UNITED STATES OF AMERICA
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 **PUBLIC VERSION**

COMPLAINT COUNSEL'S MOTION TO COMPEL RESPONSES TO INTERROGATORIES AND ADMISSIONS FROM RESPONDENT UPSHER-SMITH CORPORATION

Pursuant to Section 3.38 of the Federal Trade Commission's Rules of Practice, complaint counsel moves for an order deeming certain requests for admissions admitted or compelling Upsher-Smith to provide full and complete responses to the requests; AND for an order compelling Upsher-Smith to provide full and complete responses to certain interrogatories. The bases of this motion are contained in the accompanying Memorandum in Support of Complaint Counsel's Motion to Compel Responses to Interrogatories and Admissions from Respondent Upsher-Smith Corporation.

Respectfully Submitted,

Bradley Albert

Counsel Supporting the Complaint

Bureau of Competition
Federal Trade Commission
Washington, DC 20580

Date: January 2, 2002

UNITED STATES OF AMERICA
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 **PUBLIC VERSION**

MEMORANDUM IN SUPPORT OF COMPLAINT COUNSEL'S MOTION TO COMPEL RESPONSES TO INTERROGATORIES AND ADMISSIONS FROM RESPONDENT UPSHER-SMITH

In this motion, complaint counsel seeks to compel respondent Upsher-Smith to provide proper answers to complaint counsel's interrogatories and requests for admissions. Pursuant to Section 3.22(f) of the Commission's Rules, we conferred with Upsher in good faith to discuss the deficiencies with Upsher's discovery responses.[1] Upsher agreed to supplement some of its responses by December 18, 2001. At this point, however, we have received revisions only to certain of the disputed interrogatories. Upsher's supplementation did little to cure the serious deficiencies in its answers. Since the parties appear to have differing views as to what constitutes an appropriate response, complaint counsel seeks an order from this Court requiring Upsher to:

Provide full and complete answers to interrogatories 2-6, 10-13, and 15;[2]

---

[1] Declaration of Clifton Smith (Attachment A).

[2] *See* Upsher's Interrogatory Responses (Attachment B); Upsher's Supplemental Responses (Attachment C).

Provide clear and specific responses to Complaint Counsel's First Set of Admission Requests Nos. 3-11;[3] and

Provide clear and specific responses to Complaint Counsel's Revised Third Set of Admission Requests Nos. 21-27, 58, 60, 78, 84, 85, 87, 100, 103, 124, 129-33, 135, 136, 139, 141-43, 158, 173, 174, 176, 178, 241, 294, 330, 332, 334.[4]

I. Upsher's Interrogatory Responses are Non-Responsive

Complaint counsel's first set of 15 interrogatories requested that Upsher provide the basis of, and factual support for, Upsher's dispute of core allegations raised by the Commission's complaint:

The challenged agreement harms consumers by delaying Upsher's entry with a lower-cost generic K-Dur 20 product (Int. Nos. 2 and 6);

Schering's $60 million payment was in consideration for Upsher's delayed entry, not for the Niacor-SR license (Int. Nos 3, 4, 10, 11, 12, and 15);

Niacor-SR license had little value to any pharmaceutical company, other than Schering in the context of this agreement (Int. No. 5); and

The challenged agreement restricts Upsher's ability to bring to market even non-infringing versions of Schering's K-Dur product (Int. No. 13).

The Commission's Rule on interrogatories requires that each interrogatory be answered "fully." 16 C.F.R. § 3.35(a)(2). To answer an interrogatory "fully," as this Court has recently explained, Upsher must "sufficiently identify[] documents," "stat[e] facts," and "elaborat[e] on legal contentions." *In re Schering-Plough and Upsher-Smith*, Order Granting Schering's Motion

---

[3] *See* Upsher's Response to Complaint Counsel's First Set of Requests for Admissions (Attachment D).

[4] *See* Upsher's Response to Complaint Counsel's Revised Third Set of Requests for Admissions (Attachment E).

to Compel, at *2 (Dec. 14, 2001). In response to our legitimate requests for information, however, Upsher barely responds, providing only boilerplate objections, and unspecified references to over 100 boxes of documents submitted by Upsher during discovery. Such a response falls far short of Upsher's obligations under the Rules and this Court's recent decision.

For example, in Interrogatory No. 4, complaint counsel asked Upsher to describe the basis for the contention made in its Statement of the Case that "the drugs being licensed – most notably Niacor SR but the others as well – had value in line with the consideration received from Schering." (*See* Int. No. 4). This interrogatory seeks information from Upsher about one of the central issues in this case: Are the rights to Niacor-SR worth a $60 million non-contingent payment, as respondents contend, or is the Niacor-SR license simply a means to hide Schering's substantial payment to delay Upsher's generic K-Dur 20 entry. Notwithstanding the obvious relevance of the requested information, Upsher recites its boilerplate objection:

> th[e] interrogatory [is] irrelevant, vague, overly broad, overly burdensome, and not reasonably likely to lead to the discovery of admissible evidence.

Upsher has the burden to substantiate these objections, yet it offers nothing to explain how discovery of facts about Upsher's core contention could possibly be "irrelevant."[5] Having failed to substantiate its boilerplate objections, Upsher must answer the interrogatory with whatever factual information it has.

---

[5] *See Burns v. Imagine Films Entertainment, Inc.*, 164 F.R.D. 589, 592-93 (W.D.N.Y. 1996) (general discovery objections without sufficient specificity to allow court to ascertain objectionable character of request are improper); *Chubb Intergrated Sys. Ltd. v. National Bank of Washington*, 103 F.R.D. 52, 58 (D.D.C. 1984) ("General objections are not useful to the court ruling on a discovery motion"); *In re Folding Carton Antitrust Litigation*, 83 F.R.D. 251, 254 (N.D. Ill. 1978) (bare assertions of undue burden or irrelevance are insufficient to satisfy burden to establish the basis for objections).

> Answers to interrogatories must be responsive, full, complete and unevasive. . . . [T]he answering party will be required to give the information available to him, if any, through his attorney, investigators, employed by him or on his behalf or other agents or representative whether personally known to the answering party or not.

Continental Illinois Nat'l Bank & Trust Co. v. Caton, 136 F.R.D. 682, 684 (D. Kan. 1991) (quoting *Miller v. Doctor's General Hospital*, 76 F.R.D. 136, 140 (W.D. Okla. 1977). Ignoring this obligation, however, Upsher refuses to provide any support for its contention, as requested by the interrogatory. Instead, Upsher, relying on Rule 3.35(c), merely refers complaint counsel to over 100 boxes of documents.

> Subject to and without waiving objections and pursuant to 3.35(c) of the Federal Trade Commission Rules of Practice, Upsher refers Complaint Counsel to documents already produced to Complaint Counsel in Upsher-Smith's and Schering Plough's extensive and thorough document production and among other documents, SP170001-170002. Upsher also refers Complaint Counsel to the expert reports of William Kerr (Exhibit 5 in particular) and Walter Bratic.

Upsher's reliance on Rule 3.35(c), however, makes a mockery of this provision. Rule 3.35(c) allows a party, like Upsher, to produce records in place of responding "fully" to an interrogatory, only if two conditions are met: (1) the party provides "sufficient detail to permit the interrogating party to identify readily the individual documents from which the answer may be ascertained"; and (2) the relative burdens of research are "substantially the same" for both

parties." 16 C.F.R. §3.35(b)(2)(c).[6] Upsher's response does not come close to satisfying either of these pre-conditions.

First, Upsher makes no effort to satisfy the threshold specificity requirement. It does not identify specific documents from which complaint counsel's answer may be derived. To the contrary, Upsher directs complaint counsel to the mass of business records produced in over 100 boxes.[7] Such evasive references to large numbers of documents is clearly inadequate under the rules and the case law.[8]

Additionally, even if Upsher had identified a discrete set of documents, the relative burden of deriving the answer would be substantially greater for complaint counsel than for Upsher. The interrogatory seeks facts supporting Upsher's contention. Only Upsher knows

---

[6] *See Puerto Rico Aqueduct and Sewer Authority v. Clow* Corp., 108 F.R.D. 304, 307 (D. P.R. 1985) (finding that the interrogated party satisfied the specificity requirement by organizing, assembling, and identifying documents by serial number, explaining how the information can be found in the documents, and offering reasonable assistance to defendants); *Oleson v. Kmart Corp.*, 175 F.R.D. 560, 564 (D.Kan. 1997) ("To rely on [the option to produce records], the responding party must specifically identify which documents contain the requested information in its answer to the interrogatory. If the party cannot comply with these requirements, it must otherwise answer the interrogatory fully and completely").

[7] Upsher's supplemental response, which merely adds citations to a single two-page document and to a couple of its expert reports, does not satisfy Upsher's obligation to answer the interrogatory fully and completely. *Schering-Plough Corp.*, Dkt. No. 9297, Order Compelling Complaint Counsel to Supplement Interrogatory Responses (Dec. 14, 2001).

[8] *Fine Paper Antitrust Litigation*, 685 F.2d 810, 823 (3rd Cir. 1982) (quoting Advisory Committee on the Rules, Fed. R. Civ. P. 33(c) (amended to 33(d) in 1993)); *see also Oleson v. Kmart Corp.*, 175 F.R.D. at 564 ("A party may not refer generically to past or future production of documents"); *Atlanta Shipping Corporation, Inc. v. Cross & Brown Company*, 113 F.R.D. 108, 111-112 (S.D.N.Y. 1986) (referring the interrogating party to large numbers of boxes does not "adequately direct the [interrogating party] to the pertinent documents so as to comply with Rule 33[d]").

which documents or information Upsher relied upon in forming its contention. Upsher should be directed to answer the interrogatory "fully" by "identifying documents," "stating facts," and "elaborating on legal contentions."[9]

Upsher's responses and supplemental responses to complaint counsel's other interrogatories are similarly deficient. Complaint counsel is entitled to proper responses to these interrogatories. Accordingly, complaint counsel requests that the Court order Upsher to respond "fully" to Interrogatory Nos. 2, 3, 4, 5, 6, 10, 11, 12, 13, and 15.

II. Upsher's Admission Responses are Non-Responsive

Complaint counsel served three sets of requests for admissions on Upsher regarding facts relevant to issues in this case. Upsher objected to, or failed to respond properly to, many of these requests. Upsher's improper responses fall into four general categories: (1) denial based on improper objections; (2) improper refusals to admit or deny; (3) improper answers that fail to admit or deny the essential truth of the request; and (4) improper referral to documents. The parties have conferred in good faith regarding the matters covered by this motion and have reached impasse.[10] Accordingly, complaint counsel seeks an order under Commission Rule

---

[9] In response to our interrogatories, Upsher occasionally identifies the testimony of certain individuals. Upsher cannot escape its obligation to provide full responses to the interrogatories with vague references to some deposition transcripts. *See Oleson v. Kmart Corp.* at 564.

[10] Upsher had agreed to provide supplemental responses to some of the disputed requests for admissions by December 18, 2001. By the date of this filing, however, we had not received any supplemental responses. Should Upsher provide revised answers which respond properly to our requests, we will notify the Court accordingly.

3.38(a)(1) deeming the requests discussed below admitted, or compelling Upsher to properly answer them.

Requests for admissions are encouraged under the Rules to narrow the issues for trial. By "separat[ing] the wheat from the chaff,"[11] proper responses to requests for admissions serve to focus the parties' and the judge's attention on those matters truly in dispute.[12] A response is proper only if it is "clear, specific, direct and straightforward. Evasive or equivocal answers are improper." *Sterling Drug Inc.*, 1976 FTC Lexis 272 at *2-3. If a partial or qualified answer is possible in good faith, it should be given. Rule 3.32(b). On the other hand, denials must "fairly meet the substance of the requested admission." *Id.* If a responding party cannot honestly either admit or deny a request, if must "set forth in detail" its reasons. *Id.* Upsher's improper responses fail to meet these basic requirements and should be rejected.

Denials Based on Improper Objections

In response to Requests 58, 60, 78, 85, 87, 142, 143, 158, and 241, Upsher raises improper objections and then refuses to admit or deny the "essential truth of the request." Upsher claims that these requests are vague and ambiguous, impossible to answer, and/or that the information is beyond Upsher's knowledge. Complaint counsel fails to see how the terms "possibility" (No. 58), "would prevail" (No. 60), "profits" (No. 142), "lower" (No. 142), "September 2001" (No. 143), "at least a 20% discount" (No. 143), "substitution" (No. 158), and

[11] *Beatrice Foods Company*, 1979 FTC Lexis 597 at *2.

[12] *See General Motors Corp.*, 1977 FTC Lexis 293 at *3 (admissions "expedite the trial and relieve the parties of the costs of proving facts that will not be disputed at the trial"); *Sterling Drug Inc.*, 1976 FTC Lexis 272 at *1 -2.

"verbally responded" (No. 241) would prevent Upsher from providing a good faith answer to these requests. Nor does Upsher describe why the terms are vague or otherwise problematic, therefore failing to satisfy its obligations under Rule 3.32(b) to "set forth in detail" the reasons it can neither admit nor deny the requests. *See Audiotext Communications Network, Inc. v. US Telecom, Inc.*, 1995 WL 625744, at *2 (D. Kan Oct. 5, 1995). Moreover, Upsher must respond to requests for admissions even if they have ambiguous or undefined phrases as long as any ambiguity can be explained in a qualification. *Id.* at *6.[13]

Upsher objects to Requests 58 and 60 on the basis that they call for speculation.[14] Request 58 states:

> At the time of the Schering/Upsher Agreement, there was a possibility that Upsher could have won the Schering/Upsher Patent Litigation if it continued the Schering/Upsher Patent Litigation.

This request does not require Upsher to predict the outcome of the patent infringement litigation. That would call for speculation. It only asks whether a particular outcome was possible, a fact which either is true or not, and which Upsher should admit or deny.

Upsher's objection that Requests 85 and 87 are "impossible to answer" is without merit. These requests ask whether Upsher will contest the fact that Upsher would receive Schering's $60 million payment even if it abandoned the development of Niacor-SR. Complaint counsel fails to see how these requests could be "impossible to answer," as Upsher claims, given that

---

[13] *See also Beatrice Foods Co.*, 1979 FTC Lexis 597, at *11 (Oct. 15, 1979) (rejecting objection concerning vague language).

[14] Many of Upsher's responses raise similar deficiencies. As a result, complaint counsel discusses only examples of the disputed answers.

Schering had no trouble admitting precisely the same requests.[15] Upsher should be required to provide a direct response to these simple requests, as required by Rule 3.32.

Upsher refuses to answer Request 142, which asks whether Upsher will dispute that its Average Selling Price of generic K-Dur is 20% less than the Average Selling Price of Schering's K-Dur 20. Upsher claims that it cannot answer this straightforward request because "it assumes facts concerning the uniformity of price and customer." This objection makes no sense. The request specifically takes into account that price may differ depending on the customer. That is why Average Selling Price is a defined term based on Upsher's own document – USL 07075. (Attachment G). Upsher should be required to provide a proper answer to this request.

Request No. 158 asks about the rate of substitution from a brand product to an AB-rated generic equivalent. Upsher refuses to answer, objecting that the request is "irrelevant to this matter," and "beyond its knowledge." Contrary to Upsher's claim, the request is directly relevant to this case. The fact that generic entry significantly reduces the sales of the brand product almost immediately explains why companies like Schering and Upsher enter into agreements to prevent, delay, and hinder generic entry.

And it is no excuse that the information sought may be beyond Upsher's knowledge. *See also* Upsher Response to Request No. 241. Since the issue is whether Upsher seriously intends to dispute the requested fact, Upsher must admit it even if it lacks direct personal knowledge, but does not intend to place that fact in issue. *General Motors Corp.*, 1977 FTC Lexis 293, at *3-4. Moreover, Upsher is required to make a "reasonable inquiry" to answer these requests. If Upsher

---

[15] *See* Respondent Schering-Plough Corporation's Objections and Responses to Complaint Counsel's Revised Second Request for Admissions Nos. 70 and 72 (Attachment F)

can neither admit nor deny these requests after such a "reasonable inquiry," it can only be because it possesses no evidence on the requested point. In that case, Upsher should be prohibited from offering any evidence disputing Requests 158 and 241 at trial.

Improper Refusals to Admit or Deny

Upsher responses to Requests 173, 174, 176, 178, 294, 330 and 332 are also deficient. These requests ask whether Upsher will dispute certain facts about its activities relating to Niacor-SR and its discussions with Schering about those activities. For example, Request 173 asks whether Upsher ever "informed Schering that Upsher intended to seek or considered seeking FDA approval for an ANDA for Niacor-SR." Upsher claims it can neither admit nor deny this fact concerning its own conduct. Upsher either intends to present evidence disputing this request or not. If it does not intend to place this facts in issue, Upsher should admit the fact, in whole or in part with qualifications, even if it lacks direct knowledge. *See General Motors Corp.* 1977 FTC Lexis, at *3-4. And if Upsher possesses no information on the matter, it should state so, and be precluded from offering any such evidence at trial. Otherwise, these requests seek relevant information and we are entitled to know whether Upsher intends to dispute these facts at trial.

Improper Answers that Fail To Admit or Deny the Essential Truth of the Request

In its responses to Requests 21-27, 84, 103, 124, 129-33, 136, 139, 141, and 334, Upsher fails to meet the substance of the request.[16] These responses are improper and should be deemed

[16] *See Sterling Drug Inc.*, 1976 FTC Lexis 272, at *3 (June 16, 1976) ("[T]he answer must fairly meet the substance of the requested admission").

admitted, or Upsher should be compelled to provide proper answers. For example, Request 132 makes a straightforward statement:

> In April 1997, Upsher projected that sales of its generic version of K-Dur 20 would come only at the expense of K-Dur 20 or other bioequivalent generic K-Dur 20 products.

In response, Upsher denies the request, and states that Upsher did not "establish a company-wide position as to future sales." The request does not ask about company-wide projections. The definition of "Upsher" includes Upsher or any of its employees.[17] Thus, the request asks simply whether Upsher or any of its employees made the stated projections. Additionally, Upsher improperly objects that any projections would "have limited probative value, given their reliance upon speculative assumptions." This is not the proper place to dispute the weight of factual evidence.[18] Upsher's response must admit or deny the truth of the fact. If Upsher believes the fact should be given little weight, it is free to argue that at trial. For now, however, complaint counsel is entitled to know whether Upsher intends to dispute the fact itself. Upsher's responses to requests 84, 103, 124, 129-33, 136, 139, 141, and 334 are similarly deficient. These requests should be deemed admitted, or Upsher should provide proper responses.

Upsher's responses to requests 21-27 are also evasive and non-responsive. For example, Request 21 asks simply whether a meeting was held on April 29, 1997 in which possible launch date scenarios for Upsher's generic version of K-Dur 20 were discussed. Rather than provide a

---

[17] *See* Definition No. 12 in Complaint Counsel's Revised Third Set of Requests for Admissions (Attachment H).

[18] *See General Motors Corporation*, 1977 FTC Lexis 293, at *4 ("By admitting to a fact, a party does not waive later argument that under applicable substantive law the admitted fact is of limited or no relevance").

direct answer to this straightforward request, Upsher rambles on about why the fact of these discussions should not be afforded much weight:

> Upsher-Smith objects to the Request because it is vague and ambiguous, because, among other reasons, the terms "meeting," "possible," "scenarios" and "discusses" are unclear. Subject to and without waiving its objections, Upsher-Smith admits that there was a meeting of certain Upsher-Smith personnel on or about April 29, 1997. There was not, however, any discussion of "possible" launch date scenarios. Launch was not legally or practically possible any time in the foreseeable future as of April 29, 1997. Patent litigation with Schering-Plough was continuing, and the timing and terms of its outcome were highly uncertain. The 30-month stay under Hatch-Waxman was in effect, and FDA had not granted final approval. Furthermore, as a practical matter Upsher-Smith could not produce launch quantities. For these reasons among others, any discussion of any launch dates at the April 29, 1997 meeting was necessarily highly theoretical and hypothetical. Therefore, Upsher-Smith denies the Request.

Upsher's equivocal response "evades the central point of the requested admission": Did Upsher discuss possible launch dates for its generic K-Dur 20 product at a particular meeting in April 1997?[19] Upsher must admit or deny this fact. Arguments about the significance of this fact should be saved for another day.

Improper Referral to Documents

Upsher neither admits nor denies Requests 3-11 in the First Set of Admissions and Request 100 in the Revised Third Set of Admissions. Instead, it refers complaint counsel to particular documents. Such a response is improper.

In Request 3, for example, we ask Upsher to confirm its revenues for the year ending 1996. This is a simple request and we are entitled to a straightforward answer. Rather than provide this direct response, however, Upsher refers us to a particular document, USL01636-52

---

[19] *General Motors Corp.*, 1977 FTC Lexis 293, at * 6 (Jan. 28, 1977).

"for information on this subject matter." Of course, that document contains the answer to our request, but Upsher refuses to admit or deny it.[20] We are entitled to know whether Upsher intends to contest the stated proposition. Upsher should be directed to admit or deny this and other similar requests.

Karen G. Bokat
Bradley S. Albert
Clifton Smith
Steve Vieux

Complaint Counsel

Dated: January 2, 2002

[20] *Beatrice Foods*, 1979 FTC Lexis at * 11 (requests may seek confirmation or denial of a fact concerning a particular document); *see also Diederich v. Dept. of the Army*, 132 F.R.D. 614, 617 (S.D.N.Y. 1990) ("[O]bjections that documents or regulations 'speak for themselves' also are improper");

Attachment A

UNITED STATES OF AMERICA
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

DECLARATION OF CLIFTON L. SMITH

Pusuatn to 16 C.F.R. § 3.22(f), I, Clifton Smith, declare the following:

1. I am a staff attorney in the Federal Trade Commission's Health Care Services and Products Division and have been involved as complaint counsel in the above-captioned matter. I submit this declaration to represent that complaint counsel has attempted to confer with Upsher-Smith in a good faith effort to resolve by agreement the issues raised in complaint counsel's motion. Complaint counsel and Upsher have been unable to reach an agreement.

2. On Wednesday, December 12, 2001, I engaged in a telephone conference call with Upsher's counsel, including Rajeev Malik and Gustav Chiarello, regarding complaint counsel's concerns over the adequacy of Upsher's responses to interrogatory and admission requests. After discussing the interrogatories in some detail, Upsher agreed to consider supplementing some of the interrogatories and to follow-up with a second conference call on Friday, December 14 to discuss the supplemental responses.

Complaint counsel agreed to provide, and did provide, a complete list of admission responses which complaint counsel believes to be inadequate prior to the Friday conference call.

3. On Friday, December 14, 2001, I spoke by telephone with Gustav Chiarello regarding both Upsher's supplementation of interrogatories and admissions. Mr. Chiarello agreed that Upsher would provide supplemental responses to some of the interrogatories by close of business on Wednesday, December 19. We also agreed that for some responses, Upsher and complaint counsel had reached impasse as to other responses.

4. On Monday, December 17, I again spoke by telephone with Mr. Chiarello. At that time, Mr. Chiarello agreed to supplement certain admission responses by Wednesday, December 19.

5. As of today, Wednesday, December 26, I have not received Upsher's supplemental responses to complaint counsel's requests for admissions.

I affirm that the foregoing is a true statement of events to the best of my knowledge.

Clifton L. Smith
Complaint Counsel
601 Pennsylvania Ave., NW
Washington, DC 20580
Phone (202) 326-2055
Fax (202) 326-3384

Dated: December 26, 2001

Attachment B

UNITED STATES OF AMERICA
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

UPSHER-SMITH'S RESPONSES TO COMPLAINT COUNSEL'S FIRST SET OF INTERROGATORIES

In accordance with the Federal Trade Commission Rule of Practice § 3.35 and the May 3, 2001 Scheduling Order, Upsher-Smith hereby responds and objects to Complaint Counsel's first set of interrogatories as follows:

GENERAL OBJECTIONS TO INTERROGATORIES, INSTRUCTIONS, AND DEFINITIONS

The following general objections apply to each instruction, and document or information request and shall have the same force and effect as if fully set forth in the objection to each interrogatory. Hereinafter, the terms "document" and "documents" shall be equivalent and either terms shall mean both the singular and plural.

1. Upsher-Smith objects to the number of interrogatories Complaint Counsel have propounded as they exceed twenty-five in number, including all subparts, in violation of both Federal Trade Commission Rule of Practice § 3.35 and Judge Chappell's Scheduling Order.

