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In the Matter of Schering-Plough Corporation, et al.
Docket No. 9297

Opinion of the Commission

By Leary, Commissioner:

I. Introduction and Statement of Issues

This challenging case raises important policy issues at the intersection of patent law and antitrust law. It involves the settlement of patent litigation between the manufacturer of a patented drug and two would-be generic competitors, in the context of the Drug Price Competition and Patent Term Restoration Act (commonly known as the Hatch-Waxman Act), 21 U.S.C. § 355 (2001). This statute, passed in 1984, was intended to facilitate earlier entry by the manufacturers of generic drugs (the "generic"), and thereby reduce average prices paid by consumers. At the same time, Congress wanted to preserve incentives for continued innovation by research-based pharmaceutical companies (the "pioneer").[1]

The legislative compromise modified the risks and incentives in patent litigation for both pioneer and generic manufacturers. Among other things, the compromise made it possible for a generic to challenge a pioneer's patent before the generic actually enters the market, with significantly less exposure to risk of a large damage verdict if the patent is successfully defended. On the other hand, the pioneer can get an automatic stay of up to 30 months – in effect a "preliminary injunction" – without meeting the burden of proof required in a customary patent challenge.

The predictable result has been an increase in pioneer/generic patent litigation and an increase in litigation settlements. The Commission has studied

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[1] H.R. Rep No. 98-857, pt. 1, at 14-15 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647-48.

litigation under Hatch-Waxman in some depth,[2] and has challenged other settlements as anticompetitive.[3] A common theme of these challenges has been that particular settlement terms delayed generic entry that otherwise would have been likely to occur. The other cases were resolved by consent orders, however, and this is the first time the Commission has addressed pioneer/generic patent settlements with the benefit of a full administrative trial and record. Notwithstanding the novelty of some issues, we have been able to examine and analyze that record under established antitrust and economic principles.[4]

The Initial Decision dismissed the complaint. After a *de novo* factual and legal review, we reverse and enter an order.

A. The Complaint

The Commission complaint, issued on March 30, 2001, charged that Respondents Schering-Plough Corporation ("Schering"), Upsher-Smith Laboratories, Inc. ("Upsher") and American Home Products Corporation ("AHP") violated Section 5 of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. § 45, by entering into agreements to delay the entry of low-cost generic competition to Schering's prescription drug K-Dur 20.[5]

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[2] Federal Trade Commission, Generic Drug Entry Prior to Patent Expiration: An FTC Study (July 2002), *available at* <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf>.

[3] *Abbott Labs.*, Dkt. No. C-3945 (May 22, 2000) (consent order), *complaint available at* <http://www.ftc.gov/os/2000/05/c3945complaint.htm>; *Geneva Pharm., Inc.*, Dkt. No. C-3946 (May 22, 2000) (consent order), *complaint available at* <http://www.ftc.gov/os/2000/05/c3946complaint.htm>; *Hoechst Marion Roussel, Inc.*, Dkt. No. 9293 (May 8, 2001) (consent order), *complaint available at* <http://www.ftc.gov/os/2000/03/hoechstandrxcomplaint.htm>.

[4] In addition, as discussed below, we have had the benefit of a number of judicial opinions that specifically address settlements of patent litigation under Hatch-Waxman processes.

[5] This opinion uses the following abbreviations for citations:

1. The Agreement Between Schering and Upsher

Schering sells two extended-release microencapsulated potassium chloride products, K-Dur 20 and K-Dur 10,[6] which are used to treat patients with low potassium or hypokalemia. Both products are covered by a formulation patent, which expires on September 5, 2006. In August 1995, under procedures established by the Hatch-Waxman Act, Upsher filed an Abbreviated New Drug Application ("ANDA") with the Food and Drug Administration ("FDA") to market Klor Con M20, a generic version of Schering's K-Dur 20. This abbreviated procedure allows a generic manufacturer to avoid the duplication of expensive safety and effectiveness studies, so long as it proves that its drug is bioequivalent

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Comp. - Complaint
ID - Initial Decision of the Administrative Law Judge
IDF - Numbered Findings of Fact in the Initial Decision
CX - Complaint Counsel Exhibit
SPX - Schering-Plough Exhibit
USX - Upsher-Smith Exhibit
JX - Joint Exhibit
Tr. - Transcript of Testimony before the Administrative Law Judge
IH - Transcript of Investigational Hearing
Dep. - Transcript of Deposition
App. Br. - Appeal Brief of Counsel Supporting the Complaint
Schering Ans. Br. - Schering-Plough Answering Brief
Upsher Ans. Br. - Upsher-Smith Answering Brief
Rep. Br. - Reply Brief of Counsel Supporting the Complaint
O.A. - Transcript of Oral Argument on Appeal

References to investigational hearing or deposition transcripts included in the trial record as exhibits are made using the exhibit number with the witness's name and type of interview provided in parentheses (CX 1511 (Kapur dep.)).

The Appendix to this opinion identifies the witnesses and other people referenced in the opinion.

[6] The number in the product names refers to dosage strengths: the "20" tablets contain twice as much potassium as the "10" tablets. Russo, Tr. 3415.

to the pioneer manufacturer's already approved drug product. As part of this application, however, the generic must provide certain assurances about patents that claim the referenced drug or a method of using it. Upsher certified that Schering's patent was either invalid or not infringed by the Upsher product, a so-called "Paragraph IV" certification. Upsher subsequently notified Schering of this application and certification, as required by the Act.[7]

Schering then sued Upsher for patent infringement in the United States District Court for the District of New Jersey on December 15, 1995. Under Hatch-Waxman, this lawsuit triggered an automatic waiting period of up to 30 months for final FDA approval of Upsher's product. On June 17, 1997, on the eve of trial, Schering and Upsher settled their patent litigation. The automatic 30-month stay was still in effect but would expire in a year, at the latest. In this settlement agreement, Schering agreed to make payments totaling $60 million to Upsher and Upsher agreed not to enter the market with any generic version of Schering's K-Dur 20 before September 2001, over four years later. As part of the settlement agreement, Upsher also licensed Schering to market six Upsher products in prescribed territories.[8] Among other things, the complaint asserts that Schering's $60 million payment was unrelated to the value of these Upsher products, but rather was an inducement for Upsher's agreement to defer generic entry.

The complaint charges that Schering and Upsher violated Section 5 of the FTC Act by agreeing that Upsher would "not compete by marketing any generic version of Schering's K-Dur 20 until September 2001." Comp. ¶ 68. It states that this agreement "unreasonably restrains commerce," and thus invokes the standards of Section 1 of the Sherman Act. Comp. ¶¶ 68, 69. The complaint further invokes the standards of Section 2 of the Sherman Act, by charging that Schering "engaged in conduct intended to unlawfully preserve . . . [its] monopoly power" and that it "conspired . . . [to] monopolize." Comp. ¶¶ 70, 71.

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[7] These procedures are spelled out in 21 U.S.C. § 355(j). The significance of the Hatch-Waxman Act in the antitrust analysis will be discussed below.

[8] The products are Niacor-SR, Klor Con 8, Klor Con 10, Klor Con M20, Prevalite, and Pentoxifylline. CX 348.

In its prosecution of this case, Complaint Counsel argued that the settlement amounted to a horizontal agreement between the pioneer competitor (Schering) and a potential generic competitor (Upsher) that the potential competitor would defer entry, in return for the payment of money by the pioneer to the generic (sometimes referred to as a "reverse payment"[9]). Counsel claimed that this conduct was either *per se* illegal or subject to condemnation in a truncated proceeding.

2. The Agreement Between Schering and American Home Products

In December 1995, ESI Lederle Inc. ("ESI"), a division of American Home Products Corporation, also submitted an ANDA to the FDA to market a generic version of Schering's K-Dur 20, with its own Paragraph IV certification. Schering sued ESI for patent infringement in the United States District Court for the Eastern District of Pennsylvania on February 16, 1996. This case was settled in principle by AHP and Schering in January 1998 and the final agreements were concluded in June of that year. As part of this settlement, AHP agreed that it would not market any generic version of Schering's K-Dur 20 before January 2004, and Schering agreed to make payments totaling $30 million. Schering also licensed two products from AHP.[10]

The complaint's characterization of the Schering/AHP agreements parallels its characterization of the Schering/Upsher agreement. The complaint states that the Schering payments were not related to the value of the licenses, and thus induced AHP to agree to the delay of its own generic product.

As noted above, AHP was named as a respondent when the Commission issued the complaint in this matter. Before the Commission's case came to trial, however, AHP agreed to a settlement, and the Commission approved a final consent order with AHP in April 2002. The legality of the agreement between Schering and AHP remains in issue, however, with respect to Schering.

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[9] The payment is characterized as "reverse" because it flows from the pioneer to the generic, unlike the more common provisions of a patent litigation settlement where the alleged infringer pays royalties to the patent holder in exchange for a license.

[10] The products are enalapril and buspirone. CX 480.

B. The Defenses

Both Schering and Upsher denied that their settlement agreement was unlawful and argued additional defenses, which may be summarized as follows.

First, Respondents state there is no proof that the settlement agreement delayed the entry of generic competition for K-Dur 20. Schering's patent, which must be presumed to be valid, did not expire until September 2006, five years after the agreed-upon entry date. They argue that there is no way to know whether generic entry would have been possible at an earlier date in the absence of proof on the merits of the patent litigation.

Second, Respondents state that any assumed agreement on entry was ancillary to a legitimate, procompetitive objective, namely, the settlement of patent litigation. This settlement preserved public and private resources, and the resultant certainty ultimately led to more intense competition.

Third, Respondents state that the $60 million payment to Upsher was not a payment for delayed entry but rather reasonable compensation for the side agreement involving the six products that Upsher licensed to Schering.

Respondent Schering similarly denies that the AHP agreement was unlawful and relies on the same defenses related to patent validity and the procompetitive benefits of a litigation settlement. Schering also asserts that the agreement was crafted in response to intense judicial pressures for settlement.

C. The Initial Decision

On June 26, 2002, after a two-month trial, the Administrative Law Judge dismissed the complaint in an Initial Decision that contains 121 pages and 431 numbered findings of fact. We disagree with many of the factual and legal conclusions in the Initial Decision. Notwithstanding the complexity of this matter, it is possible to identify two fundamental legal errors in the Initial Decision that led ultimately to an erroneous conclusion.

First, the Initial Decision asserted that Schering's patent gave it the legal right to exclude a generic competitor from the market, absent proof that the patent was not valid or that the generic products did not infringe. Since Complaint

Counsel did not prove either invalidity or non-infringement, the Initial Decision assumed it was not possible to conclude that the settlement agreements in issue delayed generic entry that would otherwise have occurred. ID at 4, 103-05. This conclusion is incorrect.

The Respondents did not dispute that there were separate agreements between the pioneer, Schering, and two generic competitors, Upsher and AHP, to settle two patent cases. It is also not disputed that these agreements included provisions that provided for unconditional payments from the pioneer to the two generics and also specified the time of generic entry. The issue is whether these unconditional payments were likely to have anticompetitive effects because they delayed generic entry beyond the dates that would have been agreed upon in the absence of the payments. We explain below why this question can be answered without an inquiry into the merits of the patent litigation.

Second, the Initial Decision assumed that Complaint Counsel had to prove a "relevant product market," under a traditional full-blown rule-of-reason analysis. The Initial Decision rejected Complaint Counsel's argument that market definition is not necessary when direct evidence of anticompetitive effects can be shown. ID at 4, 84-85. This ruling is also incorrect.

We follow the Supreme Court's guidance, as expressed in the *California Dental* case,[11] and explained at length in the Commission's recent *PolyGram Holding* opinion.[12] The appropriate antitrust analysis extends over a continuum, ranging from *per se* condemnation of particularly egregious conduct to a detailed examination of more ambiguous behavior, responsive to the facts of individual cases. Here, we will need to undertake a more detailed examination of market effects than was required either in *California Dental* or in *PolyGram Holding*, but the guiding principles are the same. We review the agreements in this case under the rule-of-reason standard, but apply a different methodology from that set out in the Initial Decision. We conclude that the Initial Decision's approach – which

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[11] *California Dental Ass'n v. FTC*, 526 U.S. 756, 770 (1999).

[12] *PolyGram Holding, Inc.*, 5 Trade Reg. Rep. (CCH) ¶ 15,453 at 22,453-58 (FTC 2003), *available at* <http://www.ftc.gov/os/2003/07/polygramopinion.pdf>, slip op. at 13-29.

defines a relevant market, calculates shares, and then draws inferences from these shares and from other industry characteristics – is not the most appropriate way to proceed in cases like this one where more direct evidence of competitive effects is available.

Once Complaint Counsel have demonstrated anticompetitive effects under the standard we apply, Respondents must demonstrate that the challenged provisions are justified by procompetitive benefits that are both cognizable and plausible.[13] Because the Initial Decision concluded that Complaint Counsel had not satisfied their initial burden, it did not separately evaluate Respondents' affirmative justifications outlined in Part I.B. above. We do so.

In addition to these fundamental legal errors, we disagree with the Initial Decision's factual conclusion that the licenses granted to Schering were adequate consideration for the payments made by Schering, and that therefore the payments were not for delay. ID at 107-12. Our review of the record compels a contrary conclusion.

The Commission may review *de novo* both the factual findings and the legal conclusions of the Administrative Law Judge. 16 C.F.R. § 3.54(a). This *de novo* review includes findings on the credibility of witnesses.[14] On the basis of the totality of the record evidence, we have made *de novo* findings of fact that differ substantially from those in the Initial Decision. We identify these factual findings specifically and discuss their significance throughout the opinion. We do, however, adopt other findings of fact in the Initial Decision, to the extent they are consistent with this opinion, most specifically those relating to jurisdiction (IDF 1-12) and certain facts about the Schering/AHP agreement (IDF 370-75).

D. Summary and Conclusions

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[13] *See id.*, 5 Trade Reg. Rep. at 22,458-59, slip op. at 31-32.

[14] *Horizon Corp.*, 97 F.T.C. 464, 857 n.77 (1981). This general rule is subject to the caveat that an administrative law judge has the opportunity to observe the witnesses in a live setting, but no findings of the Initial Decision in this case were based specifically on the demeanor of a witness on the stand.

Part II of this opinion discusses the sufficiency of Complaint Counsel's affirmative case. It will set forth in more detail the fundamental elements of the rule-of-reason methodology that we have applied and show that this methodology is consistent with existing authority. We examine the record evidence relating to both the predicted and the actual effects of the entry of generic competition for Schering's K-Dur 20 product, and we make our own factual findings. We find that Complaint Counsel have met their initial affirmative burden.

Part II of the opinion also addresses the Initial Decision's conclusion that it is not possible to determine whether the Schering/Upsher and the Schering/AHP settlements delayed entry unless we first decide the merits of the underlying patent disputes. We find that this requirement is not supported by law or by logic.

In Part III of the opinion, we address Respondent's affirmative defense that the agreement between Schering and Upsher was ancillary to the legitimate settlement of a patent dispute. We recognize that litigation settlements can conserve public and private resources and create other efficiencies. This does not mean, however, that all settlements are procompetitive, and we find that there is insufficient evidence to support the defense in this case.

In Part IV of the opinion, we address at length the claims that Schering paid Upsher $60 million for licenses rather than for delay. Our conclusion – based on the cumulative impact of numerous documents, conversations and events – is that there was a direct nexus between Schering's payment and Upsher's agreement to delay its competitive entry, and that this payment substantially exceeded Schering's reasonable expectation of the value of the Upsher licenses. The details of this particular case-specific issue may not be of the same general interest as other matters discussed in Parts II and III of the Opinion, and we therefore discuss these other matters before we consider the facts on the valuation of the licenses.

In Part V, we separately discuss the particular facts and legal analysis of the Schering/AHP agreement. There is far less record evidence on this agreement but we apply the same methods of analysis and reach the same conclusions as we have done earlier with respect to the Schering/Upsher agreement. In Part VI, we explain why it is not necessary or appropriate to address the monopolization counts. In Part VII we explain why we need not rule on certain evidentiary matters.

In conclusion, after a *de novo* review of the record, we reject many of the findings of fact in the Initial Decision and substitute our own findings, and we further reverse the ultimate decision to dismiss the complaint. We find that both the Schering/Upsher and the Schering/AHP agreements violated Section 5 of the Federal Trade Commission Act. We conclude that there is sufficient proof of adverse competitive effects; that it is not necessary to inquire into the merits of the underlying patent disputes; that the parties have not proved their ancillarity defenses; and that the payments from the pioneer to the generics were, in whole or in substantial part, consideration for delay rather than for products licensed from the generic.

Accordingly, we reverse the Initial Decision and enter an appropriate order, which is discussed in Part VIII. We note here that the order does not prohibit all settlement agreements that specify a generic entry date coupled with the payment of "value" to the generic, but excepts payments that are limited to litigation costs up to $2 million if the Commission has been notified of the settlement.

II. The Sufficiency of Complaint Counsel's Affirmative Proof

A. Complaint Counsel's Initial Burden

The essence of Complaint Counsel's claim is that Schering agreed to pay Upsher some part of $60 million in return for Upsher's agreement to defer the launch of its generic product.[15] It is undisputed that there was an agreement that specified a future entry date and that money was paid. There is, however, a dispute over the competitive impact of the agreement and the appropriate legal standard to apply when resolving that issue.

The Commission recognized in *PolyGram Holding* that once an "agreement" has been proved, the prosecutor's initial burden varies according to the individual

[15] Similar claims with respect to Schering's settlement with AHP will be discussed separately in Part V.

facts of the case.[16] We do not focus on labels but on the question of which party has the burden of producing what kind of evidence and when.[17] *PolyGram Holding* involved conduct that we called "inherently suspect."[18] In that kind of case, the focus is on the nature of the *restraint*, and the likelihood of competitive harm is readily apparent or can "easily be ascertained."[19] A prosecutor's initial burden can be satisfied by showing that anticompetitive effects are likely, on the basis of "past judicial experience and current economic learning."[20]

In cases like this one, where the conduct is not inherently suspect, the prosecutor has the burden of demonstrating actual or likely market effects by reference to facts specific to the case. However, proof of these effects does not necessarily mandate the approach followed in the Initial Decision – namely, an effort to define the "relevant market" coupled with an effort to balance an undifferentiated set of factors like those listed in *Brown Shoe v. United States*.[21] As will appear in the detailed discussion of the evidence that follows, more direct methods are available and are preferable.[22]

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[16] *PolyGram Holding, Inc.*, 5 Trade Reg. Rep. at 22,466 n.66, slip op. at 49 n.66.

[17] A preoccupation with labels can lead, at the extreme, to an essentially meaningless distinction between *per se* analysis and rule-of-reason analysis that is completed in "the twinkling of an eye." Phillip E. Areeda & Herbert Hovenkamp, 7 Antitrust Law ¶ 1508a, at 391 (2003). We believe that the structure, outlined here and in our *PolyGram Holding* opinion, reflects a growing recognition of the limitations of semantics.

[18] *PolyGram Holding, Inc.*, 5 Trade Reg. Rep. at 22,456, slip op. at 22-23.

[19] *California Dental Ass'n v. FTC*, 526 U.S. 756, 770 (1999).

[20] *PolyGram Holding, Inc.*, 5 Trade Reg. Rep. at 22,459-60, slip op. at 29.

[21] *Brown Shoe Co. v. United States*, 370 U.S. 294, 321-22 (1962).

[22] The distinction between indirect and direct proof of market effects is not related to the sheer quantity of evidence that a prosecutor needs to introduce. Direct proof of competitive effects, on which we rely in this case, is not the same as a truncated analysis that would be appropriate in those cases where the nature of

In this case, Complaint Counsel made an alternative argument that the settlement agreements in issue should be characterized as either *per se* illegal or presumptively anticompetitive.[23] Translated into the terms of the structure outlined above, their claim was that the nature of the restraint is sufficiently troublesome to obviate specific proof of market effects.

There is some logical and legal support for this proposition. The essence of the complaint is that the pioneer paid the generics not to compete for a period of time, which could be *per se* illegal in other contexts. Absent a legitimate business justification,[24] naked agreements between competitors to allocate business by customers or geographic areas are routinely condemned out of hand. *See, e.g.*, *Palmer v. BRG of Georgia, Inc.*, 498 U.S. 46 (1990); *Timken Roller Bearing Co. v. United States*, 341 U.S. 593 (1951). We believe that a naked agreement to pay a potential competitor to delay its entry date could logically be treated the same way because an allocation of time is analogous to an allocation of geographic space. The effects of horizontal agreements to allocate business are well understood, and it is not imperative for the Commission or a court to have firsthand experience with the practice in a specific industry context.[25]

There is also recent authority in the same industry to support a claim of *per se* illegality. In the *Cardizem CD Antitrust Litigation*, 332 F.3d 896, 908 (6th Cir. 2003), the court found that it was *per se* illegal for a pioneer drug company to pay money to a generic manufacturer in return for a commitment to delay entry. The

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the restraint dominates. Direct proof is not necessarily a shortcut method; it is rather a method that relies on the most probative available evidence.

[23] App. Br. at 40, 70.

[24] As articulated in the recent *PolyGram Holding* opinion, a legitimate business justification must be both plausible and cognizable. 5 Trade Reg. Rep. at 22,459, slip op. at 30-32.

[25] *Cf. Arizona v. Maricopa County Med. Soc.*, 457 U.S. 332, 350-51 (1982) (*per se* rule does not have to "be rejustified for every industry that has not been subject to significant antitrust litigation").

current trend of authority seems to be moving in another direction, however.[26] The even more recent decisions in *Valley Drug Co. v. Geneva Pharmaceuticals Inc.*, 344 F.3d 1294 (11th Cir. 2003) (reversing the district court), and in the *Ciprofloxacin Hydrochloride Antitrust Litigation*, 261 F. Supp. 2d 188 (E.D.N.Y. 2003), expressly considered contrary authority and declined to apply the *per se* label. *See also In re Tamoxifen Citrate Antitrust Litig.*, 262 F. Supp. 2d 17 (E.D.N.Y. 2003).

