

No. 04-10688-AA

IN THE UNITED STATES COURT OF APPEALS  
FOR THE ELEVENTH CIRCUIT

---

SCHERING-PLOUGH CORP.,  
UPSHER-SMITH LABORATORIES, INC.,  
*Petitioners,*

v.

FEDERAL TRADE COMMISSION,  
*Respondent.*

---

PETITION FOR REVIEW  
OF A FINAL ORDER OF THE  
FEDERAL TRADE COMMISSION

---

BRIEF OF RESPONDENT  
FEDERAL TRADE COMMISSION

---

SUSAN A. CREIGHTON  
*Director, Bureau of Competition*

BRADLEY S. ALBERT  
ELIZABETH R. HILDER  
MICHAEL B. KADES  
*Attorneys, Bureau of Competition*

FEDERAL TRADE COMMISSION  
600 PENNSYLVANIA AVENUE, N.W.  
WASHINGTON, DC 20580

WILLIAM E. KOVACIC  
*General Counsel*

JOHN D. GRAUBERT  
*Principal Deputy General Counsel*

JOHN F. DALY  
*Deputy General Counsel for Litigation*

IMAD D. ABYAD  
*Attorney*

FEDERAL TRADE COMMISSION  
600 PENNSYLVANIA AVENUE, N.W.  
WASHINGTON, DC 20580  
(202) 326-2375

July 27, 2004

**CERTIFICATE OF INTERESTED PERSONS**

Pursuant to Rules 26.1 and 27.1(a)(9) of the Rules of the Court of Appeals for the Eleventh Circuit, respondent Federal Trade Commission hereby submits the following list of persons who have an interest in the outcome of this matter, and whose names were omitted from petitioners Schering-Plough Corporation's and Upsher-Smith Laboratories, Inc.'s Certificates of Interested Persons:

Alden F. Abbott, Assistant Director, Bureau of Competition, FTC.

Imad D. Abyad, Attorney, Office of General Counsel, FTC.

Bradley S. Albert, Attorney, Bureau of Competition, FTC.

Jeffrey W. Brennan, Attorney, Bureau of Competition, FTC.

D. Michael Chappell, Administrative Law Judge, FTC.

Susan A. Creighton, Director, Bureau of Competition, FTC.

John F. Daly, Deputy General Counsel for Litigation, FTC.

Federal Trade Commission, Respondent.

Andrew Ginsburg, Attorney, Bureau of Competition, FTC.

John D. Graubert, Principal Deputy General Counsel, FTC.

Pamela Jones Harbour, Commissioner, FTC.

Appeal No. 04-10688  
Schering-Plough Corp. v. FTC

Elizabeth R. Hilder, Attorney, Bureau of Competition, FTC.

Michael B. Kades, Attorney, Bureau of Competition, FTC.

William E. Kovacic, General Counsel, FTC.

Thomas Krattenmaker, Advisor, Bureau of Competition, FTC.

Thomas B. Leary, Commissioner, FTC.

Markus H. Meier, Deputy Assistant Director, Bureau of Competition, FTC.

Judith A. Moreland, Bureau of Competition, FTC.

Timothy J. Muris, Chairman, FTC.

Melvin H. Orlans, Bureau of Competition, FTC.

David R. Pender, Deputy Assistant Director, Bureau of Competition, FTC.

Orson Swindle, Commissioner, FTC.

Mozelle W. Thompson, Commissioner, FTC.

Michael S. Wroblewski, Assistant General Counsel for Policy Studies, FTC.

## **STATEMENT REGARDING ORAL ARGUMENT**

The Federal Trade Commission agrees with the petitioners that this case raises important issues at the intersection of patent law and antitrust law, and that oral argument may assist this Court's resolution of this case.

**TABLE OF CONTENTS**

TABLE OF CITATIONS ..... -v-

GLOSSARY ..... -xiii-

STATEMENT OF JURISDICTION ..... -xiv-

STATEMENT OF ISSUES PRESENTED ..... -1-

STATEMENT OF THE CASE ..... -2-

    A. Nature of the Case, the Course of Proceedings, and the Disposition  
        Below ..... -2-

    B. Statement of the Facts ..... -3-

        1. Schering’s K-Dur 20 ..... -3-

        2. The Hatch-Waxman Regulatory Framework ..... -3-

        3. The Economic Impact of Generic Entry ..... -4-

        4. The Schering-Upsher Settlement ..... -7-

        5. The Schering-AHP Settlement ..... -9-

        6. The Commission’s Ruling ..... -10-

STANDARD OF REVIEW ..... -14-

SUMMARY OF ARGUMENT ..... -15-

ARGUMENT ..... -17-

I.	THE COMMISSION’S FINDINGS ARE DUE A HIGH DEGREE OF DEFERENCE AND THE MERE EXISTENCE OF ALTERNATIVE INFERENCES OR CONCLUSIONS IS INSUFFICIENT TO SET THEM ASIDE . . . . .	-17-
II.	SUBSTANTIAL EVIDENCE SUPPORTS THE COMMISSION’S FINDING THAT SCHERING PAID UPSHER TO DELAY GENERIC ENTRY . . . . .	-23-
	A. The Commission Found Substantial Evidence That Schering Paid for Upsher’s Deferred Entry . . . . .	-23-
	B. Petitioners’ Alternative Explanations for the \$60 Million Payment are Contrary to the Record Evidence . . . . .	-28-
III.	IT IS UNDISPUTED THAT SCHERING PAID AHP IN EXCHANGE FOR THE LATTER’S DELAYED ENTRY TO THE MARKET . . . . .	-36-
IV.	THE COMMISSION PROPERLY APPLIED A RULE OF REASON ANALYSIS TO CONCLUDE THAT SCHERING PAID ITS COMPETITORS NOT TO COMPETE . . . . .	-37-
	A. A Patentee’s “Exclusionary Right Cannot be Exploited in Every Way” . . . . .	-39-