2. Upsher-Smith objects to providing any information or documents in response to these interrogatories that would cause Upsher-Smith or its executives, officers, or other principals to waive or otherwise lose any privilege against self-incrimination, joint defense privilege, or any other applicable privilege, immunity, protection, or restriction.

3. Upsher-Smith objects to providing any information or documents in response to these interrogatories that is protected by the attorney-client privilege or the work-product doctrine, the privilege against self-incrimination, joint defense privilege, or any other applicable privilege, immunity, protection or restriction.

4. Upsher-Smith objects to providing any information or documents in response to these interrogatories that are not discoverable or the scope of which exceeds the obligations of discovery under the Federal Trade Commission's Rules of Practice or other applicable law.

5. Upsher-Smith objects to providing any information or documents in response to these interrogatories to the extent that disclosure or production would cause Upsher-Smith annoyance, embarrassment, oppression, undue burden, or expense.

6. Upsher-Smith objects to providing any information or documents in response to these interrogatories to the extent that the information or document sought is of public record or is equally accessible and available to Complaint Counsel or is already in the possession of

Complaint Counsel, the Commissioners, the General Counsel, the office of Administrative Law Judges, or the Secretary in his capacity as custodian or recorder of any such information, or their respective staffs.

7. Upsher-Smith objects to responding to interrogatories or producing documents to the extent that the instructions and definitions contained in these interrogatories are not reasonably calculated to lead to the discovery of admissible evidence, or are unduly burdensome, overly broad, irrelevant, unduly vague or ambiguous, or attempt to alter the plain meaning or undertaking of any term, or attempt to impose obligations on Upsher-Smith that are inconsistent with or beyond those required under the Federal Trade Commission's Rules of Practice or other applicable laws.

8. Upsher-Smith objects to the instructions and the interrogatories to the extent that they are unreasonably cumulative or duplicative, the information or document is obtainable from some other source that is more convenient, less burdensome, or less expensive; Complaint Counsel has already had ample opportunity by discovery in this action to obtain the information or documents sought; and the burden and expense of the proposed discovery outweigh its likely benefit.

9. Upsher-Smith objects to any attempt in the interrogatories to require the production of documents that are not within Upsher-Smith's exclusive possession, custody, or control. Upsher-Smith's responses will be based only upon such information and documents as are available to, and known to, Upsher-Smith and its current employees at the time of such production. Upsher-Smith's responses will be based upon reasonable and diligent searches and

inquiries to locate and identify responsive non-privileged documents in their possession, custody or control.

10. Upsher-Smith objects to the instructions contained in the interrogatories to the extent that they seek to impose burdens or obligations that exceed those imposed by the Federal Trade Commission's Rules of Practice, and any other applicable statutory and decisional laws.

11. Upsher-Smith objects to the definition of "Upsher" as it is overly broad and not reasonably calculated to lead to the discovery of admissible evidence as it includes persons and entities not necessarily under the control of Upsher-Smith.

12. By answering any interrogatories, Upsher-Smith does not waive any of the above objections, any defenses in any underlying action, or admit any liability in any underlying action.

INTERROGATORIES RESPONSES AND OBJECTIONS

1. Since the date of the first sale of Upsher's generic version of K-Dur 20, state by month the Net Sales and Gross Profit Upsher received from the sale of generic K-Dur 20 in the United States.

Specific Objections to Interrogatory 1: Upsher-Smith objects to this interrogatory as irrelevant, vague, overly broad, overly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence. The success of a generic version of K-Dur 20 has nothing to do with the issue of whether the Upsher-Smith/Schering settlement was anti-competitive, or any other issue in this case. Furthermore, Upsher-Smith objects to the definition of "Net Sales" and "Gross Profits," as defined in the instructions, as it is vague and does not fairly represent the plain meanings of those terms.

Response: Subject to and without waiving any objections, Upsher-Smith's generic version of K-Dur 20 has been on the market since September 1, 2001. Additionally, Upsher-Smith's generic version of K-Dur 20 has not been on the market for a sufficient period of time in order to calculate net sales or gross profit. It is important to note that any calculation of sales or profits for the generic

version of K-Dur is artificially inflated because Schering's K-Dur 20 is being sold on a limited basis to consumers due to manufacturing issues Schering must address with the Food & Drug Administration.

2. Identify each generic product launched by Upsher, and for each such product describe in detail, and set forth the time involved to complete, each activity or effort undertaken by Upsher to prepare to launch the product once Upsher received tentative approval of that generic product's ANDA from the FDA.

Specific Objections to Interrogatory 2: Upsher-Smith specifically objects to this interrogatory as irrelevant, vague, overly broad, overly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence. Because this interrogatory does not specify a time frame, it would appear to call for ANDA launch records for ***each and every*** generic product launched by Upsher-Smith since the founding of the company. Furthermore, it is unclear, in this context, what "detail" means, in that the interrogatory could be seeking thousands of pages of irrelevant scientific reports detailing ***each and every*** minor analysis or investigation involved in ***each and every*** ANDA product Upsher-Smith has produced including other products that are not relevant to this case. In addition, the interrogatory is plainly overly broad and unduly burdensome as it fails to define the terms activity or effort, which could be interpreted to mean the smallest, most inconsequential task, placing an overwhelming burden on Upsher-Smith to respond. Finally, the details of each activity and effort undertaken by Upsher-Smith to prepare for ANDA product launches is not relevant to the time it would have taken for the products at issue in this case as each product faces unique challenges.

Response: Subject to and without waiving objections, Upsher-Smith's launch of Klor Con M10 and M20 was unprecedented in scale. Upsher-Smith had never undertaken a product launch of this size and magnitude. Pursuant to Federal Trade Commission Rule of Practice § 3.35(c), Upsher-Smith refers Complaint Counsel to the testimony of Scott Gould, Chuck Woodruff, Paul Kralovec, Mark Robbins, Phil Dritsas and Ian Troup. Upsher-Smith also refers Complaint Counsel to the documents already produced in Upsher-Smith's extensive and thorough document production for the specific details including the time involved and the activities required to prepare for this product launch.

3. Describe in detail the basis for the statement in Upsher's Statement of the Case, at p. 1, that generic competition probably would not have occurred prior to September 1, 2001 "if Upsher had won, given the appeal process and the logistics of a new product launch."

Specific Objections to Interrogatory 3: Upsher-Smith specifically objects to this interrogatory as irrelevant, vague, overly broad, overly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence. Upsher-Smith also objects to this interrogatory as premature to the extent that it asks,

prior to the close of discovery, for Upsher-Smith to describe in detail the basis for that statement. Furthermore, the interrogatory is argumentative and calls for a legal conclusion as to the right of other firms to enter the potassium chloride market.

Response: Subject to and without waiving objections, the information requested in this interrogatory has already been provided in a number of submissions to Complaint Counsel, including among others Upsher-Smith's expert reports and through the testimony of Scott Gould, Chuck Woodruff, Paul Kralovec, Mark Robbins, Phil Dritsas and others, including individuals yet to be deposed. Pursuant to § 3.35(c) of the Federal Trade Commission's Rules of Practice, Upsher-Smith also refers Complaint Counsel to documents already produced to Complaint Counsel in Upsher-Smith's extensive and thorough document production.

4. Describe in detail the basis for the statement in Upsher's Statement of the Case, at p. 2, that "the drugs being licensed - most notably Niacor SR but the others as well - had value in line with the consideration received from Schering."

Specific Objections to Interrogatory 4: Upsher-Smith specifically objects to this interrogatory as irrelevant, vague, overly broad, overly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence. Upsher-Smith also objects because the documents are equally accessible and available to Complaint Counsel and they are already in their possession. Furthermore, this interrogatory is premature to the extent that it asks, prior to the close of discovery, for Upsher-Smith to describe in detail the facts that form the basis for the statement.

Response: Subject to and without waiving objections, the information requested in this interrogatory has already been provided in a number of submissions to Complaint Counsel, including among others Upsher-Smith's and Schering-Plough's expert reports and the testimony of Ian Troup, Denise Dolan, Philip Dritsas, Paul Kralovec, Victoria O'Neill, Mark Robbins, and others, including individuals yet to be deposed. Pursuant to § 3.35(c) of the Federal Trade Commission's Rules of Practice, Upsher-Smith also refers Complaint Counsel to documents already produced to Complaint Counsel in Upsher-Smith's extensive and thorough document production.

5. Describe in detail, including identification of the companies, summary of the substantive discussions, and listing of the amount of upfront payments discussed, the basis for the statement in Upsher's Statement of the Case, at p. 2, that "Upsher-Smith also had substantive discussions with major pharmaceutical companies about licensing Niacor SR in Europe, at least one of which indicated a willingness to pay substantial upfront payments."

Specific Objections to Interrogatory 5: Upsher-Smith specifically objects to this interrogatory as irrelevant, vague, overly broad, overly burdensome, and not

reasonably calculated to lead to the discovery of admissible evidence. Furthermore, it is unclear how much "detail" the interrogatory seeks. Furthermore, the interrogatory seeks confidential business information of non-parties, and it solicits information beyond Upsher-Smith's exclusive possession, custody, or control. Upsher-Smith also objects to this interrogatory as premature to the extent that it asks, prior to the close of discovery, for Upsher-Smith to describe in detail the basis for that statement.

Response: Subject to and without waiving objections, the information requested in this interrogatory has already been provided to Complaint Counsel and can be found in the testimony from, among others, Victoria O'Neill, Mark Halverson, and James Egan. Pursuant to § 3.35(c) of the Federal Trade Commission's Rules of Practice, Upsher-Smith also refers Complaint Counsel to documents already produced to Complaint Counsel in Upsher-Smith's and Moreton Company's extensive and thorough document production.

6. Describe in detail the methodology by which Upsher has priced Upsher's generic version of K-Dur 20.

Specific Objections to Interrogatory 6: Upsher-Smith specifically objects to this interrogatory as irrelevant, vague, overly broad, overly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence. Upsher-Smith's pricing methodology is irrelevant. Furthermore, Upsher-Smith objects as this interrogatory is premature to the extent that it asks, prior to the close of discovery, for Upsher-Smith to describe in detail the basis for that statement.

Response: Subject to and without waiving objections, the information requested in this interrogatory has already been provided to Complaint Counsel and can be found in the testimony of Denise Dolan, Paul Kralovec, Philip Dritsas, among others, as well as in the testimony of individuals that still must be deposed before the close of fact discovery.

7. Does Upsher contend that a product produced according to its ANDA No. 74-726 would have infringed U.S. Patent No. 4,863,743 if sold prior to September 1, 2001? If the answer is anything other than an unequivocal no, describe in detail the factual and legal bases for that infringement, and the factual and legal bases why the arguments made by Upsher with respect to non-infringement in the Schering/Upsher Patent Litigation are incorrect.

Specific Objections to Interrogatory 7: Upsher-Smith specifically objects to this question because it is vague and unclear as U.S. Patent No. 4,863,743 expires on September 5, 2006, not September 1, 2001. Upsher-Smith also objects to the interrogatory as it seeks an admission to a material element of the case and calls for an impermissible legal conclusion.

Response: Subject to and without waiving objections, Upsher-Smith does not and could not know whether the court system would conclude that its product infringed Schering-Plough's patent. Upsher-Smith was aware that litigation is uncertain, particularly patent litigation. Upsher-Smith has provided the information requested in interrogatory 7 from the testimony of from among others, Philip Dritsas, Denise Dolan, Paul Kralovec, Victoria O'Neill, Ian Troup, and Mark Robbins. This information is also found in the pleadings to the Schering/Upsher-Smith Patent Litigation, the expert reports in that litigation, as well as Upsher-Smith's and Schering-Plough's expert reports submitted to Complaint Counsel October 8, 2001, and Upsher-Smith's extensive and thorough document production both during the investigation and during discovery in this proceeding.

8. Describe in detail, including the identification of each state and each managed care plan, the basis for Upsher's contention, in Paragraph 19 of it [sic] Answer to the Complaint, "that some states and managed care plans do not reimburse for the use of K-Dur to treat potassium deficiency, known as hypokalemia, and mandate the use of equally efficacious, readily available, and lower cost potassium chloride supplement products which are readily available in the market and compete with K-Dur 20."

Specific Objections to Interrogatory 8: Upsher-Smith objects to interrogatory 8 on the grounds that it is irrelevant, vague, overly broad, or overly burdensome. In particular, Upsher-Smith objects to interrogatory 8 on the grounds that it is unduly burdensome and irrelevant to identify *each* state and *each* managed care plan that supports this contention. Furthermore, Upsher-Smith objects to interrogatory 8 on the grounds that it is already known to Complaint Counsel, and equally available to both parties.

Response: Subject to and without waiving objections Upsher-Smith responds as follows. Some Michigan, California, and Tennessee plans do not reimburse for K-Dur 20. To date, Upsher-Smith has found a number of managed-care plans that do not reimburse for K-Dur 20. For example, some Kaiser, Merck-Medco, and John Deere plans do not reimburse for K-Dur 20.

9. Describe in detail, including the identification of each product, the basis for Upsher's contention, in Paragraph 21 of its Answer to the Complaint, that "there are numerous products that are readily available in the market at lower cost and are reasonable therapeutic alternatives to K-Dur 20."

Specific Objections to Interrogatory 9: Upsher-Smith objects to interrogatory 9 on the grounds that it is irrelevant, vague, overly broad, and overly burdensome. In particular, Upsher-Smith objects to interrogatory 9 on the grounds that it is unduly burdensome and irrelevant to state *each* product that supports this contention. Moreover, Upsher-Smith specifically objects to this interrogatory as premature to the extent that it asks, prior to the close of discovery, for Upsher-Smith to describe in detail the basis for that statement. Furthermore, Upsher-Smith objects to

interrogatory 9 on the grounds that it is already known to Complaint Counsel, and equally available to both parties.

Response: Subject to and without waiving objections, Upsher-Smith responds as follows. Some of these products include: Klor-Con M10, Klor-Con 8, Slow-K, Kaon-Cl 8, Generic potassium chloride 8 mEq tablets, K-Tab, Klotrix, K-Dur (10mEq), Kaon-Cl 10, Generic potassium chloride 10mEq tablets, Micro-K 8, Micro-K 10, K-Lease, Generic potassium chloride 10 mEq capsules, Koachlor-SF, Kaon-Cl 20%, Kaochlor, Kay Ciel, Rum-K, Generic potassium chloride liquid products, K-Lyte, K-Lyte Cl, K-Lyte DS, K-Lyte Cl-50, Klor-Con EF, Klorvess, Generic potassium chloride effervescent tablets, K-Lor, Klor-Con, Kay Ciel, Generic potassium chloride powders for oral solution. In multiple cases, there are several generic manufacturers of potassium chloride. Furthermore, the information requested in interrogatory 9 has already been provided to Complaint Counsel in testimony from, among others, Philip Dritsas, Denise Dolan, Victoria O'Neil. Pursuant to Federal Trade Commission Rule of Practice § 3.35(c), Upsher-Smith also refers Complaint Counsel to documents already produced to Complaint Counsel in Upsher-Smith's extensive and thorough document production.

10. Describe in detail the basis for Upsher's contention, in Paragraph 24 of its Answer to the Complaint, that "K-Dur is not clinically superior to any of the many other potassium chloride supplement products that are readily available in the market as low cost alternatives from multiple sources in many different dosage forms and strengths."

Specific Objections to Interrogatory 10: Upsher-Smith objects to interrogatory 10 on the grounds that it is vague, overly broad, and overly burdensome. This interrogatory seems to request a "detail[ed]" analysis and clinical comparison of ***all*** other low-cost potassium chloride supplement products available in the market. Furthermore, Upsher-Smith specifically objects to this interrogatory as premature to the extent that it asks, prior to the close of discovery, for Upsher-Smith to describe in detail the basis for that statement.

Response: Subject to and without waiving objections, the information requested in interrogatory 10 has already been provided to Complaint Counsel in Upsher-Smith's extensive and thorough document production. Pursuant to Federal Trade Commission Rule of Practice § 3.35(c), Upsher-Smith also refers Complaint Counsel to Upsher-Smith's document production.

11. Describe in detail the basis for Upsher's contention, in Paragraph 43 of its Answer to the Complaint, that Upsher "never had any intention of committing the substantial resources necessary to support a commercial launch of Klor Con M20 until after the final disposition of the patent infringement litigation in its favor through appeal."

Specific Objections to Interrogatory 11: Upsher-Smith objects to interrogatory 11 on the grounds that it is vague, overly broad, and overly burdensome. In particular, it

is unclear what the word "detail" requires in this context. Furthermore, Upsher-Smith objects to interrogatory 11 on the grounds that it the information sought is already available and known to Complaint Counsel.

Response: Subject to and without waiving objections, the information requested in interrogatory 11 has already been provided to Complaint Counsel in the testimony of, among others, Ian Troup, Mark Robbins, Scott Gould, Philip Dritsas and Paul Kralovec, as well as Upsher-Smith's expert reports. Furthermore, pursuant to Federal Trade Commission Rule of Practice § 3.35(c), Upsher-Smith also refers Complaint Counsel to documents already produced to Complaint Counsel in Upsher-Smith's extensive and thorough document production.

12. Describe in detail the basis for Upsher's contention, in Paragraph 46 of its Answer to the Complaint, that "Niacor SR was particularly promising and valuable."

Specific Objections to Interrogatory 12: Upsher-Smith objects to interrogatory 12 on the grounds that it is vague, overly broad, and overly burdensome. In particular, it is unclear what the word "detail" requires in this context. Upsher-Smith specifically objects to this interrogatory as premature to the extent that it asks, prior to the close of discovery, for Upsher-Smith to describe in detail the basis for that statement. In addition, Upsher-Smith objects to this interrogatory as it is argumentative. Upsher-Smith also objects to this interrogatory as premature to the extent that it asks, prior to the close of discovery, for Upsher-Smith to describe in detail the basis for that statement. Furthermore, Upsher-Smith objects to this interrogatory because it requests information that is already available to Complaint Counsel

Response: Subject to and without waiving objections, the information requested in interrogatory 12 has already been provided to Complaint Counsel in Upsher-Smith's extensive and thorough document production. Pursuant to Federal Trade Commission Rule of Practice § 3.35(c), Upsher-Smith refers Complaint Counsel to those documents. Additionally, this information is provided to Complaint Counsel in the testimony of Victoria O'Neill, Ian Troup, Paul Kralovec, Denise Dolan, Philip Dritsas, among others, as well as the expert reports submitted by Upsher-Smith.

13. Describe in detail, including identification of the provisions at issue, the basis for Upsher's contentions, in Paragraph 10 of its Defenses and Affirmative Defenses filed with its Answer to the Complaint, that certain provisions of the agreement (a) "are, if anything, ancillary to the agreement's primary purpose"; (b) "had no demonstrable effect on the parties' behavior"; and (c) "were necessary to ensure that the parties could not evade their settlement obligation not to infringe Schering's patents."

Objections to Interrogatory 13: Upsher-Smith objects to interrogatory 13 on the grounds that it is vague, overly broad, and overly burdensome. In particular, it is

unclear what the word "detail" requires in this context. Upsher-Smith also objects to this interrogatory as it is argumentative and calls for a legal conclusion as to the parties settlement obligations, and what would or would not infringe Schering's patents. Furthermore, Upsher-Smith specifically objects to this interrogatory as premature to the extent that it asks, prior to the close of discovery, for Upsher-Smith to describe in detail the basis for that statement.

Response: Subject to and without waiving objections, the information requested in interrogatory 13 has already been provided to Complaint Counsel in Upsher-Smith's extensive and thorough document production. Pursuant to Federal Trade Commission Rule of Practice § 3.35(c), Upsher-Smith refers Complaint Counsel to those documents. Additionally, this information is provided to Complaint Counsel in the testimony of Ian Troup and Mark Robbins, among others, as well as the expert reports submitted by Upsher-Smith and Schering-Plough.

14. Identify each instance since January 1, 1995, where Upsher paid $1 million or more in licensing fees and, in return, obtained a license for another company's pharmaceutical product (or otherwise obtained the right to market a pharmaceutical product that the other company owned or on which it held the patent rights). For each such instance:

(a) identify the company or entity receiving such payments;

(b) identify the pharmaceutical product(s) for which such payments were made;

(c) specify the projected annual dollar value of sales (at the time the parties entered into the license) of the pharmaceutical product(s) in the United States and other countries or regions (*e.g.*, Europe) covered by the license;

(d) specify the projected net present value of sales (at the time the parties entered into the license) of the pharmaceutical products(s) in the United States and other countries or regions (*e.g.*, Europe) covered by the license;

(e) state the amount of the licensing fees to be paid under the terms of the license;

(f) state whether any or all of the licensing fees were unconditional or nonrefundable and, to the extent that they were not unconditional or nonrefundable, describe the circumstances under which any such fees could be or were to be refunded to Upsher;

(g) state whether under the license the licensor could receive and not refund to the licensee payments received or to be received, where the licensor failed to perform its obligations under the license (*e.g.*, failed to seek FDA approval of the product, failed to conduct or complete clinical trials necessary for FDA approval);

(h) state whether any or all of the licensing fees were milestone payments and, if so, state the circumstances under which the milestone payments could be or would be paid;

(i) state whether any royalty payments were provided for under the license and, if so, state the circumstances under which the royalty payments could be or would be paid (including royalty rates provided for);

(j) state whether any other form of compensation was provided for under the license and, if so, state the form of compensation (*e.g.*, stock, shared development costs) and the circumstances under which such compensation could be or would be paid; and

(k) describe the regulatory status at the time of the license of the pharmaceutical product(s) in each country in which any rights to sell or market the product were transferred to Schering in consideration for the licensing fees (*e.g.*, for the United States describe the status of FDA review and approval).

Objections to Interrogatory 14: Upsher-Smith objects to interrogatory 14 on the grounds that Complaint Counsel has exceeded the interrogatories permitted under both Federal Trade Commission Rule of Practice 3.35 and Judge Chappell's Scheduling Order. Upsher-Smith objects to interrogatory 14 on the grounds that it is irrelevant, vague, overly broad, overly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence. In particular, this interrogatory requests information regarding products that are not at issue or remotely relevant in the case. Furthermore, Upsher-Smith specifically objects to this interrogatory as premature to the extent that it asks, prior to the close of discovery, for Upsher-Smith to describe in detail the basis for that statement. Upsher-Smith also objects to this interrogatory because it requests information that is already available to Complaint Counsel.

Response: Subject to and without waiving objections, the information requested in interrogatory 14 has already been provided to Complaint Counsel in Upsher-Smith's extensive and thorough document production. Pursuant to § 3.35(c) of the Federal Trade Commission's Rules of Practice, Upsher-Smith refers Complaint Counsel to those documents. Additionally, this information is provided to Complaint Counsel through the testimony of Ian Troup and Victoria O'Neill, among others, as well as the expert reports submitted by Upsher-Smith and Schering-Plough.

15. Identify each instance since January 1, 1995, where Upsher obtained a license for another company's generic pharmaceutical product (or otherwise obtained the right to market a generic pharmaceutical product that the other company owned or on which it held the patent rights). For each such instance:

(a) identify the company or entity from which Upsher obtained such a license; and

(b) identify the pharmaceutical product(s) licensed.

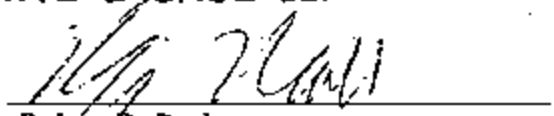
Objections to Interrogatory 15: Upsher-Smith objects to interrogatory 15 on the grounds that Complaint Counsel has exceeded the interrogatories permitted under both Federal Trade Commission Rule of Practice 3.35 and Judge Chappell's Scheduling Order. Moreover, Upsher-Smith objects to interrogatory 15 on the grounds that it is irrelevant, vague, overly broad, overly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence. This interrogatory requests information regarding "each" instance since January 1, 1995, where Upsher obtained a license for another company's generic pharmaceutical product, including products that are not at issue in this case. Furthermore, Complaint Counsel requests information on "generic" pharmaceutical products without providing a clear definition of exactly what they understand this word to mean. Upsher-Smith also objects to this interrogatory as it seeks redundant information that Complaint Counsel has either previously requested or already maintains in its possession.