In addition to the crosscurrents in the case law, we recognize – as discussed further below – that agreements of the kind challenged here can be procompetitive in limited circumstances. For example, a settlement that includes payments to a cash-starved generic might, in some circumstances, permit earlier entry than would otherwise occur. We do not believe that special circumstances of this kind have been established here, but the fact that such efficiencies are theoretically possible makes us reluctant to deal summarily with the agreements at issue in this case. *See California Dental Ass'n v. FTC*, 526 U.S. at 777-78.

We note that these and other potential efficiencies are also cited in support of an argument that the challenged agreements are ancillary to the settlement of litigation – an outcome that is claimed to be efficient and procompetitive overall. It is, of course, appropriate to consider an ancillarity claim, even if a particular contract term would be condemned summarily if it stood alone;[27] therefore, the

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[26] The *Cardizem* case also can be distinguished on its facts. In *Cardizem*, there were additional potentially anticompetitive commitments by the generic that are not present here. Unlike the present case, *Cardizem* involved an interim rather than a final settlement, so it would be more difficult to claim that the agreement was ancillary to an efficient disposition of the litigation. The opinion did not need to consider a claim that the generic was paid by the pioneer for licenses rather than for delayed entry. We also do not believe the opinion has taken adequate account of Supreme Court decisions that mandate a more nuanced approach. *See, e.g., California Dental Ass'n v. FTC*, 526 U.S. 756 (1999); *National Collegiate Athletic Ass'n v. Board of Regents of the University of Oklahoma*, 468 U.S. 85 (1984).

[27] *See, e.g., Rothery Storage & Van Co. v. Atlas Van Lines, Inc.*, 792 F.2d 210 (D.C. Cir. 1986), *cert. denied*, 479 U.S. 1033 (1987); United States Dep't of Justice and Federal Trade Comm'n, Antitrust Guidelines for Collaborations

mere existence of an ancillarity claim does not determine the form of analysis that should be applied. However, Respondents' claim here is that the challenged agreements were ancillary to the settlement of *patent* litigation. The fact that "one of the parties owned a patent . . . [which] grants its owner the lawful right to exclude others" was a complicating factor which induced the *Valley Drug* court to reject a *per se* standard. *Valley Drug*, 344 F.3d at 1304-06.[28] The existence of claimed patent rights was also a dispositive fact for the Administrative Law Judge in this case. ID at 4, 103-04.

We believe that it is necessary to recognize that patent issues exist as we address Complaint Counsel's initial burden of proof, and the issues cannot be resolved in a summary way – at least, not in this case of first impression for the Commission. Instead, we need to explain the reasons why the merits of the underlying patent claims are not dispositive. We also need to address the particular competitive significance of generic substitutes for patented drugs, as evidenced by economic studies, by the expectations of firms in the market, and by actual market events.

In this case, we will apply and build on fundamental principles that were discussed at length in *PolyGram Holding* – a Commission opinion that was itself based on a synthesis of recent Supreme Court decisions. Our *PolyGram Holding* opinion explains that bright-line distinctions are normally not particularly helpful; the appropriate methods of analysis extend over a continuum. This case differs from *PolyGram Holding*, however, not because the principles are different, but because it occupies a different place along the continuum. While a "scrutiny of the restraint itself" was sufficient in *PolyGram Holding*,[29] the facts of this case require

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Among Competitors, § 3.2 (2000), *reprinted in* 4 Trade Reg. Rep. (CCH) ¶ 13,161, *available at* <http://www.ftc.gov/os/2000/04/ftcdojguidelines.pdf>.

[28] *See also Ciprofloxacin Hydrochloride*, 261 F. Supp. 2d at 249 ("[T]he exclusionary effect of the patent must be considered before making any determination as to whether the alleged restraint is per se illegal.").

[29] 5 Trade Reg. Rep. at 22,458, slip op. at 29. We leave open the question whether it would be appropriate to apply this test in a future case that involved a patent settlement with payments from the pioneer to the generic manufacturer that appear to be substantially larger than reasonably anticipated costs of litigation.

us to look beyond the nature of the challenged restraint and consider the nature of the market. As noted above, this market inquiry differs from the inquiry outlined in the Initial Decision.

B. The Evidence in Support of Complaint Counsel's Case

Complaint Counsel's affirmative case was based on an economic model, buttressed by contemporaneous records. The lead witness was an economic expert, Professor Timothy F. Bresnahan, who relied on the following three-prong test to determine whether the Schering patent settlements were anticompetitive.

> First: Did Schering have "monopoly power" in the market for K-Dur 20?
> Second: Were generics a threat to this monopoly power?
> Third: Did Schering make a payment to defer generic entry?

Bresnahan, Tr. 418-19.

Although we rely on Professor Bresnahan's testimony in part, we do not adopt his terminology. We are here concerned with whether a particular agreement was, in the language of the Sherman Act, a prohibited "restraint of trade." *See Northwest Wholesale Stationers, Inc. v. Pacific Stationery & Printing Co.*, 472 U.S. 284, 289 (1985). It is obviously necessary to identify the "trade" that arguably has been unreasonably restrained, but this identification is not the same thing as defining a legal "market" that can be "monopolized."[30] As explained in more detail below, it is not necessary to rely on indirect proof that Schering has a monopoly share in a relevant market when the competitive effects of the "restraint" can be shown directly.[31] Moreover, in the circumstances of this case, the first two prongs of the Bresnahan test really depend on the same evidence, because the particular significance of generic entry is what actually defines the appropriate area of trade to consider. This particular significance drives the Hatch-Waxman

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[30] The Initial Decision fails to appreciate this distinction, when it says that "Complaint Counsel cannot prove an effect without first proving by market definition what is claimed to be affected." ID at 85-86. The products affected by the challenged conduct were clearly identified.

[31] *See FTC v. Indiana Fed'n of Dentists*, 476 U.S. 447, 460 (1986).

regulatory scheme, and is recognized in the Respondents' internal documents and in the arguments of their counsel. Conversely, the third prong of the Bresnahan test really involves consideration of two separate issues, namely, (i) the rationale for focusing on whether there was a payment by Schering, and (ii) whether Schering, in fact, paid money for deferred entry. Resolution of this latter issue requires detailed factual discussion, contained in Part IV of this opinion.

1. The Competitive Effects of Generic Entry

Most cases that are not resolved by a summary analysis begin with the definition of a "relevant market," under various tests sanctioned by case law or by agency guidelines, followed by the calculation of the sales shares of various players and concentration ratios, and conclude with an evaluation of various industry-specific factors. *See*, *e.g.*, *Brown Shoe Co. v. United States*, 370 U.S. 325 (1962); *FTC v. H.J. Heinz Co.*, 246 F.3d 708 (D.C. Cir. 2001); U.S. Dep't of Justice & Federal Trade Comm'n, Horizontal Merger Guidelines (1992), *reprinted in* 4 Trade Reg. Rep. (CCH) ¶ 13,104 ("Horizontal Merger Guidelines"). In this case, the Administrative Law Judge found that Complaint Counsel had not proved their case in the traditional way, and viewed this failure as a fatal flaw. ID at 84-95. We disagree, and hold that the Initial Decision misstates the requirements for proof of a violation when a summary analysis is inappropriate.[32]

There are a variety of ways to analyze market impact under the rule of reason. In *FTC v. Indiana Fed'n of Dentists*, 476 U.S. at 460-61, the Supreme Court said that "the finding of actual, sustained adverse effects on competition . . . is legally sufficient to support a finding that the challenged restraint was unreasonable even in the absence of elaborate market analysis." A number of lower court decisions have followed this principle. *See*, *e.g.*, *Todd v. Exxon Corp.*, 275 F.3d 191, 206 (2d Cir. 2001) (evidence of "an actual adverse effect on competition . . . arguably is more direct evidence of market power than calculations

[32] The error is perhaps understandable because some in the antitrust community have become so accustomed to the traditional way of proceeding that they forget that this complex market analysis provides only an *indirect* indication that trade has been or may be restrained. It is not necessary to weigh all of these factors if a case presents more *direct* evidence of actual or likely competitive effects.

of elusive market share figures"); *Toys "R" Us v. FTC*, 221 F.3d 928, 937 (7th Cir. 2000) (market power can be proved "through direct evidence of anticompetitive effects"); *United States v. Baker Hughes Inc.*, 908 F.2d 981, 992 (D.C. Cir. 1990) ("'[m]arket share is just a way of estimating market power, which is the ultimate consideration,' and . . . '[w]hen there are better ways to estimate market power, the court should use them'" (quoting *Ball Mem'l Hosp. v. Mutual Hosp. Ins.*, 784 F.2d 1325, 1336 (7th Cir. 1986))).

The Initial Decision briefly acknowledges Complaint Counsel's reliance on *Indiana Federation of Dentists* for the proposition that direct proof of anticompetitive effects is sufficient. The Initial Decision concludes that no such direct effects were proven because Complaint Counsel's expert did not conduct elaborate price studies. ID at 91. However, *Indiana Federation of Dentists* did not say that price studies are necessary to prove direct anticompetitive effects. On the contrary, the Supreme Court found:

> A concerted and effective effort to withhold (or make more costly) information desired by consumers for the purpose of determining whether a particular purchase is cost justified is likely enough to disrupt the proper functioning of the price-setting mechanism of the market that it may be condemned *even absent proof that it resulted in higher prices or . . . the purchase of higher priced services than would occur in its absence*.

FTC v. Indiana Fed'n of Dentists, 476 U.S. at 461-62 (emphasis added). The justification for use of direct evidence in this case is even stronger than it was in *Indiana Federation of Dentists* because the predicate offense was not just an effort to withhold useful information, but rather an agreement to defer entry by a potential competitor.

Similarly, the Seventh Circuit did not require price studies to find anticompetitive effects in *Toys "R" Us, Inc. v. FTC*. The court concluded that horizontal agreements that limited the distribution of particular toys to a class of retailers had obvious price effects, but did not detail what they were:

> [I]t was clear that [Toys "R" Us's] boycott was having an effect in the market. It was remarkably successful in causing the 10 major toy manufacturers to reduce output of toys to the warehouse clubs, and

> that reduction in output protected TRU from having to lower its prices to meet the clubs' price levels. Price competition from conventional discounters . . . imposed no such constraint. . . . Taking steps to prevent a price collapse through coordination of action among competitors has been illegal at least since *United States v. Socony-Vacuum Oil Co.* Proof that this is what TRU was doing is sufficient proof of actual anticompetitive effects that no more elaborate market analysis was necessary.

221 F.3d at 937 (citations omitted).

The Commission itself very recently explained in the *PolyGram Holding* opinion that "the evaluation of horizontal restraints takes place along an analytical continuum in which *a challenged practice is examined in the detail necessary to understand its competitive effect.*" *PolyGram Holding, Inc.*, 5 Trade Reg. Rep. at 22,456, slip op. at 22 (emphasis added).[33] We will apply this approach as we evaluate the evidence of competitive effects that was submitted as part of Complaint Counsel's case.[34]

It is important to remember what this case is and is not about. If we were evaluating the potential effects of a merger between Schering and another manufacturer of potassium chloride supplements that are functionally interchangeable with Schering's K-Dur 20, a broad market definition encompassing all prescription oral potassium supplements, which the Administrative Law Judge adopted in this case (ID at 87, citing IDF 29-118), might well be appropriate. This hypothetical merger might have some effect on the sales or prices of K-Dur 20, and it might have a more profound effect on innovation in the therapeutic category, even though the looming threat of future generic competition could ultimately transform the market entirely. A merger that

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[33] This statement is supported directly by the Supreme Court's observation in *California Dental* that "[w]hat is required . . . is an enquiry meet for the case, looking to the circumstances, details, and logic of a restraint." *California Dental Ass'n*, 526 U.S. at 781.

[34] As stated above, the effects of the restraint involved in *PolyGram Holding* did not require the same market analysis as the restraint involved in this case.

threatens competition in some substantial respect is not necessarily benign just because more substantial threats exist.

This case, however, is precisely concerned with that more substantial threat of generic competition, and there is credible evidence in the record – largely ignored in the Initial Decision – which indicates that generic entry was a uniquely significant market event, and recognized as such by both parties. Their predictions about the likely effects of generic entry, which were consistent with historic experience of other branded drugs, are just as compelling as predictions based on market shares. Moreover, these predictions turned out to be true. We therefore analyze that evidence in some detail, and set forth our own findings of fact and legal conclusions in the immediately following paragraphs. Because we have concluded that the Initial Decision's treatment of the "market" issue is inappropriate for this case, we do not adopt the Initial Decision's voluminous factual findings on the issue.[35]

2. Findings of Fact on the Competitive Effects of Schering's Agreement With Upsher

At the time of the agreement, both Schering and Upsher expected that generic entry would have a substantial impact on Schering's sales. Upsher's Klor Con M20 would have been (and eventually was) the first "AB-rated"[36] generic substitute for K-Dur 20. Easy substitutability at the pharmacy level, combined with state substitution mandates and managed care incentives,[37] would have caused

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[35] We do not reject the findings (IDF 25-118) because they are erroneous but because they are not relevant to our legal analysis of the challenged settlement agreement.

[36] Generic drugs that are AB-rated to a reference drug are considered by the FDA to be therapeutically equivalent to, and substitutable for, the reference drug. Hoffman, Tr. 2278.

[37] In most states, a pharmacist is permitted to substitute an AB-rated generic product for a brand name drug, unless the physician directs otherwise. Hoffman, Tr. 2278; Teagarden, Tr. 197-98; CX 1493 at 81 (Dolan Dep.); Schering Answer at ¶ 18. A pharmacist cannot substitute a generic that is not AB-rated for a branded drug without the physician's approval. Bresnahan, Tr. 491; Russo, Tr. 3468. In

Schering to lose rapidly a large volume of its sales to Upsher's lower-priced generic substitute. The entry of a lower-cost generic is a direct consumer benefit, by itself, wholly apart from the impact on other potassium chloride supplements. A settlement with Upsher that provided for delayed entry of this lower-cost generic product would enable Schering to maintain its sales of, and profits from, K-Dur 20 for a considerable period of time – but at significant cost to consumers. Schering's anticipated loss of sales because of generic entry provides an indication of the magnitude of the settlement's anticompetitive effects.[38]

Schering's 1997 Operating Plan, dated November 11, 1996, clearly shows that Schering expected that generic entry would dramatically erode K-Dur sales in 1998 and 1999. K-Dur sales revenues were projected to fall by 17% in 1998 and an additional 33% in 1999 from the sales levels estimated for 1997. CX 118 at SP 2300218aa. Similarly, an internal Schering analysis in June 1997, before the settlement agreement, predicted that total K-Dur revenues would drop from $190 million in 1997 to $113 million in 2000, and to $70 million in 2001. CX 750 at SP2300307aa; *see also* CX 123 at SP004811 (*in camera*). The settlement, which deferred the threat of generic entry, significantly altered Schering's K-Dur forecasts. The 1998 Operating Plan – dated November 14, 1997, after the settlement with Upsher – shows projected increases in K-Dur sales each year through 2000.[39] CX 118 at SP2300218aa-219aa.

Upsher's predictions were similar. An April 1992 analysis predicted that its entry (assumed to occur in late 1997) would reduce K-Dur 20 revenues from $184

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some states, pharmacists are required to substitute an AB-rated generic unless the physician directs otherwise. Bresnahan, Tr. 1178; Addanki, Tr. 5998. In addition to state mandatory substitution laws, Medicaid policies and managed care plans also tend to encourage generic substitution. CX 18 at SP 23 00044 (1997 K-Dur Marketing Plan); Bresnahan, Tr. 491-93.

[38] The magnitude of the expected impact on average prices can be calculated from Respondents' own internal estimates. *See* discussion below.

[39] Sales of K-Dur 10 and K-Dur 20 are combined in these documents. K-Dur 20 accounted for 86% of total K-Dur sales during 1997. CX 62.

million in 1997 to $122 million in 1999.[40] This Upsher document predicts the effects of its entry on total 20 mEq revenues for all manufacturers, namely, a drop from $184 million in 1997 to $148.5 million in 1999 (a 19% decline), even as the total number of tablets sold was expected to increase from 560 million in 1997 to 665 million in 1999 (a 19% increase). CX 150 at USL08538.[41] A simple calculation indicates that the weighted average price per tablet was expected to decline more than 30 percent, from 33 cents to 22 cents.[42]

AHP's predictions were [redacted from public record version

redacted from public record version]

The expectations of both Respondents and AHP are consistent with the impact on brand-name pharmaceutical sales generally observed upon entry of the first generic competitor. Studies by the Congressional Budget Office ("CBO") and economists have explored this phenomenon,[43] and all have reached similar

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[40] Upsher anticipated revenues of $16 million in 1999 from sales of Klor Con M20, and expected that another generic (likely Warrick) would earn $10.5 million. CX 150 at USL08538.

[41] Also, during the negotiations with Schering, Upsher sought $60-70 million based on its calculation of Schering's lost profits due to earlier entry. Hoffman IH at 35; Hoffman, Tr. 3544; Driscoll IH at 67. AHP made a similar demand. CX 1508 at 99-100 (Hoffman IH); *see also* Rule, Tr. 2583-84 (addressing antitrust implications of payments based on lost profits of pioneer).

[42] Upsher expected its own Klor Con M20 and another "20" product to be priced at 50% of Schering's price per tablet and the average selling price of Schering's K-Dur 20 to fall 20% due to competition. CX 150.

[43] Our opinion is not predicated on these studies standing alone. We rely on Respondents' own analyses, but we note that economic literature consistently shows that generic entry lowers overall average prices significantly in this industry.

conclusions about the impact on sales and average prices. The CBO study,[44] for example, looked at 21 drugs that first encountered generic competition between 1991 and 1993. After one year, these drugs had lost an average of 44% of sales revenue (and 42.8% of prescriptions) from drugs dispensed through pharmacies to their generic counterparts. The CBO study also found that the retail price of the generic drugs was 25% less than that of the brand-name drugs, on average. Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* at 28 (July 1998); *see also* Richard G. Frank & David S. Salkever, *Generic Entry and the Price of Pharmaceuticals*, 6 J. Econ. & Mgmt. Strategy 75, 89 (1997) ("The substantial shift in market share from brand-name to generic producers (40%-50%) along with the significantly reduced price of generic substitutes (25%-30% lower) means that the average price of a prescription for a compound subject to generic competition has fallen."); Henry G. Grabowski & John M. Vernon, *Brand Loyalty, Entry, and Price Competition in Pharmaceuticals After the 1984 Drug Act*, 35 J.L. & Econ. 331, 335 (1992) (the "general pattern is that generics enter at a significant discount to the pioneering product [and] . . . the prices of the pioneering brands remain higher than their generic competitors and actually increase in nominal terms"; "[a]verage market price [weighted by sales of the brand and generic] declined by a little more than 10 percent per year in the first two years after generic entry"); Richard E. Caves, *et al.*, *Patent Expiration, Entry, and Competition in the U.S. Pharmaceutical Industry*, Brookings Papers on Economic Activity: Microeconomics 1 (1991) (analysis found that the price of the first generic producer is about 40% below the pre-patent expiration branded price of the drug).

The actual decline in K-Dur sales following the September 2001 entry of Upsher's Klor Con M10 and Klor Con M20 is also consistent with the expectations of both Respondents and AHP. When Upsher entered the market, its generic product was priced at approximately 50% of the price of K-Dur 20. Rosenthal, Tr. 1559. The impact on Schering's K-Dur 20 sales was dramatic: total prescriptions fell from 1,158,000 in November 2000 to 391,000 in November 2001. Schering's lost sales of 767,000 prescriptions are almost precisely offset by the sales of

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[44] Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry*, July 1998.

703,000 prescriptions of new generic versions of K-Dur.[45] (Prescriptions for Upsher's generic version were 639,000 and Warrick's were 64,000, up from zero the previous year.[46]) During the same period, the total prescriptions for all potassium chloride products remained roughly constant.[47] In the years prior to generic entry in 2001, the sales trends for K-Dur 20 had been similar to those for all potassium chloride products.[48] CX 62-65; *see also* SPX 1123 at AHP 1300115, 1300117. Schering's concerns about generic entry were obviously well founded.

3. Schering's Attempt to Discount These Competitive Effects

Schering advances two arguments in an attempt to explain away the significance of a growth in generic sales at the expense of pioneer sales. Schering argues, first, that part of the generic's sales performance is attributable to state laws that mandate the substitution of lower-priced generic drugs and the fact that payors often insist on such substitution. Schering argues, second, that the sales of its own drug are also adversely affected by the fact that it is common practice in the

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[45] In its post-trial brief (Apr. 15, 2002, pp. 92-93), Upsher insists that some unspecified part of the decline in Schering's sales was due to supply problems. *See also* ID at 99. If this is true, the magnitude of the actual loss of sales overstates the actual harm to competition from the settlement, and an assessment of damages would require us to measure this effect. However, our purpose here is to ascertain liability rather than damages, and the decline in sales is dramatic and consistent with the expectations of the parties. CX 62-65, 1480.

[46] Warrick Pharmaceuticals Corporation is a subsidiary of Schering that produces generic pharmaceutical products. In some situations, Warrick produces generic versions of Schering's patented products when another generic version of the drug has entered the market.

[47] Total prescriptions were 2,716,000 in November 2000 and 2,758,000 in November 2001. CX 1480 at SP 089837. This pattern of sales might suggest that K-Dur 20 and its generic substitutes were actually in a relevant "market" by themselves, if it were necessary to define a market in this case.

[48] Evidence of this kind might have a bearing on whether Schering was a monopolist before generic entry, but we do not reach that issue in this case. *See* Part VI, below.

industry for the pioneer drug manufacturer to cut back on sales promotion efforts after a generic substitute becomes available. Schering Ans. Br. at 72-74. There is obviously a concern that sales promotion will confer a "free riding" benefit on all competitors, but these concerns apparently are magnified for a particularly close competitor like a generic. We accept that the factual predicate for these arguments may well be true, but these facts actually support Complaint Counsel's case rather than Schering's. They merely underscore the well-recognized unique impact of generic competition.