B.	The Commission Fully Considered the Exclusionary Power of Schering’s Patent, Consistent with <i>Valley Drug</i> . . . . .	-43-
C.	Direct Record Evidence of Anticompetitive Effects Obviates the Need for Indirect Product Market Analysis . . . . .	-50-
D.	No Countervailing, Procompetitive Benefits of the Challenged Agreements Were Present in This Case . . . . .	-54-
	CONCLUSION . . . . .	-59-
	CERTIFICATE OF COMPLIANCE	
	CERTIFICATE OF SERVICE	

## TABLE OF CITATIONS

### FEDERAL CASES

<i>Addyston Pipe &amp; Steel Co. v. United States,</i>	
175 U.S. 211, 20 S. Ct. 96 (1899) .....	39
<i>Andrx Pharms., Inc. v. Biovail Corp. International,</i>	
256 F.3d 799 (D.C. Cir. 2001) .....	40, 46
<i>Ball Mem 'l Hosp., Inc. v. Mutual Hosp. Ins., Inc.,</i>	
784 F.2d 1325 (7th Cir. 1986) .....	51
<i>Blackburn v. Sweeney,</i>	
53 F.3d 825 (7th Cir. 1995) .....	39
<i>Brand Name Prescription Drugs Antitrust Litigation,</i>	
186 F.3d 781 (7th Cir. 1999) .....	5
<i>California Dental Association v. FTC,</i>	
526 U.S. 756, 119 S. Ct. 1604 (1999) .....	53, 54
<i>CFTC v. Wellington Precious Metals, Inc.,</i>	
950 F.2d 1525 (11th Cir. 1992) .....	22
<i>Cinderella Career and Finishing Schools, Inc. v. FTC,</i>	
425 F.2d 583 (D.C. Cir. 1970) .....	21

<i>Colonial Stores Inc. v. FTC,</i>	
450 F.2d 733 (5th Cir. 1971) .....	15, 18
<i>Colony Square Co. v. Prudential Insurance Co. of America,</i>	
819 F.2d 272 (11th Cir. 1987) .....	20
<i>Copperweld Corp. v. Independence Tube Corp.,</i>	
467 U.S. 752, 104 S. Ct. 2731 (1984) .....	39
<i>Engine Specialties, Inc. v. Bombardier Ltd.,</i>	
605 F.2d 1 (1st Cir. 1979) .....	40
<i>Equifax, Inc. v. FTC,</i>	
678 F.2d 1047 (11th Cir. 1982) .....	18, 22
<i>Ethyl Gasoline Corp. v. United States,</i>	
309 U.S. 436, 60 S. Ct. 618 (1940) .....	42
<i>FTC v. Algoma Lumber Co.,</i> 291 U.S. 67, 54 S. Ct. 315 (1934) .....	14
<i>FTC v. Indiana Federation of Dentists,</i>	
476 U.S. 447, 106 S. Ct. 2009 (1986) .....	10, 14, 15, 50, 51
<i>Foremost Dairies, Inc. v. FTC,</i>	
348 F.2d 674 (5th Cir. 1965) .....	14
<i>Froelich v. Senior Campus Living LLC,</i>	
355 F.3d 802 (4th Cir. 2004) .....	28

<i>Hernandez v. National Transport Safety Board,</i>	
15 F.3d 157 (10th Cir. 1994) .....	19
<i>Kopac v. NLRB,</i>	
668 F.2d 946 (7th Cir. 1982) .....	21
<i>Markman v. Westview Instruments, Inc.,</i>	
517 U.S. 370, 116 S. Ct. 1384 (1996) .....	43
<i>Mylan Pharms., Inc. v. Shalala,</i>	
81 F. Supp. 2d 30 (D.D.C. 2000) .....	44
<i>NLRB v. Bogart Sportswear Manufacturing Co., Inc.,</i>	
485 F.2d 1203 (5th Cir. 1973) .....	19
<i>Olin Corp. v. FTC,</i>	
986 F.2d 1295 (9th Cir. 1993) .....	15
<i>Palmer v. BRG of Georgia, Inc.,</i>	
874 F.2d 1417 (11th Cir. 1989), <i>rev'd</i> , 498 U.S. 46, 111 S. Ct. 401	
(1990) .....	50
<i>Palmer v. BRG of Georgia, Inc.,</i>	
498 U.S. 46, 111 S. Ct. 401 (1990) .....	39
<i>Parker v. Bowen,</i>	
788 F.2d 1512 (11th Cir. 1986) .....	21

<i>Terazosin Hydrochloride Antitrust Litigation,</i>	
164 F. Supp. 2d 1340 (S.D. Fla. 2000) .....	49
<i>Todd v. Exxon Corp.,</i>	
275 F.3d 191 (2d Cir. 2001) .....	50
<i>Toys "R" Us v. FTC,</i>	
221 F.3d 928 (7th Cir. 2000) .....	50
<i>United States v. Baker Hughes, Inc.,</i>	
908 F.2d 981 (D.C. Cir. 1990) .....	51
<i>United States v. Griffith,</i>	
334 U.S. 100, 68 S. Ct. 941 (1948), <i>overruled on other grounds</i> .....	39
<i>United States v. Line Material Co.,</i>	
333 U.S. 287, 68 S. Ct. 550 (1948) .....	42
<i>United States v. Masonite Corp.,</i>	
316 U.S. 265, 62 S. Ct. 1070 (1942) .....	42, 55, 57
<i>United States v. Microsoft Corp.,</i>	
253 F.3d 34 (D.C. Cir. 2001) .....	40
<i>United States v. Ramirez-Chilel,</i>	
289 F.3d 744 (11th Cir. 2002), <i>cert. denied</i> , 537 U.S. 1114, 123 S. Ct. 850	
(2003) .....	22