Response: Subject to and without waiving objections, the information requested in Interrogatory 15 has already been provided to Complaint Counsel through the testimony of among others, Victoria O'Neill.

Dated: October 22, 2001

Respectfully submitted,

WHITE & CASE LLP

By: 

Robert D. Paul
J. Mark Gidley
Christopher M. Curran
Rajeev K. Malik
601 Thirteenth Street, N.W.
Washington, D.C. 20005-3807
Telephone: (202) 626-3600
Facsimile: (202) 639-9355

Attorneys for Upsher-Smith Laboratories, Inc.

Attachment C

UNITED STATES OF AMERICA
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

UPSHER-SMITH'S SUPPLEMENTAL RESPONSES TO COMPLAINT COUNSEL'S FIRST SET OF INTERROGATORIES

In accordance with Section 3.35 of the Federal Trade Commission Rules of Practice, Upsher-Smith hereby responds and objects to Complaint Counsel's First Set of Interrogatories and provides supplemental answers as follows:

GENERAL OBJECTIONS TO INTERROGATORIES, INSTRUCTIONS, AND DEFINITIONS

The following general objections apply to each instruction, and document or information request and shall have the same force and effect as if fully set forth in the objection to each interrogatory. Hereinafter, the terms "document" and "documents" shall be equivalent and either term shall mean both the singular and plural.

Upsher-Smith objects to the number of interrogatories Complaint Counsel have propounded as they exceed twenty-five in number, including all subparts, in violation of both Federal Trade Commission Rule of Practice § 3.35 and Judge Chappell's Scheduling Order.

1. Upsher-Smith objects to providing any information or documents in response to these interrogatories that would cause Upsher-Smith or its executives, officers, or other principals to waive or otherwise lose any privilege against self-incrimination, joint defense privilege, or any other applicable privilege, immunity, protection, or restriction.

2. Upsher-Smith objects to providing any information or documents in response to these interrogatories that is protected by the attorney-client privilege or the work-product doctrine, the privilege against self-incrimination, joint defense privilege, or any other applicable privilege, immunity, protection or restriction.

3. Upsher-Smith objects to providing any information or documents in response to these interrogatories that are not discoverable or the scope of which exceeds the obligations of discovery under the Federal Trade Commission's Rules of Practice or other applicable law.

4. Upsher-Smith objects to providing any information or documents in response to these interrogatories to the extent that disclosure or production would cause Upsher-Smith annoyance, embarrassment, oppression, undue burden, or expense.

5. Upsher-Smith objects to providing any information or documents in response to these interrogatories to the extent that the information or document sought is of public record or is equally accessible and available to Complaint Counsel or is already in the possession of Complaint Counsel, the Commissioners, the General

Counsel, the office of Administrative Law Judges, or the Secretary in his capacity as custodian or recorder of any such information, or their respective staffs.

6. Upsher-Smith objects to responding to interrogatories or producing documents to the extent that the instructions and definitions contained in these interrogatories are not reasonably calculated to lead to the discovery of admissible evidence, or are unduly burdensome, overly broad, irrelevant, unduly vague or ambiguous, or attempt to alter the plain meaning or undertaking of any term, or attempt to impose obligations on Upsher-Smith that are inconsistent with or beyond those required under the Federal Trade Commission Rules of Practice or other applicable laws.

7. Upsher-Smith objects to the instructions and the interrogatories to the extent that they are unreasonably cumulative or duplicative, the information or document is obtainable from some other source that is more convenient, less burdensome, or less expensive; Complaint Counsel has already had ample opportunity by discovery in this action to obtain the information or documents sought; and the burden and expense of the proposed discovery outweigh its likely benefit.

8. Upsher-Smith objects to any attempt in the interrogatories to require the production of documents that are not within Upsher-Smith's exclusive possession, custody, or control. Upsher-Smith's responses will be based only upon such information and documents as are available to, and known to, Upsher-Smith and its current employees at the time of such production. Upsher-Smith's responses will be based upon reasonable and diligent searches and inquiries to locate and identify responsive non-privileged documents in their possession, custody or control.

9. Upsher-Smith objects to the instructions contained in the interrogatories to the extent that they seek to impose burdens or obligations that exceed those imposed by the Federal Trade Commission's Rules of Practice, and any other applicable statutory and decisional laws.

10. Upsher-Smith objects to the definition of "Upsher" as it is overly broad and not reasonably calculated to lead to the discovery of admissible evidence as it includes persons and entities not necessarily under the control of Upsher-Smith.

11. By answering any interrogatories, Upsher-Smith does not waive any of the above objections, any defenses in any underlying action, or admit any liability in any underlying action.

INTERROGATORIES RESPONSES AND OBJECTIONS

1. Since the date of the first sale of Upsher's generic version of K-Dur 20, state by month the Net Sales and Gross Profit Upsher received from the sale of generic K-Dur 20 in the United States.

Specific Objections to Interrogatory 1: Upsher-Smith objects to this interrogatory as irrelevant, vague, overly broad, overly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence. The success of a generic version of K-Dur 20 has nothing to do with the issue of whether the Upsher-Smith/Schering settlement was anti-competitive, or any other issue in this case. Furthermore, Upsher-Smith objects to the definition of "Net Sales" and "Gross Profits," as defined in the instructions, as it is vague and does not fairly represent the plain meanings of those terms.

Supplemental Response: Subject to and without waiving any objections, Upsher-Smith provided Complaint Counsel with documents on October 31, 2001 and December 10, 2001 that contain information on Upsher-Smith's net sales of Klor Con M20. Upsher-Smith will provide data on gross profits for Upsher-Smith's potassium chloride supplements in early January.

3. Describe in detail the basis for the statement in Upsher's Statement of the Case, at p. 1, that generic competition probably would not have occurred prior to September 1, 2001 "if Upsher had won, given the appeal process and the logistics of a new product launch."

Specific Objections to Interrogatory 3: Upsher-Smith specifically objects to this interrogatory as irrelevant, vague, overly broad, overly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence. Upsher-Smith also objects to this interrogatory as premature to the extent that it asks, prior to the close of discovery, for Upsher-Smith to describe in detail the basis for that statement. Furthermore, the interrogatory is argumentative and calls for a legal conclusion as to the right of other firms to enter the potassium chloride market.

Supplemental Response: Subject to and without waiving any objections, Upsher-Smith would not have launched Klor Con M20 without final resolution of the patent infringement litigation, up to and including a final appellate and perhaps even a Supreme Court decision. Any launch prior to this final resolution of the patent infringement litigation would have placed Upsher-Smith at a significant risk of having to pay substantial damages in case a lower court's decision was subsequently reversed on appeal. The combination of the lack of final resolution of the patent litigation and enormous ramp-up for successfully launching the new product, would have pushed Upsher-Smith's entry date beyond September 1, 2001. Pursuant to § 3.35(c) of the Federal Trade Commission Rules of Practice, Upsher-Smith also refers Complaint Counsel to Upsher-Smith's and Schering Plough's extensive document production, and among other documents, Upsher-Smith FTC 088067, Upsher-Smith FTC 123136-123137 and Upsher-Smith FTC 088477-088480 along with the expert report of William Kerr and in particular Exhibits 1-4 to his expert report.

4. Describe in detail the basis for the statement in Upsher's Statement of the Case, at p. 2, that "the drugs being licensed - most notably Niacor SR but the others as well - had value in line with the consideration received from Schering."

Specific Objections to Interrogatory 4: Upsher-Smith specifically objects to this interrogatory as irrelevant, vague, overly broad, overly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence. Upsher-Smith also objects because the documents are equally accessible and available to Complaint Counsel and they are already in their possession. Furthermore, this interrogatory is premature to the extent that it asks, prior to the close of discovery, for Upsher-Smith to describe in detail the facts that form the basis for the statement.

Supplemental Response: Subject to and without waiving any objections and pursuant to § 3.35(c) of the Federal Trade Commission Rules of Practice, Upsher-Smith refers Complaint Counsel to documents already produced to Complaint Counsel in Upsher-Smith's and Schering Plough's extensive and thorough document

production and among others documents, SP170001-170002. Upsher-Smith also refers Complaint Counsel to the expert reports of William Kerr (Exhibit 5 in particular) and Walter Bratic.

5. Describe in detail, including identification of the companies, summary of the substantive discussions, and listing of the amount of upfront payments discussed, the basis for the statement in Upsher's Statement of the Case, at p. 2, that "Upsher-Smith also had substantive discussions with major pharmaceutical companies about licensing Niacor SR in Europe, at least one of which indicated a willingness to pay substantial upfront payments."

Specific Objections to Interrogatory 5: Upsher-Smith specifically objects to this interrogatory as irrelevant, vague, overly broad, overly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence. Furthermore, it is unclear how much "detail" the interrogatory seeks. Furthermore, the interrogatory seeks confidential business information of non-parties, and it solicits information beyond Upsher-Smith's exclusive possession, custody, or control. Upsher-Smith also objects to this interrogatory as premature to the extent that it asks, prior to the close of discovery, for Upsher-Smith to describe in detail the basis for that statement.

Supplemental Response: Subject to and without waiving any objections and pursuant to § 3.35(c) of the Federal Trade Commission Rules of Practice, Upsher-Smith refers Complaint Counsel to documents already produced to Complaint Counsel in Upsher-Smith's and Schering Plough's extensive and thorough document production and among others documents, USL 11810-USL 11811, Moreton 0000700-Moreton 0000702 and Moreton 0000046-Moreton 0000049.

12. Describe in detail the basis for Upsher's contention, in Paragraph 46 of its Answer to the Complaint, that "Niacor SR was particularly promising and valuable."

Specific Objections to Interrogatory 12: Upsher-Smith objects to interrogatory 12 on the grounds that it is vague, overly broad, and overly burdensome. In particular, it is unclear what the word "detail" requires in this context. Upsher-Smith specifically objects to this interrogatory as premature to the extent that it asks, prior to the close of discovery, for Upsher-Smith to describe in detail the basis for that statement. In addition, Upsher-Smith objects to this interrogatory as it is argumentative. Upsher-Smith also objects to this interrogatory as premature to the extent that it asks, prior to the close of discovery, for Upsher-Smith to describe in detail the basis for that statement. Furthermore, Upsher-Smith objects to this interrogatory because it requests information that is already available to Complaint Counsel.

Supplemental Response: Subject to and without waiving any objections and pursuant to § 3.35(c) of the Federal Trade Commission Rules of Practice, Upsher-Smith refers Complaint Counsel to Upsher-Smith's and Schering Plough's extensive and thorough document production and among other documents, USL 11810-11811,

Moreton 0000046-Moreton 0000049 and SP 00040-SP 00047. Upsher-Smith also refers Complaint Counsel to the expert report of William Kerr (in particular Exhibits 6-12) and Walter Bratic.

14. Identify each instance since January 1, 1995, where Upsher paid $1 million or more in licensing fees and, in return, obtained a license for another company's pharmaceutical product (or otherwise obtained the right to market a pharmaceutical product that the other company owned or on which it held the patent rights). For each such instance:

(a) identify the company or entity receiving such payments;

(b) identify the pharmaceutical product(s) for which such payments were made;

(c) specify the projected annual dollar value of sales (at the time the parties entered into the license) of the pharmaceutical product(s) in the United States and other countries or regions (*e.g.*, Europe) covered by the license;

(d) specify the projected net present value of sales (at the time the parties entered into the license) of the pharmaceutical products(s) in the United States and other countries or regions (e.g., Europe) covered by the license;

(e) state the amount of the licensing fees to be paid under the terms of the license;

(f) state whether any or all of the licensing fees were unconditional or nonrefundable and, to the extent that they were not unconditional or nonrefundable, describe the circumstances under which any such fees could be or were to be refunded to Upsher;

(g) state whether under the license the licensor could receive and not refund to the licensee payments received or to be received, where the licensor failed to perform its obligations under the license (*e.g.*, failed to seek FDA approval of the product, failed to conduct or complete clinical trials necessary for FDA approval);

(h) state whether any or all of the licensing fees were milestone payments and, if so, state the circumstances under which the milestone payments could be or would be paid;

(i) state whether any royalty payments were provided for under the license and, if so, state the circumstances under which the royalty payments could be or would be paid (including royalty rates provided for);

(j) state whether any other form of compensation was provided for under the license and, if so, state the form of compensation (*e.g.*, stock, shared development costs) and the circumstances under which such compensation could be or would be paid; and

(k) describe the regulatory status at the time of the license of the pharmaceutical product(s) in each country in which any rights to sell or market the product were transferred to Schering in consideration for the licensing fees (*e.g.*, for the United States describe the status of FDA review and approval).

Objections to Interrogatory 14: Upsher-Smith objects to interrogatory 14 on the grounds that Complaint Counsel has exceeded the interrogatories permitted under both Federal Trade Commission Rule of Practice 3.35 and Judge Chappell's Scheduling Order. Upsher-Smith objects to interrogatory 14 on the grounds that it is irrelevant, vague, overly broad, overly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence. In particular, this interrogatory requests information regarding products that are not at issue or remotely relevant in the case. Furthermore, Upsher-Smith specifically objects to this interrogatory as premature to the extent that it asks, prior to the close of discovery, for Upsher-Smith to describe in detail the basis for that statement. Upsher-Smith also objects to this interrogatory because it requests information that is already available to Complaint Counsel.

Supplemental Response: Subject to and without waiving any objections, Upsher-Smith is not aware of any such agreements at this time.

Dated: December 21, 2001

Respectfully submitted,

WHITE & CASE LLP

By: _____

Robert D. Paul
J. Mark Gidley
Christopher M. Curran
Rajeev K. Malik
601 Thirteenth Street, N.W.
Washington, D.C. 20005-3807
Telephone: (202) 626-3600
Facsimile: (202) 639-9355

Attorneys for Upsher-Smith Laboratories, Inc.

Attachment D

UNITED STATES OF AMERICA
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 PUBLIC

UPSHER-SMITH'S OBJECTIONS AND RESPONSES TO COMPLAINT COUNSEL'S FIRST SET OF REQUESTS FOR ADMISSIONS

Pursuant to Federal Trade Commission Rules of Practice §3.32 Upsher-Smith Laboratories, Inc. submits these objections and responses to Complaint Counsel's First Set of Requests for Admissions to Upsher-Smith. The full text of each request is set forth below in italics, followed by Upsher-Smith's objections and responses. Provision of a response to any request shall not constitute a waiver of any applicable objection, privilege, or other right.

REQUESTS FOR ADMISSIONS

Request No. 1: Upsher-Smith is a legally organized corporation under the laws of the state of Minnesota.

ANSWER: Upsher-Smith admits that it is a corporation organized under the laws of the state of Minnesota.

Request No. 2: Upsher-Smith filed articles of incorporation with the state of Minnesota on May 1, 1970.

ANSWER: Upsher-Smith admits that it filed articles of incorporation with the state of Minnesota on May 1, 1970.

Request No. 3:

ANSWER:

Request No. 4:

ANSWER:

Request No. 5:

ANSWER:

Request No. 6:

ANSWER:

Request No. 7:

ANSWER:

Request No. 8:

ANSWER:

Request No. 9:

ANSWER:

Request No. 10:

ANSWER:

Request No. 11:

ANSWER:

Request No. 12: *Upsher-Smith manufactures pharmaceutical products at its facilities in Minnesota.*

ANSWER: Upsher-Smith admits that it manufactures pharmaceutical products at its facilities in Minnesota.

Request No. 13: *In 1997, Upsher-Smith manufactured pharmaceutical products at its facilities in Minnesota.*

ANSWER: Upsher-Smith admits that in 1997 it manufactured pharmaceutical products at its facilities in Minnesota.

Request No. 14:

ANSWER:

Request No. 15:

ANSWER:

Request No. 16: *Active pharmaceutical ingredients for its pharmaceutical products are shipped to Upsher-Smith's facilities in Minnesota by suppliers from facilities of those suppliers located outside Minnesota.*

ANSWER: Upsher-Smith objects to this Request as vague and ambiguous as it does not define "active pharmaceutical ingredients." Subject to this objection, Upsher-Smith admits that some ingredients for its pharmaceutical products are received from suppliers' facilities located outside Minnesota.

Request No. 17: *In 1997, active pharmaceutical ingredients for its pharmaceutical products were shipped to Upsher-Smith's facilities in Minnesota by suppliers from facilities of those suppliers located outside Minnesota.*

ANSWER: Upsher-Smith objects to this Request as vague and ambiguous as it does not define "active pharmaceutical ingredients." Subject to this objection, Upsher-Smith admits that some ingredients for its pharmaceutical products were received from suppliers' facilities located outside Minnesota in 1997.

Request No. 18: Upsher-Smith receives payments transferred across state lines in exchange for its pharmaceutical products.

ANSWER: Upsher-Smith objects to this Request as the expression "payments transferred across state lines in exchange for pharmaceutical products" is vague and ambiguous. Subject to this objection, Upsher-Smith admits that it receives some payments by mail from other states in exchange for pharmaceutical products.

Request No. 19: *In 1997, Upsher-Smith received payments transferred across state lines in exchange for its pharmaceutical products.*

ANSWER: Upsher-Smith objects to this Request as the phrase "payments transferred across state lines in exchange for pharmaceutical products" is vague and ambiguous. Upsher-Smith admits that in 1997 it received some payments by mail from other states.

Request No. 20: Upsher-Smith authorizes transfer of funds across state lines in exchange for active pharmaceutical ingredients.

ANSWER: Upsher-Smith objects to this Request as the phrases "transfer of funds" and "active pharmaceutical ingredients" are vague and ambiguous. Upsher-Smith admits that it has paid funds across state lines in exchange for ingredients.

Request No. 21: In 1997, Upsher-Smith authorized transfer of funds across state lines in exchange for active pharmaceutical ingredients.

ANSWER: Upsher-Smith objects to this Request as the phrases "transfer of funds" and "active pharmaceutical ingredients" are vague and ambiguous. Upsher-Smith admits that it in 1997 it paid funds across state lines in exchange for ingredients.

Request No. 22:

ANSWER:

Request No. 23:

ANSWER:

Request No. 24:

ANSWER:

Request No. 25:

ANSWER:

Request No. 26:

ANSWER:

Dated. September 10, 2001

Respectfully submitted,

WHITE & CASE LLP

By: _____

Robert D. Paul
J. Mark Gidley
Christopher M. Curran
Gustav P. Chiarello
601 Thirteenth Street, N.W.
Washington, D.C. 20005-3807
Telephone: (202) 626-3600
Facsimile: (202) 639-9355

Attorneys for Upsher-Smith Laboratories, Inc.

CERTIFICATE OF SERVICE

I, J. Carlos Alarcon, hereby certify that on September 10, 2001, I caused a copy of Upsher-Smith's Objections and Responses to Complaint Counsel's First Set of Requests for Admissions to be served upon the following persons by courier delivery.

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

Karen G. Bokat
Federal Trade Commission, 3115
601 Pennsylvania Avenue, N.W.
Washington, DC 20580

Laura S. Shores
Howrey Simon Arnold & White
1299 Pennsylvania Avenue, N.W.
Washington, DC 20004

Cathy Hoffman
Arnold & Porter
Thurman Arnold Building
555 Twelfth Street, N.W.
Washington, DC 20004-2113

J. Carlos Alarcon

Attachment E

UNITED STATES OF AMERICA
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 PUBLIC

UPSHER-SMITH'S OBJECTIONS AND RESPONSES TO COMPLAINT COUNSEL'S REVISED THIRD REQUESTS FOR ADMISSIONS

Pursuant to Federal Trade Commission Rules of Practice for Adjudicative Proceedings § 3.32, Upsher-Smith hereby submits these responses and objections to Complaint Counsel's Revised Third Requests for Admissions. Upsher-Smith's response to any Request shall not constitute a waiving any applicable objection privilege, immunity or other right. Furthermore, Upsher-Smith notes that it is responding to the Requests on an accelerated basis and therefore reserves the right to modify its answers in any respect.

UPSHER-SMITH'S OBJECTIONS AND RESPONSES

Request No. 4: As of September 2001, the FDA is prohibited from approving another generic version of the branded product until either (1) the First Filer's 180-day Exclusivity Period has elapsed, or (2) the First Filer relinquishes or loses its eligibility to the 180-day Exclusivity Period.

Answer:

Upsher-Smith objects insofar as the Request calls for a legal conclusion. Upsher-Smith further objects to the Request as vague and ambiguous due to, among other reasons, the lack of clarity as to the terms "prohibited," "branded product," "approving," and "eligibility." Additionally, Upsher-Smith objects that the Request is circular in that it essentially asks if exclusivity exists until it is lost. Subject to and without waiving its objections, Upsher-Smith denies the Request as it calls for information that is necessarily beyond Upsher-Smith's factual knowledge.

Request No. 8: Upsher's 180-day Exclusivity Period was triggered on September 1, 2001.

Answer:

Upsher-Smith objects to the request to the extent it requires a legal conclusion as to, among other reasons, whether Upsher-Smith has exclusivity and as to what constitutes a "trigger." Upsher-Smith further objects to the Request insofar as it does not specify the product at issue, and the term "triggered" is vague and ambiguous as used in the Request. Subject to and without waiving its objections, even assuming the Request refers to Klor-Con M20, Upsher-Smith admits that it began commercial marketing Klor-Con M20 on September 1, 2001. Upsher-Smith denies the remainder of the Request, and refers Complaint Counsel to the January 28, 1999 letter from FDA to Upsher-Smith ( ), but offers no opinion as to whether

FDA's grant of eligibility for 180-day exclusivity survived until September 2001 or would have withstood a legal challenge from a competitor.

Request No. 9: As of September 2001, no ANDA for a generic version of K-Dur 20, other than ANDA 74-726, can receive final approval from the FDA until Upsher's 180-day Exclusivity Period has expired.

Answer:

Upsher-Smith objects to the Request because it calls for a legal conclusion. Upsher-Smith further objects to the Request as overbroad and ambiguous. Subject to and without waiving its objections, Upsher-Smith denies the Request and refers Complaint Counsel to the January 28, 1999, letter from FDA to Upsher-Smith ( ), but offers no opinion as to whether FDA's grant of eligibility for 180-day exclusivity survived until September 2001 or would have withstood a legal challenge from a competitor.

Request No. 10:

Answer:

Upsher-Smith objects to the Request as vague and ambiguous because, among other reasons, the meaning of "bioequivalent to a brand product" and "brand product" is not clear.

Subject to and without waiving its objections, Upsher-Smith denies the Request as vague and confusing, and it is unclear what information is being

requested. Upsher-Smith admits that it consistently offers cost-effective alternatives to high-cost brand products.

Request No. 21:

Answer:

Upsher-Smith objects to the Request because it is vague and ambiguous, because, among other reasons, the terms "meeting," "possible," "scenarios" and "discussed" are unclear.

Request No. 22:

Answer:

Upsher-Smith objects to the Request because it is vague and ambiguous, because, among other reasons, the terms "meeting," "possible," "scenarios" and "discussed" are unclear.

Request No. 23:

Answer:

Upsher-Smith objects to the Request because it is vague and ambiguous, because, among other reasons, the terms "meeting," "possible," "scenarios" and "discussed" are unclear.

Request No. 24:

Answer:

Upsher-Smith objects to the Request because it is vague and ambiguous, because, among other reasons, the terms "meeting," "possible," "scenarios" and "discussed" are unclear.

Request No. 25:

Answer:

Upsher-Smith objects to the Request because it is vague and ambiguous, because, among other reasons, the terms "meeting," "possible," "scenarios" and "discussed" are unclear.

Request No. 26:

Answer:

Upsher-Smith objects to the Request as vague and ambiguous because, among other things, the meaning of " " is unclear. Subject to and without waiving its objections, Upsher-Smith denies the Request

Request No. 27:

Answer:

Upsher-Smith objects to the Request as vague and ambiguous because, among other things, the meaning of " " is unclear. Subject to and without waiving its objections, Upsher-Smith denies the Request as

Request No. 28:

Answer:

Upsher-Smith objects to the Request as vague and ambiguous because, among other reasons, the meaning of " " is unclear as used in the Request. Subject to and without waiving its objections, Upsher-Smith admits that

Request No. 29:

Answer:

Upsher-Smith objects to the Request as vague and ambiguous because, among other reasons, the meaning of " " and " " is unclear as used in the Request. Upsher-Smith further objects that the Request calls for information beyond Upsher-Smith's knowledge. Subject to and without waiving its objections, Upsher-Smith denies the Request because

Request No. 40: In the Schering/Upsher Patent Litigation, Upsher never took the position in papers filed with the New Jersey District Court that Upsher's generic version of K-Dur 20 infringed the '743 Patent listed in the Orange Book for K-Dur 20.