Generic pharmaceutical competition is conducted in a special legal environment that differs in significant respects from a truly unregulated market place. In addition to state generic substitution laws, competition is affected by the requirement for FDA approval and by the regulatory provisions of Hatch-Waxman. All markets are affected by regulation to one degree or another, however, and these regulations need to be accepted as real market factors in an antitrust analysis – not simply assumed away. If entry were an issue in a merger case, for example, it would be entirely appropriate for a decisionmaker to take into account import restrictions or environmental impediments to expansions of plant capacity.[49]

Moreover, in the case before us, the existence of state substitution laws, as well as payors that mandate substitution on their own, provides an additional argument for treating generic competition as likely to have a particularly substantial impact. The underlying premise of these laws and payor practices is that generic competition has the potential to lower prices, and therefore should be promoted.[50] The executives of Schering and Upsher who negotiated the settlement in issue must have been aware of these laws and practices, and the effects that they have had in their industry. The internal market predictions of their respective companies take entry into account. It is not unreasonable to assume that, armed with this knowledge, they *expected* Upsher's entry to create the precise competitive threat that actually defines the area of trade we need to focus on here.

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[49] *See* Horizontal Merger Guidelines §§ 1.43, 3.1.

[50] *See Andrx Pharms. v. Biovail Corp.*, 256 F.3d 799, 809 (D.C. Cir. 2001) ("Congress sought to get generic drugs into the hands of patients at reasonable prices – fast."), *quoting In re Barr Labs., Inc.*, 930 F.2d 72, 76 (D.C. Cir. 1991).

Similarly, if drug manufacturers react to generic entry by reducing promotions, as Respondents claim, it is further evidence that generic competition by itself has a significant effect. These reactions – along with the reactions of payors and state substitution laws – are consistent with our conclusion that generic competition is the closest substitute and that there is an adverse competitive effect, even though a broad "market" might be defined for another purpose.

Upsher advances still another argument to explain why the introduction of its own generic was so successful. It claims that the delayed entry negotiated in the settlement agreement was actually procompetitive because the company was able to increase its capacity and enter in force on a date certain, with greater market impact. Upsher Ans. Br. at 38-41. This argument appears to be inconsistent with the internal market forecasts, discussed above, which predicted substantial earlier entry. Upsher also does not explain why it needed to delay entry for over three years beyond expiration of the Hatch-Waxman stay. In fact, after the consummation of the agreement, Upsher slowed the pace of its work on the launch of Klor Con M20 and shuffled Klor Con personnel to other projects. Kralovec, Tr. 5094. Work on the launch was suspended for a time, and the new launch team was not gathered until May 1999. Kralovec, Tr. 5094; Gould, Tr. 5116, 5173. Even with this delay, Upsher considered that it was starting this work in ample time for the September 2001 launch. Kralovec, Tr. 5046-47; Gould, Tr. 5116, 5118-19. This suspension may have been a sensible business decision in the circumstances, but it undercuts any argument that a three-year delay was a requisite for substantial entry.

We therefore conclude that there is substantial evidence to support Complaint Counsel's claim that delayed generic entry in this situation would harm consumers by depriving them of the choice of a lower-cost generic version of K-Dur 20. We now discuss why we believe that Schering's payment resulted in a greater delay than would otherwise have occurred.

4. The Particular Significance of Schering's Payment

A settlement agreement is not illegal simply because it delays generic entry until some date before expiration of the pioneer's patent. In light of the uncertainties facing parties at the time of settlement, it is reasonable to assume that an agreed-on entry date, without cash payments, reflects a compromise of differing

litigation expectations.[51] Complaint Counsel's entire case proceeds on the theory that the payment of money by Schering to a potential generic entrant is what makes this case different. As Bresnahan stated:

> [W]hat matters is the difference between the amount of competition we got here . . . versus the amount of competition that was likely to occur had it not been for the payment to delay. . . . It's that comparison that matters, not the absolute amount.

Bresnahan, Tr. 614. We agree.

If there has been a payment from the patent holder to the generic challenger, there must have been some offsetting consideration. Absent proof of other offsetting consideration,[52] it is logical to conclude that the *quid pro quo* for the payment was an agreement by the generic to defer entry beyond the date that represents an otherwise reasonable litigation compromise.[53] *Cf. FTC v. Indiana*

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[51] The Commission's study of patent settlements under the Hatch-Waxman Act identified a large number of unchallenged agreements where the parties settled on a deferred entry date. The Commission study uncovered two agreements (Drug Products G and H in Chart 3-2) in which generic entry occurred under royalty-free licenses. The large majority of agreements in which generic entry occurred prior to patent expiration involved situations in which the generic applicant paid a royalty to the brand-name company during the remaining patent life (Drug Products A-F in Chart 3-2). Federal Trade Commission, Generic Drug Entry Prior to Patent Expiration: An FTC Study 29 (July 2002). These particular facts, based on a non-record source of which we take notice, have not been disputed by any of the parties (although Respondents did object to other data in the study). *See* Order Granting Motion for Leave to File Reply Memorandum; Denying Motion to Strike Reliance on FTC Study; and Permitting Each Party to File a Brief Addressing Cited Facts Contained Therein (Jan. 6, 2003).

[52] In this case, of course, Respondents have attempted (but failed) to demonstrate that there were other offsetting considerations adequate to account for the payment. *See* discussion in Parts III and IV, below.

[53] This is the first subsidiary issue subsumed in the third prong of Professor Bresnahan's test.

Fed'n of Dentists, 476 U.S. at 456 (FTC's conclusions supported by "common sense and economic theory, upon both of which the FTC may reasonably rely"); *see also* Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 Rand J. Econ. 391 (2003); Herbert Hovenkamp, *Anticompetitive Settlement of Intellectual Property Disputes*, 87 Minn. L. Rev. 1719, 1757-61 (2003).[54] The nexus between payment and delay is supported not only by simple logic but also by the plain language of the settlement agreement and the history of the negotiations between the parties. *See* Part IV, below.

According to Bresnahan, there is also a powerful incentive for the contending parties to make these agreements. The anticipated profits of the patent holder in the absence of generic competition are greater than the sum of its profits and the profits of the generic entrant when the two compete. It would be mutually beneficial for the patent holder and the challenger to defer entry of the generic and split the patent holder's profit. Bresnahan, Tr. 426-29, 495, 612-13; Goldberg, Tr. 119-20; Kerr, Tr. 6261. The resulting adverse effects on consumers are obvious.

We agree that there are strong monetary incentives for the pioneer and the generic to share the pioneer's substantial profits until the expiration of the patent, rather than compete head-to-head. The existence of these strong incentives, standing alone, obviously does not amount to proof of a law violation, but it may help to resolve conflicting inferences. *Compare Matsushita Elec. Indus. Co. v.*

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[54] We are aware of the recent opinion in *Asahi Glass Co., Ltd. v. Pentech Pharms., Inc.*, 2003 U.S. Dist. LEXIS 19370 (N.D. Ill. 2003) (Posner, J.), which questioned whether these concerns about reverse payments are based on "a sound theory." *Id.* at *21. Since the comment was made in passing and was admittedly "inapplicable" to the case before the court, we only note it here. To the extent that the court was opposed to *per se* condemnation of reverse payments, we emphasize that we have not applied a *per se* standard in this case and we have acknowledged that there are possible arguments in justification. More broadly, the court seems to be concerned that prohibition of "reverse-payment settlements would reduce the incentive to challenge patents by reducing the challenger's settlement options[.]" *Id. Any* antitrust restrictions on settlement agreements have the effect of reducing settlement options, but Judge Posner expressly states in the same opinion that some provisions should be condemned. *Id.* at *11-13.

Zenith Radio Corp., 475 U.S. 574, 591 n.15 (1986) (the Court recognized that *weak* incentives make price predation highly unlikely).

One recent district court decision expresses a different view of incentives, in a lengthy opinion that we need to address. In the *Ciprofloxacin Hydrochloride* case, 261 F. Supp. 2d 188 (E.D.N.Y. 2003), one reason for the court's rejection of a *per se* standard was its conclusion that Hatch-Waxman settlements are "unique" because the statute has distorted the relative bargaining power of the litigating parties. *Id.* at 250-52. In what the court called a "traditional scenario," a party can challenge a patent only by entering the market with its infringing product and risking a lawsuit for substantial damages. *Id.* at 251. The court went on to say that the event that triggers litigation under Hatch-Waxman – an ANDA filing with a Paragraph IV certification – is an "artificial act of infringement." *Id.* This "artificial act" eliminates the generic's potential exposure to liability for the pioneer's "enormous losses," and thus deprives the pioneer of its "traditional leverage" in litigation. *Id.* According to the court, this shift in the relative bargaining power of the parties means that "so-called reverse payments are . . . a natural by-product" of the Hatch-Waxman process. *Id.* at 252.[55]

We agree with the court that Hatch-Waxman may have altered the litigation incentives of pioneer and generic manufacturers. The statute was intended to do just that. However, because of the economic reality that generic entry causes a loss to the pioneer well in excess of the generic's anticipated profit, and the fact that damages for infringement are based on the *pioneer's* lost profit, a generic litigant still risks losses well in excess of its anticipated gains. This powerful disincentive for patent challenges may have been "traditional," but Congress specifically decided that it wanted to encourage patent challenges for pharmaceutical products. (An offsetting concession for patent holders is the automatic 30-month stay.)[56] As

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[55] This argument is cited with apparent approval in the *Valley Drug* case, 344 F.3d at 1309.

[56] H.R. Rep. No. 98-857, *supra* note 1, at 28, 1984 U.S.C.C.A.N. at 2661. *See also Andrx Pharms. v. Biovail Corp.*, 256 F.3d at 802 (Congress "interested in increasing the availability of generic drugs" but also interested in protecting "the patent rights of the pioneer applicant").

stated above, antitrust analysis must accept statutes and regulations as they are, and evaluate restraints in the context of the existing legal framework.

A payment for delayed generic entry under a Hatch-Waxman framework is no less anticompetitive than a similar payment under the "traditional" regime. The shift in the relative bargaining power of the litigating parties may mean – assuming other factors are held constant – that pioneers will have to accept earlier entry dates in settlement than they would otherwise have had to do. The baseline for a competitively benign settlement may have shifted. Whether this is good or bad is a judgment for Congress to make. Furthermore, we do not have evidence before us to justify any conclusion that payments by pioneers to generics are a "natural by-product of the Hatch-Waxman process"[57] or that Congress intended to immunize payments of this kind.

We therefore believe that the possible existence of a so-called "reverse payment" raises a red flag that distinguishes this particular litigation settlement from most other patent settlements, and mandates a further inquiry.[58] All of the pioneer/generic patent settlements that we have thus far challenged included a payment of this kind.[59] In fact, the evidence indicates that antitrust counsel for the pioneer, Schering, was also concerned about the legal implication of a possible payment to generic challengers. *See, e.g.*, CX 1494 at 71 (Driscoll IH); CX 1509 at 35 (Hoffman IH); Rule, Tr. 2583-84. However, for the reasons discussed above and in Part III below, we are not now prepared to say that all such payments should be viewed as *per se* illegal or "inherently suspect." We believe that this particular case warrants a more extensive analysis of competitive effects, without foreclosing the possibility that a more truncated process would be appropriate in some future case.

C. The Need to Address the Merits of the Underlying Patent Dispute

The Respondents argued, and the Administrative Law Judge held, that proof of anticompetitive effects requires proof on the merits of the underlying patent

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[57] *See also* discussion of ancillarity in Part III, below.

[58] *See supra* note 51.

[59] *See* cases cited *supra* note 3.

claims. ID at 4, 103-04. We deal with the argument in this segment of the opinion because it is not really a "defense" but rather a fundamental attack on the sufficiency of Complaint Counsel's affirmative case. It is also an argument that, if valid, would have an impact not only on this particular case but also on other antitrust cases before the Commission and the courts that involve the legality of patent settlements.

Respondents' argument and the conclusions of the Initial Decision on this issue have a superficial appeal. The argument proceeds as follows: Complaint Counsel have the burden of proving that the agreement delayed generic entry but failed to prove that earlier entry would have been possible in the first place, in light of the patent blockade. By statute, Schering's patent is presumed to be valid (35 U.S.C. § 282) and Complaint Counsel failed to prove it was not. Since the holder of a valid patent has the right to exclude infringing products entirely for the life of the patent, the settlement agreement was procompetitive because it permitted generic entry some five years *before* the expiration of Schering's patent.

We reject this argument for a number of independent reasons. First, Schering's presumptively valid patent did not necessarily confer a right to exclude generic entry in the circumstances of this case. Second, there is a recognized distinction between the standard for proving that an agreement is likely to cause competitive harm and the standard for proving damages after the fact. Third, we believe that an inquiry into the merits of the patent case would not be conclusive in most of our antitrust cases anyway. Fourth, we are also concerned that a mandated inquiry into these issues, as part of an antitrust review, would ultimately have a chilling effect on the efficient settlement of patent litigation.

We observe, first, that the Initial Decision suffers from a fundamental logical flaw. The fact that Schering may have held a presumptively valid formulation patent on K-Dur 20 does not mean that it had a presumptive right to preclude the entry of Upsher's generic product. One issue in the patent case – perhaps the most important one – was not whether Schering's patent was valid but rather whether Upsher's product infringed the patent. IDF 129, 130. On this issue, Schering had the burden of proof.[60] We cannot assume that Schering had a right to exclude

[60] *See, e.g., Carroll Touch, Inc. v. Electro Mechanical Systems, Inc.*, 15 F.3d 1573, 1578 (Fed. Cir. 1993). The Initial Decision assumed that Upsher had

Upsher's generic competition for the life of the patent any more than we can assume that Upsher had the right to enter earlier. In fact, we make neither assumption but rather focus on the effect that Schering's payment to Upsher was likely to have on the generic entry date which the parties would otherwise have agreed to in a settlement.

Second, we are not aware of any federal court opinions that hold it is necessary for complaint counsel in a government proceeding to offer proof on the underlying merits of the patent dispute, in order to establish their affirmative case. The point was discussed in the recent *Tamoxifen Citrate Antitrust Litigation*, 262 F. Supp. 2d 17, where the court dismissed an antitrust challenge to an agreement that settled a patent dispute between a pioneer and a generic manufacturer, with terms that included a payment from the pioneer to the generic. In return, the generic had agreed not to market its own version of the Tamoxifen drug prior to the expiration of the patent, but instead took a license to sell product manufactured by the pioneer.

In that case, however, the validity of the pioneer's patent was the crucial issue in the underlying patent dispute and, subsequent to the settlement in question, the pioneer's patent was successfully defended in litigation with three other generic challengers. In a private action for damages, after the fact, the *Tamoxifen* court had good reason to believe that the settlement did not ultimately cause consumer harm. In the present case, on the other hand, we do not attempt to assess damages but rather look at the agreement as of the time it was made to determine whether it was "unreasonable," *i.e.*, whether it likely delayed generic entry beyond the date that would have been provided in a differently crafted settlement.

A contemporaneous opinion from the same district court in the *Ciprofloxacin Hydrochloride Antitrust Litigation*, discussed at length above in connection with another issue, expressly rejected the argument that an antitrust attack on a Hatch-Waxman settlement requires proof on the merits of the underlying patent case. Notwithstanding the fact that the underlying patent dispute between the pioneer and the generic manufacturers involved patent validity, not infringement, and the fact that subsequent to the settlement the pioneer had

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the burden of proving either patent invalidity or "*that its product . . . did not infringe Schering's patent*." ID at 103 (emphasis added). This is not correct.

successfully defended the validity of its patent in litigation with others, the court found that the existence of an antitrust violation does not depend on the merits of the patent case.[61] At the time of the settlement, the parties did not know who would ultimately prevail, and the court noted that

> . . . the challenged agreements allowed [the generic] to accept cash in exchange for an agreement to halt the process by which a court would make . . . a determination [of patent validity and infringement] – a process encouraged by the Hatch-Waxman Amendments and beneficial to consumers.

Ciprofloxacin Hydrochloride, 261 F. Supp. 2d at 204. The court therefore rejected the pioneer's argument that it was patent law, not the agreement, that precluded generic entry. Although the court also rejected plaintiffs' claim of *per se* illegality, it indicated that the matter could proceed under a rule-of-reason inquiry. *Id*. at 210-11.

We agree with the reasoning of the *Ciprofloxacin Hydrochloride* court on this issue. The merits of the patent litigation may be crucial in an action for damages but we are here concerned only with legal liability, and we focus on the state of the world as it was perceived by the parties at the time that they entered into the settlement agreement, when they could not be sure how the litigation would turn out.[62]

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[61] The *Ciprofloxacin* court appropriately cautions that the standard for proof of damages may be different. *Ciprofloxacin Hydrochloride*, 261 F. Supp. 2d at 199.

[62] The uncertainty posed by patent litigation is, of course, only one of many types of uncertainty that affect whether a new product can be successfully introduced into a market. But the existence of such uncertainties cannot justify an agreement whose very purpose is to ensure against an increase in competition, by guaranteeing that the new product will not be introduced. If, for example, an incumbent entered into an agreement with a would-be market entrant in which the latter agreed to delay or forgo introduction of a new product, it would be no defense to argue that the new product *might* not have succeeded in any event.

A similar view was expressed by the court in *Valley Drug*, cited earlier for its rejection of a *per se* standard. In *Valley Drug*, the sole issue in the underlying patent litigation was patent validity and, after an interim settlement, the patent in issue had been declared invalid in a separate proceeding. The court said:

> We reject the appellees' argument that the agreements by Geneva and Zenith not to produce infringing products are subject to *per se* condemnation and treble-damages liability merely because the '207 patent was subsequently declared invalid. We begin with the proposition that the reasonableness of agreements under the antitrust laws are [sic] to be judged at the time the agreements are entered into.

Valley Drug, 344 F.3d at 1306 (citations omitted).

The court went on to say:

> Patent litigation is too complex and the results too uncertain for parties to accurately forecast whether enforcing the exclusionary right through settlement will expose them to treble damages if the patent immunity were destroyed by the mere invalidity of the patent.

Id. at 1308.

The *Valley Drug* opinion, of course, was concerned only with the narrow issue of whether a subsequent finding of patent invalidity necessarily made it *per se* illegal for the pioneer patent holder to pay a generic challenger for entry delay – even though the litigation outcome was uncertain at the time. We believe, however, that the underlying logic of the opinion has a broader application. We question the utility of a rule that would give decisive weight to an after-the-fact inquiry into the merits of the patent issues in a settled case. This is the third independent basis for our conclusions.

In an extreme case, the inquiry might be helpful. If it appeared that the patent claim was objectively a sham, any agreement to delay generic entry might be viewed as anticompetitive, regardless of the other terms. Conversely, if it appeared that the generic's Paragraph IV certification was objectively a sham, it might be difficult to claim that an agreed-on entry date before the patent

termination involved an unacceptable delay.[63] The problem is that the bulk of the cases will lie in between.[64]

An after-the-fact inquiry by the Commission into the merits of the underlying litigation is not only unlikely to be particularly helpful, but also likely to be unreliable. As a general matter, tribunals decide patent issues in the context of a true adversary proceeding, and their opinions are informed by the arguments of opposing counsel. Once a case settles, however, the interests of the formerly contending parties are aligned. A generic competitor that has agreed to delay its entry no longer has an incentive to attack vigorously the validity of the patent in issue or a claim of infringement. We observe this natural phenomenon in the present case. Upsher's ANDA filing had certified that Schering's K-Dur 20 patent was either invalid or not infringed by Upsher's product. Later on, Upsher's counsel in the patent litigation represented to the court that the only impediment to its immediate entry was the automatic Hatch-Waxman stay. CX 1705 at USL PLD 004242 (*in camera*); Kerr, Tr. 6744-45. After the settlement, Upsher's views dramatically changed. At trial, Paul Kralovec, Upsher's CFO, testified that, because of the financial risk arising from damages for infringement, a decision was made that Upsher would not market Klor Con M20 until the outcome of the litigation was known. Kralovec, Tr. 5037-38.

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[63] A case like *Tamoxifen* (discussed above), where patent validity was the only issue and the patent had been repeatedly upheld, might also be included in this category.

[64] Take the simplest possible case as an example. Suppose it appears *post* settlement that each party reasonably had a 50/50 expectation of victory. Does this mean that a 50/50 split of the remaining patent term would be the only reasonable settlement? This assumption would not necessarily be true for reasons that the Respondents themselves have addressed in great detail. *See* Part III, below. The parties may have very different financial resources, profit expectations and risk preferences, with consequently differing views on the costs and benefits of further litigation. These differing views would have an effect on the outcome of settlement negotiations, and litigation odds cannot be converted directly into the legally acceptable period of delayed entry.

The fact that the generic's counsel has switched sides does not destroy all potential for an adversary proceeding. It is theoretically possible for Complaint Counsel to step in for the generic's newly complaisant counsel and champion the generic's abandoned claims, or the Commission could weigh conflicting opinions of opposing experts. If it were logically necessary to decide the issue of patent validity in order to decide whether the agreements in issue here were reasonable, we would do so – regardless of the difficulties. However, for the reasons discussed, it is not necessary.

Finally, we have considered the serious uncertainties that would confront parties who seek to settle patent litigation if the Commission undertook to examine the underlying merits itself later on, and gave them conclusive weight. Under the standard we adopt here, if the parties simply compromise on the entry date, standing alone, they do not need to worry about a later antitrust attack. This test may not be perfect, but at least it is easy to apply at the time of settlement, when the outcome of the patent case is uncertain. If a subsequent examination of the merits were decisive, the parties could not be sure. If the generic's position were later determined to be invalid, then any entry short of patent expiration would likely be immune from attack. If, however, the pioneer's position were found to be invalid, *any* delay would be suspect. Respondents' argument might serve their interests in this particular case, but it could have a chilling effect on patent settlements down the road, and thus make it harder for parties to enjoy the advantages of certainty.[65]

For these various reasons, we believe that it would not be necessary, practical, or particularly useful for the Commission to embark on an inquiry into the merits of the underlying patent dispute when resolving antitrust issues in patent settlements. To the extent that the opinion of the Administrative Law Judge is predicated on any such requirement, it is reversed.[66]

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[65] *See Valley Drug*, 344 F.3d at 1306-07; Willig, Tr. 7148, 7173-75.