<i>United States v. Singer Manufacturing Co.</i> ,	
374 U.S. 174, 83 S. Ct. 1773 (1963) .....	42, 45, 55
<i>Universal Camera Corp. v. NLRB</i> ,	
340 U.S. 474, 71 S. Ct. 456 (1951) .....	18
<i>Valley Drug Co. v. Geneva Pharms., Inc.</i> ,	
344 F.3d 1294 (11th Cir. 2003), <i>petition for cert. filed</i> (No. 03-1175, Feb.	
16, 2004), <i>conditional petition for cert. filed sub nom. Walgreen Co. v.</i>	
<i>Abbott Labs.</i> (No. 03-1178, Feb. 13, 2004) .....	passim
<i>Verizon Committees, Inc. v. Law Offices of Curtis V. Trinko, LLP</i> ,	
__ U.S. __, 124 S. Ct. 872 (2004) .....	57, 58
<i>Yarn Processing Patent Validity Litigation</i> ,	
541 F.2d 1127 (5th Cir. 1977) .....	24
<i>Zenith Radio Corp. v. Hazeltine Research, Inc.</i> ,	
395 U.S. 100, 89 S. Ct. 1562 (1969), <i>rev'd on other grounds</i> ,	
401 U.S. 321, 91 S. Ct. 725 (1971) .....	40, 41

**FEDERAL STATUTES**

5 U.S.C. § 557(b) .....	19
15 U.S.C. § 45 .....	2

15 U.S.C. § 45(c) . . . . .	14, 17
16 C.F.R. § 3.54(a) . . . . .	19
21 U.S.C. § 355(j) . . . . .	4
21 U.S.C. § 355(j)(2)(A)(vii) . . . . .	4
21 U.S.C. § 355(j)(5)(B)(iii) . . . . .	4
21 U.S.C. § 355(j)(5)(B)(iv) . . . . .	8
Pub. L. No. 98-417, 98 Stat. 1585 (1984) . . . . .	3
Pub. L. No. 108-173, 117 Stat. 2461 (2003) . . . . .	57

**STATE STATUTES**

Conn. Gen. Stat. Ann. § 17b-274 . . . . .	6
---	---

**MISCELLANEOUS**

ABA Section of Antitrust Law, <i>Antitrust Law Developments</i> (5th ed. 2002) . . . . .	53
XII Phillip E. Areeda, Herbert Hovenkamp, <i>Antitrust</i> <i>Law</i> (1999 & 2004 Supp.) . . . . .	40, 45, 56, 57
David A. Balto, <i>Pharmaceutical Patent Settlements: The Antitrust Risks</i> , 55 Food & Drug L.J. 321 (2000) . . . . .	46

Richard E. Caves, et al., <i>Patent Expiration, Entry, and Competition in the U.S. Pharmaceutical Industry</i> , Brookings Papers on Economic Activity, Microeconomics (1991) . . . . .	5
Congressional Budget Office, <i>How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry</i> (1998) . . . . .	5
Thomas F. Cotter, <i>Refining the "Presumptive Illegality" Approach to Settlements of Patent Disputes Involving Reverse Payments: A Commentary on Hovenkamp, Janis &amp; Lemley</i> , 87 Minn. L. Rev. 1789 (2003) . . . . .	38
Henry G. Grabowski & John M. Vernon, <i>Brand Loyalty, Entry, and Price Competition in Pharmaceuticals after the 1984 Drug Act</i> , 35 J.L. & Econ. 331 (1992) . . . . .	5
Herbert Hovenkamp et al., <i>Anticompetitive Settlement of Intellectual Property Disputes</i> , 87 Minn. L. Rev. 1719 (2003) . . . . .	38, 44, 45
H.R. Rep. No. 98-857, 1984 U.S.C.C.A.N. 2647 . . . . .	56
Maureen A. O'Rourke & Joseph F. Brodley, <i>An Incentives Approach to Patent Settlements: A Commentary on Hovenkamp, Janis and Lemley</i> , 87 Minn. L. Rev. 1767 (2003) . . . . .	38

Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 RAND J. Econ. 391  
(2003) ..... 38, 41

U.S. Dep’t of Justice & Federal Trade Commission, *Antitrust Guidelines for the  
Licensing of Intellectual Property* (1995) ..... 4

[www.Andrx.com](http://www.Andrx.com) ..... 56

[www.Schering-Plough.com](http://www.Schering-Plough.com) ..... 56

## GLOSSARY

For ease of reference, the following abbreviations and citation forms are used in this brief:

Op. - The Commission's Opinion

ID - Initial Decision of the Administrative Law Judge

CX - Complaint Counsel Exhibit

SPX - Schering-Plough Exhibit

USX - Upsher-Smith Exhibit

Tr. - Transcript of Trial Testimony before the Administrative Law Judge

IH - Transcript of Investigational Hearing Testimony\*

Dep. - Transcript of Deposition Testimony\*

---

\* 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 (*e.g.*, CX 1511 (Kapur Dep.)).