Answer:

Complaint Counsel has access to all the papers and documents referred to in the Request, and these documents provide the best evidence to the positions Upsher-Smith may or may not have taken in the litigation referenced in the Request. Upsher-Smith objects to the Request

insofar as it requires Upsher-Smith to review information already provided to Complaint Counsel to answer the Request. Moreover, Upsher-Smith notes that a position taken in a court proceeding does not necessarily constitute an admission in a subsequent proceeding. Finally, Upsher-Smith notes that the New Jersey District Court never found non-infringement. Subject to and without waiving its objections, Upsher-Smith on information and belief admits the Request.

Request No. 41: In the Schering/Upsher Patent Litigation, Upsher had a reasonable basis for asserting that, with respect to the '743 Patent, prosecution history estoppel applied so as to preclude Schering from asserting that Upsher's generic version of K-Dur 20 infringed the '743 Patent.

Answer:

Upsher-Smith objects on the grounds that the Request calls for a legal conclusion as to whether an argument advanced in litigation had a "reasonable basis." Upsher-Smith further objects to the Request because the issue posed in the Request was never considered by the Court. Upsher-Smith notes that a position taken in a prior court proceeding does not constitute an admission in a subsequent proceeding. Subject to and without waiving its objections, after diligent inquiry Upsher-Smith can neither admit nor deny the Request.

Request No. 43 : In the Schering/Upsher Patent Litigation, Upsher never took the position in papers filed with the New Jersey District Court that the '743 Patent was valid.

Answer:

Complaint Counsel has access to all the papers and documents referred to in the Request, and these documents provide the best evidence to the positions Upsher-Smith may or may not have taken in the litigation referenced in the Request. Upsher-Smith objects to the Request insofar as it requires Upsher-Smith to review information already provided to Complaint Counsel to answer the Request. Moreover, Upsher-Smith notes that a position taken in a court proceeding does not necessarily constitute an admission in a subsequent proceeding. Upsher-

Smith further notes there is a strong presumption as to the validity of a patent. Subject to and without waiving its objections, Upsher-Smith upon information and belief admits it did not take the position that the '743 Patent was valid, but Schering-Plough did and the Court never resolved the issue.

Request No. 44: In the Schering/Upsher Patent Litigation, Upsher never took the position in papers filed with the New Jersey District Court that the '743 Patent was enforceable.

Answer:

Complaint Counsel has access to all the papers and documents referred to in the Request, and these documents provide the best evidence to the positions Upsher-Smith may or may not have taken in the litigation referenced in the Request. Upsher-Smith objects to the Request insofar as it requires Upsher-Smith to review information already provided to Complaint Counsel to answer the Request. Moreover, Upsher-Smith notes that a position taken in a court proceeding does not necessarily constitute an admission in a subsequent proceeding. Subject to and without waiving its objections, upon information and belief Upsher admits it did not take the position that the '743 Patent was enforceable, but Schering-Plough did and the court never resolved the issue.

Request No. 51: The New Jersey District Court made no finding that Upsher's generic version of K-Dur 20 was likely to infringe the '743 Patent.

Answer:

Upsher-Smith objects to the Request insofar as it requires Upsher-Smith to review the information already provided to Complaint Counsel to answer the Request. Moreover, Upsher-Smith notes that a position taken in a court proceeding does not necessarily constitute an admission in a subsequent proceeding. Subject to and without waiving its objections, upon

information and belief, Upsher-Smith admits that the District Court made no finding that Upsher-Smith's generic version of K-Dur 20 was likely or unlikely to infringe the '743 Patent.

Request No. 52: The New Jersey District Court made no finding that the '743 Patent is not invalid.

Answer:

Upsher-Smith objects to the Request insofar as it requires Upsher-Smith to review the information already provided to Complaint Counsel to answer the Request. Moreover, Upsher-Smith notes that a position taken in a court proceeding does not necessarily constitute an admission in a subsequent proceeding. Upsher-Smith also objects to the Request on the grounds that it is confusing, as Complaint Counsel prepared the Request in terms of a triple-negative. Further, Upsher-Smith notes that there is a strong presumption as to the validity of a patent. Subject to and without waiving its objections, upon information and belief, Upsher-Smith admits that the District Court made no finding that the '743 patent was valid or invalid.

Request No. 53: The New Jersey District Court made no finding that the '743 Patent is enforceable.

Answer:

Upsher-Smith objects to the Request insofar as it requests Upsher-Smith to review all of the information already provided to Complaint Counsel to answer the Request. Moreover, Upsher-Smith notes that a position taken in a court proceeding does not necessarily constitute an admission in a subsequent proceeding. Subject to and without waiving its objections, upon information and belief Upsher-Smith admits that the New Jersey District Court made no finding that the '743 patent is enforceable or unenforceable.

Request No. 58: At the time of the Schering/Upsher Agreement, there was a possibility that Upsher could have won the Schering/Upsher Patent Litigation if it continued the Schering/Upsher Patent Litigation.

Answer:

Upsher-Smith objects that the Request requires a legal conclusion. Upsher-Smith further objects to the Request as vague. The terms "possibility" and "won" have not been defined and are confusing and ambiguous. The Request is also argumentative. Furthermore, the Request calls for speculation and is therefore denied.

Request No. 59: At the time of the Schering/Upsher Agreement, Upsher believed that it could have won the Schering/Upsher Patent Litigation if it continued the Schering/Upsher Patent Litigation.

Answer:

Upsher-Smith objects to the Request as vague and overbroad. Upsher-Smith objects to the Request in that it seeks information protected by Attorney-Client Privilege. The terms "Upsher believed" and "won" have not been defined and are vague and ambiguous. Upsher-Smith is a corporation and unable to form a collective belief as a factual matter. Thus, the Request is denied.

Request No. 60: At the time of the Schering/Upsher Agreement, it was not certain that Schering would prevail in the Schering/Upsher Patent Litigation.

Answer:

Upsher-Smith objects to the Request as vague and ambiguous. The terms "not certain" and "would prevail" have not been defined and are vague and confusing. Upsher-Smith is a corporation unable to form a collective belief as a factual matter. Upsher-Smith objects to and denies the Request insofar as it requires speculation on the part of Upsher-Smith.

Request No. 72: On November 20, 1998, Upsher received final FDA approval for its generic version of K-Dur 20.

Answer:

Upsher-Smith objects to the Request as it seeks a legal conclusion as to final FDA approval. Upsher-Smith objects to the term "final" as vague and ambiguous. Upsher-Smith refers Complaint Counsel to which is the best evidence of the information sought in the Request. Subject to and without waiving its objections, Upsher-Smith admits the Request.

Request No. 73: As of November 20, 1998, FDA law and regulations permitted Upsher to begin the commercial sale of its generic version of K-Dur 20.

Answer:

Upsher-Smith objects to the Request insofar as it requires a legal conclusion as to "FDA law and regulations." Moreover, Upsher-Smith objects to the term "FDA law and regulations" as vague and ambiguous. Upsher-Smith denies the Request because, upon information and belief, Upsher-Smith had to meet other FDA requirements prior to beginning the commercial sale of Klor Con M20.

Request No. 74: Upsher did not begin the commercial sale of its generic version of K-Dur 20 on November 20, 1998 or at any time prior to September 1, 2001.

Answer:

Upsher-Smith objects to the Request to the extent the term "commercial sale" requires a legal conclusion. Upsher-Smith further objects to the Request as vague, because the phrase "begin the commercial sale" is vague and can have multiple meanings. Subject to and without waiving its objections, Upsher-Smith admits the Request.

Request No. 78:

Answer:

Request No. 83:

Answer:

Request No. 84:

Answer:

Request No. 85:

Answer:

Request No. 87:

Answer:

Request No. 88:

Answer:

Request No. 89:

Answer:

Request No. 90:

Answer:

Upsher-Smith objects to the Request as it calls for information necessarily beyond its knowledge as to action by

Request No. 95:

Answer:

Upsher-Smith objects to the Request because it calls for information beyond Upsher-Smith's knowledge.

Request No. 96:

Answer:

Upsher-Smith objects to the Request because it calls for information beyond Upsher-Smith's knowledge.

Request No. 97:

Answer:

Upsher-Smith objects to the Request because it calls for information beyond Upsher-Smith's knowledge.

Request No. 98:

Answer:

Upsher-Smith objects to the Request as it requests information beyond the knowledge of Upsher-Smith.

Request No. 99:

Answer:

Request No. 100:

Answer:

Request No. 103:

Answer:

Request No. 104:

Answer:

Request No. 105:

Answer:

Request No. 106:

Answer:

Request No. 120: The Schering/Upsher Agreement was not presented to the New Jersey District Court for approval.

Answer:

Upsher-Smith objects to the Request insofar as it requests Upsher-Smith to review the information already provided to Complaint Counsel to answer the Request. Subject to and without waiving its objections, Upsher-Smith, upon information and belief, admits that the Schering/Upsher Agreement was not presented to the New Jersey District Court for approval.

Further, Upsher-Smith, upon information and belief, notes that the New Jersey District Court never requested and never required that the Agreement be submitted.

Request No. 121: The New Jersey District Court did not approve the Schering/Upsher Agreement.

Answer:

Upsher-Smith objects to the Request insofar as it requests Upsher-Smith to review the information already provided to Complaint Counsel to answer the Request. Subject to and without waiving these objections, Upsher-Smith, upon information and belief, admits that the New Jersey District Court did not approve the Schering/Upsher-Smith Agreement. Upsher-Smith notes, upon information and belief, that the New Jersey District Court never required and did not request approval of the Agreement.

Request No. 122: The Schering/Upsher Agreement was not presented to any federal district court for approval.

Answer:

Upsher-Smith objects to the Request insofar as it requests Upsher-Smith to review the information already provided to Complaint Counsel to answer the Request. Subject to and without waiving its objections, Upsher-Smith, upon information and belief, admits that the Schering/Upsher-Smith Agreement was not presented to any federal district court for approval. Upon information and belief, Upsher-Smith notes that no federal district court required or requested that the Agreement be so presented.

Request No. 123: The Schering/Upsher Agreement was not approved by any federal district court.

Answer:

Upsher-Smith objects to the Request insofar as it requests Upsher-Smith to review the information already provided to Complaint Counsel to answer the Requests. Subject to and without waiving its objections, Upsher-Smith, upon information and belief, admits that the Agreement was not approved by any federal district court. Upsher-Smith notes, upon information and belief, that no federal district court required or requested that the Agreement be approved.

Request No. 124:

Answer:

Request No. 129:

Answer:

Request No. 130:

Answer:

Request No. 131:

Answer:

Request No. 132:

Answer:

Request No. 133:

Answer:

Request No. 135:

Answer:

Request No. 136:

Answer:

Request No. 138:

Answer:

Request No. 139:

Answer:

Request No. 140:

Answer:

Request No. 141:

Answer:

Request No. 142:

Answer:

Request No. 143:

Answer:

Request No. 157: Warrick, a part of Schering, began selling a bioequivalent alternative to K-Dur 20 in September 2001.

Answer:

Upsher-Smith objects to the Request because it seeks information beyond Upsher-Smith's knowledge. Subject to and without waiving its objections, Upsher-Smith, upon information and belief, admits that Warrick began selling a generic alternative to K-Dur 20 earlier this year.

Request No. 158: Substitution from a brand product to its bioequivalent or AB-rated generic product occurs at a faster rate in 2001 than it did in 1997.

Answer:

Upsher-Smith objects to the Request because it is vague and overbroad, because, among other reasons, the terms "substitution," and "bioequivalent" are vague as used in the Request. Upsher-Smith further objects because the Request calls for information beyond its knowledge, and any such answer would require speculation on the part of Upsher-Smith. Upsher-Smith further objects to the Request insofar as it requests information that is irrelevant to the allegations in this matter. Subject to and without waiving its objections, Upsher-Smith denies the Request because it calls for speculation, and calls for information irrelevant to this matter.

Request No. 161:

Answer:

Request No. 163:

Answer:

Request No. 173:

Answer:

Request No. 174:

Answer:

Request No. 176:

Answer:

Request No. 178:

Answer:

Request No. 179:

Answer:

Request No. 180:

Answer:

Request No. 241:

Answer:

Request No. 274: Elevated levels of liver enzyme SGOT in the bloodstream are an indication of either liver disease or liver damage.

Answer:

Upsher-Smith objects to the Request as vague and ambiguous. Subject to and without waiving its objections, Upsher-Smith denies the Request. Assuming SGOT refers to "serum glutamic oxaloacetic transaminase," elevated SGOT levels may be found in organs other than the

liver and may be the result of muscle damage unrelated to the liver, such that elevated SGOT levels do not necessarily indicate "liver disease or liver damage."

Request No. 275: Elevated levels of liver enzyme SGPT in the bloodstream are an indication of either liver disease or liver damage.

Answer: Upsher-Smith objects to the Request as vague and ambiguous. Subject to and without waiving its objections, Upsher-Smith denies the Request. Assuming SGPT refers to "transaminase, serum glutamic pyruvic," this enzyme is normally present in liver and heart cells and may be elevated due to an insult to the heart, such as from a heart attack, or even from certain medications, such as, for example, Advil. Interpretation of elevated SGPT depends on context.

Request No. 285:

Answer:

Request No. 286:

Answer:

Request No. 287:

Answer:

Request No. 288:

Answer:

Request No. 289:

Answer:

Request No. 290:

Answer:

Request No. 291:

Answer:

Request No. 292:

Answer:

Request No. 294:

Answer:

Request No. 299:

Answer:

Request No. 301:

Answer:

Request No. 302:

Answer:

Request No. 304:

Answer:

Request No. 306:

Answer:

Request No. 310:

Answer:

Request No. 312: Kos's Niaspan product was a once-daily formulation of niacin.

Answer:

Upsher-Smith objects to "was" as used in the Request as vague, confusing and ambiguous as to time. Upsher-Smith objects to the Request to the extent it implies the formulation of Kos's Niaspan changed at some point. Subject to and without waiving its objections, Upsher-Smith admits that in 1997 Kos's Niaspan product was a once-daily formation of niacin.

Request No. 318:

Answer:

Request No. 319:

Answer:

Request No. 320:

Answer:

Request No. 322:

Answer:

Request No. 324:

Answer:

Request No. 329:

Answer:

Request No. 330:

Answer:

Request No. 332:

Answer:

Request No. 334:

Answer:

Dated: November 13, 2001

Respectfully submitted,

WHITE & CASE LLP

By: _____

Robert D. Paul
J. Mark Gidley
Christopher M. Curran
Rajeev K. Malik
601 Thirteenth Street, N.W.
Washington, D.C. 20005-3807
Telephone: (202) 626-3600
Facsimile: (202) 639-9355

Attorneys for Upsher-Smith Laboratories, Inc.

CERTIFICATE OF SERVICE

I, Dennis Kelly, hereby certify that on November 13, 2001, I caused a copy of Upsher-Smith's Responses And Objections To Complaint Counsel's Revised Third Request For Admissions to be served upon the following persons by facsimile, electronic mail and on November 14, 2001 by hand delivery:

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

Karen G. Bokat
Federal Trade Commission, 3115
601 Pennsylvania Avenue, N.W.
Washington, DC 20580

Laura S. Shores
Howrey Simon Arnold & White
1299 Pennsylvania Avenue, N.W.
Washington, DC 20004

Dennis M. Kelly

Attachment F

PUBLIC VERSION

UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

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

RESPONDENT SCHERING-PLOUGH CORPORATION'S OBJECTIONS AND RESPONSES TO COMPLAINT COUNSEL'S REVISED SECOND REQUEST FOR ADMISSIONS

Pursuant to Federal Trade Commission ("FTC") Rule of Practice Section 3.32, respondent Schering-Plough Corporation ("Schering") submits these objections and responses to Complaint Counsel's Revised Second Request for Admissions.

GENERAL OBJECTIONS AND STATEMENT

Schering objects to Complaint Counsel's Revised Second Requests for Admissions to the extent that they seek to impose on Schering burdens or duties inconsistent with or in addition to those requested under the FTC's Rules of Practice. Schering further objections to the "Definitions" and "Instructions" provided with these requests to the extent that they are vague or ambiguous and to the extent that they impose requirements beyond those imposed by the FTC's Rules of Practice.

GENERAL OBJECTIONS TO COMPLAINT COUNSEL'S DEFINITIONS AND INSTRUCTIONS

1. Schering objects to Complaint Counsel's definition of "Schering," on the ground that it is overly broad and unduly burdensome. Schering objects to the extent that these definitions would require Schering to search for and provide information on behalf of its or any other companies' predecessors, divisions, subsidiaries, and affiliates to the extent that such entities are not substantially involved in the pricing, marketing, sale, or distribution of Schering's brand name pharmaceutical products. Schering also objects to the extent that such entities are not substantially involved in the settlement of patent disputes or the valuation of licensing arrangements. Schering further objects to the extent that the definitions would require Schering to provide information not within its possession, custody, or control. Schering objects to the terms "agents" to the extent that it purports to encompass inside or outside counsel because such an interpretation would require Schering to search for and provide information protected by the attorney-client privilege or the attorney work product doctrine.

2. Schering objects to Complaint Counsel's definition of "Schering/AHP Points of Agreement," as overly broad, inaccurate and confusing. Schering objects to the extent that the definition describes the "Schering/AHP Points of Agreement" as an "Agreement" and the inaccurate inference that the points of agreement reflect the final terms agreed upon by the parties with respect to settlement and licensing issues. The "Schering/AHP Points of Agreement" is an agreement in principle that established the overall objectives of the parties with respect to settlement and pharmaceutical licensing.

3. Schering objects to Complaint Counsel's definition of "Schering/Upsher Agreement" as inaccurate. Schering objects to the extent that Complaint Counsel defines the Agreement as having been reached on June 17, 1997. To the contrary, the Agreement was signed and executed by the parties on June 18, 1998.

4. Schering objects to Complaint Counsel's definition of "June 1998 Schering/AHP Agreement" on the ground that it is inaccurate and confusing. Schering objects to the extent that Complaint Counsel defines the Agreement as being contained in documents SP 13 00070-00089. The June 1998 Agreement between Schering and AHP also contains the documents SP 13 00070-00089 - SP 15 00053-00152.

5. Schering objects to Complaint Counsel's definition of "Schering's June 1997 Niacor-SR Evaluation" as inaccurate, incomplete and confusing. Schering objects to Complaint Counsel's definition to the extent that it inaccurately attempts to limit the scope of Schering's evaluation.

6. Schering objects to Complaint Counsel's definition of "Schering's Regulatory Affairs Group" as overly broad, vague and confusing. Schering does not use the term "Regulatory Affairs Group" and, as defined by Complaint Counsel, the term could include any number of Schering employees. Further, Mr. Thomas Lauda does not refer to a "Schering's Regulatory Affairs Group" in his September 24, 2001, deposition.

7. Schering objects to Complaint Counsel's definition of "Schering's Manufacturing Group" as overly broad, vague and confusing. Schering does not have a discrete "Manufacturing Group," as implied in Complaint Counsel's definition. By contrast, Complaint Counsel's definition could include any number of employees within Schering that have responsibility for aspects of the planning for and actual manufacture of pharmaceutical products.

8. Schering objects to Complaint Counsel's definition of "Schering's Intellectual Property Group" as overly broad, vague and confusing. Schering does not have a discrete "Intellectual Property Group," as implied by Complaint Counsel's definition. By contrast, Complaint Counsel's definition could include any number of employees within Schering that have responsibility for aspects of intellectual property protection and review.

9. Schering objects to Complaint Counsel's definition of "Average Selling Price" as vague and confusing and provides no discernable definition of the actual meaning of the term. "Average Selling Price" is not a term that is used by Schering in its business conduct and is not a term that has been used by Schering in its interrogatories. Further, Complaint Counsel's definition of "Average Selling Price" is derived from Upsher documents and any definition attributed to the term by Upsher is not known to Schering. Moreover, as the term "Average Selling Price" has not been used in the current request, Schering objects to its unnecessary inclusion within these requests.

SPECIFIC OBJECTIONS AND REQUESTS

The full text of each request is set forth below in italics, followed by Schering's objections and responses. Provision of a response to any request shall not constitute a waiver of any applicable objection, privilege, or other right and, unless otherwise specifically stated, Schering denies each of Complaint Counsel's requests. In addition, the general objections set forth above are incorporated into each specific response below as if set forth fully therein. In those instances in which Schering responds by noting that it can neither admit nor deny the request, the information Schering currently possesses is inadequate to provide a more substantive response, and Schering is making reasonable inquiry with respect to such request. Finally, Schering reserves the right to supplement these responses as necessary.

Request No. 8: *As of September 2001, the FDA is prohibited from approving another generic version of the branded product until either (1) the First Filer's 180-day Exclusivity Period has elapsed, or (2) the First Filer relinquishes or loses its eligibility to the 180-day Exclusivity Period.*

Answer: Schering objects to this request on the ground that it is a pure question of law, calling for a pure legal conclusion.

Request No. 13: *As of September 2001, no ANDA for a generic version of K-Dur 20, other than ANDA 74-726, can receive final approval from the FDA until Upsher's 180-day Exclusivity Period has expired.*

Answer: Schering can neither admit nor deny this request on the ground that the law is unclear regarding whether, as of September 2001, no ANDA for a generic version of K-Dur 20, other than ANDA 74-726, can receive final approval from the FDA until any period of exclusivity enjoyed by Upsher has expired.

Request No. 29: *In the Schering/Upsher Patent Litigation, Upsher never took the position in papers filed with the New Jersey District Court that Upsher's generic version of K-Dur 20 infringed the '743 Patent listed in the Orange Book for K-Dur 20.*

Answer: Admitted.

Request No. 32: *In the Schering/Upsher Patent Litigation, Upsher never took the position in papers filed with the New Jersey District Court that the '743 Patent was valid.*

Answer: Admitted.

Request No. 33: *In the Schering/Upsher Patent Litigation, Upsher never took the position in papers filed with the New Jersey District Court that the '743 Patent was enforceable.*

Answer: Admitted.

Request No. 39: *The New Jersey District Court made no finding that Upsher's generic version of K-Dur 20 infringed the '743 Patent.*

Answer: Admitted. The Schering/Upsher litigation was settled before trial, and therefore, the New Jersey District Court made no findings one way or the other.

Request No. 40: *The New Jersey District Court made no finding that Upsher's generic version of K-Dur 20 was likely to infringe the '743 Patent.*

Answer: Admitted. The Schering/Upsher litigation was settled before trial, and therefore, the New Jersey District Court made no findings one way or the other.

Request No. 41: *The New Jersey District Court made no finding that the '743 Patent is not invalid.*

Answer: Admitted. The Schering/Upsher litigation was settled before trial, and therefore, the New Jersey District Court made no findings one way or the other.

Request No. 42: *The New Jersey District Court made no finding that the '743 Patent is enforceable.*

Answer: Admitted. The Schering/Upsher litigation was settled before trial, and therefore, the New Jersey District Court made no findings one way or the other.

Request No. 47: *At the time of the Schering/Upsher Agreement, there was a possibility that Upsher could have won the Schering/Upsher Patent Litigation if it continued the Schering/Upsher Patent Litigation.*

Answer: Schering admits that, in any litigation, there is a "possibility" that either side "could" win.

Request No. 48: *At the time of the Schering/Upsher Agreement, Schering believed that Upsher could have won the Schering/Upsher Patent Litigation if it continued the Schering/Upsher Patent Litigation.*

Answer: Schering objects to this request to the extent that it calls for information protected by the attorney-client privilege. Subject to and without waiving the foregoing objection, Schering admits that, in any litigation, there is a possibility that either litigant "could" win.

Request No. 49: *At the time of the Schering/Upsher Agreement, it was not certain that Schering would prevail in the Schering/Upsher Patent Litigation.*

Answer: Schering admits that, in any litigation, it is "not certain" which party will prevail.

Request No. 57: *On November 20, 1998, Upsher received final FDA approval for its generic version of K-Dur 20.*

Answer: Admitted.

Request No. 58: *As of November 20, 1998, FDA law and regulations permitted Upsher to begin the commercial sale of its generic version of K-Dur 20.*

Answer: Admitted.

