffman points out repeatedly in his testimony that his view that a first

ANDA submitter with a paragraph IV certification that loses its patent infringement suit brought by the branded drug manufacturer is nevertheless entitled to 180-day exclusivity is based on his understanding of the law "as it stands today." *See* Tr. at 10:2287-91 (Joel Hoffman). He also points out that the present state of the law on this issue is not the same as it was at the time of the Schering/Upsher settlement agreement (Tr. at 10:2291), and how Complaint Counsel's statements as to the entitlement to 180-day exclusivity of a losing first ANDA filer are "not a bad statement of how things stood" "on or prior to June 17, 1997." Tr. at 10:2290. Since the Schering/Upsher patent infringement litigation was scheduled for trial to begin in June of 1997, it makes no sense to read Complaint Counsel's allegations concerning Schering's entitlement to exclusivity if it lost its litigation with Schering to refer to the present, rather than to the relevant time period during which Schering and Upsher were engaged in their patent infringement lawsuit. There is no basis, therefore, for concluding that Mr. Hoffman's opinions on the current state of the law regarding a losing ANDA filer's entitlement to exclusivity are inconsistent with Complaint Counsel's allegations.

3. Complaint counsel has offered no proof of "concerted action" or "concerted agreement" regarding the triggering of the 180-day exclusivity period.

1.483. There is no reference to 180-day exclusivity in the June 17, 1997 agreement between Schering and Upsher-Smith. (5 Tr. 915 (Bresnahan)).

Complaint Counsel's Response to Finding No. 1.483:

Complaint counsel has no specific response.

1.484. Upsher-Smith did not conspire with Schering to manipulate Upsher's 180-day period. (23 Tr. 5495 (Troup)).

Complaint Counsel's Response to Finding No. 1.484:

This proposed finding is contrary to more reliable evidence, and is irrelevant. The settlement agreement itself evidences an agreement (which is legally equivalent to "conspiring") between Schering and Upsher, and which includes their agreement that Upsher would not be permitted to enter the market with its generic K-Dur 20 product until September 1, 2001. CX 348. Contrary to respondents' after-the-fact explanations, it is far more reasonable to infer that the parties to that agreement knew what 180-day exclusivity rights Upsher was, or might be, entitled to as the first ANDA submitter with a ¶ IV certification for that product. In fact, it would be unreasonable to conclude that the parties entered into their agreement, involving payment of tens of millions of dollars to Upsher by Schering, and involving important business decisions and property rights, without such knowledge and awareness on the part of both parties to the agreement. Moreover, whether or not Schering and Upsher specifically conspired to manipulate Upsher's exclusivity is legally irrelevant to whether or not their agreement was anticompetitive and illegal. Upsher's entitlement to 180-day exclusivity was a factor affecting operation of the market for K-Dur 20 and generic alternatives to it. Upsher's exclusivity was a factor in the effectiveness of the settlement agreement in protecting

Schering's economic interest in K-Dur 20. The anticompetitive effects that resulted from the settlement agreement are not considered lawful or less anticompetitive merely because those effects may have been more effective in blocking competition due to circumstances existing in the market in which the agreement operated. The actual and likely competitive effects of the agreement are attributed to the parties to that agreement, whether or not they specifically agreed to manipulate this other factor in the functioning of the market.

a. Schering and Upsher never mentioned the Hatch-Waxman exclusivity period during their settlement negotiations.

1.485. During the negotiations between Schering and Upsher-Smith, there was no discussion of the 180-day period. (15 Tr. 3551 (JOEL Hoffman); 23 Tr. 5493 (Troup); 16 Tr. 3838-39 (Cannella)).

Complaint Counsel's Response to Finding No. 1.485:

This proposed finding is irrelevant. *See* CPRF 1.484.

1.486. The subject of 180-day exclusivity was never raised in any way during the settlement negotiations by anybody on either side of the negotiating table. (15 Tr. 3551 (JOEL Hoffman); 23 Tr. 5493 (Troup); 16 Tr. 3838-39 (Cannella)). Mr. Troup has never had a discussion with Schering about Upsher's enjoying 180-day exclusivity. (23 Tr. 5493 (Troup)).

Complaint Counsel's Response to Finding No. 1.486:

This proposed finding is irrelevant. *See* CPRF 1.484.