[66] For reasons also discussed above, however, this conclusion about what the Commission needs to do in this case does not necessarily have any bearing on what a private plaintiff may need to do in order to prove damages.

III. The Ancillarity Defense

Both Schering (implicitly) and Upsher (expressly) plead that even if the $60 million payment to Upsher were deemed to have been traded for delay, it was justified as ancillary to a legitimate, pro-consumer agreement, namely, the settlement of a patent dispute. Schering Answer at ¶¶ 1-3; Upsher Answer at Defenses ¶ 10. They offered evidence – principally through their expert witness, Professor Robert Willig – that Professor Bresnahan's paradigm was overly simplistic. Professor Willig testified that the payment of net consideration from the pioneer to the generic must be considered in the overall context of procompetitive patent settlements that it may facilitate. We, therefore, will examine these claims under familiar principles applicable to ancillarity defenses.

The Antitrust Guidelines for Collaborations Among Competitors[67] set out the analytic framework that we will apply in this situation.[68] These Guidelines (Sec. 3.2) provide that even a provision that would be *per se* illegal standing alone can qualify for rule-of-reason treatment in certain circumstances. Therefore, even if we assume that Schering overtly agreed to pay Upsher a substantial sum for delayed entry, it is necessary to examine that payment in the context of an overriding purpose to settle the patent case.

Under the Guidelines, respondents who assert an ancillarity claim have the burden of showing three things (Sec. 3.2):

(i) that there is an "efficiency-enhancing integration of economic activity . . .";
(ii) that the arguably ancillary agreement is "reasonably related to the integration . . ."; and

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[67] *See* Antitrust Guidelines for Collaborations Among Competitors, *supra* note 27.

[68] The Guidelines are intended to reflect current law, not to catalyze changes. *See* Susan S. DeSanti, Guideposts in the Analysis: The Federal Trade Commission and U.S. Department of Justice, Antitrust Division Competitor Collaboration Guidelines, Address Before the Houston Bar Association (Dec. 7, 1999), *available at* <http://www.ftc.gov/speeches/other/antitrustguidelines.htm>.

(iii) that it is also "reasonably necessary to achieve . . . [the] pro-competitive benefits" of the overall arrangement.

Id.

We accept Willig's testimony that there are likely to be efficiencies associated with the settlement of patent disputes between pioneer and generic manufacturers. *See, e.g.*, Willig, Tr. 7134, *et seq*. A settlement can save public and private resources that would otherwise be consumed by litigation, and it can provide certainty that will encourage business investment. We also recognize, as he testified, that there may be hypothetical situations where a procompetitive settlement could require payment of some money to the generic challenger. This means that we are unwilling to say reverse payments included in a settlement agreement are always illegal.[69] On the other hand, the mere articulation of hypothetical circumstances where reverse payments could ultimately facilitate an efficiency-enhancing settlement does not mean that a particular settlement is legal. If Complaint Counsel have made out a *prima facie* case that the agreement was anticompetitive, the burden is on these Respondents to demonstrate that these hypothetical circumstances describe the realities of the present case. They have not done so.

Willig hypothesized, for example, that a "cash starved" generic may actually be able to enter earlier and more effectively if it receives some up-front support from the pioneer manufacturer. Willig, Tr. 7180, 7188, 7258. It is possible that this trade might ultimately yield competitive benefits, but a respondent that relies on this argument also must show that the generic, in fact, was cash starved; explain why the pioneer was the best source for the necessary funds; and demonstrate that the up-front support actually resulted in an entry date earlier than would be expected without it. We have no evidence that would establish these conclusions. To the contrary, Upsher expressly waived any intention to rely on financial need as

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[69] *See Bristol-Myers Squibb Co.*, FTC Dkt. No. C-4076 (Section XII(B)(1)(b) of Decision and Order does not prohibit respondent from settling patent infringement litigation with a payment from the pioneer to generic manufacturer if payment is less than $2 million or expected litigation costs), *available at* <http://www.ftc.gov/os/2003/03/bristolmyersdo.pdf>. *See also* Final Order in this case, at Paragraph II.

a defense in this action.[70] It is true that Schering may have believed Upsher needed the money because Upsher's lead negotiator said so repeatedly in the course of the settlement discussions, but it is also true that Schering did not rely on any such belief to establish the legality of the $60 million payment. *See* discussion in Part IV.B., below. As a matter of fact, Upsher was not cash-constrained; the company passed on to its shareholders an amount equal to or in excess of the sums received from Schering. Kralovec, Tr. 5067.

There are other possibilities. Risks and costs associated with litigation are avoided by settlement. If the generic challenger is more optimistic about the litigation outcome than the pioneer, a pioneer may be willing to pay some money to bridge the gap in the expectations. Willig, Tr. 7195; Addanki, Tr. 5761, 5776, 5793. It is also possible that there are widely differing risk preferences. A judgment-proof generic manufacturer may be willing to hold out for "unreasonable" settlement terms because its downside risks of damage exposure are small.[71] Addanki, Tr. 5793-94.

We recognize that additional legitimate justifications can also exist, and this is another reason why we do not apply a truncated analysis in this particular case. However, once Complaint Counsel have made out a *prima facie* case of actual anticompetitive effects, Respondents must do more than suggest hypothetical benefits.[72]

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[70] CX 1693 (Letter from Rajeev K. Malik to Yaa A. Apori Providing Upsher's Responses to Specifications 4, 5 and 8 of Complaint Counsel's First Request for Production of Documents (Aug. 28, 2001) ("The agreement is Upsher-Smith does not have to produce documents in response to Specification 8 [requesting financial information]. In exchange, Upsher-Smith commits to Complaint Counsel that it will not raise a defense that uses Upsher-Smith's financial condition as a justification for entering into the licensing agreement with Schering-Plough.")).

[71] For the reasons discussed above, it may be difficult to identify a particular settlement demand as objectively "unreasonable."

[72] *PolyGram Holding, Inc.*, 5 Trade Reg. Rep. at 22,459, slip op. at 30-31 ("a justification must plausibly create or improve competition.").

In this case, the sheer magnitude of the payment from the pioneer to the generic is a particular source of concern. Even if we assume arguendo that there had been enough evidence to show that the hypothetical speculations of Respondents' experts actually applied to the facts of this case, the evidence could not justify a payment of any amount close to the $60 million involved here. We deal with an ancillarity defense predicated on the notion that there is a strong public policy in favor of litigation settlements – even if the settlements may involve agreements that might be illegal standing alone. But, these public policy considerations are just one weight on the scale; they do not mean that all settlements are presumptively efficient regardless of the cost.[73]

We conclude that Respondents' ancillarity defense has failed. A payment in the order of $60 million could not be defended under these facts as a reasonably necessary element of a settlement that is procompetitive overall. The parties did not show that the hypothetical situations where such a payment might be justified actually were present in this case. The ancillarity claim is rather based on after-the-fact rationalization. During the course of the settlement negotiations, recounted in detail below, Upsher's representatives seemed to be entirely oblivious to the potential legal consequences of their demand that money be paid for delayed entry. Schering's representatives were sensitive to these concerns but believed that the solution was to find some side deal that would justify the payment by itself. We now examine Schering's "solution."

IV. Consideration for the Upsher Licenses Granted to Schering

Complaint Counsel have conceded that there is no liability in this matter if the licenses that Upsher granted to Schering were adequate consideration for the $60 million payment from Schering to Upsher. App. Br. at 3. We interpret this to mean that Complaint Counsel's test is whether $60 million was a fair price for the licenses from Schering's standpoint, regardless of what they were worth to

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[73] Herbert J. Hovenkamp, *et al.*, *Anticompetitive Settlement of Intellectual Property Disputes*, 87 Minn. L. Rev. 1719 (2003) (payment by a pioneer to a generic in excess of litigation costs is not an economically efficient solution to the dispute and likely biases the negotiated entry date toward later entry).

Upsher.[74] We express no view as to whether a concession of this kind is necessarily appropriate. Since, however, it is the basis on which this case has been litigated, we will proceed on the same premise.

This is also an issue on which Complaint Counsel have conceded that they bear the ultimate burden of proof. O.A. at 30 ("we have the burden to prove the payment was for delay"). This is not to say that Complaint Counsel bear the burden of proving the actual value of the licenses. What we understand they have undertaken to prove is (i) that there is a nexus between the payment by Schering and Upsher's agreement to delay its competitive entry, and (ii) that the preponderance of the evidence shows that this payment exceeded, by a substantial amount, Schering's reasonable expectation of the value of the Upsher licenses. App. Br. at 22-24 (" . . . the Commission need not conclude that the license for [Niacor-SR] was a 'sham' or that it lacked any value to Schering."). This is the standard that we will apply.

The Initial Decision contains extensive findings on this issue. However, for reasons that will become clear, many specific findings and the ultimate factual conclusions in the Initial Decision are flawed. Accordingly, we review the entire factual record *de novo,* and, where appropriate, substitute our own findings and conclusions for those in the Initial Decision. We will focus on (A) the plain language of the agreement; (B) the background and history of the settlement negotiations; (C) the extent of Schering's internal investigation of the value of the Upsher licenses, considered in light of the information it had already obtained in the course of recently terminated negotiations with another company for a similar product; and (D) the inferences that may appropriately be drawn from the subsequent conduct of the parties and after-the-fact opinions about the value of the licenses.

This part of the opinion is necessarily detailed. There is no single event, no single communication, that determines the outcome. Our conclusion that Complaint Counsel have sustained their burden on the critical valuation issue

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[74] Complaint Counsel's witness Bresnahan testified that "if Schering-Plough had made a stand-alone determination that it was getting as much in return from these products as it was paying, then I would infer that they were not paying for delay." Bresnahan, Tr. 964-65.

rather depends on the cumulative impact of the extensive record evidence in this case.

A. The Language of the Settlement Agreement

The "Detailed Agreement Terms" between Upsher and Schering provide, in pertinent part:

> 3. Upsher-Smith agrees that it will not market in the United States its KLOR CON® M20 potassium chloride product, or any other sustained release microencapsulated potassium chloride tablet, prior to September 1, 2001.
>
> * * *
>
> 11. In consideration for the licenses, rights and obligations described in paragraphs 1 through 10 above, SP licensee [a Schering affiliate] shall make the following payments to Upsher-Smith: . . .

CX 348 at USL03186, USL03188.

The contract then sets out a schedule for payment of $60 million, keyed to specific time periods following approval by the Schering Board. The payments are not dependent on milestones in the development of products licensed from Upsher to Schering, such as FDA filings or approvals.[75] The only ongoing affirmative obligation of Upsher, apart from its commitment not to enter before September 1, 2001, is a promise that it will not assist ESI or any other party that challenges Schering's patent. CX 348, Par. 6.

We do not believe this contractual language is conclusive by itself. What it does show is that at least part of the consideration for the $60 million payment was Upsher's commitment to delay entry, something that Schering's in-house counsel has readily conceded. Hoffman, Tr. 3565-67. Even more significant, payment was not conditioned on Upsher's cooperation with Schering in the development of the

[75] Additional contingent milestone payments that could total $10 million were negotiated for the launch of Niacor-SR in nine other countries.

licensed product. The omission may well have been deliberate because, after the Agreement became effective, Upsher did practically nothing to cooperate and Schering did not seem to care. *See* discussion in Part IV.D., below.

B. Background and History of the Negotiations

The Initial Decision relies on direct trial testimony of several individuals for a description of the negotiations between the parties that resulted in the June 17, 1997 agreement. IDF 131-55. It does not cite contradictory cross-examination testimony or investigational hearing testimony of several of these individuals, nor does it explain why this testimony was given no weight – even when the contradictory testimony is corroborated by documentary evidence.[76] There are particularly significant discrepancies in the testimony of Ian Troup, Upsher's President and Chief Operating Officer, and John Hoffman, Schering's Associate General Counsel. Accordingly, as detailed below, the Commission discounts inconsistent trial testimony of these two individuals.

The Initial Decision also does not cite important deposition testimony of a primary negotiator for Schering in the early meetings between the two companies (Martin Driscoll, Vice President of Sales and Marketing for Key Pharmaceuticals), even when it is consistent with his investigational hearing testimony. *See*, *e.g.*, CX 1494 at 65-66 (Driscoll IH); CX 1495 at 58-59 (Driscoll Dep.) (views of the parties about payments to Upsher and entry into the market). The Initial Decision relies

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[76] Upsher continues to press its objection to the use of the testimony of Schering executives during the investigational hearings and to rely on a pretrial ruling that this testimony is not admissible against Upsher. Upsher Ans. Br. at 22 n.2, citing Tr. 297-98. We do not agree with this ruling. *See Gibson v. FTC*, 682 F.2d 554, 568 (5th Cir. 1982) ("[T]he Commission Rules of Practice [§ 3.43(b)] permit the introduction of hearsay evidence, provided that it meets the standards of materiality, reliability and relevance."). The hearing transcripts in issue are verbatim statements of the witnesses, and Upsher does not explain why they are unreliable. In any event, however, we rely on these transcripts merely to corroborate evidence from other sources. The testimony specifically affected by this ruling is contained in CX 1483, 1494, 1508, 1510, 1515 and 1531. There is independent support for any factual findings in this Opinion that may also refer to these exhibits.

on direct testimony of some witnesses for facts about which they had no firsthand knowledge and for which other individuals with differing testimony would have been more reliable sources. For example, IDF 136 relies on Hoffman, who did not attend either the May 28 or the June 3 meeting, for a description of the events at these meetings. IDF 145 relies on Troup's recollection of a discussion with Schering personnel of certain clinical data about Niacor-SR, but these Schering employees had no knowledge of these issues.

The Initial Decision also relies on self-serving statements of the parties without weighing contradictory, and more reliable, evidence.[77] For example, IDF 145 indicates that the parties discussed "the market potential for Niacor-SR" and that they also "discussed niacin combination therapy, the advantages of Niacor-SR versus immediate-release niacin, the flushing side effects and Niacor-SR's effects on Lp(a)." Troup's statements, on which the finding is based, are contradicted by Schering's lead negotiator, Raman Kapur, who testified that there was no scientific discussion on the merits of Niacor-SR. CX 1511 at 71-72 (Kapur Dep.) (indicating no discussion of Niacor-SR's clinical results). Indeed, the Initial Decision fails to note that the discussions did not include Schering personnel with knowledge about niacin-related products. None of the Schering personnel involved in the recently terminated negotiations with Kos Pharmaceuticals were involved in the Upsher negotiations; Driscoll, the only person with firsthand knowledge of the Kos product, had dropped out of the negotiations with Upsher at this point.

In light of these shortcomings, the Commission has undertaken a *de novo* review of the record and substitutes the following findings for IDF 131-55. It is necessary to cite the testimony of many individuals. Throughout this opinion, we

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[77] To avoid any possible misunderstanding, we emphasize that we do not automatically discount testimony simply because it is self-serving. Most witnesses with knowledge of the facts have some stake in the outcome of a proceeding like this one – intellectual or emotional, if not financial. However, when the trial testimony of a strongly self-interested witness conflicts with the same witness's earlier testimony in a more unguarded moment, with contemporaneous documents, or with statements of less interested witnesses, it is necessary to take account of these alternative versions of the facts.

have identified the affiliations of all witnesses when they are first mentioned, and these identifications are also set out in an Appendix.

1. Findings of Fact on the Negotiations Between Schering and Upsher

In April or May 1997, Troup first approached Schering about a possible settlement of the patent litigation. Troup, Tr. 5397, 5407-09. The parties held a series of meetings over the course of the month before trial in an attempt to reach a settlement of the patent litigation.

The initial settlement meeting took place between Driscoll and Troup at Schering's office in Kenilworth, New Jersey on May 21, 1997. Troup, Tr. 5409-10. This was the first of five face-to-face meetings between Schering and Upsher. Troup stated that his settlement objective was to obtain the earliest possible launch date for Klor Con M20 without incurring the damages that could arise from patent infringement. Troup, Tr. 5411-12. Driscoll recalled that Troup said in the initial meeting that the only way Upsher would settle the patent litigation was for payment of $60 million to $70 million and the ability to market within the year (an entry date). CX 1494 at 65-66 (Driscoll IH); CX 1495 at 58-59 (Driscoll Dep.). Driscoll recalled that the $60 million to $70 million was the estimated adverse impact on Schering of Upsher's entry and that Troup wanted a percentage of that impact. CX 1494 at 67 (Driscoll IH). It was value that Upsher had to have.[78] CX 1495 at 58 (Driscoll Dep.). Driscoll stated forcefully that Schering would not pay. CX 1494 at 66 (Driscoll IH); CX 1495 at 58 (Driscoll Dep.).

At this meeting or the next, Driscoll and Troup discussed the possibility that Schering might permit Upsher's generic version of K-Dur to come to market in late 2005 or early 2006, before the expiration of Schering's patent. Troup, Tr. 5412.

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[78] Upsher's insistence on a payment persisted throughout the negotiations. *See* CX 338 (summary forwarded to the Schering Board when it approved the settlement agreement in issue, stating, "In the course of our discussions with Upsher-Smith they indicated that a prerequisite of any deal would be to provide them with a guaranteed income stream for the next twenty-four months to make up for the income that they had projected to earn from the sales of Klor Con had they been successful in their suit.").

Troup stated that Upsher wanted to be on the market at an earlier date and that it would have problems with cash flow if its entry were delayed until 2005. Troup, Tr. 5413. There is, however, no record support for Troup's claim of financial need (Kralovec, Tr. 5067), and Upsher disclaimed any intention to rely on it, in order to avoid disclosure of financial information during the discovery stage of this proceeding.[79]

The parties met again at Upsher's offices in Plymouth, Minnesota, on May 28 and June 3, 1997. Driscoll and Raman Kapur, President of Schering's Warrick subsidiary that markets generic drug products, attended these meetings on behalf of Schering. Troup and consultant Andrew Hirschberg attended on behalf of Upsher. Troup, Tr. 5417; CX 1511 at 8-10 (Kapur Dep.); Schering First Admissions Nos. 7-9, 11-12; Upsher Second Admissions Nos. 9-10, 13-14, 22. At the May 28, 1997 meeting, Kapur indicated he was interested in the possibility of licensing some of Upsher's generic products. Troup, Tr. 5420.

At the May 28 and June 3, 1997 meetings, the parties discussed several possibilities for business opportunities, such as a co-marketing arrangement with respect to Schering's K-Dur or a joint venture where Schering would invest $14 million into Upsher's research and development efforts. CX 1511 at 14-15 (Kapur Dep.); Troup, Tr. 5433-34; USX 477 (Troup's contemporaneous notes of the June 3, 1997 meeting). They also discussed the possibility that Schering might license one or more Upsher products. The discussion during the May 28 meeting focused on settlement of the K-Dur litigation and there was a brief discussion of licensing cholestyramine (one of the generic products Upsher ultimately licensed to Schering as Prevalite) at the end of the meeting. CX 1511 at 14 (Kapur Dep.). The parties did not discuss Niacor-SR until the June 3 meeting and Upsher did not provide written material to Schering personnel at this meeting. CX 1530 at 70 (Troup Dep.); CX 1511 at 14 (Kapur Dep.); CX 1495 at 62 (Driscoll Dep.); CX 1511 at 16 (Kapur Dep.); Troup, Tr. 5420, 5430-34.

Driscoll was aware of the market opportunity for Niacor-SR because he had been involved in evaluating the market for other, nearly identical projects. CX 1495 at 70-71, 73 (Driscoll Dep.). Troup was willing to consider the possibility of

[79] *See* Part III, above.

licensing Niacor-SR to Schering outside the United States, because Upsher had no international presence. Troup, Tr. 5432.

During the course of the May 28 and June 3, 1997 meetings, Troup again suggested that Schering make a payment in connection with a settlement of the patent suit. CX 1511 at 18-19 (Kapur Dep.). Troup stressed Upsher's need to replace the revenue it would lose if it did not have a generic K-Dur 20 product on the market. CX 1511 at 18-19 (Kapur Dep.).

During the course of the May 28 and June 3, 1997 meetings, the parties discussed various dates for Upsher's entry with its generic version of K-Dur 20. CX 1511 at 22-23 (Kapur Dep.). Troup preferred an earlier date. CX 1511 at 23-24 (Kapur Dep.); CX 1529 at 100 (Troup IH); Troup, Tr. 5505-5507. The record evidence is unclear on who offered the September 1, 2001 date. Driscoll does not indicate, in either his investigation hearing or deposition testimony, that he offered a date earlier than 2005. Kapur recalled, however, that Driscoll told Upsher the earliest date he could offer for Upsher's entry was September 2001. CX 1511 at 23 (Kapur Dep.).

Regardless of who offered the September 1, 2001 entry date, the weight of the evidence indicates that the parties had not agreed upon the entry date of September 1, 2001 at the end of the June 3 meeting. Troup testified in his investigational hearing that the date had not been agreed to and that he would get back to Schering on the entry date after the June 3, 1997 meeting. CX 1529 at 100 (Troup IH). In his later deposition and trial testimony he stated that the date was settled by the end of the June 3, 1997 meeting, although he stated that he did not remember exact dates. CX 1530 at 82 (Troup Dep.). Hoffman, who attended his first meeting with Upsher personnel on June 12, testified both in his investigational hearing and on cross-examination at trial that the entry date was not even settled upon until after the next meeting on June 12, 1997. Hoffman, Tr. 3563; CX 1509 at 42 (Hoffman IH). Although Hoffman's direct trial testimony and deposition testimony are to the contrary, we find that his testimony on cross and the earlier investigational hearing is more credible. Therefore, we find that the negotiations on an entry date cannot be viewed as concluded by June 3, 1997, nor do we find that it was a matter separate and apart from other terms and provisions in the final agreement dated June 17, 1997.

Driscoll recalled that he ended his participation in the negotiations with Upsher after the June 3 meeting, even though he was head of the affiliate responsible for K-Dur. He stated that Troup wanted money to settle and Schering would not pay, so he decided to let the lawyers work it out. CX 1494 at 71-72 (Driscoll IH).