## **STATEMENT OF JURISDICTION**

This is an appeal from an Order of the Federal Trade Commission, entered pursuant to Section 5(b) of the Federal Trade Commission Act, 15 U.S.C. § 45(b). This Court has jurisdiction to review the Commission's Order pursuant to Section 5(c) of the Act, 15 U.S.C. § 45(c).

## STATEMENT OF ISSUES PRESENTED

1. Whether the Commission's factual findings – including its finding that petitioner Schering paid potential generic competitors to delay market entry – are supported by substantial evidence.

2. Whether the Commission properly concluded that petitioners' agreements to delay the introduction of lower-cost generic drugs were unreasonable restraints of trade, in light of the established competitive benefits of generic entry in this case and petitioners' failure to demonstrate any procompetitive justifications.

3. Whether the Commission's analytical framework is consistent with this Court's guidance in *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294 (11<sup>th</sup> Cir. 2003), *petition for cert. filed* (No. 03-1175, Feb. 16, 2004), *conditional petition for cert. filed sub nom. Walgreen Co. v. Abbott Labs.* (No. 03-1178, Feb. 13, 2004).

## STATEMENT OF THE CASE

### *Nature of the Case, Course of Proceedings, and the Disposition Below*

This case concerns a challenge by the Federal Trade Commission (the “FTC” or the “Commission”) to agreements between Schering-Plough Corporation (“Schering”), the manufacturer of a brand-name drug called “K-Dur 20,” and two manufacturers of generic counterparts, Upsher-Smith Laboratories, Inc. (“Upsher”) and American Home Products Corporation (“AHP”). In those agreements, the parties settled pending patent litigation, and the two generic manufacturers agreed to forbear marketing their generic drugs until specified dates in exchange for guaranteed cash payments totaling \$60 million to Upsher and \$15 million to AHP. As a result of these agreements, Schering continued to enjoy supracompetitive profits from K-Dur 20 for several more years, at the expense of consumers.

The Commission issued its administrative complaint on March 30, 2001, charging that Schering’s agreements with Upsher and AHP violated the FTC Act, 15 U.S.C. § 45. AHP entered into a consent agreement in April 2002 and is no longer party to this action. Trial against Schering and Upsher took place between January 23 and March 22, 2002. The administrative law judge’s Initial Decision (“ID”) dismissed the complaint. ID 103-112. The Commission reversed, concluding on *de novo* review that the ALJ had erred in several key factual

findings as well as in his legal analysis. *See* Opinion of the Commission (“Op.”). The Commission entered an order against Schering and Upsher to cease the practices in question, and this review proceeding followed.

### ***Statement of the Facts***

#### **1. Schering’s K-Dur 20**

Schering’s K-Dur 20 is a potassium chloride supplement generally taken as a long-term therapy in conjunction with drugs for high blood pressure or congestive heart disease. It was the most frequently prescribed potassium supplement, with annual sales reaching \$170 million by 1997. The active ingredient in K-Dur 20, potassium chloride, is in common use and is unpatentable. Schering owns a *formulation* patent (the ‘743 patent) that relates only to the type and viscosity of the material that coats the potassium chloride crystals, providing the tablet with its extended-release mechanism. Thus, a generic manufacturer can use the active ingredient in K-Dur 20 without infringing Schering’s patent, so long as it uses a coating not covered by that patent. Upsher and AHP asserted (to the FDA and in litigation) that their products were such non-infringing generic substitutes.

#### **2. The Hatch-Waxman Regulatory Framework**

This case arises in the regulatory context of the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984),

commonly known as the “Hatch-Waxman Act.”<sup>1</sup> The Act allowed for accelerated FDA approval of a drug through an Abbreviated New Drug Application (“ANDA”) upon showing that the new “generic” drug is “bioequivalent” to an already approved “pioneer” or “brand-name” drug. 21 U.S.C. § 355(j). The FDA may not approve the ANDA prior to the expiration of any patent that covers the existing drug unless the applicant certifies that the referenced patent is either invalid or is not infringed by the new generic product (a so-called “Paragraph IV Certification”). 21 U.S.C. § 355(j)(2)(A)(vii). The patent holder may challenge such certification by filing a patent infringement suit within 45 days of receiving notification of it, thus invoking a 30-month stay period during which the FDA approval is put on hold awaiting judicial resolution of the patent litigation. 21 U.S.C. § 355(j)(5)(B)(iii).

### **3. The Economic Impact of Generic Entry**

Although the ownership of a patent does not automatically confer market power on the patentee,<sup>2</sup> empirical research in the pharmaceutical industry shows that the impact of the entry of generic substitutes on the sale of certain brand-name

---

<sup>1</sup> This Court reviewed the relevant regulatory background in *Valley Drug, supra*, 344 F.3d at 1296-98.

<sup>2</sup> See *Antitrust Guidelines for the Licensing of Intellectual Property* § 2.2 (U.S. Dep’t of Justice & FTC 1995).

drugs is both rapid and dramatic.<sup>3</sup> In these circumstances a brand-name manufacturer that can forestall generic entry frequently does have market power.<sup>4</sup> Within the first full year after launch of a generic product, branded drugs lose an average of 44% of their sales to the new, significantly lower-priced generic entrant.<sup>5</sup> State drug-substitution laws and the policies of private health organizations contribute significantly to this dramatic impact. Virtually all states encourage generic competition through laws that allow pharmacists to dispense an “AB-rated” generic drug when presented with a prescription for its branded counterpart, unless the physician directs otherwise.<sup>6</sup> Similarly, many health plans, including Medicaid and other public assistance programs, capitalize on those substitution laws by encouraging or even mandating the use of generic versions of

---

<sup>3</sup> E.g., Henry G. Grabowski & John M. Vernon, *Brand Loyalty, Entry, and Price Competition in Pharmaceuticals after the 1984 Drug Act*, 35 J.L. & Econ. 331 (1992); Richard E. Caves, et al., *Patent Expiration, Entry, and Competition in the U.S. Pharmaceutical Industry*, Brookings Papers on Economic Activity, Microeconomics (1991).

