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

To: The Honorable D. Michael Chappell
Administrative Law Judge

COMPLAINT COUNSEL'S STATEMENT OF THE CASE

In accordance with the Scheduling Order entered on May 3, 2001, complaint counsel submit this statement of the case: (1) identifying the legal and factual matters to be decided at trial; (2) reporting on compliance with discovery; and (3) reporting on the status of settlement discussions.

I. Introduction

This case arises out of Schering Plough's agreements with two companies that were seeking to market low-cost generic versions of Schering's widely-prescribed potassium chloride supplement known as K-Dur 20. The Commission's complaint charges that under these agreements Schering paid Upsher-Smith Laboratories and American Home Products Corporation (AHP), millions of dollars as a means of inducing them to delay launching their generic K-Dur

20 products. In the case of Upsher-Smith, Schering's $60 million payment for delayed entry was disguised as a fee to license certain products held by Upsher-Smith. The AHP agreement, while it also includes a license, involves direct payments for delay.

The agreements were intended to preserve Schering's monopoly profits from K-Dur 20. By 1995, Schering's substantial revenues from K-Dur 20 were threatened because Upsher and AHP were each seeking FDA approval to enter with a generic version. Although it held a patent on K-Dur 20 that did not expire until 2006, Schering was vulnerable, because the patent is a very narrow one relating to the extended-release mechanism of the product and thus could be designed around. And Schering had a great deal at stake, because the well-documented effect of generic entry is to cause a precipitous drop in the market share of the brand name drug. Consequently, Schering settled its patent infringement actions against Upsher and AHP, in each case paying the alleged infringer. Those payments secured a delay in generic entry and thereby protection for Schering's revenue stream from K-Dur 20.

In any industry, paying potential competitors to forestall entry would raise obvious antitrust concerns. In the pharmaceutical industry, the stakes for consumers could not be clearer. Delaying generic entry means denying consumers access to more affordable medications critical to their health and well-being. This case seeks to vindicate those consumer interests.

II. Background

Potassium chloride supplements treat hypokalemia (in lay terms, potassium deficiency), a condition that often arises among people who take medication to treat high blood pressure. People with hypokalemia have no alternative to potassium chloride and, because high blood pressure is a chronic condition, must take potassium chloride for the rest of their lives. Although

potassium chloride supplements are administered in many forms (powder, tablets, and capsules), the most popular dosage form is a 20 mEq (milliequivalent), extended-release tablet; that dosage form is the easiest to take and leads to higher patient compliance. Schering markets K-Dur 20, the only extended-release 20 mEq potassium chloride supplement, with annual sales in excess of $200 million. Since at least the early 1990s, Schering has been the only potassium chloride supplement manufacturer to continually raise price while, at the same time, increase its unit sales and revenue, circumstances that reflect Schering's monopoly power in its K-Dur 20 product.

Until this month, Schering faced no competition from a generic version of its K-Dur 20 product. A bioequivalent generic would have offered (and now will offer) consumers all the benefits of K-Dur at a significantly reduced price. Generic entry would have caused (and now will cause) Schering to lose significant sales and profits.

Although Schering owns a patent claiming K-Dur that expires in 2006, Schering expected generic entry well before that time. The 4,863,743 ('743) patent does not (and could not) cover potassium chloride alone, which is a common and unpatentable substance; rather, it is directed to a specific coating used in Schering's potassium chloride tablet, K-Dur 20. The coating slowly releases the potassium chloride over time, making it a sustained release product. This coating is comprised of ethyl cellulose with a viscosity greater than 40 centipoise in combination with either hydroxypropylcellulose or polyethylene glycol. Therefore, a generic manufacturer could sell a generic, bioequivalent K-Dur 20 as long as it did not use the coating described in the '743 patent as the sustained-release mechanism. In 1996, Schering forecasted that generic entry would occur in 1997 and would cause Schering to lose over 20% of its K-Dur revenues annually.