1.487. Professor Bresnahan is aware of no evidence that 180 day exclusivity was ever discussed during the settlement negotiations between Schering and Upsher. (5 Tr. 913-14 (Bresnahan)). Professor Bresnahan does not allege that that 180 day exclusivity was ever discussed during the settlement negotiations between Schering and Upsher. (5 Tr. 913 (Bresnahan)).

Complaint Counsel's Response to Finding No. 1.487:

This proposed finding is irrelevant. *See* CPRF 1.484.

b. Upsher did not expect exclusivity

1.488. In 1997, Upsher-Smith understood that as a result of settling and not going to court and prevailing, Upsher lost any entitlement to the 180-day exclusivity period. (20 Tr. 4666 (Dritsas); 23 Tr. 5491 (Troup)). Mr. Dritsas believed that if Upsher had won the lawsuit without a settlement, Upsher would have had 180 days of exclusivity. (20 Tr. 4667 (Dritsas)).

Complaint Counsel's Response to Finding No. 1.488:

This proposed finding is irrelevant. *See* CPRF 1.484.

The proposed finding is also not supported by the evidence. Mr. Troup actually testified that he was "unclear in the extreme as to what the situation was" as to Upsher's entitlement to the 180-day exclusivity period when it settled with Schering in June 1997. Mr. Troup is only able to provide his "best guess." Tr. at 23:5491 (Troup).

1.489. On February 1, 1999, Upsher-Smith received a letter from the FDA informing Upsher-Smith that it was eligible for 180 day exclusivity for Klor Con M20. (CX 611; 17 Tr.

4024 (Halvorsen); 20 Tr. 4852 (Dritsas)). Mr. Halvorsen was surprised upon receiving the letter. (17 Tr. 4024 (Halvorsen)).

Complaint Counsel's Response to Finding No. 1.489:

This proposed finding is contrary to more reliable evidence. A September 1999 Upsher document states that Upsher contacted the FDA in order to request and obtain a revised approval letter that specifically acknowledged Upsher's exclusivity.

> "Upsher-Smith has six months exclusivity beginning on the first day Upsher-Smith introduces product into interstate commerce. This exclusivity relates to being the first to file an ANDA product against a product with a patent. Upsher-Smith contacted the FDA regarding the need to receive a revised approval letter to ensure this is outlined. This revised letter has been received by regulatory." CX 190 at Upsher-Smith-FTC-138948.

In view of the above evidence, Mr. Halvorsen's testimony as to his surprise at receiving the letter regarding exclusivity from the FDA either is not credible, or it is irrelevant, because it indicates that he was not the official at Upsher who knew about exclusivity issues relating to Upsher's generic K-Dur 20 product.

4. Any Upsher exclusivity is solely the result of a change in federal law.

1.490. The development of the law under the Hatch-Waxman Act is something that neither Upsher nor Schering could influence as of June 1997. (5 Tr. 982 (Bresnahan)).

Complaint Counsel's Response to Finding No. 1.490:

This proposed finding is irrelevant. The issue in this case is whether the agreements between Schering and Upsher, and Schering and AHP, were anticompetitive and illegal. Whether or not Schering or Upsher could influence the development of the law under the Hatch-Waxman Act has no bearing on the competitive effects of these private agreements.

1.491. Commissioner Thomas B. Leary, speaking only for himself, stated that 180-day "[e]xclusivity is a statutorily-sanctioned asset of the first generic." Thomas B. Leary, "Antitrust Issues in the Settlement of Pharmaceutical Patent Disputes, Part II, May 17, 2001.

Complaint Counsel's Response to Finding No. 1.491:

This proposed finding is irrelevant, and is not supported by the evidence in this matter. Whether entitlement to 180-day exclusivity is an asset or not is irrelevant to any issue in this case. Moreover, the opinion of one individual – in this case, a single FTC commissioner – is not probative of the truth of the legal assertion, and does not even represent the opinion of the Federal Trade Commission on that point. Finally, the cited reference has not been admitted into evidence in this proceeding, and Commissioner Leary's statement is not a fact "not subject to reasonable dispute in that it is either (1) generally known within the territorial jurisdiction of the trial court or (2) capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned," as required for judicial notice under Rule 201(B) of the Federal Rules of Evidence. It therefore is not evidence in this matter, and does not properly support the

proposed finding's claim of what Commissioner Leary said..

1.492. On June 17, 1997, there was substantial uncertainty as to whether Upsher-Smith was entitled to exclusivity given its settlement with Schering. (11 Tr. 2362-64 (JOEL Hoffman); SPX 1277 at ¶ 24).