<sup>4</sup> See *Brand Name Prescription Drugs Antitrust Litig.*, 186 F.3d 781, 787 (7<sup>th</sup> Cir. 1999) (Posner, C.J.).

<sup>5</sup> Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry*, xiii (1998).

<sup>6</sup> An “AB-rated” generic drug is one that has been approved by the FDA as bioequivalent to a reference drug.

branded drugs whenever possible. Schering Answer ¶ 19; Goldberg, Tr. 122. *See, e.g.,* Conn. Gen. Stat. Ann. § 17b-274 (mandating the dispensing of generic substitutes to recipients of public assistance).

K-Dur 20's rapid sales erosion as a result of generic entry was predicted by Schering and Upsher, and then realized once generic substitutes entered the market. Op. 19, 22. Although Schering's patent covering K-Dur 20 did not expire until 2006, Schering did not expect its patent to prevent all generic competition, nor did Upsher expect to wait until patent expiration before entering.<sup>7</sup> Indeed, Schering predicted that generic entry would occur long before its patent's expiration, and adjusted its business forecasts accordingly to show a dramatic drop in the sales of K-Dur 20. Op. 20; CX 746 at SP2300375; CX 115 at SP004794; CX 122A at SP2300295; CX 122F at SP2300316; CX 122J at SP2300325-326.<sup>8</sup>

---

<sup>7</sup> As noted above, Schering's patent did not cover the product's active ingredient, but only a particular *formulation* of the product.

<sup>8</sup> Schering's internal business documents warned that "direct generic competition is expected" and might arrive by 1997 or 1998. CX 13 at SP003044; Op. 20. Indeed, by 1997, Schering was actively planning for generic competition, by preparing to launch its own generic version of K-Dur 20 – even purchasing the packaging supplies. CX 682; *see also* CX 122B at SP2300298; CX 122E at SP2300310. Schering has launched generic versions of its own drugs in the past only in response to or in anticipation of other generic entry. CX 1510 (Kapur IH) at 30-31.

#### **4. The Schering-Upsher Settlement**

In August 1995, Upsher filed an ANDA to market “Klor Con M20,” a generic version of Schering’s K-Dur 20. Op. 3. In connection with its ANDA, Upsher made a Paragraph IV Certification that Schering’s patent was either invalid or not infringed, and notified Schering accordingly. Op. 4. On December 15, 1995, Schering sued Upsher for patent infringement, thus triggering the 30-month automatic stay on Upsher’s ANDA. *Id.*

In March 1997, Upsher received tentative FDA approval of its ANDA, CX 233, and a week later, asked the court hearing the patent litigation to lift the 30-month stay on FDA final approval. Op. 34. Upsher represented to the court that the only impediment to its immediate entry was the automatic Hatch-Waxman stay. *Id.*; CX 1705 at USLPLD004242 (*in camera*); Kerr, Tr. 6744-45; CX 1706 at USLPLD004262, 67 (*in camera*). Upsher also took various concrete steps to prepare for product launch, including purchasing raw materials and reserving time with its contract manufacturer for production of commercial-scale quantities. CX 1502 (Gould Dep.) at 13-16, 17, 40-42; CX 266.

Schering and Upsher began negotiating a settlement about a month prior to the June 1997 trial date. Op. 44; Troup, Tr. 5407-10. Upsher’s status as the first filer of an ANDA for a generic K-Dur 20 dramatically strengthened its negotiating

position, and it made clear to Schering that it expected to be paid to stay off the market.<sup>9</sup> CX 1529 (Troup IH) at 111-12. Indeed, from the very beginning, Upsher's president, Ian Troup, made a demand of \$60-70 million from Schering, Tr. 320 – a figure that fell between the parties' estimates of Schering's loss in the event of generic entry, CX 128 at SP2300325a; CX 150 at USL08536, 38, 39; and Upsher's loss in the event of delayed entry until 2001. CX 283 at SP018781; *see also* Troup, Tr. 5413-14; CX 338 at SP1200268.

On June 17, 1997, on the eve of trial, Schering and Upsher entered into an agreement that settled their patent litigation. Op. 4. Schering agreed to pay Upsher – unconditionally – the \$60 million it had demanded. Op. 4; CX 348. In return, Upsher agreed to forgo marketing its Klor Con M20 product until September 2001. Op. 4; CX 348 at USL03186. Upsher also agreed to grant Schering a license to market six Upsher products in prescribed territories. Op. 4. The unconditional payments were justified to Schering's board of directors as a “prerequisite of any deal” and as dictated by Upsher's desire for a “guaranteed

---

<sup>9</sup> Under certain circumstances, the first filer of an ANDA is granted a 180-day “exclusivity period” during which it can market its new drug free from other generic competition. 21 U.S.C. § 355(j)(5)(B)(iv). Thus, Schering faced competition not only from Upsher, but also from the other generic manufacturers that were potentially blocked from entry until Upsher began marketing its product.

income stream” to compensate it for lost Klor Con M20 revenue. CX 338 at SP1200270.