Request No. 59: *Upsher did not begin the commercial sale of its generic version of K-Dur 20 on November 20, 1998 or at anytime prior to September 1, 2001.*

Answer: Admitted.

Request No. 63: *Under the Schering/Upsher Agreement, the phrase "any other sustained release microencapsulated potassium chloride tablet" could include a microencapsulated potassium chloride tablet that did not infringe the '743 Patent.*

Answer: Admitted because the potassium chloride tablet at issue in the Schering/Upsher patent litigation could itself be a tablet that did not infringe. As a result of the Schering/Upsher settlement, this issue was not resolved by the court. The language quoted was intended to include other microencapsulated potassium chloride tablets presenting the same or similar litigable issues.

Request No. 68: *Under the Schering/Upsher Agreement, Schering's $60 million in Up-Front Payments to Upsher were unconditional.*

Answer: Denied. Under the Schering/Upsher Agreement, the payments to Upsher were conditional upon, amongst other things, board approval and the obligations of good faith and fair dealing.

Request No. 69: *Under the Schering/Upsher Agreement, Schering's $60 million in Up-Front Payments to Upsher were not contingent on Upsher taking any actions or satisfying any conditions concerning the development of Niacor-SR.*

Answer: Admitted, except that Upsher was obligated to make available to Schering clinical trial data and intellectual property.

Request No. 70: *Under the Schering/Upsher Agreement, if Upsher abandoned the development of Niacor-SR, Upsher would still receive the full $60 million in Up-Front Payments.*

Answer: Admitted, but only so long as Upsher complied with its obligation to make clinical trial data and intellectual property available to Schering.

Request No. 72: *Under the Schering/Upsher Agreement, if Upsher abandoned the development of Niacor-SR, and did not inform Schering that it, Upsher, had abandoned the development of Niacor-SR, Upsher would still receive the full $60 million in Up-Front Payments.*

Answer: Schering admits this request, excepting that the payments to Upsher were conditional upon Upsher's obligations of good faith and fair dealing.

Request No. 73: *Schering made a payment of $28 million to Upsher within 48 hours of the date on which the Schering/Upsher Agreement was approved by Schering's Board of Directors.*

Answer: Admitted.

Request No. 74: *Schering made a payment of $20 million to Upsher approximately one year from the date on which the Schering/Upsher Agreement was approved by Schering's Board of Directors.*

Answer: Admitted.

Request No. 75: *Schering made a payment of $12 million to Upsher approximately two years from the date on which the Schering/Upsher Agreement was approved by Schering's Board of Directors.*

Answer: Admitted.

Request No. 80: *Since June 1997, Schering has made no sales of Pentoxifylline pursuant to the license obtained in the Schering/Upsher Agreement.*

Answer: Admitted.

Request No. 81: *Schering had no intention, as of September 2001, to sell Pentoxifylline pursuant to the license obtained in the Schering/Upsher Agreement.*

Answer: Schering admits that, by September 2001, it no longer had plans to sell Pentoxifylline.

Request No. 82: *Since June 1997, Schering has made no sales of KLOR CON products pursuant to the license obtained in the Schering/Upsher Agreement.*

Answer: Admitted.

Request No. 83: *Schering had no intention, as of September 2001, to sell the KLOR CON products pursuant to the license obtained in the Schering/Upsher Agreement.*

Answer: Schering admits that, by September 2001, it no longer had plans to sell Klor-Con products.

Request No. 84: *Since June 1997, Schering has made no sales of Niacor-SR pursuant to the license obtained in the Schering/Upsher Agreement.*

Answer: Admitted.

Request No. 85: *Schering had no intention, as of September 2001, to sell Niacor-SR pursuant to the license obtained in the Schering/Upsher Agreement.*

Answer: Schering admits that, by September 2001, it no longer had plans to sell Niacor-SR.

Request No. 86: *Since June 1997, Schering sales of Prevalite, pursuant to the license obtained in the Schering/Upsher Agreement, have totaled less than $1 million.*

Answer: Admitted.

Request No. 87: *Schering had no intention, as of September 2001, to make any additional sales of Prevalite pursuant to the license obtained in the Schering/Upsher Agreement.*

Answer: Schering admits that, by September 2001, it no longer had plans for additional sales of Prevalite as of September 2001.

Request No. 92: *The Schering/Upsher Agreement placed no obligation on Schering to carry out any activities concerning the marketing of Niacor-SR in Europe.*

Answer: Denied. The Schering/Upsher license contemplated a "detailed agreement," and drafts of that agreement placed an obligation on Schering to carry out activities concerning the marketing of Niacor-SR in Europe.

Request No. 94: *The Schering/Upsher Agreement did not contain any warranties or representations by Upsher regarding its intellectual property rights relating to Niacor-SR.*

Answer: Denied.

Request No. 121: *In the Schering/AHP Patent Litigation, AHP never took the position in papers filed with the Pennsylvania District Court that AHP's generic version of K-Dur 20 infringed the '743 Patent listed in the Orange Book for K-Dur 20.*

Answer: Admitted.

Request No. 122: *In the Schering/AHP Patent Litigation, AHP never took the position in papers filed with the Pennsylvania District Court that the '743 Patent was valid.*

Answer: Admitted.

Request No. 123: *In the Schering/AHP Patent Litigation, AHP never took the position in papers filed with the Pennsylvania District Court that the '743 Patent was enforceable.*

Answer: Admitted.

Request No. 127: *The Pennsylvania District Court made no finding that AHP's generic version of K-Dur 20 infringed the '743 Patent.*

Answer: Admitted. The Schering/AHP litigation was settled before trial, and therefore, the Pennsylvania District Court made no findings one way or the other.

Request No. 128: *The Pennsylvania District Court made no finding that AHP's generic version of K-Dur 20 was likely to infringe the '743 Patent.*

Answer: Admitted. The Schering/AHP litigation was settled before trial, and therefore, the Pennsylvania District Court made no findings one way or the other.

Request No. 129: *The Pennsylvania District Court made no finding that the '743 Patent is not invalid.*

Answer: Admitted. The Schering/AHP litigation was settled before trial, and therefore, the Pennsylvania District Court made no findings one way or the other.

Request No. 130: *The Pennsylvania District Court made no finding that the '743 Patent is enforceable.*

Answer: Admitted. The Schering/AHP litigation was settled before trial, and therefore, the Pennsylvania District Court made no findings one way or the other.

Request No. 133: *At the time of the Schering/AHP Points of Agreement, there was a possibility that AHP could have won the Schering/AHP Patent Litigation if it continued the Schering/AHP Patent Litigation.*

Answer: Schering admits that, in any litigation, there is a "possibility" that either side "could" win.

Request No. 134: *At the time of the Schering/AHP Points of Agreement, it was not certain that Schering would prevail in the Schering/AHP Patent Litigation.*

Answer: Schering admits that, in any litigation, it is "not certain" which party will prevail.

Request No. 135: *At the time of the Schering/AHP Points of Agreement, Schering did not believe it was certain that Schering would prevail in the Schering/AHP Patent Litigation.*

Answer: Schering objects to this request to the extent that it calls for information protected by the attorney-client privilege. Subject to and without waiving the foregoing objection, Schering admits that, in any litigation, it is not "certain" which party will prevail.

Request No. 145: *Under the June 1998 Schering/AHP Agreement, Schering paid AHP $5 million within ten days of the execution and delivery of the June 1998 Schering/AHP Agreement ("Initial Payment").*

Answer: Admitted.

Request No. 148: *Under the June 1998 Schering/AHP Agreement, Schering paid AHP $10 million within 10 days of the date that AHP provided Schering with a copy of the May 11, 1999 letter from FDA ("FDA Approval Payment").*

Answer: Admitted.

Request No. 152: *The Pennsylvania District Court did not enter a court order incorporating the terms of the Schering/AHP Points of Agreement.*

Answer: Admitted.

Request No. 155: *The Pennsylvania District Court did not enter a court order incorporating the terms of the June 1998 Schering/AHP Agreement.*

Answer: Admitted.

Request No. 159: *As of September 2001, there is no pending patent infringement suit brought by Schering against Andrx alleging that Andrx's generic version of K-Dur 20 infringes the '743 Patent listed in the Orange Book for K-Dur 20.*

Answer: Admitted.

Request No. 160: *Schering does not believe that Andrx's generic version of K-Dur 20 infringes the '743 Patent.*

Answer: Schering objects to this request on the ground that it calls for information protected by the attorney client privilege.

Request No. 164: *The decline in sales from 1997 to 1998 projected in the Schering 1997 Operating Plan (SP 23 00219) reflects the expected impact of the entry of at least one generic K-Dur 20 product.*

Answer: [REDACTED: DESIGNATED RESTRICTED CONFIDENTIAL - ATTORNEY'S EYES ONLY UNDER PROTECTIVE ORDER]

Request No. 165: *The decline in sales from 1998 to 1999 projected in the Schering 1997 Operating Plan (SP 23 00219) reflects the expected impact of competition from generic K-Dur 20 products.*

Answer: [REDACTED: DESIGNATED RESTRICTED CONFIDENTIAL - ATTORNEY'S EYES ONLY UNDER PROTECTIVE ORDER]

Request No. 173: *The decline in sales projected in SP 23 00307 from 1998 to 1999 reflects the forecasted impact of the entry of at least one generic K-Dur 20 product.*

Answer: [REDACTED: DESIGNATED RESTRICTED CONFIDENTIAL - ATTORNEY'S EYES ONLY UNDER PROTECTIVE ORDER]

Request No. 174: *The decline in sales projected in SP 23 00307 from 1999 to 2000 reflects the forecasted impact of competition from generic K-Dur 20 products.*

Answer: [REDACTED: DESIGNATED RESTRICTED CONFIDENTIAL - ATTORNEY'S EYES ONLY UNDER PROTECTIVE ORDER]

Request No. 175: *The decline in sales projected in SP 23 00307 from 2000 to 2001 reflects the forecasted impact of competition from generic K-Dur 20 products.*

Answer: [REDACTED: DESIGNATED RESTRICTED CONFIDENTIAL - ATTORNEY'S EYES ONLY UNDER PROTECTIVE ORDER]

Request No. 181: *The Schering Laboratories 1998 Operating Plan (SP 23 00219a) was created after the Schering/Upsher Agreement.*

Answer: Schering admits that the page referred to as SP 23 00219a was created after the Schering/Upsher agreement.

Request No. 186: *The Schering Laboratories 1999 Operating Plan (SP 23 00220) forecast assumes that there will be no generic K-Dur 20 product sold in the United States in 1998, 1999, or 2000.*

Answer: Admitted.

Request No. 187: *The decline in sales from 2000 to 2001 in the Schering Laboratories 1999 Operating Plan (SP 23 00220) reflects the forecasted impact of the entry of at least one generic K-Dur 20 product.*

Answer: [REDACTED: DESIGNATED RESTRICTED CONFIDENTIAL - ATTORNEY'S EYES ONLY UNDER PROTECTIVE ORDER]

Request No. 226: *Upsher is selling its generic versions of K-Dur 20 and K-Dur 10 at prices as much as 50% below the price of K-Dur.*

Answer: After reasonable inquiry, the information known to or readily obtainable by Schering is insufficient to allow Schering to admit or deny if Upsher is selling its generic version of K-Dur 20 and K-Dur 10 at prices as much as 50% below the price of K-Dur. Based on available information, however, it does not appear that Upsher is selling its generic versions of K-Dur 20 and K-Dur 10 at prices as much as 50% below the price of K-Dur.

Request No. 228: *Warrick began selling a bioequivalent generic alternative to K-Dur 20 in September 2001.*

Answer: [REDACTED: DESIGNATED RESTRICTED CONFIDENTIAL - ATTORNEY'S EYES ONLY UNDER PROTECTIVE ORDER]

Request No. 229: *Substitution from a brand product to its bioequivalent or AB-rated generic products occurs at a faster rate in 2001 than it did in 1997.*

Answer: Schering objects to this request as vague, confusing and speculative and on that basis, denies it.

Request No. 231: *Warrick will price its generic K-Dur 20 product competitively with Upsher's generic version of K-Dur 20.*

Answer: Schering objects to this request as vague, overly broad and as calling for speculation as to what Warrick's price for its generic K-Dur 20 product "will" be at some undefined time in the future.

Request No. 272: *Schering's monthly profits on K-Dur 20 has fallen since Upsher introduced its generic version of K-Dur 20.*

Answer: [REDACTED: DESIGNATED RESTRICTED CONFIDENTIAL - ATTORNEY'S EYES ONLY UNDER PROTECTIVE ORDER]

Request No. 279: *The Schering policy established by SP 018744 was in effect at the time of the Schering/Upsher Agreement in June 1997.*

Answer: Admitted.

Request No. 281: *The Schering policy established by SP 018744 was in effect in June 1998.*

Answer: Admitted.

Request No. 282: *Prior to Mr. James Audibert's evaluation of the Niacor-SR in June 1997, Schering was aware that Niacin products had adverse side effects.*

Answer: Schering objects to this request as vague. Subject to this objection, Schering admits the request in part and denies in part. Schering admits that it was aware that certain niacin products had potential adverse side effects in some patients under certain conditions.

Request No. 283: *Prior to Mr. James Audibert's evaluation of the Niacor-SR in June 1997, Schering was aware that Niacin, taken in doses to treat cholesterol disorders, caused flushing.*

Answer: Admitted in part and denied in part. Schering admits that it was aware that certain niacin products, taken in doses to treat cholesterol disorders could cause flushing in some patients under certain conditions.

Request No. 301: *The Schering/Upsher Agreement was not reviewed by any person in Schering's Manufacturing Group prior to Schering entering into the Schering/Upsher Agreement.*

Answer: Denied. Based on Complaint Counsel's definition of "Schering's Manufacturing Group," as objected to, Schering denies the request.

Request No. 305: *Schering's June 1997 Niacor-SR Evaluation was not reviewed by any person in Schering's Intellectual Property Group prior to Schering entering into the Schering/Upsher Agreement.*

Answer: Denied. Based on Complaint Counsel's definitions of "Schering's June 1997 Niacor-SR Evaluation" and "Schering's Intellectual Property Group," as objected to, Schering denies the request.

Request No. 310: *Schering's June 1997 Niacor-SR Evaluation was not reviewed by any patent counsel prior to Schering entering into the Schering/Upsher Agreement.*

Answer: Admitted.

Request No. 315: *Schering's June 1997 Niacor-SR evaluation was not reviewed by any person in Schering's International Division prior to Schering entering into the Schering/Upsher Agreement.*

Answer: Denied. Schering's evaluation of Niacor-SR included evaluation by Schering's Global Marketing division, which is responsible for world wide sales.

Request No. 318: *No Schering employee involved in Schering's June 1997 Niacor-SR Evaluation discussed the terms of the Schering/Upsher Agreement with any person in its European Operations prior to Schering entering into the Schering/Upsher Agreement.*

Answer: Schering objects to this request as vague.

Request No. 333: *Schering has never conducted any clinical trials regarding the co-administration of Niacor-SR with a statin.*

Answer: Admitted.

Request No. 334: *Schering is not aware of any clinical trials conducted by Upsher regarding the co-administration of Niacor-SR with a statin.*

Answer: Denied.

Request No. 335: *Schering-Plough Research Institute has never conducted a review of the safety or efficacy of Niacor-SR.*

Answer: Admitted.

Request No. 353: *Mr. James Audibert was the only Schering employee or agent that conducted a "safety review" of Niacor-SR during Schering's June 1997 Niacor-SR Evaluation, as that term is used by Thomas Lauda, in his Investigational Hearing of September 12, 2000, page 64.*

Answer: Admitted.

Request No. 364: *Other than the Schering/Upsher Agreement, Schering has never paid $60 million or greater in non-contingent payments for a license to a pharmaceutical product that had not had yet received final FDA approval.*

Answer: Admitted.

Request No. 400: *Schering has not produced in this administrative proceeding any responses to a Sustained Release Niacin Questionnaire sent out by Jim Audibert contained in Exhibit 10 to the deposition of Thomas Lauda held on September 24, 2001.*

Answer: Admitted.

Request No. 401: *After receiving responses to a Sustained Release Niacin Questionnaire that he sent out on March 14, 1997, Jim Audibert ceased participating in discussions between Kos and Schering regarding Niaspan.*

Answer: After reasonable inquiry, the information known to or readily obtainable by Schering is insufficient to allow Schering to admit or deny when Mr. Audibert ceased participation in discussions between Kos and Schering regarding Niaspan.

Request No. 410: *The first draft proposal of what a Kos/Key deal might look like, sent by Ray Russo to Dave Heatherman on or about May 15, 1997, did not contain any upfront or non-contingent payments from Schering to Kos.*

Answer: Admitted.

Request No. 415: *During its discussions with Kos concerning Niaspan, Schering expressed concern to Kos about the potential liver toxicity effect of Niaspan.*

Answer: Schering admits that, during discussions with Kos concerning Niaspan in 1994, Schering expressed concern to Kos about the potential liver toxicity effect of Niaspan. After reasonable inquiry, the information known to or readily obtainable by Schering is insufficient to allow Schering to admit or deny the request as to communications subsequent to 1994.

Request No. 418: *Schering decided not to enter into a license agreement with Kos for Niaspan in part because of clinical data demonstrating a flushing side effect resulting from taking Niaspan.*

Answer: Denied. Schering never sought to enter into a license agreement with Kos for Niaspan. However, Schering did consider a proposal to enter into a co-marketing/detailing agreement with Kos for Niaspan.

Request No. 420: *Schering decided not to enter into a license agreement with Kos for Niaspan in part because of the size of the potential sales of Niaspan.*

Answer: Denied. Schering never sought to enter into a license agreement with Kos for Niaspan. However, Schering did consider a proposal to enter into a co-marketing/detailing agreement with Kos for Niaspan.

Request No. 428: *Prior to January 1, 2000, Schering was never informed by Upsher that Upsher intended to seek or considered seeking FDA approval of an ANDA for Kos' Niaspan product.*

Answer: After reasonable inquiry, the information known to or readily obtainable by Schering is insufficient to allow Schering to admit or deny whether it was informed by Upsher that Upsher intended to seek or considered seeking FDA approval of an ANDA for Kos' Niaspan product prior to January 1, 2000.

Request No. 429: *In September 1998, Schering was informed by Upsher that Upsher had ceased its activities directed at submitting to the FDA an NDA for Niacor-SR.*

Answer: Admitted.

Request No. 430: *Prior to September 1998, Schering had not been informed by Upsher that Upsher had ceased its activities directed at submitting to the FDA an NDA for Niacor-SR.*

Answer: After reasonable inquiry, the information known to or readily obtainable by Schering is insufficient to allow Schering to admit or deny if Schering had been informed by Upsher that Upsher had ceased its activities directed at submitting an NDA prior to September 1998.

Request No. 431: *Prior to September 1998, Schering had no discussions with Upsher about whether Upsher had reduced its level of efforts or activity directed at submitting an NDA for Niacor-SR to the FDA.*

Answer: After reasonable inquiry, the information known to or readily obtainable by Schering is insufficient to allow Schering to admit or deny whether

Schering had any discussions with Upsher prior to September 1998 about whether Upsher had reduced its level of efforts or activity directed at submitting an NDA.

Request No. 432: *Prior to September 1998, Schering was not informed by Upsher that Upsher had decided to reduce its efforts or activities directed at submitting an NDA for Niacor-SR to the FDA.*

Answer: After reasonable inquiry, the information known to or readily obtainable by Schering is insufficient to allow Schering to admit or deny if Schering had been informed by Upsher that Upsher had decided to reduce its efforts or activities directed at submitting an NDA prior to September 1998.

Request No. 433: *At the time of the Schering/Upsher Agreement, Schering was aware that niacin was available over-the-counter in Europe.*

Answer: After reasonable inquiry, the information known to or readily obtainable by Schering is insufficient to allow Schering to admit or deny Request No. 433.

Request No. 434: *On January 16, 1997, Mr. David A. Pettit sent a letter to Schering-Plough Limited seeking to determine whether Schering-Plough Limited had interest in licensing Upsher's Niacor-SR product in certain European countries.*

Answer: After reasonable inquiry, the information known to or readily obtainable by Schering is insufficient to allow Schering to admit or deny whether Mr. Pettit sent a letter to Schering-Plough Limited seeking to determine whether Schering-Plough Limited had an interest in licensing Upsher's Niacor-SR in European Countries. However, based on documents provided by Mr. Pettit, it is reasonable to conclude that Mr. Pettit sent a January 16, 1997, letter to Schering-Plough Limited seeking expressions of interest in potential Niacor-SR deal.

Request No. 435: *On January 31, 1997, Schering-Plough Limited verbally responded to Mr. David A. Pettit that it was not interested in pursuing negotiations with Upsher regarding the proposed licensing of Niacor-SR.*

Answer: After reasonable inquiry, the information known to or readily obtainable by Schering is insufficient to allow Schering to admit or deny whether Schering-Plough Limited verbally responded to Mr. Pettit that it was not interested in pursuing negotiations with Upsher regarding the proposed licensing of Niacor-SR. However, based on documents provided by Mr. Pettit, it is reasonable to conclude that someone at Schering-Plough Limited verbally declined the proposal.

Request No. 447: *The results of clinical trial 920115 for Niacor-SR reflect that Niacor-SR 1500mg/day has less efficacy in lowering LDL Cholesterol than does immediate release niacin 1500mg/day.*

Answer: Denied. The 1500mg/day dose of immediate release Niacin was not tested in clinical trial 920115.

Request No. 450: *The results of clinical trial 920115 for Niacor-SR reflect that Niacor-SR 1500mg/day has less efficacy in increasing HDL Cholesterol than does immediate release niacin 1500mg/day.*

Answer: Denied. The 1500mg/day dose of immediate release Niacin was not tested in clinical trial 920115.

Request No. 455: *Prior to the Schering/Upsher Agreement, Upsher had conducted pharmacokinetic studies with a dosage of Niacor-SR.*

Answer: Admitted.

Request No. 456: *Prior to the Schering/Upsher Agreement, the FDA requested that Upsher conduct additional pharmacokinetic studies for Niacor-SR.*

Answer: Denied in part. Prior to the Schering/Upsher agreement, the FDA required that Upsher perform one additional single-dose, 4-arm pharmacokinetic urine study.

Request No. 457: *Prior to the Schering/Upsher Agreement, Upsher did not inform Schering that it had not completed pharmacokinetic studies necessary for FDA approval of the Niacor-SR NDA.*

Answer: Admitted.

Request No. 460: *Upsher never requested assistance from Schering in conducting pharmacokinetic studies necessary for FDA approval of a Niacor-SR NDA.*

Answer: Admitted.

Request No. 465: *At the time of the Schering/Upsher Agreement, Upsher had no existing patent protection for Niacor-SR in Europe.*

Answer: Admitted.

Request No. 466: *Niaspan has a superior safety profile to Niacor-SR.*

Answer: Schering objects to this request as vague. Further, after reasonable inquiry, the information known to or readily obtainable by Schering is insufficient to allow Schering to admit nor deny whether Niaspan has a "superior safety profile" to Niacor, as no head-to-head trial was ever conducted that compared the two pharmaceuticals.

Request No. 473: *As of June 1997, Schering was not aware of any clinical trials conducted by Upsher in which Niacor-SR was take once a day at bedtime.*

Answer: Admitted. However, Schering was aware that Upsher planned to conduct Phase IIIb trials with respect to Niacor-SR.

Request No. 474: *Upsher's Niacor-SR product was a twice-daily formulation of niacin.*

Answer: Denied in part and admitted in part and denied in part. Schering objects to this request as vague, as various conflicting inferences may be drawn from the request, and on that basis, denies it. Schering admits that at the time of the agreement, Upsher's clinical trials had only involved twice-a-day dosing. However, Schering was aware at the time of the agreement that Upsher was planning to conduct two Phase III trials that involved once-a-night dosing of Niacor-SR.