Complaint Counsel's Response to Finding No. 1.492:

Complaint counsel has no specific response.

1.493. In November 1998, the FDA sent an approval letter to Upsher stating that its ANDA was approved. (10 Tr. 2273-74 (JOEL Hoffman); CX 59). Subsequently, in January 1999, the FDA sent a second letter to Upsher informing it that it was entitled to 180-day exclusivity. (10 Tr. 2274-75 (JOEL Hoffman); CX 611). FDA's letter to Upsher informing Upsher that it had 180-day exclusivity was not sent until approximately a year and a half after the Schering/Upsher settlement. (CX 611).

Complaint Counsel's Response to Finding No. 1.493:

Complaint counsel has no specific response.

5. Any 180-day exclusivity could be waived or transferred to a third party in exchange for consideration.

1.494. FDA has made it clear that a first filer may waive its exclusivity once it has begun in favor of any third party or may relinquish its right to exclusivity entirely before the period has begun. (SPX 1277 at ¶ 20; 28 Tr. 6972 (Safir); 10 Tr. 2351 (JOEL Hoffman)). While

FDA has not addressed the issue of transfer of exclusivity directly, such rights could be transferred in connection with the sale of the drug product in question or to any successor in interest of the first filer. (SPX 1277 at ¶ 20; 28 Tr. 6972-73 (Safir)).

Complaint Counsel's Response to Finding No. 1.494:

Complaint counsel has no specific response.

1.495. The issue of waiver, however, is specifically discussed in detail in FDA's 1999 proposed regulations (*see* 64 Fed. Reg. 42873, 42881) and a waiver in exchange for consideration was specifically upheld by a Court in *Boehringer Ingelheim Corp. v. Shalala* 993 F. Supp. 1 (D.D.C. 1997). *See also Granutec, Inc. v. Shalala,* 139 F.3d 889 (table), 1998 WL 153410 (4th Cir. April 3, 1998). (SPX 183; SPX 1277 at ¶ 21; 28 Tr. 6972 (Safir)).

Complaint Counsel's Response to Finding No. 1.495:

Complaint counsel has no specific response.

1.496. FDA's position on waiver has been consistent since it published its final regulations in 1994. (SPX 1277 at ¶ 21). As discussed in the preamble to the 1999 proposed regulations:

> The agency has determined that waiver of 180-day exclusivity, like waiver of new drug exclusivity, is permitted under the act and at least one ANDA applicant has successfully effected a waiver — A waiver may be particularly appropriate, for instance, when the first ANDA applicant is sued and, while its litigation is ongoing, a favorable court decision is rendered in a case involving a subsequent

applicant. Exclusivity would be awarded to the first applicant, with the 180-day period starting on the date of a final court decision in the subsequent applicant's litigation. The first applicant's ANDA may not be finally approved, however, and the applicant could not market its product. Under these circumstances, the first applicant may obtain a benefit by waiving its exclusivity period in favor of a subsequent applicant.

64 Fed. Reg. at 42881. (SPX 202; SPX 1277 at ¶ 21).

Complaint Counsel's Response to Finding No. 1.496:

Complaint counsel has no specific response.

1.497. The FTC has indicated that a prohibition against waiver or transfer of exclusivity in patent settlement agreements between pioneer and generic companies is potentially anti-competitive. *See Antitrust Issues in Settlement of Pharmaceutical Disputes,* Remarks of Commissioner Thomas B. Leary (Nov. 3, 2000). (SPX 1277 at ¶ 23; 28 Tr. 6981-82 (Safir); CX 614). Thus, not only is waiver of exclusivity for consideration permitted, it may enhance competition by expediting the entry of generic drugs to the market. (SPX 1277 at ¶ 23).

Complaint Counsel's Response to Finding No. 1.497:

The proposed finding is not supported by the cited evidence. CX 614 is not in evidence.

In addition, in Commissioner Leary's cited remarks (CX 614) he specifically states (at the top of FTC 0021565) that "I also speak only for myself, and no other Commissioner." Thus his views in CX 614 are not evidence of what "[t]he FTC has

indicated." At best, CX 614 indicates Commissioner Leary's views or interpretations of what the FTC may have "indicated," rather than directly providing the Commission's position. As such, it is not probative evidence for the statement for which it is cited. The insufficiency of CX 614 to support the proposed finding also undermines the cited support from Mr. Safir (SPX 1277 at ¶ 23 (Safir written direct testimony); Tr. at 28:6981-82 (Safir)), who bases his opinion as to the Commission's position regarding waiver of 180-day exclusivity entirely on CX 614.