### **5. The Schering-AHP Settlement**

In December 1995, ESI Lederle Inc., a division of AHP, also filed an ANDA for a generic version of K-Dur 20, with its own Paragraph IV Certification. Op. 5. On February 16, 1996, Schering sued AHP for patent infringement, prompting a stay in AHP’s ANDA, and in late 1996, Schering and AHP began settlement discussions. *Id.* Schering’s first proposal was for AHP to abandon its generic version and instead receive compensation from Schering for promoting K-Dur 20. CX 459; CX 466. In March 1997, AHP rejected the “co-promotion” idea, and proposed instead that Schering “make an appropriate payment” to AHP, in return for which, AHP would “forebear [sic] from entering the market” until “some subsequent time (for example, in 2002),” an offer which Schering eventually accepted with slightly different terms. CX 458; CX 459.

Schering and AHP settled the case in principle in January 1998 and the final agreements were concluded in June 1998. Op. 5. A portion of the settlement covered various product licenses, but it is undisputed that, separately, Schering agreed to pay AHP \$15 million not to market any generic version of Schering’s K-Dur 20 before January 2004. Op. 80 n.101.

## 6. The Commission's Ruling

The Commission first determined that it would not condemn the agreements as *per se* or presumptively unlawful. Op. 10-14. The presence of the patent dispute was “a complicating factor,” the Commission said, and accordingly “the issues cannot be resolved in a summary way.” Op. 14. Rather, the Commission found it “necessary to recognize that patent issues exist,” Op. 14, and to consider possible procompetitive justifications. Op. 13.

The Commission's extensive examination of the agreements under the rule of reason began with a consideration of the particular market context of branded versus generic competition. Citing abundant evidence that entry of generic K-Dur 20 was predicted to, and did, lower prices and take substantial sales away from Schering, and that such entry “was a uniquely significant market event, and recognized as such by both parties,” Op. 19, the Commission found direct proof that delaying generic K-Dur 20 entry would injure competition and consumers. Relying on the established principle that such direct proof of anticompetitive effects obviates the need for indirect, structural market analysis, the Commission held the ALJ had plainly erred in requiring an indirect approach based on “market definition” and a presumption keyed to market shares. Op. 16-17; *see generally* *FTC v. Indiana Federation of Dentists*, 476 U.S. 447, 460-61, 106 S. Ct. 2009,

2018-19 (1986) (“*IFD*”). The Commission accordingly set aside the ALJ’s market findings. Op. 19 & n. 35.<sup>10</sup>

The Commission then considered the agreement in the context of the patent dispute. It began with the observation that it would be reasonable to assume that a settlement between the parties providing for a future entry date without cash payments would reflect the strength of the patent as viewed by the parties. Such a settlement, resulting directly from the perceived exclusionary power of the patent, would not be illegal, the Commission explained. Op. 25-26. Turning to the large cash payments in this case, the Commission reasoned that absent some other consideration for the payments, it would be logical to conclude that Schering was buying more protection from competition than the parties expected from the litigation. The Commission confirmed this inference by examining the plain language of the agreements and the history of negotiations between the parties. Op. 26-27.

The Commission also considered whether a detailed examination of the patent issues within the antitrust case would be a better way to take account of the patent dispute when assessing competitive effects. While acknowledging that in some cases such an inquiry might be warranted, it concluded that in this instance it

---

<sup>10</sup> Schering incorrectly states that the Commission left the ALJ’s market findings “undisturbed.” Schering Br. 29 n.14.

was not. It relied on the same principles articulated by this Court in *Valley Drug*, namely: (1) the agreements should be judged as of the time they were entered, when the outcome of the patent litigation was uncertain; and (2) it would be undesirable to base liability on an after-the-fact adjudication of the patent case, because parties cannot predict how such a retrospective determination by an antitrust tribunal would turn out. Op. 31, 32-35.

The Commission addressed in detail Schering's claim that the \$60 million payment to Upsher was entirely for licenses conveyed under the settlement agreement and not for Upsher's promise to forgo entry. Op. at 39-79. In its comprehensive findings of fact, the Commission relied heavily on contemporaneous business records of the parties, and discounted certain trial testimony as against the weight of the evidence. First, the Commission noted that the terms of the contract made Upsher's agreement to forbear entry a condition of Schering payments. Op. 41-42. Second, it found that pre-agreement evidence demonstrated that the amount and unconditional nature of Schering's payment to Upsher were based on Upsher's demand that it be compensated for anticipated revenues it would forgo by agreeing to delay the launch of Klor Con M20. Op. 42-52. Third, the Commission rejected Schering's principal defense – based on an

internal sales forecast for Upsher's product – that the Upsher licenses were worth \$60 million.

The Commission found that Schering's product review was perfunctory and not consistent with what Schering required in the past to evaluate a similar commercial opportunity, Op. 52-70, and concluded: "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." Op. 79. Moreover, a more thorough, virtually contemporaneous Schering analysis of a comparable product demonstrated that Schering in fact thought these products did not justify a substantial non-contingent payment. Op. 55-60. Finally, the Commission examined evidence of the parties' post-settlement conduct, and found it consistent with the conclusion that Schering did not pay Upsher \$60 million for product licenses. Op. 70-78.

As a final step in the rule of reason analysis, the Commission considered possible procompetitive justifications. Op. 36-39. It acknowledged that certain beneficial effects on competition were "theoretically possible," Op. 13, but found no evidence that those theories applied to the challenged agreements.