Respectfully submitted,

Of Counsel:

John W. Nields, Jr.
Marc G. Schildkraut
Laura S. Shores
Charles A. Loughlin
HOWREY SIMON ARNOLD & WHITE LLP
1299 Pennsylvania Ave., N.W.
Washington, D.C. 20004
(202) 783-0800

Attorneys for Respondent
Schering-Plough Corporation

Dated: November 14, 2001

CERTIFICATE OF SERVICE

I hereby certify that this 14th day of November, 2001, I caused an original, one paper copy and an electronic copy of the foregoing Respondent's Objections and Responses to Complaint Counsel's Revised Second Request for Admissions to be filed with the Secretary of the Commission, and that two paper copies were served by hand upon:

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

and one paper copy was hand delivered upon:

Karen Bokat
Bureau of Competition
Federal Trade Commission
Washington, D.C.
601 Pennsylvania Ave, N.W.
Washington, D.C. 20580

Christopher Curran
White & Case LLP
601 13th St., N.W.
Washington, D.C. 20005

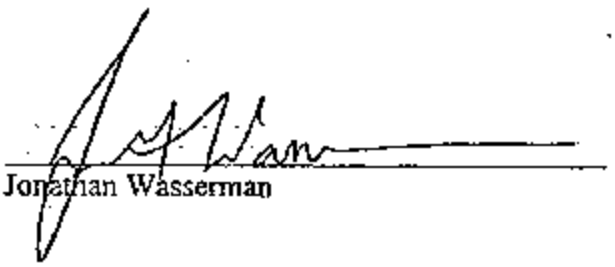
Erik T. Koons

VERIFICATION

I, Jonathan Wasserman, am an attorney employed by Schering-Plough Corporation, and am executing this Verification on behalf of Schering-Plough Corporation. The foregoing Respondent Schering-Plough Corporation's Objections and Responses to Complaint Counsel's Revised Second Request for Admissions was compiled for Schering-Plough Corporation based on such information as was available to it after making reasonable inquiries of knowledgeable persons. I have relied on others to gather such information and to prepare such responses, but believe, based on reasonable inquiry, that such answers are true and correct to the best of my knowledge, information, and belief. Legal objections to Complaint Counsel's Revised Second Request for Admissions have been stated for Schering-Plough Corporation by its attorneys.

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

Executed on November 14, 2001.



Jonathan Wasserman

Attachment G

KCI Market Projection - dollars (000)

Attachment H

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

COMPLAINT COUNSEL'S REVISED THIRD REQUESTS FOR ADMISSIONS TO RESPONDENT UPSHER-SMITH LABORATORIES, INC.

(Subject to Protective Order)

Pursuant to Federal Trade Commission ("FTC") Rules of Practice for Adjudicative Proceedings § 3.32, Complaint counsel submit these requests for admissions to respondent Upsher-Smith Laboratories, Inc ("Upsher"). Further pursuant to Judge Chappell's Order On Motions Of Schering-Plough And Upsher-Smith For Protective Order (dated November 2, 2001), Upsher is requested to respond to the 100 requests for admissions below designated by bold text on or before November 13, 2001.

DEFINITIONS

1. "Orange Book" means the FDA publication entitled *Approved Drug Products with Therapeutical Equivalence Evaluations*.

2. "AB-rated" means a rating given to a product approved under 21 U.S.C. §355(j) with an application that contains adequate scientific evidence establishing through *in vivo* and or *in vitro* studies the bioequivalence of the product to a selected reference product, as described in the Orange Book.

3. "Average Selling Price" means ASP tablet as used in document USL 07075.

4. "FDA" means the United States Food and Drug Administration, including without limitation its employees, scientists, technicians, agents, examiners and laboratories.

5. "ANDA" means an Abbreviated New Drug Application filed with the FDA pursuant to 21 U.S.C. § 355(j).

6. "NDA" means a New Drug Application filed with the FDA pursuant to 21 U.S.C. § 355(b).

7. "180-day Exclusivity Period" means the period of time established by section 505(j)(5)(B)(iv) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j) *et seq.*).

8. "Paragraph IV Certification" means the certification made to the FDA pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

9. "First Filer" means the applicant submitting the first substantially complete ANDA for a listed drug with a Paragraph IV certification to any patent in the Orange Book for the listed drug.

10. "K-Dur 20" means the potassium chloride formulation sold under that trademark.

11. "Schering" mean Schering-Plough Corporation, its domestic and foreign parents, predecessors, divisions, and wholly or partially owned subsidiaries, affiliates, partnerships, and

19. "Pennsylvania District Court" means the United States District Court for the Eastern District of Pennsylvania.

20. "'743 Patent" means U.S. Patent No. 4,863,743 issued by the U.S. Patent and Trademark Office on September 5, 1989.

21. "Schering/Upsher Patent Litigation" means the lawsuit captioned Key Pharmaceuticals, Inc. v. Upsher-Smith Laboratories, Inc., filed in New Jersey District Court, No. 95-CV-6281, in which Key Pharmaceuticals, Inc. sued Upsher for infringing patent number 4,863,743.

22. "Schering/AHP Patent Litigation" means the lawsuit captioned Key Pharmaceuticals, Inc. v. ESI-Lederle, Inc., filed in Pennsylvania District Court, No. 96-CV-4510 or No. 96-CV-1219, in which Key Pharmaceuticals sued ESI-Lederle for infringing patent number 4,863,743.

23. "Schering/AHP Points of Agreement" means the agreement reached between Schering and AHP on or about January 23, 1998 as represented by document SP 13 00635.

24. "Schering/Upsher Agreement" means the agreement reached between Schering and Upsher on June 17, 1997 as represented by document USL 03183-03193.

25. "June 1998 Schering/AHP Agreement" means the agreement reached between Schering and AHP on June 19, 1998 as represented by document SP 13 00070-00089.

26. "Schering's June 1997 Niacor-SR Evaluation" means the evaluation of Niacor-SR conducted by Schering in June 1997 preceding Schering's entering into the Schering/Upsher agreement and including documents SP 16 000035-000036, SP 16 000040-000047.

joint ventures; and all directors, officers, employees, consultants, agents and representatives of the foregoing.

12. "Upsher" means Upsher-Smith Laboratories, Inc., its domestic and foreign parents, predecessors, divisions and wholly or partially owned affiliates, partnerships, and joint ventures; and all directors, officers, employees, consultants, agents and representatives of the foregoing.

13. "AHP" means American Home Products Corporation, its domestic and foreign parents, predecessors, divisions, and wholly or partially owned subsidiaries, affiliates, partnerships, and joint ventures, including ESI-Lederle, a business unit of Wyeth-Ayerst Pharmaceuticals, Inc.; and all directors, officers, employees, consultants, agents and representatives of the foregoing.

14. "Kos" means Kos Pharmaceuticals, Inc., a Florida corporation headquartered at 1001 Brickell Bay Drive, Miami, FL, 33131.

15. "Andrx" means Andrx Corporation, a Florida corporation with its office and principal place of business located at 4001 S.W. 47th Avenue, Fort Lauderdale, Florida, 33314.

16. "Moreton Marketing" means Moreton Marketing Ltd., a company headquartered at The Old Stable Block, 7 Buttermarket, Thames Oxfordshire, OX9 3EW, United Kingdom.

17. "IPC" means International Processing Corporation, headquartered at 1100 Enterprise Drive, Winchester, KY 40391.

18. "New Jersey District Court" means the United States District Court for New Jersey.

19. "Pennsylvania District Court" means the United States District Court for the Eastern District of Pennsylvania.

20. "'743 Patent" means U.S. Patent No. 4,863,743 issued by the U.S. Patent and Trademark Office on September 5, 1989.

21. "Schering/Upsher Patent Litigation" means the lawsuit captioned Key Pharmaceuticals, Inc. v. Upsher-Smith Laboratories, Inc., filed in New Jersey District Court, No. 95-CV-6281, in which Key Pharmaceuticals, Inc. sued Upsher for infringing patent number 4,863,743.

22. "Schering/AHP Patent Litigation" means the lawsuit captioned Key Pharmaceuticals, Inc. v. ESI-Lederle, Inc., filed in Pennsylvania District Court, No. 96-CV-4510 or No. 96-CV-1219, in which Key Pharmaceuticals sued ESI-Lederle for infringing patent number 4,863,743.

23. "Schering/AHP Points of Agreement" means the agreement reached between Schering and AHP on or about January 23, 1998 as represented by document SP 13 00635.

24. "Schering/Upsher Agreement" means the agreement reached between Schering and Upsher on June 17, 1997 as represented by document USL 03183-03193.

25. "June 1998 Schering/AHP Agreement" means the agreement reached between Schering and AHP on June 19, 1998 as represented by document SP 13 00070-00089.

26. "Schering's June 1997 Niacor-SR Evaluation" means the evaluation of Niacor-SR conducted by Schering in June 1997 preceding Schering's entering into the Schering/Upsher agreement and including documents SP 16 000035-000036, SP 16 000040-000047.

27. "Schering's Regulatory Affairs Group" means the group, organization, or employees within Schering responsible for seeking FDA approval for pharmaceutical products and/or the group discussed by Mr. Thomas Lauda in his deposition dated September 24, 2001 at pages 31-32.

28. "Schering's Manufacturing Group" means the group, organization, or employees within Schering responsible for all of aspects of planning for and actual manufacture of a pharmaceutical product.

29. "Schering's Intellectual Property Group" means the group, organization, or employees within Schering responsible for all aspects of intellectual property protection and review, including the evaluation of the patent position of products considered for in-licensing.

30. "Kos Patent Cross-Licensing Agreement" means the agreement between Upsher and Kos made effective on February 7, 1997 as represented by document USL 11399-11418.

31. "Up-Front Payment" means the payments described by Paragraph 11, subparagraph (i)-(iii), of the Schering-Upsher Agreement.

32. "Milestone Payment" means the payments described by Paragraph 11, subparagraph (iv), of the Schering Upsher Agreement.

33. "Upsher's generic version of K-Dur 20" means the product which is the subject of ANDA 74-726.

34. "AHP's generic version of K-Dur 20" means the product which is the subject of ANDA 74-812.

INSTRUCTIONS

Each of these requests shall be deemed admitted unless, on or before November 13, 2001, Upsher serves a sworn written answer or objection to the requests in bold text. If objection is made to any of these bolded requests, the reasons therefore shall be stated. The answer shall specifically deny the matter or set forth in detail the reasons why Upsher cannot truthfully admit or deny the matter. Any denial shall fairly meet the substance of the requested admission. Where Upsher cannot deny the entire request for admission, Upsher shall specify so much of it as is true and qualify or deny the remainder of the request for admission. Upsher shall not give lack of information or knowledge as a reason for failure to admit or deny unless Upsher makes reasonable inquiry and after reasonable inquiry can state that the information known to or readily obtainable by Upsher is insufficient to enable it to admit or deny the request for admission. All documents referred to in the Requests for Admissions are in the possession of Upsher.

REQUESTS FOR ADMISSIONS

FDA Regulations

Request No. 1: A pharmaceutical manufacturer must file an ANDA with the FDA to receive FDA approval to market a generic product that is AB-rated to a product listed in the Orange Book.

Request No. 2: The FDA takes, on average, 12 to 18 months to review and approve an ANDA.

Request No. 3: A First Filer is eligible for the 180-day Exclusivity Period.

Request No. 4: **As of September 2001, the FDA is prohibited from approving another generic version of the branded product until either (1) the First Filer's180-day Exclusivity Period has elapsed, or (2) the First Filer relinquishes or loses its eligibility to the 180-day Exclusivity Period.**

Request No. 5: Upsher is the First Filer for a generic version of K-Dur 20.

Request No. 6: Upsher, as the First Filer for a generic version of K-Dur 20, was eligible for the 180-day Exclusivity Period from the date it submitted its ANDA.

Request No. 7: Upsher began commercial sales of its generic version of K-Dur 20 on September 1, 2001.

Request No. 8: **Upsher's 180-day Exclusivity Period was triggered on September 1, 2001.**

Request No. 9: As of September 2001, no ANDA for a generic version of K-Dur 20, other than ANDA 74-726, can receive final approval from the FDA until Upsher's 180-day Exclusivity Period has expired.

Generic Pricing

Request No. 10: **For every product that Upsher sells which is bioequivalent to a brand product, Upsher sells the product at least a 10% discount off the brand product.**

Request No. 11: For every product that Upsher sells which is bioequivalent to a brand product, Upsher sells the product at least a 20% discount off the brand product.

Request No. 12: For every product that Upsher sells which is bioequivalent to a brand product, Upsher sells the product at least a 30% discount off the brand product.

Request No. 13: For every product that Upsher sells which is bioequivalent to a brand product, Upsher sells the product at least a 40% discount off the brand product.

Request No. 14: For every product that Upsher sells which is bioequivalent to a brand product. Upsher. Upsher sells the product at least a 50% discount off the brand product.

Request No. 15: In his deposition. Philip Dritsas. Upsher's Vice President of Sales and Marketing. states "we have been looking at a scenario where would be about 40% less than the K-Dur product and there are two or three scenarios because – so nothing has been formalized. but I will tell you that's about what we're looking at."

Request No. 16: In his deposition. Philip Dritsas. Upsher's Vice President of Sales and Marketing. states. "Yes. whenever we were – at whatever time we were finally on the market and whenever other generic were on the market. I think that's a reasonable assumption there would be rapid generic erosion."

Request No. 17: When Upsher and other generic companies are selling a generic K-Dur product. there will be rapid generic erosion.

<u>Upsher's Anticipated Entry of a Generic Version of K-Dur 20</u>

Request No. 18: In 1997. Upsher produced forecasts that assumed a September 1997 launch date for its generic version of K-Dur 20.

Request No. 19: In 1997. Upsher produced forecasts that assumed an October 1997 launch date for its generic version of K-Dur 20.

Request No. 20: Document USL 06730 identifies September 9-11. 1997 as the target date for the introduction of Upsher's generic version of K-Dur 20.

Request No. 21: A meeting was held on April 29, 1997 in which possible launch date scenarios for Upsher's generic version of K-Dur 20 were discussed.

Request No. 22: In the April 29, 1997 meeting, one of the scenarios discussed involved a launch date of August 1, 1997 for Upsher's generic version of K-Dur 20.

Request No. 23: In the April 29, 1997 meeting, one of the scenarios discussed involved a launch date of October 1, 1997 for Upsher's generic version of K-Dur 20.

Request No. 24: In the April 29, 1997 meeting, one of the scenarios discussed involved a launch date of January 1, 1998 for Upsher's generic version of K-Dur 20.

Request No. 25: In the April 29, 1997 meeting, the scenario involving a January 1, 1998 launch date was referred to as the latest possibility.

Upsher's Launch Preparations

Request No. 26: Prior to the Schering/Upsher Agreement, Denise Dolan had forecasted the quantities needed to launch Upsher's generic version of K-Dur 20 in August 1997.

Request No. 27: Prior to the Schering/Upsher Agreement, Denise Dolan had forecasted the quantities needed to launch Upsher's generic version of K-Dur 20 in September 1997.

Request No. 28: By May 13, 1997, Upsher had scheduled the manufacturing of validation batches of Upsher's generic version of K-Dur 20 at IPC for the following month on June 17, 18, and 19.

Request No. 29: As of May 13, 1997, IPC was holding open the month of August 1997 for production of Upsher's launch quantities of Upsher's generic version of K-Dur 20.

The Schering/Upsher Patent Infringement Litigation

Request No. 30: On August 6, 1995, Upsher submitted to the FDA a certification stating that Upsher's generic version of K-Dur 20 did not infringe the '743 Patent listed in the Orange Book for K-Dur 20.

Request No. 31: On November 3, 1995, Upsher sent to Schering notification of its August 6, 1995 patent certification to the FDA stating that Upsher's generic version of K-Dur 20 did not infringe the '743 Patent listed in the Orange Book for K-Dur 20.

Request No. 32: Schering received a copy of Upsher's November 3, 1995 notification stating that Upsher's generic version of K-Dur 20 did not infringe the '743 Patent listed in the Orange Book for K-Dur 20.

Request No. 33: In Upsher's November 3, 1995 notification to Schering, Upsher stated that its generic version of K-Dur 20 is substantially different from the product described and claimed in the '743 Patent.

Request No. 34: On December 15, 1995, Schering filed a complaint in the Schering/Upsher Patent Litigation against Upsher, alleging infringement of the '743 Patent.

Request No. 35: In the Schering/Upsher Patent Litigation, Upsher took the position in its Answer and Counterclaims filed with the New Jersey District Court on January 26, 1996 that Upsher's generic version of K-Dur 20 did not infringe the '743 Patent listed in the Orange Book for K-Dur 20.

Request No. 36: In the Schering/Upsher Patent Litigation, Upsher took the position in its Answer and Counterclaims filed with the New Jersey District Court on January 26, 1996 that the '743 Patent is invalid.

Request No. 37: In the Schering/Upsher Patent Litigation, Upsher took the position in its Answer and Counterclaims filed with the New Jersey District Court on January 26, 1996 that the '743 Patent is unenforceable because, during the prosecution of the applications resulting in the patent, Schering failed to meet the duty of candor owed to the United States Patent and Trademark Office.

Request No. 38: In the Schering/Upsher Patent Litigation, Upsher took the position in its Answer and Counterclaims filed with the New Jersey District Court on January 26, 1996 that Schering filed the Schering/Upsher Patent Litigation for the purpose of trying to delay FDA's approval of Upsher's generic version of K-Dur 20.

Request No. 39: In the Schering/Upsher Patent Litigation, Upsher took the position in its Answer and Counterclaims filed with the New Jersey District Court on January 26, 1996 that Schering filed its Complaint in the Schering/Upsher Patent Litigation for the purpose of trying to put off for as long as possible the time when it must face competition from Upsher's generic version of K-Dur 20.

Request No. 40: In the Schering/Upsher Patent Litigation, Upsher never took the position in papers filed with the New Jersey District Court that Upsher's generic version of K-Dur 20 infringed the '743 Patent listed in the Orange Book for K-Dur 20.

Request No. 41: In the Schering/Upsher Patent Litigation, Upsher had a reasonable basis for asserting that, with respect to the '743 Patent, prosecution history

estoppel applied so as to preclude Schering from asserting that Upsher's generic version of K-Dur 20 infringed the '743 Patent.

Request No. 42: In the Schering/Upsher Patent Litigation, following Upsher's Motion for Summary Judgment on the Issue of Non-Infringement and Memorandum in Support thereof, dated October 29, 1996, Schering conceded that Upsher's generic version of K-Dur 20 did not literally infringe the '743 Patent.

Request No. 43: In the Schering/Upsher Patent Litigation, Upsher never took the position in papers filed with the New Jersey District Court that the '743 Patent was valid.

Request No. 44: In the Schering/Upsher Patent Litigation, Upsher never took the position in papers filed with the New Jersey District Court that the '743 Patent was enforceable.

Request No. 45: In the Schering/Upsher Patent Litigation, Upsher stated in papers filed with the New Jersey District Court, including its Memorandum in Support of Motion for Summary Judgment of Non-Infringement filed on October 29, 1996, that Upsher's generic version of K-Dur 20 did not infringe the '743 Patent listed in the Orange Book for K-Dur 20.

Request No. 46: In the Schering/Upsher Patent Litigation, Upsher took the position in papers filed in the New Jersey District Court, including its Memorandum in Support of Motion for Summary Judgment of Non-Infringement filed on October 29, 1996 that Upsher's generic version of K-Dur 20 is substantially different from the product described and claimed in the '743 Patent.

Request No. 47: In the Schering/Upsher Patent Litigation, Upsher had a reasonable basis for asserting that neither Span 80 nor any other substance in Upsher's generic version of K-Dur 20 is not insubstantially different than hydroxypropylcellulose and polyethylene glycol.

Request No. 48: In the Schering/Upsher Patent Litigation, Upsher had a reasonable basis for asserting that, with respect to the coating of Upsher's generic version of K-Dur 20, ethylcellulose with a viscosity of 20 cp is not insubstantially different than ethylcellulose with a viscosity of 40 cp.

Request No. 49: In the Schering/Upsher Patent Litigation, Upsher took the position in papers filed in the New Jersey District Court, including its Memorandum in Opposition to Key Pharmaceuticals, Inc.'s Motion to Dismiss filed on August 15, 1996 that the '743 Patent is invalid.

Request No. 50: The New Jersey District Court made no finding that Upsher's generic version of K-Dur 20 infringed the '743 Patent.

Request No. 51: **The New Jersey District Court made no finding that Upsher's generic version of K-Dur 20 was likely to infringe the '743 Patent.**

Request No. 52: **The New Jersey District Court made no finding that the '743 Patent is not invalid.**

Request No. 53: **The New Jersey District Court made no finding that the '743 Patent is enforceable.**

Request No. 54: No court has found that Upsher's generic version of K-Dur 20 infringed the '743 Patent.

Request No. 55: No court has found that Upsher's generic version of K-Dur 20 was likely to infringe the '743 Patent.

Request No. 56: No court has found that the '743 Patent is not invalid.

Request No. 57: No court has found that the '743 Patent is enforceable.

Request No. 58: At the time of the Schering/Upsher Agreement, there was a possibility that Upsher could have won the Schering/Upsher Patent Litigation if it continued the Schering/Upsher Patent Litigation.

Request No. 59: At the time of the Schering/Upsher Agreement, Upsher believed that it could have won the Schering/Upsher Patent Litigation if it continued the Schering/Upsher Patent Litigation.

Request No. 60: At the time of the Schering/Upsher Agreement, it was not certain that Schering would prevail in the Schering/Upsher Patent Litigation.

Request No. 61: At the time of the Schering Upsher Agreement, Upsher did not believe it was certain that Schering would prevail in the Schering Upsher Patent Litigation.

Request No. 62: At the time of the Schering Upsher Agreement, Upsher's defense that its generic version of K-Dur 20 did not infringe the '743 Patent was not objectively baseless.

Request No. 63: At the time of the Schering Upsher Agreement, Upsher's defense in the Schering/Upsher Patent Litigation that the '743 Patent was invalid was not objectively baseless.

Request No. 64: At the time of the Schering Upsher Settlement, Upsher's defense that the '743 Patent was unenforceable was not objectively baseless.

Other Generic K-Dur 20 Applications

Request No. 65: Andrx submitted to the FDA a certification stating that Andrx's generic version of K-Dur 20 did not infringe the '743 Patent listed in the Orange Book for K-Dur 20.

Request No. 66: On June 2, 1999, Andrx provided to Schering notification of Andrx's patent certification to the FDA stating that Andrx's generic version of K-Dur 20 did not infringe the '743 Patent listed in the Orange Book for K-Dur 20.

Request No. 67: Schering received a copy of Andrx's patent certification to the FDA stating that Andrx's generic version of K-Dur 20 did not infringe the '743 Patent listed in the Orange Book for K-Dur 20.

Request No. 68: As of September 2001, there is no pending patent infringement suit brought by Schering against Andrx alleging that Andrx's generic version of K-Dur 20 infringes the '743 Patent listed in the Orange Book for K-Dur 20.

Schering/Upsher Agreement

Request No. 69: The Schering/Upsher Agreement became effective on June 17, 1997.

Request No. 70: Upsher's KLOR CON M 20 product is the trademark name for Upsher's generic version of K-Dur 20.

Request No. 71: Under the Schering/Upsher Agreement, Upsher agreed not market in the United States its KLOR CON M 20 potassium chloride product, or any other sustained release microencapsulated potassium chloride tablet, prior to September 1, 2001.

Request No. 72: On November 20, 1998, Upsher received final FDA approval for its generic version of K-Dur 20.

Request No. 73: As of November 20, 1998, FDA law and regulations permitted Upsher to begin the commercial sale of its generic version of K-Dur 20.

Request No. 74: Upsher did not begin the commercial sale of its generic version of K-Dur 20 on November 20, 1998 or at any time prior to September 1, 2001.

Request No. 75: Under the Schering/Upsher Agreement, the phrase "any other sustained release microencapsulated potassium chloride tablet" would include a sustained release microencapsulated potassium chloride tablet that infringed the '743 Patent.

Request No. 76: Under the Schering/Upsher Agreement, the phrase "any other sustained release microencapsulated potassium chloride tablet" could include a sustained release microencapsulated potassium chloride tablet that infringed the '743 Patent.

Request No. 77: Under the Schering/Upsher Agreement, the phrase "any other sustained release microencapsulated potassium chloride tablet" would include a sustained release microencapsulated potassium chloride tablet that did not infringe the '743 Patent.

Request No. 78: Under the Schering/Upsher Agreement, the phrase "any other sustained release microencapsulated potassium chloride tablet" could include a sustained release microencapsulated potassium chloride tablet that did not infringe the '743 Patent.

Request No. 79: Under the Schering/Upsher Agreement, Schering was required to make an Up-Front Payment to Upsher in the amount of $28 million within 48 hours of the date on which the Schering/Upsher Agreement was approved by Schering's Board of Directors.