Schering's later forecasts projected that generic K-Dur 20 would have an even more substantial impact on branded K-Dur 20.

The possibility of generic entry arose in 1995 when two companies, first Upsher and then AHP, sought FDA approval to market generic versions of K-Dur 20. Each filed an Abbreviated New Drug Application (ANDA) certifying that its generic equivalent to K-Dur did not infringe the '743 patent. The certification (known as a Paragraph IV certification) had special implications for Upsher. As the first company to file an ANDA for K-Dur 20 with a paragraph IV certification, Upsher possibly held the eligibility for 180-days of market exclusivity under the Hatch-Waxman Act. If so, no other company's ANDA would receive final approval until 180 days after either Upsher began marketing its product or there was a court decision holding the '743 patent invalid or not infringed. In separate actions, Schering sued first Upsher and then AHP for patent infringement.

A. The Upsher-Schering Agreement

Schering's infringement suit turned on the viscosity of the material used to coat the product. Upsher consistently maintained its position of non-infringement because its product used

Upsher filed a motion for summary judgement, arguing that its product did not infringe as a matter of law. The parties began to negotiate a settlement in earnest about a month before trial.

From the beginning of the settlement negotiations, Upsher and Schering discussed Schering paying Upsher to delay marketing its generic version of K-Dur 20. Upsher's CEO, Ian

Troup, initially requested a $60-70 million payment from Schering, stating that Upsher needed income if it were to delay launching its generic version of K-Dur 20. Upsher asserted that it would win the patent litigation, enter the market, and thereby open the floodgates to other generic applicants, destroying Schering's monopoly. Schering told Upsher that a naked payment not to compete would be illegal. Schering, however, was more than willing to pay Upsher to delay its entry; the parties just needed to find a vehicle for the payment.

Eventually, the parties settled on a series of licenses from Upsher to Schering as a way to transfer the money that Upsher demanded for delaying its entry. On June 17, 1997 (one day before the commencement of trial), the parties reached the final settlement of the patent litigation. Schering agreed to pay Upsher $60 million unconditionally – the amount Upsher originally had requested. In return, Upsher agreed to delay marketing its generic version of K-Dur 20 until September 1, 2001. After that date, Upsher received a royalty-free license to sell its generic K-Dur 20 product. In addition, Upsher agreed not to market any other microencapsulated potassium chloride product until the September 1, 2001 – whether or not the product infringed the '743 patent. Finally, Upsher licensed to Schering the marketing rights outside of the United States, Canada, and Mexico for Niacor-SR, Prevalite,[1] pentoxifylline, and Klor-Con. Upsher would also receive milestone payments based on the countries in which Schering launched Niacor-SR and a royalty based on Schering's net sales of Niacor-SR.

As the evidence will show, the Niacor-SR and other licenses were nothing more than a disguise for a payment to delay entry. Schering has conceded that Prevalite, pentoxifylline, and Klor-Con had little commercial value. Schering has never paid anything close to $60 million in

[1] The Prevalite license also included the United States.

unconditional payments to license a product. Even when a product could represent a new therapeutic class, Schering has paid less than $30 million unconditionally.

Nor was Niacor-SR worth an unconditional payment, let alone one that deviated substantially from Schering's own practice:[2]

- Niacor-SR was developed as an extended-release niacin product for the treatment of cholesterol. Niacin products have been used to treat high cholesterol for years, but traditionally have had significant side effects, including causing liver toxicity and flushing.

- At the time of the agreement, Niacor-SR was still in Phase III clinical trials, it was not ready to be submitted to the FDA for approval, and its approval in the United States or Europe was uncertain.

- Schering's UK Division only recently had rejected Upsher's Niacor-SR product. It was not consulted during the settlement discussions.

- Just before it agreed to pay Upsher $60 million unconditionally, Schering had refused to make any unconditional payments for the world-wide marketing rights to a better extended-released niacin product.

- Schering did not finish a valuation of Niacor-SR prior to reaching the agreement

- Schering did virtually no due diligence, thereby ignoring or overlooking problems with Niacor-SR's safety as well as issues surrounding the existence and extent of its patent protection.