Before the parties' next face-to-face negotiation session, Hoffman spoke to Nick Cannella, Upsher's outside counsel, on or about June 10, 1997, to discuss logistics and ground rules for the upcoming meeting. Cannella, Tr. 3824-25. Upsher representatives Troup, Cannella and Hirschberg, and Schering representatives Kapur and Hoffman, met in Kenilworth, New Jersey, on June 12, 1997. Troup, Tr. 5436-38; Hoffman, Tr. 3539, 3541-42. It is unclear from the evidence whether Jeffrey Wasserstein, Schering's Vice President of Business Development, attended this meeting. CX 1532 at 25-26 (Wasserstein Dep.); CX 1510 at 54 (Kapur IH) (Kapur indicating that only he and Hoffman attended the June 12, 1997 meeting).

The purpose of the June 12, 1997 meeting was to continue discussion of the potential for settlement of the lawsuit and the licensing of certain Upsher products. CX 1509 at 34 (Hoffman IH). The parties discussed a settlement proposal under which Schering would give Upsher a royalty-free license at some time before expiration of the patent, and the timing of entry would be based on the parties' potential for success or failure in litigation. CX 1509 at 34 (Hoffman IH). Hoffman indicated that Schering would not pay to settle the litigation. CX 1509 at 35 (Hoffman IH). Hoffman testified that Upsher's consultant (Hirschberg) provided an estimate of how much Schering stood to lose if Schering lost the suit. CX 1509 at 35 (Hoffman IH); Hoffman, Tr. 3544. There was agreement at the end of this meeting that the parties would settle the litigation, through a royalty-free license at some time prior to patent expiration, but no particular date had been picked. CX 1509 at 42 (Hoffman IH). Troup again raised his desire to gain an entry date earlier than September 1, 2001, for Upsher's generic version of K-Dur. Troup, Tr. 5439; CX 1529 at 101-02 (Troup IH).[80] Troup stated at the June 12 meeting that Upsher still had "cash needs" because all of the company's cash was

[80] Upsher's own witness, Troup, apparently did not regard the entry date as settled, even as late as June 12.

tied up in two products in development – Upsher's generic version of K-Dur and its similar sustained-release niacin product, Niacor-SR. Hoffman, Tr. 3543.

Before the June 12, 1997 meeting, Upsher required Schering to sign a confidentiality agreement regarding Upsher's Niacor-SR product information. CX 1041. Troup brought to the meeting a confidential printed presentation about Upsher's Niacor-SR product. Troup, Tr. 5436-37; CX 1042. This presentation was similar to the presentations Upsher provided to Searle and the European companies interested in licensing Niacor-SR. USX 538; CX 1023.[81] Troup also provided Schering with two draft protocols for conducting post-market studies of Niacor-SR. CX 714; CX 1043. Neither Kapur nor Hoffman had participated in the earlier negotiations with Kos on a niacin-related product. *See* Part IV.C.1, below.

Troup confirmed that Upsher's offer of a Niacor-SR license extended only to non-NAFTA territories. Hoffman, Tr. 3545; Troup, Tr. 5440-41. Schering was

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[81] Through a consultant, Upsher contacted European companies to solicit interest in Niacor-SR. The first wave of contacts covered 32 companies. All but one of the companies in the first wave declined the opportunity or failed to respond. CX 888 (consultant's report summarizing responses received). The second wave of contacts covered additional smaller European companies. Four companies expressed interest in meeting with Upsher. Meetings with these four companies took place between May 28, 1997 and June 5, 1997. The meeting summaries assessed three of the potential licensees' interest as "moderate" or "low." CX 868 (Esteve meeting summary); CX 880 (Lacer meeting summary); CX 883 (Servier meeting summary). Only one partner, Pierre Fabre, was assessed as "moderately to highly interested," "if we can negotiate an acceptable deal." CX 881 at USL11826. That company expressed concerns in its meeting with Upsher about the safety of Niacor-SR, and questioned what kinds of payments might be involved because it had met with start-up companies that were asking "unreasonable payments of at least $50 million." CX 881 at USL11825-26. These tepid results were reported back to Troup. USX 1532 at 145 (O'Neill IH); Troup, Tr. 5570; USX 596-98; CX 880.

The other potential partner, Searle, "had no interest in further pursuing the product" because of questions about Niacor-SR's safety, in particular its toxicity profile. Egan, Tr. 7886.

disappointed that Upsher would not consider a partnership for Niacor-SR in the United States (CX 1511 at 26-27 (Kapur Dep.)), but remained interested in the opportunity to market the product internationally. Troup, Tr. 5443-44. Kapur also expressed his continued interest in Upsher's cholestyramine and Pentoxifyilline products. Hoffman, Tr. 3545.

Troup made a brief presentation on Niacor-SR and brought written materials. Hoffman, Tr. 3544. Troup had not attended Upsher's presentations to other potential European partners, and none of the Upsher employees who had given the Niacor-SR presentation to other potential partners – including Halvorsen, Freese, and O'Neill – were present at the meeting with Schering. Troup, Tr. 5436-38; Hoffman, Tr. 3541-42. The parties discussed the market potential for Niacor-SR. Hoffman, Tr. 3547-48; Troup, Tr. 5441-43; Cannella, Tr. 3868. Troup referred to Kos Pharmaceuticals' Niaspan product, its market capitalization and sales potential, to show that Upsher's Niacor-SR niacin product had tremendous potential. Troup, Tr. 5441-43; Cannella, Tr. 3829-30.

The June 12, 1997 meeting included a preliminary discussion of the price for the Niacor-SR product. Troup asked for $70-80 million in his first offer to Schering. Troup, Tr. 5449; Hoffman, Tr. 3545; CX 1511 at 44-45 (Kapur Dep.); Cannella, Tr. 3829. Troup did not base his asking price on Upsher's own estimates of the potential market for Niacor-SR. Upsher had not yet forecasted sales for the European/ex-U.S. markets, but its sales projections for the U.S. market were uniformly low.[82] A series of Upsher internal projections in 1996 and 1997 (before the Agreement) predicted sales in the $10 million range or below in the first year; the highest estimate was for $20 million in sales in the second year of one projection. CX 234 at USL12785, USL12797; CX 322 at 05287; CX 778 at 15531. As of September 1997, Upsher projected U.S. sales for Niacor-SR of only $9.6 million and $11.5 million in its first and second years on the market. CX 1094 at 11935; *see also* CX 930 at 13191 (July 1997 projection of $7-8 million for Niacor-SR sales in 2003). These projections were based on Upsher's perception –

[82] Troup testified that he considered the ex-U.S. market to be about the same size as the U.S. market. Troup, Tr. 5528. Kos, Searle, and Schering believed that the U.S. market potential was larger than the ex-U.S. market. CX 1470 at SP 002748 (Schering's Contact Report of April 9, 1997 describing meeting with Kos); Egan, Tr. 7915-16.

based on actual sales data, not estimates – that the sustained-release niacin market had *decreased* in both dollar and volume terms. CX 929 at USL 13138 (March 1997).

Schering told Upsher it would continue to analyze the issues and the clinical data for Niacor-SR and would get back to Upsher about its interest in pursuing a deal for Niacor-SR. Hoffman, Tr. 3545-46; Cannella, Tr. 3832. The parties also discussed potential licenses for other Upsher products, including Prevalite and Pentoxifylline (Troup, Tr. 5445-46; Hoffman, Tr. 3545), but these other products were not part of the deal at this point. Hoffman, Tr. 3545. The parties had not reached agreement on the settlement or licensing at the conclusion of this meeting. Hoffman, Tr. 3545.

Shortly before or after the June 12, 1997 meeting with Upsher in Kenilworth, Kapur and Driscoll briefed Schering's president of pharmaceuticals worldwide, Raul Cesan, on the Upsher negotiations. CX 1510 at 66-67 (Kapur IH); CX 1511 at 29-30 (Kapur Dep.). Kapur told Cesan that they had discussed with Troup whether there were any potential business opportunities that would be valuable to both Schering and Upsher, and that Troup had suggested a possible deal for Niacor-SR in markets outside of the United States. CX 1511 at 30 (Kapur Dep.). Cesan asked Kapur to contact Tom Lauda, Schering's Vice President of Global Marketing, to see if Lauda would be interested in marketing Niacor-SR internationally. CX 1511 at 30-31 (Kapur Dep.); CX 1489 at 14 (Cesan Dep.).

In accordance with Cesan's instructions, Kapur telephoned Lauda and told him that Schering was considering a licensing opportunity for Upsher's sustained-release niacin product that would cost Schering approximately $60 million, and asked if Global Marketing would perform an assessment of the product to see if it would be worth $60 million to Schering. Lauda, Tr. 4342-43. This is the same sum that Troup had demanded to settle the patent litigation.

Lauda asked James Audibert, head of Schering's Global Marketing's cardiovascular unit, to perform a commercial assessment of Upsher's Niacor-SR product. Lauda, Tr. 4344. Lauda told Audibert that a packet of information about the product would be delivered and Kapur was available to answer any questions that Audibert might have. Lauda, Tr. 4404. Lauda did not tell Audibert any amount that Schering expected to pay for the license, and Audibert was unaware

that the Niacor-SR opportunity had any connection to a patent suit. Audibert, Tr. 4113.

The final meeting between Schering and Upsher took place on June 16, 1997, in Upsher's office in Plymouth, Minnesota. Troup, Tr. 5452; Hoffman, Tr. 3550. Kapur, Hoffman, Wasserstein, and Schering's in-house attorney Paul Thompson attended for Schering; Troup, Hirschberg, and Cannella (via telephone) participated on behalf of Upsher. Hoffman, Tr. 3546; Troup, Tr. 5452; Cannella, Tr. 3834. The discussion again centered on the patent settlement and Upsher's claim that it needed cash flow to run its business. CX 1532 at 30 (Wasserstein Dep.). This testimony is confirmed by Hoffman, who recalled that Troup linked Schering's proposal for a license to take effect in the future with Upsher's cash needs in the interim. CX 1509 at 76 (Hoffman IH).

Discussion then turned to the valuation of the package of Upsher products, including Niacor-SR and Pentoxifylline for the ex-NAFTA countries and cholestyramine worldwide. Troup, Tr. 5453. Over the course of the meeting, Upsher offered to license its wax matrix 8 and 10 mEq products and Klor Con M20 to Schering for the ex-NAFTA countries. Troup, Tr. 5453. Troup still wanted $80 million. Troup, Tr. 5455; Hoffman, Tr. 3547; Cannella, Tr. 3835. Schering made a counter-offer of $60 million, which Upsher accepted. Cannella, Tr. 3835; Troup, Tr. 5458.

The parties discussed, either at the June 16 meeting or shortly thereafter, that the $60 million would be paid in installments. Troup, Tr. 5459-60; Hoffman, Tr. 3547; CX 1511 at 74-75 (Kapur Dep.). To bridge the gap between Upsher's asking price and Schering's counter-offer, the parties negotiated additional milestone payments for launch of Niacor-SR in nine different countries throughout the world, including $2 million for Japan and $1 million each for eight other countries, totaling $10 million in milestones. CX 1511 at 72-73 (Kapur Dep.); Cannella, Tr. 3836; Hoffman, Tr. 3547; Troup, Tr. 5458-59. (These milestones were never reached, and the payments were not made.) Troup also asked for two different levels of royalties on Niacor-SR: a 10% royalty on annual net sales up to $50 million and a 15% royalty on annual net sales in excess of $50 million. Troup, Tr. 5459; CX 347 at SP 12 00195.

Audibert completed his commercial assessment of Niacor-SR on June 17, 1997, one day after the final face-to-face meeting. SPX 2. Audibert and Lauda

may have discussed Audibert's assessment before Audibert completed it (Lauda, Tr. 4345; CX 1483 at 30 (Audibert IH)), but the record evidence is unclear on when or how the results of the assessment were communicated to the team (Kapur, Hoffman, Wasserstein, or Thompson) negotiating with Upsher. The documentary evidence shows that Audibert's assessment was faxed to Kapur on June 17, 1997, one day after the parties agreed to the $60 million term. Lauda testified that there was no urgency to the commercial assessment, and he did not work on it over the weekend (June 14 and 15). Lauda, Tr. 4383; CX 1515 at 103 (Lauda IH). Audibert did not have discussions with Kapur or Wasserstein before completing the assessment. CX 1484 at 103 (Audibert Dep.). Wasserstein did not recall what analysis had been completed by the time of the June 16 meeting or who told him about the financial assessment of Niacor-SR, although he recalled that the team knew the information and it was an assumption going forward. CX 1531 at 67-68 (Wasserstein IH). The results of this assessment are discussed below.

2. Factual Conclusions About the Negotiations

These specific findings demonstrate that, throughout the settlement negotiations, Upsher made the connection between delayed entry and the payment of money by Schering. At every negotiation session, Troup demanded compensation in return for an agreement on an entry date. Moreover, the negotiations on entry date were not concluded by June 3, 1997, and agreement on the entry date was directly linked to agreement on the other terms and conditions in the June 17, 1997 contract. Schering fully understood the essence of Upsher's demand for money in return for delay, and was aware that an outright payment for delay raised legal problems. Schering relied on the Upsher licenses to provide an ostensible justification for the $60 million payment.

The record as a whole further demonstrates, however, that the Schering participants in the settlement negotiations (Kapur, Hoffman, Wasserstein, and Thompson) were not knowledgeable enough about the products licensed from Upsher to determine for themselves whether the Upsher licenses were worth the payments agreed upon. We now turn to the question whether, notwithstanding their unfamiliarity with the safety, efficacy, and commercial aspects of the licensed products at issue, there is other evidence from which to determine whether the Upsher licenses likely were worth $60 million.

C. Schering's Internal Evaluation of the License Opportunities

To understand whether the license for Niacor-SR was worth $60 million to Schering,[83] it is important to place the license in the context of Schering's efforts to license another sustained-release niacin product from Kos Pharmaceuticals ("Kos") in the first half of 1997. Various Schering personnel devoted substantial time and resources to an evaluation of Kos's Niaspan product and its market opportunities. Like the Initial Decision (IDF 201-61), this section discusses both what Schering learned about sustained-release niacin during the Kos negotiations, and Schering's evaluation of the Niacor-SR license. For the reasons summarized immediately below, however, the discussion of these issues in the Initial Decision is seriously flawed and it is necessary for us to substitute our own factual findings.

The Initial Decision relies primarily on the direct testimony of two individuals – Raymond Russo, the marketing director of Schering's Key division for cardiovascular products in the United States, and James Audibert, Russo's counterpart for territories outside of the United States – for a description of the negotiations between Schering and Kos about the Niaspan opportunity. Although Russo led Schering's negotiations with Kos from February 1997 through June 1997, Audibert did not participate in the meetings with the Schering team after the end of March or early April 1997. Thus, to the extent Audibert is the source for facts beyond the date his participation ended (*e.g.*, IDF 208 and 242), the Commission has substituted its own findings from more reliable sources.

The Initial Decision also fails to consider the testimony of Driscoll, who was Russo's supervisor and was responsible for terminating the negotiations with Kos

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[83] The evidence is clear that the $60 million payment related to Niacor-SR, and that the other products were "throw-ins" and not separately evaluated as consideration for the Agreement. CX 1511 at 63 (Kapur Dep.); *id.* at 93-94 ("the deal was for Niacor"); CX 1530 at 88 (Troup Dep.); Troup, Tr. 5594-95; CX 1510 at 71-72 (Kapur IH) ("Q. Was the $70 million value just for the Niacor license? A. Yeah. Everything else was sort of a flow in, basically for the Niacor product."); CX 1515 at 86-87 (Lauda IH) (Lauda was told that Niacor-SR's profitability would have to be enough to warrant a $60 million up-front payment); CX 338 (presentation to Schering Board of Directors describes the other licenses as "less significant" than Niacor-SR; there is no NPV calculation for those licenses); Hoffman, Tr. 3562, 3569 (recognizing that Niacor-SR was the main licensing opportunity).

in June 1997, based on Niaspan's safety and efficacy issues and its limited commercial potential. The Commission finds Driscoll's testimony, and his memorandum dated June 9, 1997, which summarizes the commercial and product safety- and efficacy-related reasons for ending the Kos negotiations (CX 558), more probative than the deposition and direct testimony of Russo, Audibert, and Lauda (recited in IDF 207-08, 219, 242, 255, 258).

The Initial Decision also does not give adequate weight to other contemporaneous business documents that provide reliable and probative evidence of the events during the Kos negotiations. In particular, the Initial Decision does not rely on the contact reports (*i.e.*, internal summaries of the conference calls or meetings) between Schering and Kos personnel of March 13 (CX 577), April 9 (CX 1047), and May 21, 1997 (CX 557); Russo's memorandum of March 26, 1997, describing the negotiations to date and issues to be resolved going forward (SPX 21); and Audibert's March 14, 1997 questionnaire to Schering's international subsidiaries (CX 544).

Similarly, the Initial Decision fails to appreciate the implications of Schering's own market research on sustained-release niacin products (CX 576; SPX 231 (*in camera*)), and Schering's inexplicable failure to take account of that research when it evaluated Upsher's Niacor-SR product. For example, Schering's own domestic market research on sustained-release niacin in April 1997 contained nine conclusions that raise significant concerns about the commercial potential for Niaspan. CX 576. The Initial Decision's only reference to this market research is one phrase contained in one of the conclusions. IDF 211. This one statement is not representative of the other seven conclusions in the report. The Initial Decision also fails to consider fully what the conclusions in Schering's European market research (SPX 231 (*in camera*) suggest about opportunities for cholesterol drugs in Europe. *See* IDF 235-36.

Schering relied heavily on the calculations of Audibert to support its claim that the payment to Upsher was reasonable, but the Initial Decision mischaracterizes the task that Lauda asked Audibert to perform. Rather than conducting "an evaluation of Niacor-SR to determine whether its product profile satisfied the market opportunity" (IDF 243), Audibert simply responded to a request that he produce a sales forecast and a profit and loss statement for Niacor-SR. To the extent the Initial Decision implies that Audibert evaluated the

safety and efficacy of Niacor-SR (*see, e.g.*, IDF 247), the Commission disregards it.

The Initial Decision relies on Audibert's direct testimony to prove that the Niacor-SR license was worth $60 million, without weighing it against the knowledge that Schering had acquired through its domestic and European market research (CX 576; SPX 231 (*in camera*)) and the reservations that Schering personnel had expressed about sustained-release niacin (CX 558). *See, e.g.,* IDF 249 (discussing Schering's own market research that showed a product with a profile similar to Niacor-SR would not be well received as a monotherapy); IDF 239-41 (detail regarding what Audibert learned about the safety and efficacy of sustained-release niacin through the Kos negotiations).

Because of the Initial Decision's failure to take adequate account of various probative documents and its misplaced reliance on testimony of certain individuals, the Commission substitutes the following findings for the findings in IDF 201-61.

1. Findings of Fact on Schering's Evaluation of Kos's Niaspan

a. Schering's Research into Kos's Niaspan Product

Kos filed an NDA for Niaspan with the FDA in May 1996. SPX 18 at 002776. Schering was interested in Niaspan in early 1997. Driscoll believed that a sustained-release niacin product "that met the unmet needs that existed in the marketplace could be big." CX 1494 at 85 (Driscoll IH); *see also* CX 1495 at 73 (Driscoll Dep); Audibert, Tr. 4116-17. Driscoll also stated that Schering was interested in niacin primarily as a complementary agent to statins, the primary pharmaceutical compounds used to treat high cholesterol. CX 1494 at 86 (Driscoll IH).

Other Schering personnel stated they were interested in Niaspan not only as a late-stage product that could generate revenues in the near term, but also because Niaspan presented an opportunity for Schering to sell a cholesterol-lowering product in advance of its launch of ezetimibe, a drug that Schering was developing for the same purpose. Audibert, Tr. 4108-11; Russo, Tr. 3437-38; SPX 21 at 002771 (Russo's memo outlining Niaspan opportunity).

In February 1997, Schering distributed to members of its Cardiovascular Licensing Group a confidential information package provided by Kos in connection with the Niaspan opportunity. SPX 924. This package contained overview information on Niaspan, a copy of its proposed labeling, and a published report of a clinical study conducted with Niaspan.

In 1997, Russo was Key's marketing director for cardiovascular products in the United States. Audibert, Tr. 4109-10; Russo, Tr. 3409-10. Russo led the negotiations with Kos on its Niaspan product. Russo, Tr. 3449. Driscoll supervised Russo. CX 1494 at 88 (Driscoll Dep.). Audibert was Russo's counterpart, responsible for territories outside the United States, and was for a time involved in the negotiations with Kos regarding Niaspan. CX 1483 at 77-78 (Audibert IH); CX 1484 at 132 (Audibert Dep.); Audibert, Tr. 2450, 2452, 4109; Russo, Tr. 3439.

By the time of Schering's negotiations with Kos, the FDA had completed its medical review of Niaspan and was discussing labeling with Kos. Russo, Tr. 3445; Audibert, Tr. 4102, 4105. During the first half of 1997, Kos was seeking a co-promotion arrangement for Niaspan, meaning that both parties to the deal would be involved in the sales and marketing of the Niaspan product. Russo, Tr. 3449; CX 577 at SPCID2 1A 00110 (Schering's March 13, 1997 report of contact with Kos). This arrangement differs from one in which the company that took a license would retain all control and all sales proceeds after royalties are paid. Russo, Tr. 3449-50.

Schering and Kos personnel communicated by conference call on March 13, 1997. Russo, Audibert, and Karin Gast, Director of Business Development, participated on behalf of Schering; Daniel Bell, President and CEO, and others participated on behalf of Kos. CX 577. Audibert wanted to find out whether Niaspan had a better side effect profile than immediate-release niacin, especially in the areas of flushing and itching. CX 1484 at 39 (Audibert Dep.). He also had concerns about hepatotoxicity. CX 1484 at 39-40 (Audibert Dep.). Audibert indicated that he wanted to see data from clinical studies (CX 1484 at 45 (Audibert Dep.)), and he wanted to see the charts and study reports with information on safety and efficacy. CX 1484 at 57 (Audibert Dep.). Kos did not provide this information to Schering. CX 1484 at 59 (Audibert Dep). Audibert's deposition testimony is corroborated by Schering's contact report prepared by Gast

summarizing the call, in which Audibert "in particular wanted to know what is the safety profile for Niaspan." CX 577 at SPCID2 1A 00109.