Request No. 80: Under the Schering/Upsher Agreement, Schering was required to make an Up-Front Payment to Upsher in the amount of $20 million one year from the date on which the Schering/Upsher Agreement was approved by Schering's Board of Directors.

Request No. 81: Under the Schering/Upsher Agreement, Schering was required to make an Up-Front Payment to Upsher in the amount of $12 million two years from the date on which the Schering/Upsher Agreement was approved by Schering's Board of Directors.

Request No. 82: Under the Schering/Upsher Agreement, Schering was required to make Up-Front Payments to Upsher totaling $60 million.

Request No. 83: **Under the Schering/Upsher Agreement, the Schering's $60 million in Up-Front Payments to Upsher were unconditional.**

Request No. 84: Under the Schering/Upsher Agreement, the Schering's $60 million in Up-Front Payments to Upsher were not contingent on Upsher taking any actions or satisfying any conditions concerning the development of Niacor-SR.

Request No. 85: **Under the Schering/Upsher Agreement, if Upsher abandoned the development of Niacor-SR, Upsher would still receive the full $60 million in Up-Front Payments.**

Request No. 86: Under the Schering/Upsher Agreement, if Upsher abandoned the development of Niacor-SR, Upsher was under no obligation to inform Schering that it, Upsher, had abandoned the development of Niacor-SR.

Request No. 87: **Under the Schering/Upsher Agreement, if Upsher abandoned the development of Niacor-SR, and did not inform Schering that it, Upsher, had abandoned**

the development of Niacor-SR, Upsher would still receive the full $60 million in Up-Front Payments.

Request No. 88: Schering made a payment of $ 28 million to Upsher within 48 hours of the date on which the Schering/Upsher Agreement was approved by Schering's Board of Directors.

Request No. 89: Schering made a payment of $20 million to Upsher approximately one year from the date on which the Schering/Upsher Agreement was approved by Schering's Board of Directors.

Request No. 90: Schering made a payment of $12 million to Upsher approximately two years from the date on which the Schering/Upsher Agreement was approved by Schering's Board of Directors.

Request No. 91: Under the Schering/Upsher Agreement, Schering obtained an exclusive paid-up royalty free license to make, have made, import, export, use, offer for sale and sell Upsher's Pentoxifylline product in all countries other than Canada, the United States and Mexico.

Request No. 92: Under the Schering/Upsher Agreement, Schering obtained an exclusive paid-up royalty free license to make, have made, import, export, use, offer for sale and sell Upsher's Prevalite product in all countries other than Canada and Mexico.

Request No. 93: Under the Schering/Upsher Agreement, Schering obtained an exclusive paid-up royalty free license to make, have made, import, export, use, offer for sale and sell Upsher's KLOR CON 8, KLOR CON 10, AND KLOR CON M20, products in all countries other than Canada, the United States and Mexico.

Request No. 94: Under the Schering/Upsher Agreement, Schering obtained an exclusive paid-up royalty free license to make, have made, import, export, use, offer for sale and sell Upsher's Niacor-SR product in all countries other than Canada, the United States and Mexico.

Request No. 95: Since June 1997, Schering has made no sales of Pentoxifylline pursuant to the license obtained in the Schering/Upsher Agreement.

Request No. 96: Since June 1997, Schering has made no sales of KLOR CON products pursuant to the license obtained in the Schering/Upsher Agreement.

Request No. 97: Since June 1997, Schering has made no sales of Niacor-SR pursuant to the license obtained in the Schering/Upsher Agreement.

Request No. 98: Since June 1997, Schering sales of Prevalite, pursuant to the license obtained in the Schering/Upsher Agreement, have totaled less than $ 1 million .

Request No. 99: Under the Schering/Upsher Agreement, Schering agreed to pay to Upsher Milestone Payments within 10 days of the first commercial sale of Niacor-SR by Schering or its licensee in certain designated countries.

Request No. 100: Under the Schering/Upsher Agreement, Schering agreed to pay to Upsher royalties of at least 10% on aggregate worldwide annual net sales (as defined in the agreement) of Niacor-SR by Schering or its licensee.

Request No. 101: The Schering/Upsher Agreement placed no obligation on Upsher to carry out activities necessary to develop and obtain FDA approval to market Niacor-SR.

Request No. 102: The Schering/Upsher Agreement placed no obligation on Upsher to satisfy any milestones concerning FDA approval for Niacor-SR.

Request No. 103: The Schering/Upsher Agreement placed no obligation on Schering to carry out any activities concerning the marketing of Niacor-SR in Europe.

Request No. 104: The Schering/Upsher Agreement did not contain any warranties or representations by Upsher regarding its ownership of or rights to Niacor-SR.

Request No. 105: The Schering/Upsher Agreement did not contain any warranties or representations by Upsher regarding its intellectual property rights relating to Niacor-SR.

Request No. 106: Schering and Upsher have not entered into the "Detailed Agreement" as defined in the Schering/Upsher Agreement.

Request No. 107: Under paragraph 3 of the Schering Upsher Agreement, the license granted to Upsher under the '743 patent to make or sell Klor-Con M20 would become effective on the date that a court of last resort rules the Detailed Agreement (as that term is used in the paragraph II of the Schering Upsher Agreement) invalid and the license granted to Upsher under the '743 patent valid.

Request No. 108: Under paragraph 12 of the Schering Upsher Agreement, if a court or governmental authority declares the licenses granted to Schering pursuant to paragraphs 7-10 void, Schering does not make any additional payments to Upsher.

Request No. 109: Under paragraph 12 of the Schering Upsher Agreement, if a court or governmental authority declares the licenses granted to Schering pursuant to paragraphs 7-10 void. Upsher retains payments made by Schering prior to the court or governmental authority decision voiding the licenses granted to Schering.

Request No. 110: If, on December 31, 1997, a court of last resort had declared that the Schering/Upsher Agreement as whole void, including the licenses granted to Schering, and had declared the license granted to Upsher valid, Upsher would have received $28 million from Schering.

Request No. 111: If, on December 31, 1998, a court of last resort had declared that the Schering/Upsher Agreement as whole void, including the licenses granted to Schering, and had declared the license granted to Upsher valid, Upsher would have received $48 million from Schering.

Request No. 112: If, on December 31, 1997, a court of last resort had declared that the Schering/Upsher Agreement as whole void, including the licenses granted to Schering, and had declared the license granted to Upsher valid, Upsher's license to the '743 patent would have become effective on December 31, 1997.

Request No. 113: If, on December 31, 1998, a court of last resort had declared that the Schering/Upsher Agreement as whole void, including the licenses granted to Schering, and had declared the license granted to Upsher valid, Upsher's license to the '743 patent would have become effective on December 31, 1998.

Request No. 114: If, on December 31, 1997, a court of last resort had declared that the Schering/Upsher Agreement as whole void, including the licenses granted to Schering, and had declared the license granted to Upsher valid, Upsher could have launched its Klor Con M20 on December 31, 1997 without being liable for infringing the 743 patent.

Request No. 115: If, on December 31, 1998, a court of last resort had declared the licenses granted to Schering void and had declared the license granted to Upsher valid, Upsher

could have launched its Klor Con M20 on December 31, 1998 without being liable for infringing the '743 patent.

Request No. 116: If, on December 31, 1997, a court of last resort had declared that the Schering Upsher Agreement as whole void, including the licenses granted to Schering, and had declared the license granted to Upsher valid, Upsher's agreement not to market its Klor-Con M20 product would have terminated on December 31, 1997.

Request No. 117: If, on December 31, 1998, a court of last resort had declared that the Schering Upsher Agreement as whole void, including the licenses granted to Schering, and had declared the license granted to Upsher valid, Upsher's agreement not to market its Klor-Con M20 product would have terminated on December 31, 1998.

Request No. 118: On June 24, 1997, Schering's board of directors met and authorized Schering's officers to execute or cause to be executed all agreements or arrangements with Upsher discussed at said meeting.

Request No. 119: On June 24, 1997, Schering's board of directors met and authorized Schering's officers to enter a license agreement with Upsher for rights to market four of Upsher's products.

Request No. 120: The Schering/Upsher Agreement was not presented to the New Jersey District Court for approval.

Request No. 121: The New Jersey District Court did not approve the Schering/Upsher Agreement.

Request No. 122: The Schering/Upsher Agreement was not presented to any federal district court for approval.

Request No. 123: The Schering/Upsher Agreement was not approved by any federal district court.

Projected Impact of Generic Entry on K-Dur Price

Request No 124: In 1997, Upsher projected that it would price its generic version of K-Dur 20 at 50% of the price of K-Dur 20's post-generic entry price.

Request No. 125: In USL 08543 and USL 08544, Upsher assumes that its generic version of K-Dur 20 would be priced at 75% of K-Dur 20.

Request No. 126: In USL 08543 and USL 08544, Upsher assumes that its generic version of K-Dur 20 would be launched on October 1, 1997.

Request No. 127: In USL 08543, Upsher projects that sales of its generic version of K-Dur 20 would come only at the expense of K-Dur 20 or other bioequivalent generic K-Dur 20 products.

Request No. 128: In April 1997, Upsher projected the impact of the entry of generic K-Dur 20 products.

Request No. 129: In April 1997, Upsher projected that K-Dur 20 sales in dollars would be 30.1% lower in 1998 than in 1997.

Request No. 130: In April 1997, Upsher projected that K-Dur 20 sales in dollars would be 4.9% lower in 1999 than in 1998.

Request No. 131: In April 1997, Upsher projected that K-Dur unit sales would be 12.6% lower in 1998 than in 1997.

Request No. 132: In April 1997, Upsher projected that K-Dur unit sales in dollars would be 4.9% lower in 1999 than in 1998.

Request No. 133: In April 1997, Upsher projected that sales of its generic version of K-Dur 20 would come only at the expense of K-Dur 20 or other bioequivalent generic K-Dur 20 products.

Request No. 134: In June 1997, Upsher expected that the price of generic K-Dur 20 would be more than 20% below the price of K-Dur 20.

Request No. 135: In June 1997, Upsher expected that sales in units of K-Dur 20 would fall after the entry of a generic K-Dur 20 product.

Request No. 136: In June 1997, Upsher expected that dollar sales of K-Dur 20 would fall after the entry of a generic K-Dur 20 product.

Request No. 137: In June 1997, Upsher expected that profits for K-Dur 20 would fall after the entry of a generic K-Dur 20 product.

Request No. 138: As of September 2001, Upsher expects the price of generic K-Dur 20 to be at least 20% below the price of K-Dur 20.

Request No. 139: As of September 2001, Upsher expects that sales in units of K-Dur 20 would fall after the entry of a generic K-Dur 20 product.

Request No. 140: As of September 2001, Upsher expects that dollar sales of K-Dur 20 would fall after the entry of a generic K-Dur 20 product.

Request No. 141: As of September 2001, Upsher expects that profits for K-Dur 20 would fall after the entry of a generic K-Dur product.

Entry of Generic K-Dur 20

Request No. 142: Upsher's profits for its generic version of K-Dur 20 for 2001 and 2002 would be lower if Upsher were to have launched its product in January 2002 rather than September 2001.

Request No. 143: As of September 2001, Upsher's Average Selling Price of its generic version of K-Dur 20 is at least a 20% discount to the Average Selling Price of K-Dur 20.

Request No. 144: As of September 2001, Upsher's Average Selling Price of its generic version of K-Dur 20 is at least a 30% discount to the Average Selling Price of K-Dur 20.

Request No. 145: As of September 2001, Upsher's Average Selling Price of its generic version of K-Dur 20 is at least a 40% discount to the Average Selling Price of K-Dur 20.

Request No. 146: As of September 2001, Upsher's Average Selling Price of its generic version of K-Dur 20 is at least a 50% discount to Average Selling Price of K-Dur 20.

Request No. 147: On September 1, 2001, Upsher announced that it was launching its generic versions of K-Dur 20 and K-Dur 10.

Request No. 148: On September 1, 2001, Upsher began selling its generic versions of K-Dur 10 and K-Dur 20.

Request No. 149: In September 2001, Upsher began selling its generic versions of K-Dur 20 and K-Dur 10.

Request No. 150: On September 1, 2001, Upsher announced that its generic versions of K-Dur 20 and K-Dur 10 "are the first and only bioequivalent alternatives to widely-prescribed K-Dur 20 mEq and K-Dur 10 mEq."

Request No. 151: As of September 5, 2001, Upsher's generic versions of K-Dur 20 and K-Dur 10 were the only bioequivalent or AB-rated alternatives to K-Dur 20 mEq and K-Dur 10 mEq.

Request No. 152: Upsher's generic versions of K-Dur 20 and K-Dur 10 are the first bioequivalent or AB-rated alternatives to K-Dur 20 mEq and K-Dur 10 mEq.

Request No. 153: Upsher's generic versions of K-Dur 20 and K-Dur 10 are the only bioequivalent or AB-rated alternatives to K-Dur 20 mEq and K-Dur 10 mEq.

Request No. 154: On September 1, 2001, Upsher announced that its generic versions of K-Dur 20 and K-Dur 10 were "available at up to 50 percent of the cost of K-Dur."

Request No. 155: Upsher is selling its generic versions of K-Dur 20 and K-Dur 10 at prices as much as 50% below the price of K-Dur.

Request No. 156: On September 1, 2001, Upsher announced that its goal was to have a 50% unit share of the microencapsulated, potassium chloride market by the end of 2001.

Request No. 157: Warrick, a part of Schering, began selling a bioequivalent alternative to K-Dur 20 in September 2001.

Request No. 158: Substitution from a brand product to its bioequivalent or AB-rated generic product occurs at a faster rate in 2001 than it did in 1997.

<u>Evaluation of Niacor-SR License</u>

Request No. 159: During Schering's June 1997 Niacor-SR Evaluation, Schering did not request from Upsher any clinical data beyond the data included in document SP 16 00061-112.

Request No. 160: During Schering's June 1997 Niacor-SR Evaluation, Schering never received any clinical data from Upsher regarding the co-administration of Niacor-SR with a statin.

Request No. 161: Schering never received any clinical data from Upsher regarding the co-administration of Niacor-SR with a statin.

Request No. 162: Schering has never conducted any clinical trials regarding the co-administration of Niacor-SR with a statin.

Request No. 163: Upsher has never conducted any clinical trials regarding the co-administration of Niacor-SR with a statin.

Request No. 164: Document SP 16 00061-112 states that Upsher had not filed U.S. Patent No. 5,126,145 in Europe.

Request No. 165: Document SP 16 00061-112 states that Upsher filed U.S. Patent No. 5,268,181 in Europe but that the status of that patent in Europe was pending.

Request No. 166: Only two patents concerning Niacor-SR (U.S. Patent Nos. 5,268,181 and 5,126,145) are discussed in document SP 16 00061-112.

Request No. 167: Prior to entering into the Schering/Upsher Agreement, Schering never requested from Upsher the prosecution history concerning U.S. Patent No. 5,268,181.

Request No. 168: Prior to entering into the Schering/Upsher Agreement, Schering never requested from Upsher any information concerning U.S. Patent No. 5,268,181.

Request No. 169: Prior to entering into the Schering/Upsher Agreement, Schering never requested from Upsher the prosecution history concerning U.S. Patent No. 5,126,145.

Request No. 170: Prior to entering into the Schering/Upsher Agreement, Schering never requested from Upsher any information concerning U.S. Patent No. 5,126,145.

Negotiations with Kos

Request No. 171: In May 1996, Kos filed an NDA for a sustained release niacin product called Niaspan.

Request No. 172: At the time of the Schering/Upsher Agreement, Upsher had not yet filed its NDA for Niacor-SR.

Request No. 173: Upsher never informed Schering that Upsher intended to seek or considered seeking FDA approval for an ANDA for Niacor-SR.

Request No. 174: Prior to January 1, 2000, Upsher never informed Schering that Upsher intended to seek or considered seeking FDA approval for an ANDA for Niacor-SR.

Request No. 175: In September 1998, Upsher informed Schering that Upsher had ceased its activities directed at submitting an NDA for Niacor-SR to the FDA.

Request No. 176: Prior to September 1998, Upsher had not informed Schering that Upsher had ceased its activities directed at submitting an NDA for Niacor-SR to the FDA.

Request No. 177: Prior to September 1998, Schering had no discussions with Upsher about whether Upsher had reduced its level of efforts or activity directed at submitting an NDA for Niacor-SR to the FDA

Request No. 178: Prior to September 1998, Upsher had not informed Schering that Upsher had decided to reduce its efforts or activities directed at submitting an NDA for Niacor-SR to the FDA

Upsher's Efforts to Identify Niacor-SR License

Request No. 179: Upsher retained Moreton Marketing in 1996 to identify potential licensees for Upsher's Niacor-SR product in certain European countries.

Request No. 180: Mr. David A. Pettit of Moreton Marketing was involved in identifying potential licensees for Upsher's Niacor-SR product in certain European countries.

Request No. 181: On January 16, 1997, Mr. David A. Pettit sent a letter to Beafour Ipsen International S.A. seeking to determine whether Beafour Ipsen International S.A. had interest in licensing Upsher's Niacor-SR product in certain European countries.

Request No. 182: On or about January 21, 1997, Beafour Ipsen International responded to Mr. David A. Pettit that it was not interested in pursuing negotiations with Upsher regarding the proposed licensing of Niacor-SR.

Request No. 183: On January 16, 1997, Mr. David A. Pettit sent a letter to Bayer AG seeking to determine whether Bayer AG had interest in licensing Upsher's Niacor-SR product in certain European countries.

Request No. 184: On January 21, 1997, Bayer AG responded to Mr. David A. Pettit that it was not interested in pursuing negotiations with Upsher regarding the proposed licensing of Niacor-SR.

Request No. 185: On January 16, 1997, Mr. David A. Pettit sent a letter to Solvay Pharma S.A. seeking to determine whether Solvay Pharma S.A. had interest in licensing Upsher's Niacor-SR product in certain European countries.

Request No. 186: On or about January 24, 1997, Solvay S.A. responded to Mr. David A. Pettit that it was not interested in pursuing negotiations with Upsher regarding the proposed licensing of Niacor-SR because "[t]he statins group of products are actually widely prescribed and there is not much room anymore for nicotinic acids" and Solvay Pharma S.A. is "not certain that sufficient sales can be generated to make a launch profitable." as reflected in document USL 09096.

Request No. 187: On January 16, 1997, Mr. David A. Pettit sent a letter to Schwarz Pharma A.G. seeking to determine whether Schwarz Pharma A.G. had interest in licensing Upsher's Niacor-SR product in certain European countries.

Request No. 188: On or about January 22, 1997, Schwarz Pharma AG responded to Mr. David A. Pettit that it was not interested in pursuing negotiations with Upsher regarding the proposed licensing of Niacor-SR.

Request No. 189: On January 16, 1997, Mr. David A. Pettit sent a letter to Boehringer Manheim GmbH seeking to determine whether Boehringer Manheim GmbH had interest in licensing Upsher's Niacor-SR product in certain European countries.

Request No. 190: On or about January 23, 1997, Boehringer Manheim GmbH responded to Mr. David A. Pettit that it was not interested in pursuing negotiations with Upsher regarding the proposed licensing of Niacor-SR "due to limited market volume and the known side effects of Niacin," as reflected in document USL 09108.

Request No. 191: On January 16, 1997, Mr. David A. Pettit sent a letter to Boehringer Ingelheim GmbH seeking to determine whether Boehringer Ingelheim GmbH had interest in licensing Upsher's Niacor-SR product in certain European countries.

Request No. 192: On or about January 27, 1997, Boehringer Ingelheim GmbH responded to Mr. David A. Pettit that it was not interested in pursuing negotiations with Upsher regarding the proposed licensing of Niacor-SR.

Request No. 193: On January 16, 1997, Mr. David A. Pettit sent a letter to Luitpold Pharma GmbH seeking to determine whether Luitpold Pharma GmbH had interest in licensing Upsher's Niacor-SR product in certain European countries.

Request No. 194: On or about February 4, 1997, Luitpold Pharma GmbH responded to Mr. David A. Pettit that it was not interested in pursuing negotiations with Upsher regarding the proposed licensing of Niacor-SR.

Request No. 195: On January 16, 1997, Mr. David A. Pettit sent a letter to Abbott Laboratories, Inc. seeking to determine whether Abbott Laboratories, Inc. had interest in licensing Upsher's Niacor-SR product in certain European countries.

Request No. 196: As of April 21, 1997, Abbott Laboratories, Inc. had not responded to Mr. David A. Pettit that it had any interest in pursuing negotiations with Upsher regarding the proposed licensing of Niacor-SR.

Request No. 197: On January 16, 1997, Mr. David A. Pettit sent a letter to Akzo Pharma International b.v. seeking to determine whether Akzo Pharma International b.v. had interest in licensing Upsher's Niacor-SR product in certain European countries.

Request No. 198: On February 4, 1997, Akzo Nobel Pharma responded to Mr. David A. Pettit that it was not interested in pursuing negotiations with Upsher regarding the proposed licensing of Niacor-SR.

Request No. 199: On January 16, 1997, Mr. David A. Pettit sent a letter to Asta Medica AG seeking to determine whether Asta Medica AG had interest in licensing Upsher's Niacor-SR product in certain European countries.

Request No. 200: As of April 21, 1997, Asta Medica AG had not responded to Mr. David A. Pettit

Request No. 201: On January 16, 1997, Mr. David A. Pettit sent a letter to AB Astra seeking to determine whether AB Astra had interest in licensing Upsher's Niacor-SR product in certain European countries.

Request No. 202: On February 6, 1997, Astra AB responded to Mr. David A. Pettit that it was not interested in pursuing negotiations with Upsher regarding the proposed licensing of Niacor-SR.

Request No. 203: On January 16, 1997, Mr. David A. Pettit sent a letter to Byk Gulden Lomerg Chemisch Fabrik GmbH seeking to determine whether Byk Gulden Lomerg Chemisch Fabrik GmbH had interest in licensing Upsher's Niacor-SR product in certain European countries.

Request No. 204: On or about March 4, 1997, Byk Gulden Lomberg Chemische Fabrik GmbH responded to Mr. David A. Pettit that it was not interested in pursuing negotiations with Upsher regarding the proposed licensing of Niacor-SR because it did "not expect that a product like Niacor can get a sufficient market share in Europe in the highly competitive segment of lipid lowering agents," as reflected in document USL 09089.

Request No. 205: On January 16, 1997, Mr. David A. Pettit sent a letter to Cilag-Janssen Pharmaceutica N.V. seeking to determine whether Cilag-Janssen Pharmaceutica N.V. had interest in licensing Upsher's Niacor-SR product in certain European countries.

Request No. 206: On February 5, 1997, Janssen Pharmaceutica N.V. responded to Mr. David A. Pettit that it was not interested in pursuing negotiations with Upsher regarding the proposed licensing of Niacor-SR. It said that "[w]hen combining the risks involved with nicotonic acid on the one hand and the market strength and market presence of the statins on the other hand, we have to unfortunately conclude that we wish to elect to renounce on the opportunity kindly provided to us." as reflected in document Moreton 0000385.

Request No. 207: On January 16, 1997, Mr. David A. Pettit sent a letter to DuPont Pharmaceuticals Limited seeking to determine whether DuPont Pharmaceuticals Limited had interest in licensing Upsher's Niacor-SR product in certain European countries.

Request No. 208: On February 5, 1997, DuPont Pharmaceuticals Limited responded to Mr. David A. Pettit that it was not interested in pursuing negotiations with Upsher regarding the proposed licensing of Niacor-SR.

Request No. 209: On January 16, 1997, Mr. David A. Pettit sent a letter to Ferring AB seeking to determine whether Ferring AB had interest in licensing Upsher's Niacor-SR product in certain European countries.

Request No. 210: As of April 21, 1997, Ferring AB had not responded to Mr. David A. Pettit that it had any interest in pursuing negotiations with Upsher regarding the proposed licensing of Niacor-SR.

Request No. 211: On January 16, 1997, Mr. David A. Pettit sent a letter to Hoechst Marion Roussel AG seeking to determine whether Hoechst Marrion Roussel AG had interest in licensing Upsher's Niacor-SR product in certain European countries.

Request No. 212: On February 17, 1997, Hoechst Marion Roussel responded to Mr. David A. Pettit that it was not interested in pursuing negotiations with Upsher regarding the proposed licensing of Niacor-SR.