By entering into the agreement with Upsher-Smith, Schering ensured that Upsher-Smith would not bring its generic version of K-Dur to market prior to September 1, 2001. In addition, Schering's agreement with Upsher would likely obstruct all other generic applicants' entry into the K-Dur 20 market because Upsher's status as the first-filer meant it might be eligible for the 180-day exclusivity period. Although FDA regulations would have required Upsher-Smith to

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[2] Whether or not Niacor-SR may have been worth the milestone and royalty payments that the parties negotiated, the issue is whether it warranted an unconditional payment of the magnitude provided by the agreement.

"successfully defend" a patent suit to be eligible for the 180-day exclusivity period, in January of 1997, a federal district court enjoined the FDA from applying its successful defense regulation and intimated that the successful defense regulation was inconsistent with the statute and thus invalid. *Mova Pharmaceuticals Corp. v. Shalala*, 955 F. Supp. 128 (D.D.C. 1997). Thus, at the time the parties entered their agreement in June 1997, there was a possibility that Upsher would be eligible for the exclusivity period despite having settled with Schering. Upsher's agreement to delay marketing its product thus was likely to delay all generic competition to K-Dur 20 until September 1, 2001, unless a subsequent applicant could get a court decision finding the '743 patent invalid or not infringed by its product.[3]

B. Uncertainty About the Status of the 180-Day Exclusivity

The impact of the Upsher settlement on other generic manufacturers was not just theoretical, because AHP had also filed an ANDA. If Upsher maintained the 180-day exclusivity, that exclusivity could block AHP until March 2002 (180-days after Upsher's entry date under its settlement), unless AHP obtained a court decision declaring that AHP's product did not infringe the '743 patent or that the '743 patent was invalid.[4]

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[3] Under 21 U.S.C. 355(j)(5)(B)(iv), the FDA is precluded from approving any subsequent application until 180 days after the earlier of: (1) the first filer commercially markets the drug under the ANDA, or (2) the date of a decision of a court finding the patent which is the subject of the paragraph IV certification invalid or not infringed. These conditions are known as the "commercial marketing" trigger and the "court decision" trigger, respectively. Under the agreement, there would have been no court decision in the lawsuit between Schering and Upsher-Smith, and Upsher-Smith would have refrained from commercially marketing its product until September 1, 2001.

[4] Just as there was uncertainty whether the first-filer had to successfully defend a patent suit to be eligible for the 180-day exclusivity, there was uncertainty, at the time of the AHP agreement, whether a subsequent filer's court victory would trigger the exclusivity period. In

(continued...)

Developments after the Upsher settlement, however, made it appear less likely that Upsher would retain its 180-day exclusivity. In July 1997, another district court found FDA's successful defense regulation valid and binding on the FDA. *See Granutec, Inc. v. Shalala*, 1997 WL 1403894 (E.D.N.C. July 3, 1997); *rev'd*, 1998 U.S. App. LEXIS 6683 (4th Cir. 1998). In November of that year, the FDA announced that it would adhere to the regulation and apply the successful defense requirement. 62 Fed. Reg. 63268 (November 11, 1997). These developments increased the possibility that Upsher lost its eligibility for the exclusivity period by settling with Schering.

C. The AHP-Schering Agreement

In late 1997, AHP threatened Schering's K-Dur 20 profits in two ways. First, if the successful defense requirement were upheld or if a second filer's court victory could trigger the 180-day exclusivity, AHP might be able to enter the K-Dur 20 market before September 2001 and destroy Schering's monopoly. Second, even if AHP could not enter before Upsher, AHP could be the second entrant and would have taken additional sales from Schering's branded K-Dur product. In addition, if Schering were to launch its own generic product through its generic subsidiary, Warrick, AHP's entry could take sales from Warrick or force Warrick to lower its prices.