Schering's agreement with AHP on its face showed a promise to defer entry in exchange for payments. Following the analytical approach it applied to the

Upsher agreement, and considering once again that the parties were settling a patent dispute with uncertainty about the litigation outcome,<sup>11</sup> the Commission could therefore readily conclude that this agreement was an unreasonable restraint. Op. 80-81.

Having found both agreements unlawful, the Commission vacated the ALJ's decision and entered a prospective order.

### ***Standard of Review***

“The findings of the Commission as to the facts, if supported by evidence, shall be conclusive.” 15 U.S.C. § 45(c). Thus, reviewing courts may not “make [their] own appraisal of the [evidence], picking and choosing ... among uncertain and conflicting inferences.” *IFD*, 476 U.S. at 454, 106 S. Ct. at 2015 (quoting *FTC v. Algoma Lumber Co.*, 291 U.S. 67, 73, 54 S. Ct. 315, 318 (1934)); accord *Foremost Dairies, Inc. v. FTC*, 348 F.2d 674, 676 (5<sup>th</sup> Cir. 1965) (“[I]t is not our function to weigh the evidence or consider the credibility of witness....

Furthermore, reasonable inferences drawn from the facts by the Commission are not to be disturbed”). Rather, “the court must accept the Commission’s findings of fact if they are supported by such relevant evidence as a reasonable mind might accept as adequate to support a conclusion.” *IFD*, 476 U.S. at 454, 106 S. Ct. at

---

<sup>11</sup> Testimony at trial indicated that AHP had raised serious issues regarding Schering’s patent position. Banaker, Tr. 6386-92, 6405-11.

2015-16. This deferential standard also applies to the Commission's findings regarding the economic effects of particular conduct. *Olin Corp. v. FTC*, 986 F.2d 1295, 1297 (9<sup>th</sup> Cir. 1993).

Review of the Commission's legal analysis and conclusions is *de novo*, "although even in considering such issues the courts are to give some deference to the Commission's informed judgment." *IFD*, 476 U.S. at 454, 106 S. Ct. at 2016; accord *Colonial Stores Inc. v. FTC*, 450 F.2d 733, 740 n.14 (5<sup>th</sup> Cir. 1971) ("even when the Commission's findings are framed in terms of legal conclusions, their presumptive validity is considerable").

### **SUMMARY OF ARGUMENT**

This Court recognized in *Valley Drug* that the Hatch-Waxman Act encouraged generic manufacturers to challenge weak or narrow patents, 344 F.3d at 1298, and that the mere assertion of a patent does not excuse all forms of anticompetitive conduct. *Id.* at 1304-05. In this case, after an extensive rule of reason analysis of the record evidence, the Commission found that through these settlements, Schering avoided challenges to its patent and unlawfully obtained a period of freedom from competition, for which it agreed to share a portion of its resulting supracompetitive profits with its rivals.

Schering and Upsher (“petitioners”) insist that these significant payments had nothing to do with delayed generic entry, but instead were “up-front royalties” for licenses obtained by Schering to market various Upsher products. The Commission found as a fact, based on substantial evidence, that the payments were, “in whole or in substantial part, consideration for delay rather than for products licensed from the generic.” Op. 10. Petitioners attempt to re-try this factual issue in this Court, but the Commission is entitled to draw its own inferences and conclusions from the evidence and those conclusions must be upheld even if other conceivable inferences can be proposed. This standard does not change if the Commission disagrees with its ALJ: it is ultimately the Commission’s responsibility to find the relevant facts.

Furthermore, the Commission’s approach is fully consistent with this Court’s direction in *Valley Drug* that the fact finder consider the potential exclusionary power of the relevant patent. Plainly, the Court did not intend that a fact-finder replicate full-blown patent litigation – the *Valley Drug* panel actually had such an analysis available but deemed it irrelevant to the question at hand. How successful the patentee was likely to be in excluding, through the judicial process, the threatened competition can be answered by the actions of the parties themselves, without speculation about the outcome of a now-hypothetical case.

Nor was the Commission positing that the parties would have entered an *alternate* settlement that would have been less anticompetitive: the question was whether *this* settlement produced less competition than was likely to have occurred absent the payments. The Commission’s conclusion that it did has ample support in the record.

Petitioners’ purportedly procompetitive justifications for the agreements are either merely hypothetical with no basis in the facts of this case, or would not excuse an antitrust violation. Moreover, Congress has articulated the relevant policy considerations in the Hatch-Waxman Act, which recognized the value of legitimate patent protection, but also encouraged patent challenges and accelerated market entry of low-cost generic drugs. These objectives are subverted when patent holders buy off potential challengers in order to deter generic entry.

### **ARGUMENT**

#### **I. THE COMMISSION’S FINDINGS ARE DUE A HIGH DEGREE OF DEFERENCE AND THE MERE EXISTENCE OF ALTERNATIVE INFERENCES OR CONCLUSIONS IS INSUFFICIENT TO SET THEM ASIDE**

Congress mandated that the Commission’s findings of fact be “conclusive” if supported by evidence. 15 U.S.C. § 45(c). This Court and its predecessor have long applied this mandate with a high degree of deference to the Commission:

[The Commission is] an administrative agency whose primary function, by explicit Congressional mandate, is the finding of facts. We have consistently reiterated – and we emphasize the point again now – that when Congress has vested in a Federal agency plenary authority to investigate and regulate particular forms of commercial or economic activity, entrusting it with primary responsibility for the resolution of complex and usually sharply disputed factual issues, appellate court review of the exercise of that authority is confined by the narrow perimeter of the substantial evidence rule.