Kos's labeling also made statements about reduced risk of hepatotoxicity development with its compound, but Kos was unwilling to share any information to verify the claim. CX 1495 at 128-29 (Driscoll Dep.). Schering asked Kos for more information, including Niaspan's clinical results that supported the label claims. CX 1495 at 96 (Driscoll Dep.). In Driscoll's view, the data that Kos did provide Schering (CX 924) showed that the incidence of flushing in the pivotal clinical trial was too high. CX 1494 at 85-86 (Driscoll IH). In addition to the safety and side effect profile information that Schering did not receive, Schering also did not receive Kos's market research on physician interest in a sustained-release niacin product. CX 1494 at 89 (Driscoll IH); CX 1495 at 100 (Driscoll Dep.).

One day after the March 13, 1997 conference call with Kos, Audibert sent a questionnaire to Schering's international subsidiaries that inquired about their interest in sustained-release niacin and sought information about cholesterol treatment in their countries. He does not recall whether he received any responses. CX 1484 at 52-53 (Audibert Dep); CX 544. After sending this questionnaire to Schering's international subsidiaries, Audibert did not participate further in negotiating with Kos. CX 1484 at 76-77 (Audibert Dep.).

On March 26, 1997, Russo prepared a memorandum summarizing four outstanding issues that had to be resolved for the Niaspan opportunity to be viable. Russo, Tr. at 3495-96; CX 546. These included: (a) a guarantee that Schering would have input into promotional and strategic efforts; (b) an equitable method to recognize revenue; (c) due diligence regarding patent status, final labeling, manufacturing capabilities, and product liability; and (d) Schering's evaluation of the commercial potential of the product, which included an assessment of the product's worldwide potential. CX 546. Russo "assume[d] that the safety profile, levels of liver toxicity, side effects, and approved indications would be consistent with the proposed labeling included in the Kos package." CX 546 at 2770. Schering "would of course subject any deal to this [sic] criteria." CX 546 at 2770.

On April 9, 1997, Schering personnel (Russo, Toni DeMola, Gast, and David Grewcock) visited Kos Pharmaceuticals to discuss the Niaspan product opportunity and the issues in the March 26, 1997 Russo memorandum. CX 1047.

The contact report summarizing the meeting states that Kos knew "that Niaspan will have to overcome some rather negative perceptions about niacin within the patient/medical community and that it is very important that the product get on managed care formularies." CX 1047 at SP 002747. The contact report also notes that Dan Bell "realizes that the market potential [of Niaspan] in Europe (and probably also in Japan) is quite limited." CX 1047 at SP 002748.

Following the April 9, 1997 meeting with Kos, Schering worked to put together broad deal terms that it ultimately would present to Kos. Russo, Tr. 3455. Part of that process involved an assessment of the product's value to Schering, and Russo produced three sales scenarios – a "base" case, an "upside" forecast, and a "downside" forecast for the years 1997 through 2007. Russo, Tr. 3456. He then priced each of these three scenarios under two different sets of pricing assumptions (a higher price and a lower price), so that, in total, he created six different sales forecasts. Russo, Tr. 3457; CX 550.

According to the sales forecast documents, Russo proceeded through multiple steps to arrive at the projected sales figures. CX 550. He first projected the overall U.S. population for each year, and then estimated through third-party data the percentage of patients that are likely to be managed with a prescription for lipid disorders. He then examined the total eligible patient population and how many of these patients would likely receive a prescription of any kind. He assessed what he thought Schering's position would be in the market for niacin. He made estimates for sales and promotion to expand the market. Russo, Tr. 3458. He then determined how many patients would be treated with niacin and how many of those patients would be treated specifically with Niaspan. Russo testified that, under his most realistic scenario, projected sales in the United States were $134 million in 2002, rising thereafter to $193 million, based on the co-promotion deal under consideration with Kos. Russo, Tr. 3457-63, 3472; CX 550 at SP 002743; CX 551 at SP 002731.

Schering's market research in the United States included efforts to determine physician interest in sustained-release niacin. Audibert, Tr. 2393-94; Russo, Tr. 3447-48, 3501-02; CX 576. A market research report entitled "A Qualitative Evaluation of the Opportunity for Niaspan in Multiple Lipid Disorders – Telephone Interviews with Lipid Specialists" (Apr. 1997) contained nine

conclusions. Six of the conclusions[84] are: (1) The 10 experts tend to be strong supporters of niacin, as opposed to general practice physicians that tended to avoid niacin. These experts point out that niacin "does all the right things" to manage lipids. (2) The experts avoid use of sustained-release niacin because of diminished efficacy and concern regarding liver toxicity. The experts pointed out that successful use of niacin requires a very motivated physician as well as patient, and that expanding niacin use will require a major commitment to physician and patient education. (3) Most niacin use is in combination with a statin, which has become the mainstay of lipid management, but several experts commented that this adjunctive role may lessen as new products are used. (4) The fibric acids (a competitor to niacin) are widely used in Europe, and several physicians reported being quite impressed with fenofibrate. (5) Although the experts would welcome an effective, safe, FDA-approved sustained-release niacin, the single study Schering discussed with them did not sell them on Niaspan and they needed larger, longer studies and trials in combination with a statin to be convinced on the safety issue. (6) Physicians voiced numerous concerns and questions about safety, side effect claims, and use with a statin, and they need "compelling evidence" to support the safety and side effect claims, which "go against our experience" with niacin. A successful sustained-release niacin product will take time and "a significant promotional investment." CX 576 at SP 020709-12.

In the spring of 1997, Audibert began coordinating with Schering's European subsidiaries to establish an advisory panel with European experts in cholesterol management to obtain market research about its cholesterol drug in development – ezetimibe. Audibert, Tr. 4301-02 (*in camera*); SPX 221 at SP 002895-2898 (*in camera*). This panel concluded that a large market for the product does not exist unless it is "very inexpensive and very safe." SPX 231 at 002949.

b. Termination of Schering's Negotiations with Kos

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

[84] The other three conclusions discuss the relative merits of altering levels of particular components of total lipids as treatment methods.

launched. Patel, Tr. 7543. Schering proposed to Kos a co-promotion arrangement in which both companies would sell and market the product together. Russo, Tr. 3589 (*in camera*); CX 554 (*in camera*). Schering proposed a 50/50 profit and loss split (Russo, Tr. 3589-90 (*in camera*); CX 554 (*in camera*); Patel, Tr. 7665 (*in camera*); SPX 619 (*in camera*)) and also suggested that it would give Kos a 10% to 15% royalty payment on the total sales of its product. Russo, Tr. 3589-90 (*in camera*); CX 554 (*in camera*). One week after submitting its proposal, Schering had a conference call with Kos to discuss the written proposal. SPX 230; SPX 35 (*in camera*); Patel, Tr. 7667 (*in camera*). Kos did not react favorably to Schering's proposal. Russo, Tr. 3465. Bell, the Chief Operating Officer of Kos, told Schering representatives that its offer was practically "insulting," and that he was "offended" by it. SPX 230; Patel, Tr. 7669 (*in camera*). A major problem for Kos was Schering's failure to offer an up-front payment. Kos also wanted very significant milestone payments, to compensate for its research and development costs, and to reassure Kos that Schering was committed to the venture. Patel, Tr. 7531-32; CX 556 (*in camera*); CX 769 (*in camera*); Russo, Tr. 3465-66. After receiving Kos's reaction to its first proposal, Schering did not submit another proposal. Russo, Tr. 3466, 3488; CX 558.

On June 9, 1997, Driscoll recommended to his superior, Richard Zahn, that Schering discontinue discussions with Kos. CX 558. Driscoll explained in the memorandum that "the principal reason" for discontinuing negotiations was that the opportunity was not large enough to warrant distraction from Key's core businesses. He did not share the view of the outside investment analysts who indicated that the Kos product was a $250 million product. He estimated a peak year of $134 million in 2002 with a 10-year net present value of $420 million. Driscoll pointed out that Kos had not provided clinical data to substantiate its claims that Niaspan reduced niacin side effects of flushing and hepatotoxicity. He noted that Niaspan's labeling "indicates 88% of patients taking Niaspan in the pivotal clinical trial experienced flushing." CX 558 at 2719. He also explained that statins have taken a large share in the market, and that generic statins would be available in the U.S. in 1999, which could affect sales of a lower-priced niacin product such as Niaspan. Driscoll concluded there was a wide gulf on expectations. CX 1495 at 123-24 (Driscoll Dep.).

2. Findings of Fact on Schering's Evaluation of Upsher's Niacor-SR

In June 1997, Kapur telephoned Lauda and told him that Schering was considering a licensing opportunity for Upsher's sustained-release niacin product that would cost Schering approximately $60 million, and asked if Global Marketing would perform an assessment of the product. Lauda, Tr. 4342-43. It is unclear from the evidence how Kapur knew that the licensing opportunity would cost $60 million. Lauda contacted Audibert and instructed Audibert to conduct a commercial assessment of Niacor-SR for worldwide territories, excluding the United States, Canada, and Mexico ("Worldwide Ex-NAFTA"). Lauda, Tr. 4344.

Audibert was serving in June of 1997 as the Senior Director of Global Marketing for Cardiovascular Products. Audibert, Tr. 4085, 4092. His responsibilities included work on ezetimibe, the cholesterol-lowering agent Schering had in development. Audibert, Tr. 4093. By early 1997, Audibert began working with Schering's research organization to identify the patient populations in which, and products against which, ezetimibe would be tested in clinical studies. Audibert, Tr. 4094. As part of this process, Audibert was also evaluating the market for cholesterol-lowering drugs. Audibert, Tr. 4094-95.

Lauda specifically asked Audibert to develop a sales forecast and a profit and loss statement for Niacor-SR based on the information provided in a 52-page data package. CX 1484 at 109-10 (Audibert Dep.). Audibert began his review when he received this data package on Niacor-SR on Thursday afternoon, June 12, 1997, and completed his work on Tuesday morning, June 17, 1997. Audibert, Tr. 4113, 4163; Lauda, Tr. 4344-45. The package included summary results from the two phase III pivotal clinical trials conducted by Upsher to obtain registration of Niacor-SR. Audibert, Tr. 4113-15, 4171; CX 1042; Halvorsen, Tr. 3907-08. The package also included information on two draft protocols for phase III-B studies that Upsher was planning to conduct once the NDA was filed. Audibert, 4113-15; SPX 71-72; Halvorsen, Tr. 4025. One protocol would evaluate the use of Niacor-SR in combination with a statin, and the other would evaluate Niacor-SR when administered as a single evening dose. Audibert, Tr. 4115; SPX 71-72.

The clinical data from Upsher's pivotal trials showed that Niacor-SR reduced LDL cholesterol between 15% and 20%. Audibert, Tr. 4123; CX 1042 at SP 1600082, SP 1600097. This reduction is comparable to that resulting from use of Niaspan. CX 924 at SP 002789, SP 002792. Both the Niacor-SR and Niaspan reductions exceeded the 15% regulatory hurdle, but were less than the 20% reduction that Schering's market research indicated would be necessary to market

the product as a monotherapy. SPX 231 at 002944-45 (*in camera*). Upsher's summary clinical data for Niacor-SR showed that the overall incidence of flushing was comparable to that of Niaspan. *Compare* SPX 3 at 160088 (on Niacor-SR) *with* SPX 924 at SP 002809 (on Niaspan). Moreover, the Upsher data showed that even though the number of flushing occurrences was lower, on a per patient basis, than with immediate-release niacin (*see* SPX 3 at 16 00089 (graph at top of page) and Audibert, Tr. 4118-19), the occurrences were just as severe as those experienced among patients taking immediate-release niacin. SPX 3 at SP 16 00088 (graph at top of page).

The clinical data from Upsher's pivotal trials showed that adverse effects on the liver increased with stronger doses of Niacor-SR. CX 1042 at SP 1600090; CX 1483 at 73-74 (Audibert IH). Audibert testified that the incidence of liver enzyme elevations in the Niacor-SR pivotal trials was consistent with that of cholesterol-lowering drugs generally, and was substantially lower than the 66% incidence associated with prior sustained-release niacin products. Audibert, Tr. 4104-05, 4121-24. Audibert's evaluation of the results of the Niacor-SR pivotal trials also revealed that the liver enzyme elevations experienced in that small percentage of patients returned to normal when the drug was discontinued. Audibert, Tr. 4121-22; CX 1042 at SP 16 00093. These results are comparable to the information that Schering had when it had evaluated Kos's Niaspan product. *See* SPX 924 at SP 002811.

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

First, Audibert determined the current size of the market and made a projection of the future growth of that market for a period of 10 years based on IMS data representing the current size of the cholesterol-lowering market worldwide, excluding the U.S., Canada and Mexico ("Worldwide Ex-NAFTA"), the territories in which the license to Niacor-SR was available. SPX 5; CX 1483 at 109-10 (Audibert IH). The IMS data indicated that the size of the cholesterol-lowering market in those territories in 1996 was $4 billion. SPX 5. Audibert's

handwritten notations on the IMS data reflect his calculation of prior growth in this market at a rate of 10%, 22% and 6% in the previous three years. SPX 5 at SP 16 00447. Audibert estimated an average annual growth of 15% in 1997, 1998 and 1999, and a lower growth rate of 10% thereafter. SPX 2 at SP 16 000046. Audibert projected the market share Niacor-SR could achieve based on his experience with this type of product and this type of profile, given the existing competitive landscape. CX 1483 at 100-02 (Audibert IH). Audibert believed that Niacor-SR would obtain an initial market share of only .75%, rising for just two years to 1.5%, and then decreasing thereafter to 1%. Audibert, Tr. 4127-29; SPX 2 at SP 16 00047.

Having estimated the overall size of the market and a market share for this product over a 10-year period, Audibert used multiplication to determine projected sales. Audibert, Tr. 4127. Audibert's formal written assessment for Niacor-SR, dated June 17, 1997, includes tables illustrating his annual projections of market size and market share, from which he calculated annual dollar sales. Audibert, Tr. 4127-29; SPX 2 at SP 16 00046-47. The sales projected for each of these years, in millions, were:

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

SPX 2 at SP 16 00047.

On the basis of his sales projections, Audibert then prepared a written profit and loss analysis. Audibert, Tr. 4138-39; SPX 6. The annual profit and loss calculations were created by deducting the cost of goods sold (estimated at a standard 10% of sales) from his sales forecasts (CX 1483 at 115-16 (Audibert IH)), as well as deducting the cost of selling and promoting Niacor-SR, which Audibert estimated to peak at $22.8 million in the third year of sales. SPX 6. Because Audibert did not know what royalty rate would be negotiated, his calculations represented the annual net profit before deducting the royalties to be paid to Upsher. Audibert, Tr. 4139.

After Audibert developed the commercial assessment (SPX 2; SPX 6), he summarized the information contained in the 52-page data package without

independently verifying it. CX 1483 at 95-96 (Audibert IH). Audibert provided background information on cholesterol-lowering products, including the current state of knowledge on niacin as an effective cholesterol-lowering agent, as well as the difficulties that had hampered prior immediate-release niacins (flushing) and sustained-release niacins (association with hepatotoxicity). SPX 2 at SP 16 00041-45. Audibert detailed the current size of the cholesterol-lowering market and the recent growth experienced in that market, and provided an assessment of why that growth was expected to continue. SPX 2 at SP 16 00043-45. He concluded that a product opportunity existed for Niacor-SR, and he provided a summary of his sales projections for Niacor-SR. SPX 2 at SP 16 00045. He attached to his assessment two tables that contained his detailed financial projections of both the future growth of the cholesterol-lowering market and sales of Niacor-SR in that market. SPX 2 at SP 16 00046-47. Audibert concluded that Niacor-SR offered a $100+ million sales opportunity for Schering. SPX 2 at SP 1600045. He provided a copy of each of these documents to Lauda. Audibert, Tr. 4138-40; Lauda, Tr. 4345-46.

On the basis of the financial projections contained in Audibert's commercial assessment and the terms of the license agreement, including the royalty payments to Upsher called for under the agreement, Wasserstein prepared a presentation for the Schering Board. SPX 26. The presentation included a calculation which indicated that Niacor-SR yielded an economic value to Schering of between $225 to $265 million, and an internal rate of return of 43%. SPX 26 at SP 16 00275.

3. Factual Conclusions on Schering's Investigation of Niaspan and Niacor-SR

We do not find that Schering's failure to pursue the Kos opportunity is conclusive evidence that it was not really interested in the Upsher product. There were deal-specific reasons that contributed to Schering's rejection of the Kos co-promotion opportunity. However, the Kos negotiations did inform several Schering personnel about the commercial problems of sustained-release niacin products – information that we need to weigh in determining whether Schering really paid $60 million for the rights to such a product.

Schering's decision to decline an opportunity to co-promote Kos's Niaspan product was made only the week before the negotiations for Niacor-SR were completed on June 17, 1997. Driscoll's June 9, 1997 memorandum to his supervisor, Richard Zahn (on which he copied all of the members of Schering's

Kos negotiating team), recommended that Schering discontinue negotiations with Kos and described these commercial problems in detail. CX 558. Driscoll wrote that "the principal reason" for discontinuing the negotiations with Kos was "based on our current assessment that Niaspan does not represent a large-enough opportunity in the marketplace, thus, sufficient revenues would not be available to Schering-Plough to warrant our involvement and distraction from our core businesses." CX 558 at 2719; *see also* SPX 56. Driscoll calculated the NPV based on the co-promotion proposal for the U.S. market and found that the expected gain would not warrant Schering's involvement, even "without consideration given to the 'lost opportunity sales' we would experience with our current brands due to our shift in promotional focus away from these products to support the marketing of Niaspan." CX 558 at 2719.[85]

Driscoll then evaluated the commercial opportunity for niacin in a market increasingly dominated by statins. Lipitor had been introduced and had a "torrid start." CX 558 at 2720. Based on Lipitor's potency and "seemingly benign side-effect profile," Driscoll stated that the need for a niacin product in combination with another cholesterol-lowering product was "greatly reduce[d]." CX 558 at 2720. According to the memorandum:

> Niaspan could be relegated to the severe hypercholesteremic patients who need a multiple drug regimen. *As a result, Niaspan's market opportunity is narrowing even prior to its introduction.* Indeed, the use of other classes of cholesterol-lowering agents such as niacin, gemfibrozil, and cholestyramine has declined since the introduction of Lipitor.

CX 558 at 2720 (emphasis added).

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[85] IDF 221-26 suggest that Kos was unable to enter into an agreement with a licensing partner because Kos's demands were unreasonable. Whatever the truth of the proposition that Kos was aggressive in its negotiations with potential partners, Kos has not been able to license Niaspan to any ex-U.S. partner, much less obtain an agreement as lucrative as the Upsher/Schering agreement. Patel, Tr. 7540. Moreover, Schering's primary reason for terminating its own negotiations with Kos was concern about the sales prospects of Niaspan – and it was not alone in these concerns. Egan, Tr. 7913-14 (Searle's view).

Although the deal contemplated with Kos was not exactly the same as the deal with Upsher – the Kos deal was to be a cross-promotion, where Kos and Schering would split the profits – Schering's view that the product had limited potential in the U.S. market transcends the specific terms of these deals. Driscoll pointed out that Kos had not provided clinical data to substantiate its claims that Niaspan reduces niacin side effects, flushing and hepatotoxicity. He stated that "it is important to note" that Niaspan's labeling "indicates 88% of patients taking Niaspan in the pivotal clinical trial experienced flushing." CX 558 at 2719; SPX 924 at SP002809.[86]

Upsher's summary clinical data for Niacor-SR showed that reduction in cholesterol and the incidence of flushing were comparable to those for Niaspan. Schering's pharmaceutical expert, Dr. Zola Horovitz, testified that the summary tables in the 52-page data package show that Niacor-SR was more effective than immediate-release niacin (Horovitz, Tr. 3642-43), and more benign than immediate-release niacin in terms of flushing (Horovitz, Tr. 3645-46) and liver enzyme elevation. Horovitz, Tr. 3632-35, 3649-51. It would be more appropriate, however, to compare Niacor-SR with Niaspan and specifically to take account of what Schering personnel who had worked on Niaspan believed were its commercial prospects. Driscoll's June 9, 1997 memorandum, discussed above, is a credible expression of their view, and we find that their expressed reservations about the safety and efficacy of Niacor-SR are more persuasive than Dr. Horovitz's opinions.[87]

One incident in the course of Schering's discussions with Kos is also particularly probative. Schering personnel saw the U.S. market as more appealing

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[86] By comparison, the summary clinical data that were provided to Audibert showed flushing incidence of 87%, 81%, and 87% for three different dosages of Niacor-SR. SPX 3 at 16 00088; Audibert, Tr. 4118 (explaining that column A is for immediate-release, while B, C, and D are Niacor-SR dosages).

[87] Upsher, too, recognized that the market opportunity for a sustained-release niacin product was narrowing. In March 1997, Upsher noted that the "total niacin market has been relatively flat in dollars while increasing 35% in units." CX 929 at USL 13138. In fact, the sustained-release niacin market had "declined 14% from the previous year" in dollar terms, and 7.7% in volume terms. *Id.*

than the European market, for which Schering later obtained the Niacor-SR rights. According to a Schering summary of a meeting with Kos on April 9, 1997, Schering recommended that it made sense to focus on the U.S. market first and hold off on ex-U.S. talks:

> Global option: we suggested that, since time is of the essence in the U.S., we concentrate on this territory first and leave ex-U.S. discussions for later. [Kos CEO] Bell did not have a problem with this. He realizes that the market potential in Europe (and probably also in Japan) is quite limited.

CX 1470 at SP 002748(DeMola/Russo memorandum dated 4/9/97). As this memorandum makes clear, both Kos and Schering shared the view that the European market for this type of product was less commercially appealing than the U.S. market.[88]

Schering's careful scrutiny of the Kos opportunity also shows the type of information Schering personnel thought was necessary for a prospective partner to provide before proceeding with a commercial opportunity for a sustained-release niacin product. In his memorandum explaining the reasons for declining the Kos opportunity, Driscoll wrote that Kos had not been forthcoming with important data necessary to fully evaluate the deal, such as its sales projections for Niaspan and "results from physician primary research conducted by Kos." CX 558 at 2720. Yet Schering did not even request sales projections or primary research relating to Niacor-SR from Upsher.