Schering and AHP began to discuss settling their patent infringement litigation in late 1996. Schering offered a date on which AHP could enter the market. In exchange for agreeing

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[4] (...continued)
Granutec, the FDA had taken the position that a subsequent ANDA filer could trigger a first filer's exclusivity period if it obtained a court decision finding the patent invalid or not infringed. *See* 1998 U.S. LEXIS 6685, *22. *See also* F-D-C Reports: "The Pink Sheet" (June 23, 1997) at 3, reprinted at 1997 WL 16952884.

to delay entry, however, AHP wanted a payment from Schering to replace the revenues it would lose from the delay. AHP's negotiating position was weakened, however, because Schering knew that AHP was having problems, unrelated to the patent issue, obtaining FDA approval for its product.

In January 1998, Schering and AHP reached an agreement in principle, and the court dismissed the patent infringement action. Under the agreement, AHP would delay its entry until January 2004 and would receive payments from Schering tied to how great a threat AHP was to Schering's monopoly. Schering agreed to pay AHP $5 million within 10 days of execution of the agreement and an additional $10 million if AHP had an approvable generic K-Dur product by June 30, 1999. The later AHP had an approvable product, the less money it would receive.[5] Thus, AHP would get more compensation the earlier it could have entered the market and undermined Schering's monopoly. Ultimately, AHP received tentative approval of its generic K-Dur product in May 1999, and Schering paid AHP the additional $10 million.

AHP also agreed to other restraints that further ensured that Schering would face no generic competition. First, AHP agreed to refrain from marketing until January 2004 not only the generic K-Dur 20 product covered by its ANDA, but also any other generic equivalent to K-Dur 20, regardless of whether the product infringed Schering's patents. Second, AHP agreed not to conduct, sponsor, file, support, or aid any company in a bioequivalence study or substitutability study for any generic version of K-Dur 10 or K-Dur 20 until 2006 (the life of the '743 patent).

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[5] The remaining payment schedule was: $5 million if AHP had an approvable product by December 31, 1999; $2.5 million if approvable by December 31, 2000; $1.25 million if approvable by December 31, 2001; and $650,000 if approvable by December 31, 2002.

Finally, AHP agreed not to market more than one version of generic K-Dur 20 between January 2004 and September 2006.

In addition to the direct payment for delayed entry, Schering paid AHP a total of $15 million ostensibly for two products it licensed from AHP. The parties did no valuation of the products before the settlement, and AHP has admitted that payment under those licenses made settlement more palatable, suggesting that part of the payment was consideration for delay. Because these payments were in addition to the direct payment for delayed entry, the settlement involves a payment not to compete even if the $15 million paid for enalapril and buspirone was a legitimate transaction.

The two agreements ensured that neither Upsher nor AHP would enter prior to the date agreed to with Upsher-Smith – September 1, 2001. In addition, Schering's settlement with AHP, which prevented AHP from bringing its product to the market until January 1, 2004, could delay the date that a second generic competitor would enter the market. A second generic would drive down the price of generics and take sales from Schering's generic subsidiary, Warrick, as well as possibly taking sales from branded K-Dur.

D. Effects of the Two Agreements

Schering's agreements with Upsher and AHP harmed consumers. For each agreement, the entry date is later than what would have been negotiated without a payment and is later than the expected outcome of litigation. As a result, Schering maintained its monopoly and continued to enjoy monopoly rents until September 1, 2001. Upsher-Smith and AHP received compensation for agreeing to delay entry. Although Schering, Upsher, and AHP all benefitted

from the agreements, consumers had to pay monopoly prices longer than if the settlements did not have a payment and longer than what was expected had the parties litigated their patent cases.

III. Legal and Factual Matters to Be Decided

The Commission's complaint charges that Schering's agreements with Upsher-Smith and AHP are: (1) unreasonable restraints of trade that delayed expected generic entry; (2) monopolization by Schering of the potassium chloride supplement market and narrower markets therein; and (3) conspiracies to monopolize the relevant markets. At this point in the proceeding, most of the factual and legal issues raised by these charges are contested, though a few legal issues raised by Schering and Upsher-Smith in pending motions to dismiss to the complaint may be resolved when those motions are decided. We note below some of the key issues to be addressed at trial.