Request No. 213: On January 16, 1997, Mr. David A. Pettit sent a letter to Medeva plc seeking to determine whether Medeva plc. had interest in licensing Upsher's Niacor-SR product in certain European countries.

Request No. 214: On February 7, 1997, Medeva Europe responded to Mr. David A. Pettit that it was not interested in pursuing negotiations with Upsher regarding the proposed licensing of Niacor-SR.

Request No. 215: On January 16, 1997, Mr. David A. Pettit sent a letter to Mundipharma International Limited seeking to determine whether Mundipharma International Limited had interest in licensing Upsher's Niacor-SR product in certain European countries.

Request No. 216: In January 1997, Mundipharma International Limited called Mr. David A. Pettit to say that it was not interested in pursuing negotiations with Upsher regarding the proposed licensing of Niacor-SR and that the side effects of nicotonic acid may be a problem.

Request No. 217: On or about January 28, 1997, Mundipharma International Limited sent a fax to Mr. David A. Pettit informing him that it was not interested in pursuing negotiations with Upsher regarding the proposed licensing of Niacor-SR.

Request No. 218: On January 16, 1997, Mr. David A. Pettit sent a letter to Novo Nordisk A/S seeking to determine whether Novo Nordisk A/S had interest in licensing Upsher's Niacor-SR product in certain European countries.

Request No. 219: On March 13, 1997, Novo Nordisk A/S responded to Mr. David A. Pettit that it was not interested in pursuing negotiations with Upsher regarding the proposed licensing of Niacor-SR.

Request No. 220: On January 16, 1997, Mr. David A. Pettit sent a letter to Hafslund Nycomed A/S seeking to determine whether Hafslund Nycomed A/S had interest in licensing Upsher's Niacor-SR product in certain European countries.

Request No. 221: As of April 21, 1997, Hafslund Nycomed A/S had not responded to Mr. David A. Pettit that it had any interest in pursuing negotiations with Upsher regarding the proposed licensing of Niacor-SR.

Request No. 222: On January 16, 1997, Mr. David A. Pettit sent a letter to Pfizer Limited – Pharmaceuticals seeking to determine whether Pfizer Limited – Pharmaceuticals had interest in licensing Upsher's Niacor-SR product in certain European countries.

Request No. 223: In April or May of 1997, Pfizer Limited - Pharmaceuticals responded to Mr. David A. Pettit that it was not interested in continuing to pursue negotiations with Upsher regarding the proposed licensing of Niacor-SR.

Request No. 224: On January 16, 1997, Mr. David A. Pettit sent a letter to Rhone-Poulenc Rorer S.A. seeking to determine whether Rhone-Poulenc Rorer S.A. had interest in licensing Upsher's Niacor-SR product in certain European countries.

Request No. 225: As of April 21, 1997, Rhone-Poulenc Rorer S.A. had not responded to Mr. David A. Pettit that it had any interest in pursuing negotiations with Upsher regarding the proposed licensing of Niacor-SR.

Request No. 226: On January 16, 1997, Mr. David A. Pettit sent a letter to Sanofi Winthrop Limited seeking to determine whether Sanofi Winthrop Limited had interest in licensing Upsher's Niacor-SR product in certain European countries.

Request No. 227: On February 3, 1997, Sanofi Winthrop Limited responded to Mr. David A. Pettit that it was not interested in pursuing negotiations with Upsher regarding the proposed licensing of Niacor-SR because, in part, of Niacor-SR's "limited commercial potential." as reflected in document USL 09104.

Request No. 228: On January 16, 1997, Mr. David A. Pettit sent a letter to Schering A.G. seeking to determine whether Schering A.G. had interest in licensing Upsher's Niacor-SR product in certain European countries.

Request No. 229: On February 4, 1997, Schering AG responded to Mr. David A. Pettit that it was not interested in pursuing negotiations with Upsher regarding the proposed licensing of Niacor-SR.

Request No. 230: On January 16, 1997, Mr. David A. Pettit sent a letter to UCB S.A. - Pharma Division seeking to determine whether UCB S.A. had interest in licensing Upsher's Niacor-SR product in certain European countries.

Request No. 231: On or about February 10, 1997, UCB S.A. responded to Mr. David A. Pettit that it was not interested in pursuing negotiations with Upsher regarding the proposed licensing of Niacor-SR.

Request No. 232: On January 16, 1997, Mr. David A. Pettit sent a letter to Yamanouchi Pharmaceutical b.v. seeking to determine whether Yamanouchi Pharmaceutical B.V. had interest in licensing Upsher's Niacor-SR product in certain European countries.

Request No. 233: On February 4, 1997, Yamanouchi Europe B.V. responded to Mr. David A. Pettit that it was not interested in pursuing negotiations with Upsher regarding the proposed licensing of Niacor-SR.

Request No. 234: On January 16, 1997, Mr. David A. Pettit sent a letter to Knoll AG seeking to determine whether Knoll AG had interest in licensing Upsher's Niacor-SR product in certain European countries.

Request No. 235: On February 4, 1997, Knoll AG responded to Mr. David A. Pettit that it was not interested in pursuing negotiations with Upsher regarding the proposed licensing of Niacor-SR because, in part, of the "small market for the product." as reflected in document USL 09118.

Request No. 236: On January 16, 1997, Mr. David A. Pettit sent a letter to Leo Pharmaceutical Products A/S seeking to determine whether Leo Pharmaceutical Products A/S had interest in licensing Upsher's Niacor-SR product in certain European countries.

Request No. 237: On February 3, 1997, Leo Pharmaceutical Products A/S responded to Mr. David A. Pettit that it was not interested in pursuing negotiations with Upsher regarding the proposed licensing of Niacor-SR.

Request No. 238: On January 16, 1997, Mr. David A. Pettit sent a letter to F. Hoffman-La Roche A.G. seeking to determine whether F. Hoffman-La Roche A.G. had interest in licensing Upsher's Niacor-SR product in certain European countries.

Request No. 239: On February 3, 1997, F. Hoffman-La Roche Ltd. responded to Mr. David A. Pettit that it was not interested in pursuing negotiations with Upsher regarding the proposed licensing of Niacor-SR.

Request No. 240: On January 16, 1997, Mr. David A. Pettit sent a letter to Schering-Plough Limited seeking to determine whether Schering-Plough Limited had interest in licensing Upsher's Niacor-SR product in certain European countries.

Request No. 241: On January 31, 1997, Schering-Plough Limited verbally responded to Mr. David A. Pettit that it was not interested in pursuing negotiations with Upsher regarding the proposed licensing of Niacor-SR.

Request No. 242: On January 16, 1997, Mr. David A. Pettit sent a letter to SmithKline Beecham plc seeking to determine whether SmithKline Beecham plc had interest in licensing Upsher's Niacor-SR product in certain European countries.

Request No. 243: As of April 21, 1997, SmithKline Beecham plc had not responded to Mr. David A. Pettit

Request No. 244: On February 3, 1997, Mr. David A. Pettit sent a letter to Laboratorios del Dr. Esteve S.A. seeking to determine whether Laboratorios Dr. Esteve S.A. had interest in licensing Upsher's Niacor-SR product in certain European countries.

Request No. 245: On September 29, 1997, Laboratorios Dr. Esteve, S.A. responded to Mr. David A. Pettit that it was not interested in pursuing negotiations with Upsher regarding the proposed licensing of Niacor-SR.

Request No. 246: On February 3, 1997, Mr. David A. Pettit sent a letter to Grunenthal GmbH seeking to determine whether Grunenthal GmbH had interest in licensing Upsher's Niacor-SR product in certain European countries.

Request No. 247: On February 21, 1997, Grunenthal GmbH responded to Mr. David A. Pettit that it was not interested in pursuing negotiations with Upsher regarding the proposed licensing of Niacor-SR.

Request No. 248: On February 3, 1997, Mr. David A. Pettit sent a letter to Meda AB seeking to determine whether Meda AB had interest in licensing Upsher's Niacor-SR product in certain European countries.

Request No. 249: On February 28, 1997, Meda Sverige AB responded to Mr. David A. Pettit that it was not interested in pursuing negotiations with Upsher regarding the proposed licensing of Niacor-SR because "the market for [nicotonic acid] products are very limited. . . and the trend is negative," as reflected in document USL 09090.

Request No. 250: On February 3, 1997, Mr. David A. Pettit sent a letter to Merckle GmbH seeking to determine whether Merckle GmbH had interest in licensing Upsher's Niacor-SR product in certain European countries,

Request No. 251: On or about April 9, 1997, Merckle GmbH responded to Mr. David A. Pettit that it was not interested in pursuing negotiations with Upsher regarding the proposed licensing of Niacor-SR because, in part, of the "low tolerability of the drug and the risk of hepatoxicity," as reflected in document USL 09086.

Request No. 252: On February 3, 1997, Mr. David A. Pettit sent a letter to Prodesfarma S.A. seeking to determine whether Prodesfarma S.A. had interest in licensing Upsher's Niacor-SR product in certain European countries.

Request No. 253: As of April 21, 1997, Prodesfarma S.A. had not responded to Mr. David A. Pettit that it had any interest in pursuing negotiations with Upsher regarding the proposed licensing of Niacor-SR.

Request No. 254: On February 3, 1997, Mr. David A. Pettit sent a letter to Recordati Industria Chemica seeking to determine whether Recordati Industria Chemica E Farmaceutica SpA had interest in licensing Upsher's Niacor-SR product in certain European countries.

Request No. 255: On March 4, 1997, Recordati SpA responded to Mr. David A. Pettit that it was not interested in pursuing negotiations with Upsher regarding the proposed licensing of Niacor-SR because it was "doubtful about the commercial prospects of a nicotonic acid based product in Italy, where this active ingredient is viewed as a somewhat outdated treatment of hyperlipidaemia," as reflected in document USL 09091.

Request No. 256: On February 3, 1997, Mr. David A. Pettit sent a letter to Institut de Recherches International Servier S.A. seeking to determine whether Les Laboratoires Servier had interest in licensing Upsher's Niacor-SR product in certain European countries.

Request No. 257: Servier informed Upsher that it was not interested in continuing to pursue negotiations with Upsher regarding the proposed licensing of Niacor-SR.

Request No. 258: On February 3, 1997, Mr. David A. Pettit sent a letter to Zambon Group SpA seeking to determine whether Zambon Group SpA had interest in licensing Upsher's Niacor-SR product in certain European countries.

Request No. 259: As of April 21, 1997, Zambon Group SpA had not responded to Mr. David A. Pettit that it had any interest in pursuing negotiations with Upsher regarding the proposed licensing of Niacor-SR.

Request No. 260: On February 3, 1997, Mr. David A. Pettit sent a letter to Zeneca Group plc seeking to determine whether Zeneca Group plc had interest in licensing Upsher's Niacor-SR product in certain European countries.

Request No. 261: On February 4, 1997, Zeneca Pharmaceuticals responded to Mr. David A. Pettit that it was not interested in pursuing negotiations with Upsher regarding the proposed licensing of Niacor-SR.

Request No. 262: On April 21, 1997, Mr. David A. Pettit sent a letter to Alfa Wassermann SpA seeking to determine whether Alfa Wassermann SpA had interest in licensing Upsher's Niacor-SR product in certain European countries.

Request No. 263: Alfa Wassermann SpA never responded to Mr. David A. Pettit about whether it had any interest in pursuing negotiations with Upsher regarding the proposed licensing of Niacor-SR.

Request No. 264: On April 21, 1997, Mr. David A. Pettit sent a letter to Les Laboratoires L. Lafon S.A. seeking to determine whether Les Laboratoires L. Lafon S.A. had interest in licensing Upsher's Niacor-SR product in certain European countries.

Request No. 265: Les Laboratoires L. Lafon S.A. never responded to Mr. David A. Pettit about whether it had any interest in pursuing negotiations with Upsher regarding the proposed licensing of Niacor-SR.

Niacor-SR - Clinical Issues

Request No. 266: Clinical trial 920115 for Niacor-SR found that 9% of the patients taking Niacor-SR 1000mg/day had an elevated level of liver enzyme SGPT in the bloodstream.

Request No. 267: Clinical trial 920115 for Niacor-SR found that 6% of the patients taking Niacor-SR 1000mg/day had an elevated level of liver enzyme SGOT in the bloodstream.

Request No. 268: Clinical trial 920115 for Niacor-SR found that 12% of the patients taking Niacor-SR 1500mg/day had an elevated level of liver enzyme SGPT in the bloodstream.

Request No. 269: Clinical trial 920115 for Niacor-SR found that 18% of the patients taking Niacor-SR 1500mg/day had an elevated level of liver enzyme SGOT in the bloodstream.

Request No. 270: Clinical trial 920115 for Niacor-SR found that 31% of the patients taking Niacor-SR 2000mg/day had an elevated level of liver enzyme SGPT in the bloodstream.

Request No. 271: Clinical trial 920115 for Niacor-SR found that 34% of the patients taking Niacor-SR 2000mg/day had an elevated level of liver enzyme SGOT in the bloodstream.

Request No. 272: Clinical trial 920115 for Niacor-SR found that the level of liver enzyme SGOT in the bloodstream increases as the dosage strength of Niacor-SR increases.

Request No. 273: Clinical trial 920115 for Niacor-SR found that the level of liver enzyme SGPT in the bloodstream increases as the dosage strength of Niacor-SR increases.

Request No. 274: Elevated levels of liver enzyme SGOT in the bloodstream are an indication of either liver disease or liver damage.

Request No. 275: Elevated levels of liver enzyme SGPT in the bloodstream are an indication of either liver disease or liver damage.

Request No. 276: The results of clinical trial 920115 for Niacor-SR reflect that Niacor-SR 1000 mg/day has less efficacy in lowering LDL Cholesterol than does immediate release niacin 1000mg/day.

Request No. 277: The results of clinical trial 920115 for Niacor-SR reflect that Niacor-SR 1500mg/day has less efficacy in lowering LDL Cholesterol than does immediate release niacin 1500mg/day.

Request No. 278: Document SP 16 00061-112 contains clinical data showing that the sustained released form of niacin tested in Upsher's clinical trial 920115 had elevated liver enzymes as compared to the immediate form version of niacin tested in Upsher's clinical trial #920115.

Request No. 279: The results of clinical trial 920115 for Niacor-SR reflect that Niacor-SR 1000 mg day has less efficacy in increasing HDL Cholesterol than does immediate release niacin 1000mg day.

Request No. 280: The results of clinical trial 920115 for Niacor-SR reflect that Niacor-SR 1500mg day has less efficacy in increasing HDL Cholesterol than does immediate release niacin 1500mg day.

Request No. 281: Document SP 16 00061-112 contains data showing that 62% of patients receiving Niacor-SR completed clinical trial 900221.

Request No. 282: 62% of patients receiving Niacor-SR completed clinical trial #900221.

Request No. 283: Document SP 16 00061-112 contains data showing that at least 32% of patients receiving Niacor-SR withdrew from clinical trial 900221 because of safety issues.

Request No. 284: 32% of patients receiving Niacor-SR withdrew from clinical trial #900221 because of safety issues.

Niacor-SR - Pharmacokinetic Studies

Request No. 285: Prior to the Schering/Upsher Agreement, Upsher had conducted pharmacokinetic studies with a dosage of Niacor-SR.

Request No. 286: Prior to the Schering/Upsher Agreement, the FDA requested that Upsher conduct additional pharmacokinetic studies for Niacor-SR.

Request No. 287: In February 1997, the FDA informed Upsher that its pharmacokinetic study was inadequate to obtain FDA approval for a NDA for Niacor-SR.

Request No. 288: After February 1997, Upsher performed no additional pharmacokinetic studies for Niacor-SR.

Request No. 289: In February 1997, Upsher knew it had to perform an additional pharmacokinetic study in order to obtain FDA approval for a NDA for Niacor-SR.

Request No. 290: By January 1998, Upsher had abandoned any intention of obtaining FDA approval for a NDA for Niacor-SR.

Request No. 291: By January 1998, Upsher had begun working on an ANDA for a generic product version of Niaspan.

Request No. 292: Prior to the Schering/Upsher Agreement, Upsher did not inform Schering that it had not completed pharmacokinetic studies necessary for FDA approval of the Niacor-SR NDA.

Request No. 293: Subsequent to the Schering/Upsher Agreement, Upsher did not inform Schering that it had not completed pharmacokinetic studies necessary for FDA approval of the Niacor-SR NDA.

Request No. 294: Upsher did not request that Schering provide assistance in conducting pharmacokinetic studies necessary for FDA approval of a Niacor-SR NDA.

Patent Status of Niacor-SR

Request No. 295: At the time of the Schering/Upsher Agreement, Upsher had only two patents issued in the United States that related to Niacor-SR, U.S. Patent Nos. 5,268,181 and 5,126,145.

Request No. 296: At the time of the Schering/Upsher Agreement, Upsher had not filed a patent application in Europe for the invention claimed in U.S. Patent No. 5,126,145.

Request No. 297: At the time of the Schering/Upsher Agreement, Upsher had filed a patent application in Europe for the invention claimed in U.S. Patent No. 5,268,181

Request No. 298: At the time of the Schering/Upsher Agreement, Upsher's patent application in Europe for the invention claimed in U.S. Patent No. 5,268,181 was pending.

Request No. 299: At the time of the Schering/Upsher Agreement, Upsher had no existing patent protection for Niacor-SR in Europe.

Request No. 300: Prior to the Schering/Upsher Agreement, Upsher had entered into the Kos Patent Cross-Licensing Agreement relating to the companies' intellectual property concerning their respective niacin products.

Request No. 301: The Kos Patent Cross-Licensing Agreement gave Kos the right to sublicense the rights Kos had to Upsher's patents 5,126,145 and 5,268,181.

Request No. 302: The Kos Patent Cross-Licensing Agreement did not provide Upsher with the right to sublicense Kos's intellectual property covered by the Kos Patent Cross-Licensing Agreement.

Request No. 303: The Kos Patent Cross-Licensing Agreement allowed Kos to practice Upsher's patents 5,126,145 and 5,268,181 and to sublicense Upsher's patents.

Request No. 304: The Kos Patent Cross-Licensing Agreement allowed Kos to sublicense Upsher's patents 5,126,145 and 5,268,181 in Europe.

Co-administration with Statin

Request No. 305: Upsher has never a conducted clinical trial regarding the co-administration of Niacor-SR with a statin.

Request No. 306: Prior to July 1997, Upsher had not conducted any clinical trials regarding the co-administration of Niacor-SR with a statin.

Comparison to Niaspan

Request No. 307: At the time of the Schering/Upsher Agreement, Upsher was aware that Kos expected to receive NDA approval for Niaspan in 1997.

Request No. 308: At the time of the Schering/Upsher Agreement, Upsher expected that Kos would receive NDA approval for Niaspan in 1997.

Request No. 309: Niaspan has a superior safety profile to Niacor-SR.

Request No. 310: As of September 1997, Upsher knew that Niaspan had a superior safety profile than Niacor-SR.

Request No. 311: Kos's Niaspan product was intended to be taken once a day at bedtime.

Request No. 312: Kos's Niaspan product was a once-daily formulation of niacin.

Request No. 313: At the time of the Schering/Upsher Agreement, Upsher was aware that Kos's Niaspan product was a once-daily formulation of niacin.

Request No. 314: Upsher's Niacor-SR was not a once a day niacin product.

Request No. 315: Upsher's Niacor-SR was not intended to be taken only once a day.

Request No. 316: Upsher's Niacor-SR was intended to be taken twice a day.

Request No. 317: Upsher's Niacor-SR was not a once a day at bedtime product.

Request No. 318: As of June 1997, Upsher had not done clinical trials of Niacor-SR in which the product was take once a day at bedtime.

Request No. 319: Upsher's Niacor-SR product was a twice-daily formulation of niacin.

Request No. 320: At the time of the Schering/Upsher Agreement, Upsher was aware that a once-daily formulation of niacin had compliance advantages over a twice-daily formulation of niacin.

Request No. 321: A once-daily formulation of niacin has compliance advantages over a twice-daily formulation of niacin.

Request No. 322: Document USL 13190 reflects that Upsher was aware that Kos' Niaspan product had superior cholesterol level results compared to Niacor-SR.

Request No. 323: Upsher was aware that Kos' Niaspan product had a superior cholesterol level results that Niacor-SR.

Request No. 324: Document USL 13190 reflects that Upsher was aware that Kos' Niaspan product had a superior side effect profile than Niacor-SR.

Request No. 325: Upsher was aware that Kos' Niaspan product had a superior side effect profile than Niacor-SR.

Efforts to Obtain FDA Approval for Niacor-SR

Request No. 326: In October 1997, Upsher decided to pursue FDA approval of an ANDA for Kos's Niaspan.

Request No. 327: Upsher never informed Schering that it intended to pursue FDA approval of an ANDA for Kos's Niaspan.

Request No. 328: In October 1997, Upsher decided to reduce its efforts or activities directed at submitting to the FDA a NDA for Niacor-SR.

Request No. 329: In or around October 1997, Upsher reduced its efforts or activities directed at submitting to the FDA a NDA for Niacor-SR.

Request No. 330: Upsher did not inform Schering during 1997 that it had decided to reduce its efforts or activities directed at submitting to the FDA a NDA for Niacor-SR.

Request No. 331: By January 1998, Upsher decided to cease efforts and activities directed at submitting to the FDA a NDA for Niacor-SR.

Request No. 332: Upsher did not inform Schering until September 1998 that it had ceased efforts and activities directed at submitting to the FDA a NDA for Niacor-SR.

Request No. 333: At the time of the Schering/Upsher Agreement, Upsher was aware that niacin was available over-the-counter in Europe.

Request No. 334: At the time of the Schering/Upsher Agreement, Upsher estimated potential U.S. sales for Niacor-SR at less than $10 million per year.

Prosecution of the '743 Patent

Request No. 335: During prosecution of the '743 Patent's application before the U.S. Patent and Trademark Office, the examiner issued an office action on August 31, 1988 rejecting independent claim 1 of the '743 Patent as unpatentable, under 35 U.S.C. § 103.

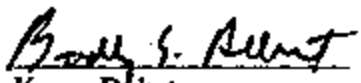
Request No. 336: During prosecution of the '743 Patent's application before the U.S. Patent and Trademark Office, Schering amended independent claim 1 on March 1, 1989, following the examiner's office action of August 31, 1988 rejecting claim 1 as unpatentable, under 35 U.S.C. § 103.

Request No. 337: During prosecution of the '743 Patent's application before the U.S. Patent and Trademark Office, Schering amended independent claim 1 on March 1, 1989 to recite an additional limitation of ethylcellulose having a viscosity greater than 40 cp.

Request No. 338: During prosecution of the '743 Patent's application before the U.S. Patent and Trademark Office, Schering's March 1, 1989 amendment to the ethylcellulose limitation of independent claim 1 was a narrowing amendment related to a rejection under 35 U.S.C. § 103.

Request No. 339: Schering did not list the '743 Patent in the Orange Book within 30 days of the issuance of the '743 Patent.

Respectfully Submitted,



Karen Bokat
Bradley S. Albert

Counsel Supporting the Complaint

Bureau of Competition
Federal Trade Commission
Washington, D.C. 20580

Dated: November 6, 2001

CERTIFICATE OF SERVICE

I, Clifton L. Smith, hereby certify that on January 2, 2002:

I caused two copies of Complaint Counsel's Motion To Compel Responses To Interrogatories And Admissions From Respondent Upsher-Smith Corporation - Public Version to be served upon the following person by hand delivery-

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

I caused one original and one copy of Complaint Counsel's Motion To Compel Responses To Interrogatories And Admissions From Respondent Upsher-Smith Corporation - Public Version to be served by hand delivery and one copy to be served by electronic mail upon the following person-

Office of the Secretary
Federal Trade Commission
Room H-159
600 Pennsylvania Avenue, N.W.
Washington, D.C. 20580

I caused copies of Complaint Counsel's Motion To Compel Responses To Interrogatories And Admissions From Respondent Upsher-Smith Corporation - Public Version to be served upon the following persons by electronic mail and Federal Express-

Laura S. Shores, Esq.
Howrey Simon Arnold & White
1299 Pennsylvania Avenue, N.W.
Washington, D.C. 20004-2402

Christopher M. Curran, Esq.
White & Case LLP
601 13th Street, N.W.
Washington, D.C. 20005

Clifton L. Smith