1.498. The June 17, 1997 settlement agreement between Schering and Upsher does not restrict or limit Upsher's ability to waive or transfer any 180-day exclusivity to which it may be entitled. (SPX 1277 at ¶ 22). The settlement agreement itself does not reference the 180 day exclusivity period at all. (CX 348; 5 Tr. 915 (Bresnahan)).

Complaint Counsel's Response to Finding No. 1.498:

Complaint counsel has no specific response.

B. There Is No Evidence Of Actual Delay Of Other Products Resulting From Upsher's Exclusivity

1.499. Professor Bresnahan is aware of no products that were blocked from entering the market due to the settlement agreement and the 180 day exclusivity rule. (5 Tr. 912 (Bresnahan)).

Complaint Counsel's Response to Finding No. 1.499:

This proposed finding is irrelevant. That Professor Bresnahan, or any other

individual, is unaware of any products having been blocked from market entry due to the Schering/Upsher settlement agreement and the "180-day exclusivity rule" is irrelevant to whether any such products actually were blocked or might have been blocked, impeded, or discouraged from pursuing any or earlier market entry as a result of the agreement and Upsher's exclusivity status. Moreover, the evidence demonstrates that AHP was eligible for final FDA approval as of May 11, 1999, and was blocked from final approval until expiration of Upsher's 180-day exclusivity. CPF 843-844, 928.

1.500. Upsher-Smith is not aware of anyone who is going to launch or who has the ability to do so after Upsher's exclusivity expired. (23 Tr. 5495 (Troup)).

Complaint Counsel's Response to Finding No. 1.500:

The proposed finding is not supported by the cited evidence, and is irrelevant. Mr. Troup is not competent to credibly testify as to the knowledge of every officer or employee of Upsher. Moreover, whether or not Upsher knows of any anyone in a position to enter the market after Upsher's exclusivity has expired is irrelevant to the actual existence of any such firm, and thus the blocking effect of the Schering/Upsher settlement agreement. Moreover, according to CX190 at Upsher-Smith-FTC-138947 (an Upsher-Smith document dated July 25, 2000, and repeating a memo that had been distributed in September 1999), "Upsher-Smith's 180-day exclusivity information regarding the M20 remains the same. Neither Andrx nor ESI Lederle will be able to launch 20mEq tablets until our exclusivity period has expired." Thus, Upsher apparently had some belief that Andrx and ESI Lederle were, or might have been, in a position to

launch their products but for Upsher's exclusivity bar to final FDA approval of those products.

1.501. Upsher-Smith's Klor Con M10 does not have 180-day exclusivity. (CX 190, at FTC 138947). Thus, another company could have launched a generic version of K-Dur 10 without regard to any 180-day exclusivity of Upsher-Smith. (CX 190, at FTC 138947). If a company launched a generic version of K-Dur 10, demand for a 20 mEq version of generic K-Dur would have "collapse[d]." (CX 190, at FTC 138947).

Complaint Counsel's Response to Finding No. 1.501:

The proposed finding is not supported by the cited evidence. The cited document, CX 190, is an unattributed internal Upsher memo which, while it may express the views of its unnamed author, or even Upsher's official views, regarding Upsher's exclusivity, is not objective or necessarily reliable evidence to support the truth of the proposed finding's assertions.

The proposed finding is also misleading and not supported by the evidence, to the extent that the finding suggests that potassium chloride products other than generics that were AB-rated to K-Dur 20 competed in any relevant way with K-Dur 20. The evidence shows that non-AB-rated products did not constrain K-Dur 20's pricing, sales, or share of sales of all potassium chloride supplements, and that such products were rarely substituted for K-Dur 20, despite sizeable premiums in the price of K-Dur 20 over the prices of those products. *See* CPF 972-987, 997-1002 (showing that K-Dur 20's prices, sales, and share of sales increased annually, and that K-Dur 20's generic substitution rate

was extremely low compared to other potassium chloride brands, despite the large effective discount relative to K-Dur 20 at which those generics were offered).

1.502. In June 1999, Andrx Corporation sent Paragraph IV certifications to Schering in connection with Andrx's ANDAs for 10 mEq and 20 mEq generic versions of K-Dur. (8 Tr. 1707, 1708-09 (Rosenthal); USX 53; USX 54). Schering did not sue Andrx for patent infringement. (12 Tr. 2621, 2654 (JOEL Hoffman)).