A. Jurisdiction

As a threshold matter, Your Honor must conclude that Schering-Plough, Upsher and AHP are corporations within the meaning of Section 4 of the FTC Act. Both Schering and AHP have admitted jurisdiction, but Upsher has denied that it is a corporation and refused to admit to the FTC's jurisdiction. Upsher's legal status thus remains a matter to be decided at trial – albeit an easily provable one.

In addition, Your Honor must decide whether or not the respondents' acts and practices, including those alleged in the complaint, are in or affect interstate commerce. Schering has admitted this allegation, but Upsher and AHP each have refused to do so. Although it is unlikely that either intends to seriously contest this allegation (Upsher has admitted that it distributes its

Minnesota-manufactured products "in every state in the United States"),[6] at present it remains an issue to be decided at trial.

B. Unreasonable Restraints of Trade

Each agreement restrains trade in two ways. Overall, Upsher and AHP each agreed to delay their respective entry in exchange for a share of Schering's monopoly profits. In addition, each agreement prohibits Upsher and AHP respectively from developing or marketing a noninfringing version of K-Dur 20.

1. Payments to Delay Entry

Complaint counsel will prove that the respondents entered into agreements not to compete, and that these agreements are *per se* unlawful and also unlawful under the rule of reason. In proving the violations, we will establish that: Schering, Upsher-Smith and AHP are potential competitors; in settling their patent litigation, they entered into agreements not to compete; the agreements had anticompetitive effects -- delaying entry of a generic version of K-Dur 20 and creating a barrier to entry by other potential competitors; and each agreement lacks any procompetitive justification. Therefore, the agreements are illegal under either a *per se* or rule of reason analysis.

The key factual issue to be established at trial is that the agreements involved payments not to compete, that is, that Schering paid its only two potential competitors at the time in order to secure their agreement to delay their entry with a low-cost generic version of K-Dur 20. The evidence will show:

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[6] *See* Letter from Rajeev K. Malik to Yaa Apori regarding Upsher-Smith's Responses to Complaint Counsel's First Request for production of Documents (August 28, 2001).

- Schering's payments induced Upsher-Smith and AHP to agree to a later entry date than either would have agreed to without the payments;
- the agreements had later generic entry dates than the respondents expected had the cases been litigated;
- the Niacor-SR and other licenses were a vehicle to transfer the payment for delay; and
- the parties had overwhelming incentives to delay entry and share the monopoly profits.

Once the nature of the agreements is established, resolution of the legal issues is a straightforward matter.

2. Restraints on Noninfringing Products

In addition, Upsher agreed not to market a noninfringing version of K-Dur 20 before September 1, 2001, and AHP agreed not to market a noninfringing version of K-Dur 20 before January 1, 2004. These are illegal *per se* without regard to Schering's payments for delay. This means the restraints on noninfringing products are illegal whether or not Upsher or AHP could have, or would have, developed another generic K-Dur 20 in the absence of the settlement.

C. Monopolization

Issues raised by the complaint charge that in entering into agreements not to compete with Upsher-Smith and AHP, Schering engaged in unlawful monopolization, include:

- whether Schering possessed monopoly power in the market for the manufacture and sale of potassium chloride supplements or narrower markets therein;
- whether Schering engaged in exclusionary conduct; and
- whether Schering acted with the intent of preserving its monopoly.

Proving Schering's monopoly power in K-Dur 20 will be a straightforward matter: all the respondents predict that generic K-Dur 20 will take almost all of its market share from K-Dur 20 and will price at a significantly lower price, and by the beginning of trial, there will be evidence on generic K-Dur's actual impact on the sales of K-Dur 20, which will confirm the predictions of the respondents. In addition, Schering has consistently raised price for K-Dur 20 while increasing its sales, despite the existence of lower cost generic potassium chloride supplements that are not bioequivalent to K-Dur 20.