Similarly, Russo's memorandum of March 26, 1997, which set out the hurdles that needed to be cleared before an opportunity with Kos could be finalized, concluded that "[f]or this [Niaspan] opportunity to be viable for [Schering] a number of issues must be resolved," including "due diligence validation of issues" such as patent status, finalized labeling, manufacturing capabilities, and product liability. SPX 21 at 002770. Schering would also "need to independently assess this product's world-wide potential," including "global potential, Managed Care impact, and strategic synergy with 58235 [a product then in development], and field force availability/fit." SPX 21 at 002771. Aside from

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[88] Searle also shared this view. Egan, Tr. 7915-16.

Audibert's projection of Niacor-SR sales, none of these tasks were undertaken with respect to Niacor-SR. Moreover, Russo "assume[d] that the safety profile, levels of liver toxicity, side effects, and approved indications would be consistent with the proposed labeling included in the Kos package. *We would of course subject any deal to this [sic] criteria*." SPX 21 at 002770 (emphasis added). By contrast, Schering's agreement with Upsher was not conditioned on validation of any representations or on any regulatory benchmarks.

Schering's own domestic market research showed that physicians had numerous concerns and questions about the safety, side effect claims, and use with a statin of sustained-release niacin. Physicians also needed "compelling evidence" to support the safety and side effect claims that "go against our experience" with niacin. The research showed that a successful sustained-release niacin product would take time and "a significant promotional investment." CX 576 at SP 020709-12.

Lauda had given Audibert, who had participated only briefly on the Schering team that evaluated Niaspan, the task of estimating Niacor-SR sales. The work that Audibert did to arrive at his sales forecasts was not nearly as extensive or as refined as the work that Russo did in his sales forecasts of the Niaspan opportunity with Kos. Russo based his sales forecasts on an analysis of the eligible patient population within the U.S., whereas Audibert used aggregate ex-U.S. sales as his starting point. Audibert did not examine eligible patient populations on a country-by-country basis as Schering's expert witness, James Furniss, testified he would have expected Schering to do. Furniss, Tr. 4273. Furniss testified that a more detailed, country-by-country analysis of a late-stage product such as Niacor-SR is important because each country has a different pricing reimbursement system and some products may be widely prescribed in one country and not in another. Furniss, Tr. 4270-71. Moreover, in contrast to Russo, who had prepared six different forecasts under various pricing assumptions for Niaspan, Audibert prepared only one sales forecast with no allowances for different market penetration statistics or pricing scenarios.

Audibert received the Upsher materials on which he based his commercial assessment no earlier than 4:30 p.m. on Thursday, June 12. He faxed the completed commercial assessment and profit and loss statement on Tuesday, June 17, at 9:30 a.m. Audibert said that the tasks he performed would take "maybe a little bit more but not – not much more" than one day to complete. Audibert, Tr.

4164. During this 5-day period Audibert did not contact personnel at Upsher to determine when the draft protocols would be started or completed, or to request the labeling for the product. Audibert, Tr. 4172-75; CX 1484 at 91-92 (Audibert Dep.). He did not contact any members of the Schering team that had just terminated discussions about Niaspan with Kos on June 9, 1997. CX 1483 at 50-52 (Audibert IH); Audibert, Tr. 4168. Instead, he based his commercial assessment on the information about Niacor-SR provided to him by Upsher. Audibert did not independently verify any of the information in the 52-page data package. He said that he based his assessment on what the product would be (*i.e.*, labeled for once-a-night dosing and administered in combination with other cholesterol products), not on what clinical tests had been done so far. Halvorsen, Tr. 4025; CX 917 at 107435; Audibert, Tr. 4172-76, 4196-97. He simply assumed that Niacor-SR would be approved for these indications even without completion of the additional clinical tests. Audibert, Tr. 4173.

These assumptions stand in direct contrast to Audibert's skepticism about the Niaspan product, for which he and Driscoll had demanded additional information to verify Kos's claims.[89] He was more cautious about Niaspan, even though Kos was much further along in obtaining approval for the indications that were of interest.

Based on the record as a whole, we find that Schering knew sustained-release niacin had significant unresolved safety issues, limited market appeal in the U.S., and even less outside of the U.S. Even if we assume that Schering had only five days to review the Niacor-SR product,[90] it could have done much more – in parallel with Audibert's work on the commercial sales projection – to ascertain whether Niacor-SR merited such a substantial, unconditional investment. For example, nobody at Schering was assigned to evaluate the likelihood of obtaining regulatory approval for Niacor-SR in the U.S. or in Europe, to examine Upsher's

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[89] The 52-page data package that Upsher provided to Schering contained information that is similar to what Kos had provided to Schering regarding the Niaspan opportunity. CX 1042 at SP1600081-85, 94; SPX 924.

[90] We recognize that the parties wanted to settle the case before the trial commenced, although it is not clear why this was an essential pre-condition for settlement. Many cases settle in the course of a trial.

regulatory file quickly, to inquire into the strength of the patents contained in the 52-page data package, to determine whether there was European patent protection, to have the specialists at the Schering-Plough Research Institute do a preliminary safety analysis, or even simply to ask Upsher whether the FDA had raised any regulatory hurdles.[91] There is no reason why the materials submitted by Upsher could not have been circulated both to Audibert and to technical, scientific, regulatory, and patent professionals for an initial, even if hurried, review.

We recognize that significant time constraints may often require a very compressed review of potential products that would fall far short of the formal due diligence that a company would otherwise conduct, given adequate time. Schering's failure to conduct formal due diligence does not, in itself, mandate a conclusion that the side deal for Upsher licenses was a pretext to mask the payment of substantial consideration for a deferred entry date.[92] However, Schering's minimal analysis of the Niacor-SR opportunity must be weighed heavily, along with the other facts in this case, as we determine whether Schering paid $60 million for licenses or for delay.

D. Inferences Derived from Conduct After the Settlement

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[91] There were regulatory hurdles. The FDA had raised issues about Niacor-SR's dosing regimen and the need for a pharmacokinetic test. Niacor-SR was to "be labeled to take with meals," CX 917 at 107435, contrary to the assumption in materials provided to Audibert that it would be once-a-night dosing. Upsher had been having trouble for some time developing the pharmacokinetic test, which profiles the rate and extent of absorption of a drug in the body (Audibert, Tr. 4181). That test's validation method was not completed until November 4, 1998. Halvorsen, Tr. 3943-44; SPX 333 at 165879.

[92] We reject any suggestion that a reasonably adequate product review must necessarily take months, because the opportunity may no longer be on the table when such a review concludes. We therefore do not rely on Dr. Levy's opinion about the acceptable parameters of due diligence. However, our own findings show there was ample record evidence to support a conclusion that Schering's analysis of the Niacor-SR opportunity was perfunctory.

The Initial Decision concluded that there was "substantial, reliable evidence to explain Respondents' post-deal conduct and attendant decisions not to pursue Niacor-SR." ID at 109. This conclusion, however, is based more on a quantitative count of individual communications between Schering and Upsher than on their substance. (IDF 263-66, 271-74, 279, 280, 282, 284, and 287-89 review the post-agreement communications between the parties from June 24, 1997 to September 24, 1998.)[93] A closer examination of the content and context of these communications reveals that most of them concerned matters necessary to *initiate* a relationship between the parties – such as confidentiality agreements and proposed amendments to the Settlement Agreement – rather than substantive matters. In fact, the parties did not communicate at all about substantive issues as important as Upsher's decision to put development of Niacor-SR on hold and its later decision to terminate Niacor-SR development altogether – decisions that essentially suspended and then wiped out the benefits that were ostensible consideration for Schering's $60 million payment.

In fact, there were virtually no substantive communications about Niacor-SR, the key licensed product. For example, IDF 282 notes that "[d]uring 1998, Upsher remained in contact with Schering-Plough regarding the licensed products" and cites four documents: CX 1088, CX 1111, SPX 251, and USX 665. CX 1088 was an aggregate of other documents; the only document included in this aggregate dated after 1997 was a copy of Upsher's October 6, 1998 letter (CX 1111) announcing the termination of its work on Niacor-SR. The other two cited documents are a January 1998 draft of the Manufacturing Agreement (USX 665) and an April 1998 letter from Ray Kapur's secretary (SPX 251) enclosing signed confidentiality agreements, a preliminary step in the relationship that took 10 months to complete after the Agreement was signed.

Many of the communications that did take place concerned tasks that were never accomplished. For example, Schering and Upsher exchanged correspondence and drafts relating to a Manufacturing Agreement that concerned such issues as the supply and delivery of the licensed products. SPX 255;

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[93] In addition to written communications, there were also some, but few, conversations between Schering and Upsher employees. IDF 316 records at least two meetings and 21 other documented communications between Schering and Upsher in 1997 after the licensing agreement, as well as some telephone calls.

Kralovec, Tr. 5050-55; USX 732; SPX 217; SPX 251 (Jan. 1998). The proposed Manufacturing Agreement was dropped, and there was no further correspondence on the subject after January 1998. USX 665.

The few requests that Schering did make for information about Niacor-SR went unfulfilled, and Schering did not continue to request the information. For example, in response to a Schering request for information on Niacor-SR, Troup agreed that Upsher would send Schering the Niacor-SR registration information in segments so that Schering would not have to wait until the full ISS/ISE (Integrated Summary of Safety and Integrated Summary of Efficacy) was completed. IDF 265; SPX 10; SPX 12 at SP 05 00013; Audibert, Tr. 4156. However, Audibert received only the protocols, and did not renew his request for information on Niacor-SR thereafter. Audibert, Tr. 4142, 4149-50, 4154-57, 4360; SPX 251.

There is virtually no correspondence about the key question in which Schering had such a substantial stake: the progress of Niacor-SR's development and the NDA. From November 12, 1997, to September 24, 1998 – when Upsher disclosed that it was no longer developing Niacor-SR – Schering and Upsher exchanged a total of two communications even though Upsher was to have submitted the NDA for Niacor-SR to the FDA in October 1997. USX 665; SPX 251. Of these two communications, only one arguably touched upon the status of Niacor-SR – an April 20, 1998 letter from the secretary of Ray Kapur, the head of Schering's Warrick generic division. SPX 251.[94] In a cover letter, Desiree Malanga enclosed executed confidentiality agreements, asked for a status report on the generic Pentoxifylline dossier, and then asked "in addition" that Upsher provide "complete information" on Niacor-SR to Thomas Lauda. SPX 251. This request for information on Niacor-SR was not honored, and Schering did not follow up. Audibert, Tr. 4156-57, 4360.[95]

The Initial Decision's findings highlight the impact of the disappointing sales of Kos's Niaspan on the parties' decisions about Niacor-SR. IDF 275-81.

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[94] The other communication was a January 12, 1998 draft of the never-finalized proposed Manufacturing Agreement. USX 665.

[95] Halvorsen testified that Upsher did provide some information on Pentoxifylline in response to this request. Halvorsen, Tr. 3980-82.

IDF 275 states that Kos's sales were below what "everyone" had expected. Neither Schering nor Searle had adopted the analysts' inflated projections for Niaspan. CX 558; Egan, Tr. 7913. Moreover, the Initial Decision ignores the clear evidence that in August 1997, well before Niaspan's sales were announced in November, Upsher was considering the abandonment of Niacor-SR (CX 1357) – primarily because of Niaspan's superior clinical profile and earlier entry. *See, e.g.*, CX 930 at USL 13192; CX 963 at 12583, 12581; CX 1357. When Upsher explained its reasons for terminating the development of Niacor-SR to Schering in 1998 (CX 1111), Kos's sales were a secondary reason for dropping the program.

In addition to significant errors of omission, the Initial Decision relies heavily on unreliable evidence and ignores other evidence that is more reliable. For example, the findings in the Initial Decision that deal with Upsher's termination of Niacor-SR place great weight on the self-serving, after-the-fact testimony of individuals like Audibert, Troup, and Lauda, which emphasizes the impact of Niaspan sales. The findings ignore contemporaneous business documents, which make it clear that disappointing sales were a subsidiary consideration. We believe that the documents are more credible.

Because of these errors and omissions in the Initial Decision, the Commission substitutes the following findings for IDF 262-89:

1. Findings of Fact on the Post-Settlement Conduct of Schering and Upsher

On July 2, 1997, eight days after Schering's Board of Directors approved the Niacor-SR license on June 24, 1997 (CX 340), Kapur informed Cesan that Global Marketing would take responsibility for Niacor-SR, while Warrick, Schering's subsidiary, would oversee development of the generic products licensed from Uphser.[96] SPX 8. At the same time, Kapur notified Lauda that the Niacor-SR deal had been approved and that Global Marketing was to take the lead in supervising Schering's international registration and marketing of Niacor-SR. SPX 7; Lauda, Tr. 4349-50. James Audibert, the Global Marketing division employee whom

[96] Schering's United Kingdom subsidiary declined the Niacor-SR opportunity and informed Upsher's consultant that the opportunity had been passed on to Schering's International Division, which to that date had not responded. CX 1363.

Schering selected as designated project leader for Niacor-SR, testified at trial that he had been appointed to coordinate the preparation of the dossier for international filing. Audibert, Tr. 4140. Audibert testified in his investigative hearing, however, that he did not know what a "designated project leader" was for Niacor-SR, that he was not sure there was one, and finally that he assumed he was it *de facto*. CX 1483 at 123-24 (Audibert IH). He did not recall that Global Marketing had been assigned responsibility for registration of Niacor-SR in Europe; this assignment confused him because "global marketing is not responsible for registering products." SPX 7; SPX 8; CX 1483 at 121-23 (Audibert IH). He did not believe that he was responsible for development and registration work for Niacor-SR, and did not work on it. CX 1484 at 1670-71 (Audibert Dep.); CX 1483 at 124-25, 127 (Audibert IH).

After the June 17, 1997 agreements, Troup alerted the various managers of departments at Upsher about the specific products being licensed by Schering and the steps to be taken for each product under the license agreement with Schering. Troup, Tr. 5481-83. By the end of July, Upsher and Schering had begun to negotiate and exchange drafts of a fuller Amended Agreement and a Manufacturing Agreement for the products from Upsher. USX 732. As of the summer of 1997, Upsher was going forward with its NDA for Niacor-SR and Upsher's primary activity was to complete the final study reports and the ISS/ISE. Halvorsen, Tr. 3975. The patient phases of all four clinical studies had concluded before June 1997 and Upsher was in the process of compiling the data. Halvorsen, Tr. 3912. These agreements, as well as the ISS/ISE, were never completed.

During June and July 1997, Upsher was working on its Niacor-SR package insert to include with its NDA submission. Freese, Tr. 4990; USX 308. By July 21, 1997, Upsher had developed a revised draft of its package insert. Freese, Tr. 4990; USX 308. Upsher's draft package insert included annotations to over 20 different niacin studies regarding the efficacy and benefits of niacin in the treatment of hypercholesterolemia. Freese, Tr. 4990; USX 308 at 110477-9. The package insert was never shown to Schering.

Before August 14, 1997, Audibert called Halvorsen regarding Niacor-SR clinical data (in the first of several communications between the two representatives). Halvorsen, Tr. 3976-77; USX 189. During that first call, Halvorsen and Audibert discussed the four clinical studies Upsher had conducted with Niacor-SR for FDA approval – the two pivotal studies and the two follow-on

studies. Halvorsen, Tr. 3976-77; USX 189. On August 14, 1997, Audibert sent Halvorsen a fax to arrange a meeting at Upsher for the week of September 15. USX 189. That meeting never took place.

Halvorsen testified that in August 1997, Upsher was still planning to file its NDA for approval of Niacor-SR at the end of 1997. Halvorsen, Tr. 3977-78. Halvorsen told Audibert that he did not believe that clinical data would be available until late October, and that what Upsher would have at that time were the final reports from the individual studies, and not the ISS/ISE. CX 780 at 00236. Schering was not told that Upsher was simultaneously considering the abandonment of all work on the Niacor-SR NDA in light of the approval of Kos's Niaspan on July 28, 1997. An August 12, 1997 Upsher memorandum "review[ed] recent changes in the marketplace that may significantly impact the potential marketability of the *Niacor SR* product." CX 1357 (emphasis in original). Kos's product would use once-a-night dosing to minimize flushing, while Niacor-SR was to have twice-a-day dosing. *Id.* According to the memorandum, "It appears that *Niacor SR* will have a similar clinical profile versus *Niaspan* as it relates to the reduction of LDL, however *Niaspan* has a decided advantage on the reduction of Triglycerides, and the increase of HDL. *Niacor SR* also seems to [. . . affect] Lipoprotein more significantly than *Niaspan*." CX 1357 at 11931 (emphasis in original). Niacor-SR "will be a late entry into the Lipid Management category. Based on the information at hand it would seem that the product would also be inferior to the *Niaspan* product. Approval of the present form of *Niacor SR* is not eminent [sic] and may face delays." *Id.* at 11932 (emphasis in original).[97] Upsher

[97] Halvorsen testified at trial that the August 12, 1997 memorandum mistakenly indicated that Upsher would "need to conduct further studies to enable Niacor SR to be marketed with indications similar to Niaspan," at additional cost and delay. Halvorsen, Tr. 3950-52, 3957-60; CX 1357 at 11932. As it turns out, Upsher found out after August 1997 that the FDA had suggested those indications on the basis of general experience with niacin, not on any "outcome studies" conducted by Kos. Halvorsen, Tr. 3950-52. Ironically, Schering was aware that these additional indications for Kos's Niaspan product had been suggested by the FDA. SPX 22 at 2746. Upsher did not contact Schering to clarify Upsher's mistaken impression, nor did Upsher attempt to clarify this question with the FDA. Regardless, Upsher's struggles with development of the pharmacokinetic test validation method and completion of the ISS/ISE show that the memorandum was

did not terminate the program at that point, but did decide in October to devote "minimal activity" to the Niacor-SR NDA. CX 963 at 12579-81.

In November 1997, Kos announced its first quarterly results for Niaspan sales in the United States. Audibert, Tr. 4156; Lauda, Tr. 4433; Halvorsen, Tr. 3956; Troup, Tr. 5480. The first published figures regarding Niaspan sales in November 1997 were a major disappointment to investors, and Kos's stock price, which had peaked around $44 per share, plummeted to $5 per share.[98] Troup, Tr. 5480. By that time, however, Upsher had already decided to devote only "minimal activity" to Niacor-SR, primarily because of Niaspan's superior clinical profile, additional indications, and earlier entry. *See, e.g.*, CX 930 at USL 13192; CX 963 at 12579-81; CX 1357. Upsher's letter to Schering, stating its reasons for terminating the development of Niacor-SR, makes clear that Kos's sales were a secondary reason for dropping the program. *See* CX 1111 (Kralovec writes that the Kos sales results "reinforced" the decision).

According to Troup, an unidentified person at Schering informed Upsher in March 1998 that Schering was no longer interested in marketing Niacor-SR outside the U.S. Although Halvorsen and Troup both were present at the meeting where Upsher decided to discontinue further work and wrap up in an unfinished state the contract research that Upsher had begun with third-party research firms, neither recalled who at Schering called with this important information, or even who at Upsher received the communication. Halvorsen, Tr. 3925; Troup, Tr. 5608-09. The information was never confirmed in writing. As noted above, the parties exchanged only two written communications in all of 1998 before the termination. USX 665; SPX 251.

In September 1998, Troup, Audibert, and Kapur had a telephone conversation about the status of Niacor-SR. Audibert, Tr. 4158-59; CX 1088 at 006-7. Troup reported that Upsher was not planning to file its NDA for FDA approval. CX 1088 at SP 05 006-07; CX 1111. In this conversation, Troup explained that Niaspan appeared to be marginally better than Niacor-SR. CX

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prescient when it concluded that Niacor-SR approval was not imminent.

[98] Schering had not shared the analysts' overly simplistic projections for Niaspan sales, nor had Searle. SPX 47; Egan, Tr. 7913-14.

1088; CX 1111; *see also* SPX 15 at 00057 (Audibert's September 1997 memo to Lauda on this discussion). Upsher believed that because Niaspan had received indications (*i.e.*, FDA approval) for arteriosclerosis and myocardial infarction and because Niacor-SR would not get those same indications without further expensive and time-consuming clinical tests, Niaspan had a market advantage over Niacor-SR. Kralovec, Tr. 5058-59; Halvorsen, Tr. 3957-60. Upsher also believed that Niaspan was superior in other ways, aside from the additional testing Upsher mistakenly believed Kos had performed. *See, e.g.*, SPX 15 at 16 00057; CX 930 at USL 13192; CX 1097; CX 1357.

For its part, Schering discontinued efforts to bring Niacor-SR to market for several reasons. Audibert, Tr. 4144-45; Lauda, Tr. 4352. As set out in Audibert's memorandum, first, Upsher believed that "Niaspan is a marginally better product than Niacor-SR in terms of safety and efficacy." CX 1088 at 05 0006. Second, Audibert noted that "in August '98, after being in the market one year, Niaspan's new Rx share for the month is only 1.1 percent" and that, "judging by the response of the investment community, the prognosis of Niaspan is poor." SPX 15 at 16 00057. The fact that Upsher had abandoned its pursuit of the NDA before it was ready to be filed meant that Schering would have to devote more of its own resources to putting together an international dossier than had originally been anticipated. Audibert, Tr. 4145; SPX 15. Finally, even if Schering had gone forward with the work to prepare the dossier, the entry of Niacor-SR in Europe would have been much later than originally anticipated. Audibert, Tr. 4145.