Complaint Counsel's Response to Finding No. 1.502:

Complaint counsel has no specific response.

1.503. Andrx wants approval for its ANDA and is working towards achieving approval. (8 Tr. 1592 (Rosenthal)). In October 1999, Andrx's spokesperson announced that Andrx's ANDA for its proposed generic version of K-Dur was "proceeding apace." (8 Tr. 1592-94 (Rosenthal)).

Complaint Counsel's Response to Finding No. 1.503:

The proposed finding contradicts other evidence. Mr. Rosenthal testified that once Andrx learned that Upsher had exclusivity, Andrx's work on its own generic K-Dur 20 product "took less of a priority." Tr. at 8:1551 (Rosenthal). Upsher's possession of the 180-day exclusivity period thus impacted the speed with which Andrx sought approval from the FDA to sell its product and thus enter the market as a generic competitor.

1.504. [redacted] Andrx believes that Upsher-Smith relinquished exclusivity when it settled the patent infringement suit with Schering. ([redacted]; SPX 1207).

Complaint Counsel's Response to Finding No. 1.504:

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

The proposed finding contradicts other more direct evidence. Mr. Rosenthal, who has been Vice-President of Sales & Marketing at Andrx since January 1999, Tr. at 8:1536 (Rosenthal), testified twice that he understood Upsher to possess the 180-day exclusivity period. Tr. at 8:1548, 1560-61 (Rosenthal).

Mr. Rosenthal further testified that once Andrx learned that Upsher had exclusivity, Andrx's work on its own generic K-Dur 20 product "took less of a priority." Tr. at 8:1551 (Rosenthal). Upsher's possession of the 180-day exclusivity period thus impacted the speed with which Andrx sought approval from the FDA to sell its product and thus enter the market as a generic competitor.

1.505. The FDA has not even tentatively approved Andrx's ANDA for a generic version of K-Dur 20. (8 Tr. 1547-48, 1553, 1591, [redacted] (Rosenthal)). [redacted].

Complaint Counsel's Response to Finding No. 1.505:

The proposed finding leaves out relevant evidence. Mr. Rosenthal testified that once Andrx learned that Upsher had exclusivity, Andrx's work on its own generic K-Dur 20 product "took less of a priority." Tr. at 8:1551 (Rosenthal). Upsher's possession of the 180-day exclusivity period thus impacted the speed with which Andrx sought approval from the FDA to sell its product and thus enter the market as a generic competitor.

1.506. [redacted]

[redacted]; USX 704).

Complaint Counsel's Response to Finding No. 1.506:

The proposed finding is misleading. [redacted]

The proposed finding also leaves out relevant evidence. Mr. Rosenthal testified that once Andrx learned that Upsher had exclusivity, Andrx's work on its own generic K-Dur 20 product "took less of a priority." Tr. at 8:1551 (Rosenthal). Upsher's possession of the 180-day exclusivity period thus impacted the speed with which Andrx sought approval from the FDA to sell its product and thus enter the market as a generic competitor.

1.507. Moreover, the settlement between Schering and Upsher-Smith allows entry by Upsher-Smith of both its Klor Con M20 and Klor Con M10 products. (SPX 92; 26 Tr. 6253 (Kerr)). At the time of the June 1997 settlement between Schering and Upsher-Smith, however, Upsher-Smith had not yet submitted an ANDA for Klor Con M10. (CX 190, at FTC 138948). Upsher-Smith did not submit its ANDA on Klor Con M10 until August 1999. (CX 190, at FTC 138948). Nonetheless, Schering gave Upsher-Smith a license to market that product on September 1, 2001. (SPX 92; 26 Tr. 6253 (Kerr)). The agreement to allow both Klor Con M10

and Klor Con M20 onto the market in September 2001 allows Upsher-Smith to market both products sooner than it otherwise could have, and is pro-competitive. (26 Tr. 6254 (Kerr)).

Complaint Counsel's Response to Finding No. 1.507:

The proposed finding leaves out relevant evidence. The '743 patent, which covers K-Dur 10 and 20, claims a particular coating for the potassium chloride crystals. CPF 67-69. [redacted] If Upsher were to have won its patent infringement suit with Schering and a court found either Upsher's product did not infringe the '743 patent or that the '743 patent was invalid/unenforceable, this result would have applied both to Upsher's Klor Con M20 and M10 products.