The exclusionary acts are the settlement agreements. Schering's monopoly power provides it with monopoly profits, which it used to buy off its potential competitors. Schering earns more as a monopolist than the combined profits that it and the generic K-Dur entrants would make under generic entry, because generic K-Dur would sell (and now is selling) at a much lower price than Schering does. Thus, Schering could pay Upsher-Smith and AHP what these entrants expected to earn, and Schering could still receive the excess monopoly profits for itself. The payments were the means to share the monopoly profits created by the generic entrant's (Upsher's or AHP's) agreement to delay its entry.

Both direct and circumstantial evidence will show that Schering saw the payment as a way to extend its economic monopoly, satisfying the intent requirement.

D. Conspiracy to Monopolize

Issues raised by the complaint's charge that respondents' agreement not to compete constitutes an unlawful conspiracy to monopolize include:

- whether there was an agreement;
- whether respondents engaged in overt acts in furtherance of the conspiracy; and

- whether Schering, Upsher-Smith, and/or AHP had specific intent to monopolize the relevant market.

The key issue for this count will be the intent element. The same evidence that will show Schering's intent under the monopolization count will show its intent under the conspiracy claim. Evidence from Upsher and AHP that each, knowing that Schering had a monopoly, wanted a payment to delay entry, and circumstantial evidence will show that each understood it was helping to maintain Schering's monopoly and benefitting from that extension.

E. Respondents' Defenses

The parties have raised various defenses to the complaint that raise legal issues, including:

- whether possession of a patent immunizes or justifies a monopolist paying potential competitors millions of dollars to delay entry;
- whether a court must adjudicate the patent infringement issues in order to decide whether a patent holder's agreements to pay potential competitors millions of dollars to delay entry violate the antitrust laws;
- whether agreements that do not constitute petitioning for government action or conduct incidental to petitioning are immune from antitrust scrutiny under the *Noerr-Pennington* doctrine.

To the extent that these legal issues are not decided by Your Honor's resolution of the pending motions to dismiss filed by Schering and Upsher-Smith, the parties may reassert these arguments at trial.

IV. Compliance with Discovery

Complaint counsel has made substantial efforts to advance the discovery process in this matter. We have fully complied with all discovery requests to date from the respondents in

accordance with Your Honor's various orders governing discovery, and we participate in on-going negotiations with the respondents. On September 10, 2001, Your Honor entered an order related to a dispute between AHP and complaint counsel of the scope of complaint counsel's search. We will supplement our document production to the extent that the order requires such an action.

The respondents' have refused to provide discovery in a timely manner and have materially hindered complaint counsel's ability to prepare for trial. Although complaint counsel has now largely reached agreements with Schering and Upsher on the scope of discovery failure to provide timely discovery has prevented complaint counsel from taking important fact depositions, required complaint counsel's experts to submit their initial reports without reviewing Schering's document production, and may hinder complaint counsel's experts ability to provide rebuttal. As a result, deadlines for the close of fact discovery, submission of expert rebuttal reports, and expert depositions may need to be moved. Complaint counsel fully expects to reach agreement on these issues with the respondents.

Finally, the respondents have listed 23 expert witnesses (compared to complaint counsel's three), which will create significant problems both for completing discovery and for trial management.

A. Schering's Response

Although Schering received complaint counsel's document request on May 11, 2001, Schering did not product a single document until mid-July. As of today, it has produced fewer than ten boxes of documents and has not provided documents responsive to 10 of the 30 specific requests. There are no major disputes on the subject matter to be produced that might explain

this failure to produce. As to any minor disputes, Schering has not responded to complaint counsel's most recent proposals. Until recently, Schering also refused to tell complaint counsel when it will complete its discovery. Although complaint counsel requested a 3.33(c) deposition on Schering's financial condition on August 9, 2001, Schering, until recently, had not made a witness available or provided any dates for the deposition. Schering, however, did not object to the deposition or provide any reason for delaying over a month in providing dates for the deposition.