As Kapur had requested on October 6, 1998, Paul Kralovec, Upsher's Chief Financial Officer, provided written confirmation of Upsher's decision to suspend its efforts on Niacor-SR. CX 1111; Kralovec, Tr. 5057; Lauda, Tr. 4428-29. In the letter, which was also copied to Troup, Kralovec again confirmed the reasons for Upsher's decision not to proceed with U.S. approval. CX 1111. Kralovec's letter based that decision "first and foremost" on FDA's requirement that Upsher complete a pharmacokinetic study, with Kos's sales performance a secondary consideration. CX 1111.[99]

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[99] The memorandum stated three reasons for Upsher's decision to discontinue the NDA, last of which is Niaspan's sales: (1) Upsher was "focusing their efforts in defending their generic amiodarone against AHP, (2) based on the clinical data, the profile of Niacor seems to be slightly inferior to Niaspan (Kos),

Neither Troup in the September 1998 telephone call, nor Kralovec in his October 1998 written confirmation, mentioned to Schering the mysterious March conversation in which someone from Schering had supposedly stated that the company did not plan to market the product outside the U.S. SPX 15; CX 1111.

2. Factual Conclusions About Post-Settlement Conduct

The evidence from the post-settlement conduct, considered as a whole, demonstrates that Schering had little interest in Niacor-SR or any of the other licensed products. The lack of communication between Upsher and Schering about the development of Niacor-SR – especially during the fall of 1997, before Kos's disappointing sales were made public and after Upsher decided unilaterally to place only minimal effort into development activities – suggests that Upsher understood Schering was not particularly interested in the licensed products.[100] This conclusion is buttressed by the fact that Upsher simply ignored Schering's sporadic requests for information, and ultimately made a unilateral decision essentially to suspend its work, without eliciting even a mild protest from Schering. The post-settlement conduct only confirms the conclusion that Schering's payment of $60 million was not consideration for the licenses.

E. Summary Factual Conclusions on the Valuation of the Upsher Licenses

There is a direct link between the payment by Schering for the Upsher licenses and Upsher's commitment not to enter before September 1, 2001. Schering's payments were neither keyed to any milestones in the development of the licensed products nor dependent on any obligations of Upsher to cooperate with Schering. At every negotiating session, Upsher's senior representative demanded compensation in return for an agreement not to enter. Some Schering representatives were concerned about the antitrust consequences of an outright

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and (3) the Kos product has not been successful in spite of Kos investing considerably more sales and promotional efforts than Upsher intended to do." SPX 15 at 1600057.

[100] Because the evidence shows that Schering had not shared the investment analysts' optimistic forecasts for Niaspan sales, the fact that Niaspan's sales were not as high as forecast fails to explain fully Schering's lackadaisical attitude.

payment to Upsher for delay, but Schering's senior management believed these obstacles could be surmounted if the payments for the Upsher licenses were justified on a stand-alone basis.

As a practical matter, the only Upsher license that Schering attempted to value related to a niacin-based product, Niacor-SR. A number of people in Schering were familiar with niacin-based products, as the result of a recently terminated negotiation involving a different niacin-based product made by another company, Kos Pharmaceuticals. These people had serious reservations about the commercial potential of such products. For reasons that the parties have not explained, none of these knowledgeable people was included in the negotiations of the final price that ostensibly would be paid for a license to Niacor-SR – nor were these knowledgeable people consulted when a single Schering employee made the "forecast" of Niacor-SR's sales and profit potential that was the basis for approval by the Schering Board.

This "forecast" was little more than a simple mathematical exercise. Even if we assume that there were serious time pressures, obvious questions were not even asked, nor were they pursued after the agreement was signed. It is not credible that Schering would have been satisfied with such a cursory examination, if management really was concerned about the value of the Upsher licenses. The post-settlement conduct of the parties reinforces these conclusions. The record demonstrates that Schering did not evidence any significant interest in the licensed products once the settlement had been concluded and, ultimately, all development was terminated. In the end, the Upsher licenses were worth nothing to Schering.

On the basis of the record as a whole, we find that there was a direct nexus between Schering's payment and Upsher's agreement to delay its competitive entry and that the magnitude of the payment was not based on Schering's evaluation of the Upsher licenses. We therefore conclude that Schering did in fact pay Upsher for delayed entry, which, in the circumstances of this case, was an agreement that unreasonably restrains commerce.

V. The Agreement Between Schering and AHP

The complaint in this case also challenges the legality of a litigation settlement between Schering and AHP, which was concluded in June 1998 –

approximately one year after the Schering/Upsher settlement. AHP agreed to a consent order based on this transaction, but Schering has continued to defend it, and the Initial Decision upheld Schering's position. Complaint Counsel appeals from this dismissal as well.

There is far less record evidence about the Schering/AHP agreement than there is about the Schering/Upsher agreement, but our analysis will proceed along the same path, highlighting the similarities and the differences between the two agreements to the extent applicable. We will examine the core elements of Complaint Counsel's case, consider whether it is necessary to address the merits of the underlying patent dispute and, finally, evaluate the ancillarity defense.[101] Based on our analysis of the record, we reverse the Initial Decision and conclude that the Schering/AHP settlement was an unreasonable agreement in violation of Section 5 of the FTC Act.

A. The Evidence in Support of Complaint Counsel's Case

The Schering/AHP agreement delayed entry of the generic product to be offered by the ESI subsidiary of AHP until January 1, 2004.[102] We obviously have no evidence on the actual market impact of ESI's generic product, but we do have evidence of predicted effects similar to the predictive evidence available for Upsher's product. [redacted from public record version]

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[101] There also was a side agreement in this settlement that provided for a payment of $15 million by Schering to AHP's ESI unit, in return for certain licenses. However, Schering has conceded that it agreed to pay another $5 million (for "legal fees") simply to induce AHP to settle the case, and it later agreed to pay $10 million more contingent on FDA approval of *ESI's generic version of K-Dur* – not the other products ESI licensed to Schering. (IDF 370-75; Schering Ans. Br. at 50.) FDA approval was obtained and the additional $10 million were paid. The total payment was thus $30 million. In these circumstances, we do not believe it is necessary to explore whether the ESI licenses were worth the $15 million ascribed to them in the settlement.

[102] The Commission's April 2002 settlement with AHP did not mandate an earlier entry date.

[redacted from public record version .][103] In addition, the economic studies cited above found that generic prices fall further as the number of generic producers increases. *See* Richard G. Frank & David S. Salkever, *Generic Entry and the Price of Pharmaceuticals*, 6 J. Econ. & Mgmt. Strategy 75, 83 (1997) ("expanded entry is consistent with a downward drift in the ratio of generic to brand-name price"); Richard E. Caves, *et al.*, *Patent Expiration, Entry, and Competition in the U.S. Pharmaceutical Industry*, Brookings Papers on Economic Activity: Microeconomics 1, 34-38 (1991); Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry*, July 1998.

The record does not contain similar predictions from the files of Schering, but we have no evidence from which we could conclude that the impact of ESI's generic would be qualitatively different from the impact of Upsher's generic. Since these predictions are consistent with the record evidence about both the predicted and the actual impact of another generic on the sales *of the same patented drug* (*see* Part II.B., above), we see no reason to arrive at a different conclusion on the likely competitive effects of an agreement that delayed ESI's entry.

B. The Need to Address the Merits of the Underlying Patent Dispute

The patent dispute between Schering and AHP, like Schering's dispute with Upsher, involved issues of infringement as well as validity. Therefore, we cannot presume either that Schering had the right to exclude or that AHP had the right to enter. For the reasons set out in Part II.C., above, we believe it is neither necessary nor helpful to delve into the merits of the patent dispute.

C. The Ancillarity Defense

We have already weighed the evidence presented by Schering's expert witnesses on the general desirability of patent settlements and the possible efficiency justifications for payments by pioneers to generic manufacturers in some situations. We therefore believe it is appropriate to deal with this issue in the context of the Schering/AHP settlement in a way that parallels the conclusions about the Schering/Upsher settlement. As discussed above, it is possible to

[103] [redacted from public record version]

envision special hypothetical cases where some payments from pioneers to generics could be efficient and beneficial to consumers. An argument that these payments facilitate and are ancillary to procompetitive settlements invokes an affirmative defense, however, and a respondent who relies on it also has the burden of demonstrating that the facts fit some special hypothetical.

A sum that ultimately amounted to $15 million was paid simply to get ESI's agreement on settlement terms that delayed generic entry until 2004. Of this amount, $5 million were ostensibly for "legal fees." This might not be an unreasonable nuisance settlement – it is probably well in excess of AHP's attorneys fees, but obviously Schering faced litigation expenses of its own. However, the additional $10 million, contingent on FDA approval of the generic product, are harder to justify. ESI was not a "cash starved" generic and there is no evidence that the payment would facilitate generic entry in force. Schering's claim is rather that ESI was adamant on the issue and that a settlement-minded judge put pressure on Schering to yield.[104]

We accept that Schering was subject to intense, and perhaps unseemly, judicial pressure to settle the patent litigation, and Schering may well have been concerned about its future litigation prospects if it resisted. In other words, the pressure could have adversely affected its perceived bargaining position. We are troubled, however, by the fact that Schering's only response to the pressure was to look for innovative ways to structure payments to AHP; the January 1, 2004 date for generic entry was apparently non-negotiable. There is no record evidence to explain why the entry date was non-negotiable from Schering's point of view or why an earlier date would have been an unsatisfactory substitute for cash from AHP's point of view. In other words, there is no explanation for the failure to even explore an obviously less restrictive alternative. As discussed above in another context,[105] the mere fact that a patent holder's bargaining position has been impaired does not justify the payment of money to a potential generic entrant.

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[104] Schering Ans. Br. at 50.

[105] *See* discussion in Part II.B.4, above, rejecting an argument that payments are justified simply because Hatch-Waxman has shifted the relative bargaining power of the parties.

As a matter of prosecutorial discretion, we might not have brought a stand-alone case based on such relatively limited evidence, and our decision on this aspect of the case will have no impact on the scope of the order we enter.[106] However, Commission determinations serve to provide prospective guidance as well as retrospective evaluations, and we believe it is important to signal our disapproval of the way that Schering responded to judicial pressures. Accordingly, we find that conduct of this kind violates the law.

VI. The Monopolization Counts

In addition to counts that invoke the conspiracy provisions of Section 1 of the Sherman Act (Comp. ¶¶ 68, 69), the complaint also pleads two counts that invoke the monopolization provisions of Sherman Act Section 2 (Comp. ¶¶ 70, 71).[107] As discussed above, there is adequate evidence to support the conclusion that the agreements to defer competition between Schering's patented drug and its generic equivalents will cause significant consumer harm, under Section 1 standards. The Upsher and AHP agreements postponed availability of substantial quantities of lower-priced therapeutically equivalent drugs and thereby caused consumer injury that is readily identifiable (even if it may not be readily quantifiable). In light of our conclusions on the conspiracy counts, it is not necessary to rule on the additional monopolization counts – and there are also affirmative reasons for declining to do so.

The proof in this case focused on the legality of two contracts, the Schering/Upsher and the Schering/AHP settlement agreements. There is no claim that unilateral conduct by anyone violated the antitrust laws. Moreover,

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[106] The Commission's Order settling the complaint with AHP is final. *See Schering-Plough Corp.*, FTC Dkt. No. 9297, Consent Order as to American Home Products Corp. (Apr. 2, 2002), *available at* <http://www.ftc.gov/os/2002/04/scheringplough_do.htm>.

[107] The counts plead a violation of Section 5 of the Federal Trade Commission Act, but the standards for applying Section 5 are, for the most part, co-extensive with the Sherman Act. *See* discussion in ABA Section of Antitrust Law, Antitrust Law Developments 607 (5th ed. 2002).

determination of liability on the monopolization counts of the complaint would not affect our views on the appropriate order in this case. We therefore do not believe it would be useful either to canvass the record to see whether there is adequate evidence to sustain these counts under the most commonly accepted standards for monopolization cases[108] or, alternatively, to consider whether the case should be remanded for further proceedings under the appropriate standards. Accordingly, we neither endorse nor reject the conclusions of the Initial Decision on these issues, but rather find that it is not appropriate for the Commission to address them at this time.

VII. The Appeal from the Administrative Law Judge's Evidentiary Rulings

Complaint Counsel have also asked the Commission to vacate four rulings by the Administrative Law Judge that excluded certain rebuttal evidence. If we were to do so, of course, it would be necessary to remand the case and reopen the

[108] Reliance on direct evidence of market effects, rather than inferences from "market" shares, is a less familiar method of proof in a Section 2 monopolization context. *See id*. at 232 n.16 and cases cited ("Numerous cases have held specifically that proof of a relevant market is an essential element of any claim for monopolization or attempted monopolization under § 2."); *but see PepsiCo, Inc. v. Coca-Cola Co.*, 315 F.3d 101, 107-08 (2d Cir. 2002); *Re/Max Int'l, Inc. v. Realty One, Inc.*, 173 F.3d 995, 1016 (6th Cir. 1999), *cert denied*, 535 U.S. 987 (2002).

record to admit the evidence.[109] For the reasons outlined below, we do not believe it is necessary to take this step at this time.

The first ruling denied discovery requested by Complaint Counsel, in order to rebut a claim that capacity constraints would have prevented Upsher from bringing its generic product to market before the agreed-on date of September 1, 2001. Since we find that Upsher's evidence on this point is insufficient, even without the rebuttal evidence, we decline to overturn the ruling on this issue.[110]

The second ruling excluded rebuttal testimony by witness Bresnahan on the substitutability of other potassium products for Schering's K-Dur 20. We have found that evidence of this kind is not material for a decision in this case, whatever relevance it might have for market definition in another kind of case. Accordingly, we decline to overturn the ruling.

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[109] The courts and the Commission apply an "abuse of discretion" standard when reviewing claims of error in evidentiary rulings at the trial or initial hearing level. *See General Elec. Co. v. Joiner*, 522 U.S. 136, 141 (1997), and cases cited therein; *Missouri Portland Cement Co.*, 77 F.T.C. 1643 (1970). While this standard means that the Commission will not routinely disturb the ALJ's denial of discovery or exclusion of evidence, the Commission may reverse a procedural decision and reopen the record, as necessary or appropriate, where the ALJ's ruling is found to be "unduly restrictive" or otherwise prejudicial or improper. *See, e.g.*, *Foster-Milburn Co.*, 51 F.T.C. 369, 371 (1954) (hearing examiner improperly denied complaint counsel's request to present scientific rebuttal witnesses); *see also* Commission Rule 3.54, 16 C.F.R. § 3.54 (reserving the Commission's discretion to exercise all of the powers it could have exercised if it had made the initial decision and, if it believes it should have additional information or views of the parties bearing upon the order to be issued, to withhold final action pending the receipt of such information or views).

[110] This does not mean that we agree with the ruling on the merits. If Complaint Counsel's chronological account is accurate, and if the evidence had been material, it seems that there could have been prejudice from a six-week delay in the resolution of the "emergency motion" in aid of discovery. *See* App. Br. at 78-81.

The third ruling excluded certain rebuttal testimony by witness Max Bazerman on risk aversion because his underlying expert report was not filed in time. The excluded testimony apparently took issue with testimony of Schering's experts that Schering was risk averse in settlement negotiations with Upsher and AHP (and, hence, presumably willing to place a high value on settlement). We do not believe that the level of Schering's risk aversion is relevant to our decision in this case.

The extent to which parties are risk averse may affect how they are willing to compromise the entry date when settling patent litigation. However, we do not challenge agreements on entry dates, standing alone. The issue in this case is whether payments from pioneer to generic have distorted the calculus that would otherwise obtain – based on whatever risk preferences the parties might have – and our opinion does not depend on testimony about relative risk preferences. Accordingly, the ruling is harmless and will not be disturbed.[111]

The fourth ruling excluded rebuttal testimony of a witness from Walgreens, again on the substitution of other products for K-Dur 20. The rejected testimony related to a market definition issue that is essentially the same as the issue involved in the second ruling, and we decline to overturn it for the same reasons.

We can revisit each of these rulings in the event that further proceedings in this case make it necessary to do so.

VIII. Conclusion

For all of the reasons outlined above, we conclude that both the Schering/Upsher and the Schering/AHP agreements violated Section 5 of the Federal Trade Commission Act. Specifically, we reverse the Initial Decision and find that the charges in the complaint that are grounded in Section 1 of the Sherman Act (Paragraphs 68-69) have been proven. We neither affirm nor reverse

[111] We again note, however, that the ruling could have been unduly prejudicial if Complaint Counsel's chronology is accurate and the evidence had been material for our decision. *See* App. Br. at 85-88.

the Initial Decision with respect to those charges in the complaint that are grounded in Section 2 of the Sherman Act (Paragraphs 70-71).

Although we find that these two settlement agreements violated Section 5, after an appropriately structured rule-of-reason inquiry, we also note that the agreements in question were consummated well before the Commission launched the investigations that resulted ultimately in complaints and consent orders in comparable situations.[112] Although counsel for Schering, at least, were aware of the particular problems posed by reverse payments and attempted (unsuccessfully) to avoid them, we do not believe that these problems were as obvious in 1997 and 1998 as they are today. Our own view of these matters has been informed by what we have learned about pioneer/generic settlements since that time. For these reasons, we have crafted an order that is appropriate in the circumstances.

The order provides for prospective relief only.[113] We have found that the agreements were unreasonable restraints of trade because they were likely to cause consumer harm that outweighed any associated pro-consumer efficiencies. We also have found that the reverse payments did, in fact, cause delay and that this delay resulted in substantial consumer harm. We have not, however, attempted to quantify the net harm to consumers and express no opinion on what it might be.

The order is modeled on Complaint Counsel's proposed remedy, with one significant exception. We delete in their entirety proposed provisions relating to a first-filing generic's 180-day exclusivity. We have not analyzed the effects of any such agreements in this opinion and believe it is inappropriate to address them in the order.

Paragraph II of the order deals with final settlements of patent litigation. It prohibits settlements under which the generic "receives anything of value" and

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[112] *See* cases cited in note 3, *supra*.

[113] It may be appropriate in the future to seek retroactive relief, like disgorgement or redress, in comparable situations. *See* FTC Policy Statement on Monetary Equitable Remedies in Competition Cases, 68 Fed. Reg. 45820 (Aug. 4, 2003), *reprinted in* 4 Trade Reg. Rep. (CCH) ¶ 13,231, *available at* <http://www.ftc.gov/os/2003/07/disgorgementfrn.htm>.

agrees to defer its own research and development, production or sales activities. Consistent with prior consent orders, there is a specific exception for payments to the generic that are linked to litigation costs, up to $2 million, and for which the Commission has been notified of the settlement.

Paragraph III of the order prohibits settlement agreements that restrict the generic's activities with respect to drug products that are subject to neither a pending claim of patent infringement nor a likely future claim. This provision is consistent with an extensive body of case law that prohibits restrictions on activities outside the scope of a patent claim.[114]

Paragraph IV of the order deals with interim settlements of pioneer/generic patent litigation. The substantive prohibition against providing "anything of value" to the generic is subject to a broad exception for agreements that are affirmatively sanctioned by a court order after notification to the Commission and full opportunity by the Commission to participate in the proceeding.

Paragraph V of the order specifies the form of notifications to the Commission that may be required, and the remaining paragraphs provide for the usual compliance reports and visitation rights. The order expires in 10 years.

We finally would like to express our appreciation to all counsel for their extensive and thoughtful submissions that have helped us to resolve this complex matter.

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[114] The basic reason is that, in the absence of a patent blockade, the arrangement "harms competition among actual or likely potential competitors . . ." U.S. Dep't of Justice & Federal Trade Comm'n, Antitrust Guidelines for the Licensing of Intellectual Property (1995) § 3.1, *reprinted in* 4 Trade Reg. Rep. (CCH) ¶ 13,132, *available at* <http://www.usdoj.gov/atr/public/guidelines/ipguide.htm>.

APPENDIX

Witnesses and People Referenced in Opinion

Sumanth Addanki, Economic Expert (Schering expert witness)

James Audibert, Schering-Plough, Senior Director of Commercial Optimization

Daniel Bell, Kos Pharmaceuticals, President and Chief Executive Officer

Timothy F. Bresnahan, Economic Expert (Complaint Counsel expert witness)

Nicholas Cannella, Upsher-Smith, Legal Counsel

Raul Cesan, Schering-Plough, President of Pharmaceuticals Worldwide

Toni DeMola, Schering-Plough, Member Cardiovascular Licensing Group

Michael Dey, ESI Lederle, Chief Executive Officer

Denise Dolan, Upsher-Smith, Marketing Official

Martin Driscoll, Schering-Plough, Vice-President of Sales and Marketing, Key Pharmaceuticals (Key marketed K-Dur 20)

James Egan, Searle, Formerly, Senior Director of Licensing and Business Development

Lori Freese, Upsher-Smith, Manager of Professional Services

James Furniss, European Pharmaceutical Expert (Schering Expert Witness)

Karin Gast, Schering-Plough, Director of Business Development

Dean Goldberg, United Healthcare, Pharmaceutical Expert (Complaint Counsel expert witness)

David Grewcock, Schering-Plough, Member Cardiovascular Licensing Group

Marc Halvorsen, Upsher-Smith, Director of Clinical and Regulatory Affairs

Andrew Hirschberg, Upsher-Smith, Consultant

John Hoffman, Schering-Plough, Associate General Counsel

Zola Horovitz, Pharmaceutical Expert (Schering expert witness)

Raman Kapur, Schering-Plough, President, Warrick Pharmaceuticals (Schering-Plough's generic drug affiliate)

William Kerr, Economic Expert (Schering expert witness)

Paul Kralovec, Upsher-Smith, Chief Financial Officer

Thomas Lauda, Schering-Plough, Executive Vice President of Global Marketing

Nelson Levy, Licensing Expert (Complaint Counsel expert witness)

Vicki O'Neil, Upsher-Smith, Business Development Official

Mukesh Patel, Kos Pharmaceuticals, Licensing and Business Development

Charles (Rick) Rule, Antitrust Expert (Upsher-Smith Witness)

Raymond Russo, Schering-Plough, Marketing Director, Key Pharmaceuticals

Russell Teagarden, Merck-Medco, Pharmaceutical Pricing Expert (Complaint Counsel expert witness)

Paul Thompson, Schering-Plough, Licensing Attorney involved with Upsher-Smith transaction

Ian Troup, Upsher-Smith, President and Chief Operating Officer

Jeffrey Wasserstein, Schering-Plough, Vice President of Business Development

Robert Willig, Economic Expert (Schering expert witness)

Richard Zahn, Schering-Plough, Executive who supervised Driscoll