The proposed finding is also contrary to more reliable evidence. The Schering/Upsher Agreement was not procompetitive and was, in fact, anticompetitive. CPF § 12 (explaining facts and economic theory as to how the Schering/Upsher Agreement delayed competition beyond what either party expected would have happened in the absence of the agreement, and how it was thus anticompetitive).

V. THE SCHERING-UPSHER SETTLEMENT DOES NOT IMPROPERLY PREVENT UPSHER FROM MARKETING NON-INFRINGING PRODUCTS

1.508. Professor Bresnahan has not identified any other product that was blocked by the language in the June 17, 1997 agreement that allegedly barred Upsher from marketing "any other sustained release microencapsulated potassium chloride tablet." (5 Tr. 984 (Bresnahan)).

Nor is Professor Bresnahan aware that either Upsher or Schering had any product in mind other than the Klor Con M20 product when they drafted their agreement. (*Id.*). Nor is there any evidence that Upsher could have developed another sustained-release microencapsulated potassium chloride product that did not infringe Schering's '743 patent. (5 Tr. 984-85, 987; SPX 1254 at 33-34 (Robbins IH)).

Complaint Counsel's Response to Finding No. 1.508:

The proposed finding leaves out relevant evidence and is therefore misleading. Two other companies both invented products that each believed did not infringe the '743 patent. CPF 814-15 (describing AHP's generic 20 mEq potassium chloride product and Paragraph IV certification that its product did not infringe the '743 patent); CPF 73 (describing Andrx's ANDA and Paragraph IV certification that its product did not infringe the '743 patent). Schering did not sue Andrx for patent infringement. CPF 73.

The last sentence of the proposed finding is not supported by the cited authority. Mr. Robbins testified only that Upsher thought it had done a "very effective job designing [around] this patent, and that after it was sued for patent infringement Upsher "didn't really at that time think about other ways of designing around" because "there was not a lot of thought gone into this about investing additional money and time to come up with another design-around strategy and just get thrown into another litigation with Schering-Plough." SPX 1254 at 33:11-34:17 (Robbins IH). Professor Bresnahan testified only that he had not conducted any investigation to determine whether Upsher could have made another product to did not infringe the patent.

1.509. Professor Bresnahan conceded that "if the contract were otherwise pro-competitive," it would be reasonable to read the language of the agreement as ruling out a "me-too product that is simply introduced under another name other than Klor Con M20 but is, in fact, Klor Con M20." (5 Tr. 985 (Bresnahan)). Such a provision would not be anticompetitive. (5 Tr. 987-88, 990-91 (Bresnahan)).

Complaint Counsel's Response to Finding No. 1.509

The proposed finding is misleading. Professor Bresnahan did not conclude that such a provision would not be anticompetitive; he testified that if the agreement were otherwise procompetitive and there were not known or suspected pipe-line products, then such a provision "might be part of a -- that procompetitive agreement" (Tr. at 5:987); that if the agreement were procompetitive, then this provision "wouldn't necessarily be anticompetitive" (Tr. at 5:988)" and that, if the rest of the agreement was procompetitive and no other products were known, then this provision "wouldn't render [the agreement] necessarily anticompetitive." Tr. at 5:991 (Bresnahan).

The proposed finding also is incomplete. Professor Bresnahan testified that the clause would serve to delay marketing of other sustained release microencapsulated potassium chloride tablets until September 2001. He testified that this provision was consistent with his analysis of the contract as anticompetitive in two respects. First, if there was another such product or Schering was concerned about the possibility of such a product, the language gets rid of more potential competition that just the competition from Klor con M20, which was the subject of the dispute. Second, it would serve as an enforcement mechanism for the underlying anticompetitive contract, by preventing

Upsher from producing another competing product.

1.510. The inclusion of clauses in the settlement agreements that affected Upsher's and ESI's exploitation of products similar to K-Dur 20 for a period of time are ancillary restraints that are necessary for a pro-competitive agreement to be feasible and viable. (24 Tr. 5798 (Addanki)).

Complaint Counsel's Response to Finding No. 1.509

The propped finding is not relevant and not supported by the evidence. Dr. Addanki is not a lawyer, and thus cannot offer a legal opinion regarding whether the agreement was pro-competitive. In addition, Dr. Addanki's opinion is unreliable and incomplete as he did not define the terms "ancillary," "feasible," or "viable;" nor did he explain how each of the collateral restraints he discussed was necessary to achieve the settlement in theory or in the actual case presented. He merely asserted his conclusion regarding this issue. Tr. at 24:5798 (Addanki).

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-Federlc
- 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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