On September 13, 2001, complaint counsel sent a letter requesting that Schering finish its document production by September 17 and produce a deponent for the 3.33(c) deposition during the week of September 24th. Schering replied that it will complete its production before the end of the month and will produce the witness for the 3.33(c) deposition on September 26th.

B. Upsher-Smith

Although Upsher received complaint counsel's document request on May 22, 2001, Upsher began its production in the middle of August. We are in the process of determining whether the production fully complies with our document request.

C. AHP

Complaint counsel served our first set of document requests to AHP on May 22, 2001 and a second request for documents on August 8, 2001. Although we have received thirty-seven boxes from AHP, its counsel will not provide a firm answer as to when AHP will fully comply with the document requests, nor will counsel indicate how many boxes of documents we can expect to receive.

As with Schering's refusal to produce documents, AHP's failure has impeded complaint counsel's ability to prepare for depositions and our expert's ability to prepare their initial, and now, rebuttal reports. We sent AHP a letter on September 13, requesting a date by which AHP will complete its production. AHP now states that it will "substantially comply" by September 27, 2001. Because AHP will not commit to a date that it will complete its production, complaint counsel, on September 17th, moved to compel AHP to complete its production by October 3, 2001.

D. Expert Discovery

Complaint counsel has identified and provided reports from three expert witnesses, Professor Timothy Bresnahan, Dr. Nelson Levy, and Mr. Joel Hoffman. Respondents have identified 23 expert witnesses (Schering has identified 12, Upsher has identified 8, and AHP has identified 4).[7] Schering and Upsher have both identified multiple experts on the same topic. For example, Upsher has identified three licensing experts, and Schering has identified four patent experts.

If Upsher and Schering were allowed to present all of their designated experts at trial, it would prolong the trial immensely. Even if each expert's direct and cross examination would take, on average, one trial date, Upsher's and Schering's expert witnesses alone would require over four weeks of trial.

In addition, should Schering and Upsher actually submit reports for 12 and 8 experts respectively, it would prevent the completion of discovery before trial. Under the current

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[7] Originally, Upsher identified ten experts but has recently removed two. The total is 23 because AHP and Schering both listed the same individual expert for settlement and negotiation.

schedule, complaint counsel has less than two weeks to submit rebuttal reports in response to the respondents' 23 expert witnesses and 27 business days to depose all of the respondents' experts. Because the respondents have not yet noticed complaint counsel's experts, complaint counsel will have to defend those depositions as well.

In light of the problems caused by the number of experts designated by Upsher and Schering, complaint counsel sent letters to both Upsher and Schering, asking them to limit their expert lists to a reasonable number. Schering refused to limit their expert list while Upsher removed two of its medical experts. Accordingly, once Upsher and Schering have supplied their expert reports on October 2nd, complaint counsel will make a proposal to Upsher and Schering on how to deal with the experts. If an agreement can not be reached by October 9th, however, complaint counsel will file a motion seeking relief from Your Honor.

V. Settlement Discussions

There have been no discussions with any of the respondents dealing with the provisions of a consent order.

Respectfully Submitted,

Karen G. Bokat

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Dated: September 18, 2001

CERTIFICATE OF SERVICE

I, Robin L. Moore, hereby certify that on September 18, 2001, I caused an original, two paper copies, and an electronic copy of Complaint Counsel's Statement of the Case to be filed with the Secretary of the Federal Trade Commission, and that two paper copies were served by hand upon:

Honorable D. Michael Chappell
Administrative Law Judge
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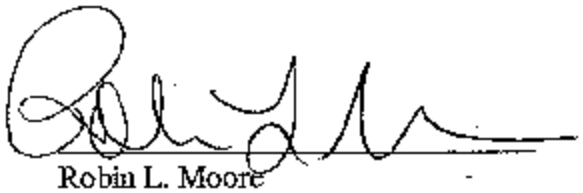

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