*Colonial Stores*, 450 F.2d at 739 (footnotes omitted). Indeed, only *patently unreasonable* findings may be set aside. *Id.* (“Findings of fact cannot and will not be set aside if the evidence in the record reasonably supports the administrative conclusion, *even though suggested alternative conclusions may be equally or even more reasonable and persuasive*”) (emphasis added); *see also Equifax, Inc. v. FTC*, 678 F.2d 1047, 1052 (11<sup>th</sup> Cir. 1982) (“The fact that two reasonable inferences could be drawn from the evidence does not detract from the Commission’s decision to choose one of those inferences”).

Petitioners’ argument that this high standard of deference is somehow diluted because the Commission disagreed with the ALJ is simply wrong. *See Schering Br. 5*. The Supreme Court has made clear that the substantial evidence standard “is not modified in any way when the [agency] and its [ALJ] disagree.” *Universal Camera Corp. v. NLRB*, 340 U.S. 474, 496, 71 S. Ct. 456, 469 (1951).

In this respect petitioners confuse the standard of review of the Commission's decision in this Court, a highly deferential one, with the *de novo* standard of the Commission's review of the ALJ's findings. Under the Administrative Procedure Act as well as the FTC's own rules, the Commission has *de novo* review authority over initial ALJ decisions and retains the authority to decide both the legal and factual questions in administrative litigation.<sup>12</sup> Thus, the question on review here is not what the ALJ found, but whether the Commission's findings are supported by substantial evidence in the record.

Many of petitioners' arguments on appeal boil down to a mere preference for the ALJ's findings of fact over the Commission's. *See, e.g.*, Upsher Br. 23-24; Schering Br. 61-64. These arguments ignore not only the Commission's role as ultimate fact-finder, but also the Commission's careful explanations of why it rejected certain of the ALJ's findings. In some instances, the ALJ's findings were based primarily on self-serving testimony, disregarding contemporaneous business documents that were clearly contradictory. *See, e.g.*, Op. 54 (discounting direct testimony of Schering witnesses in favor of *their own* prior, contemporaneous

---

<sup>12</sup> 5 U.S.C. § 557(b) (the agency "has all the powers which it would have in making the initial decision"); 16 C.F.R. § 3.54(a) (same); *see generally Hernandez v. Nat'l. Transp. Safety Bd.*, 15 F.3d 157, 158 (10<sup>th</sup> Cir. 1994) (NTSB serves as the ultimate finder of fact, even with respect to credibility determinations); *NLRB v. Bogart Sportswear Mfg. Co., Inc.*, 485 F.2d 1203, 1210 (5<sup>th</sup> Cir. 1973) (NLRB not bound by examiner's credibility determinations).

contact reports, and other written market research questionnaires and reports); Op. 71 (testimony concerning post-deal communications regarding Niacor-SR contradicted by contemporaneous documents). In other instances, the findings were simply not relevant because the ALJ had misconstrued the legal standard. *See, e.g.*, Op. 17 (ALJ improperly rejected direct evidence of anticompetitive effects for lack of “pricing studies”). The ALJ also copied verbatim much of his “Conclusions of Law and Analysis,” including “credibility” determinations, from petitioners’ trial briefs – a practice broadly condemned by reviewing courts. *See Colony Square Co. v. Prudential Ins. Co. of America*, 819 F.2d 272, 274-75 (11<sup>th</sup> Cir. 1987).<sup>13</sup> Even on review of a district court decision, where FRCP 52 applies, the reviewing court may rightly be suspicious of such findings and conclusions, and more readily find that “important evidence has been overlooked or inadequately considered” in such circumstances. *Id.* at 275 n.9.

Moreover, petitioners misconstrue the Commission’s disagreement with the ALJ findings that were ostensibly related to the “credibility” of witnesses. Schering Br. 62-63; Upsher Br. 11. The Commission’s disagreement did not flow from its judgment on the witness’s *truthfulness* – as might perhaps be revealed by demeanor – but from its different view of the *weight* that ought to be accorded to

---

<sup>13</sup> Compare ID 106 (¶ 2-3)-107 with *Upsher Trial Brief* at 1-3 and *Upsher Reply Brief* at 34-35; *see generally Reply Brief of Complaint Counsel* at 3.

the testimony, given the witness's basis of knowledge, consistency with contemporaneous recollection, and prior testimony. *See Kopac v. NLRB*, 668 F.2d 946 (7<sup>th</sup> Cir. 1982) (distinguishing credibility in the broad sense of persuasive force from witness demeanor). *See, e.g.*, Op. 43 (criticizing ALJ's reliance on self-serving testimony "without *weighing* contradictory, and *more reliable*, evidence") (emphasis added); Op. 54 (finding the contemporaneous memorandum of the Schering official in charge of the matter at issue "*more probative than the deposition and direct testimony*" of others) (emphasis added). The ALJ in fact made no findings based on witness demeanor. Op. 8 n.14. His references to "credibility" of evidence were plainly shorthand for "the weight of the evidence."

The Commission's careful treatment of the ALJ's findings distinguishes this case from *Cinderella Career and Finishing Schools, Inc. v. FTC*, 425 F.2d 583 (D.C. Cir. 1970). *See* Schering Br. 62 n.28. Although certain parts of that court's reasoning are questionable, *e.g.*, 425 F.2d at 586-87, the court clearly based its ultimate decision on its view that the Commission was "dismissing the proceedings at the [ALJ] hearing *out of hand*." *Id.* at 588 (emphasis added). As discussed above, that can hardly be said of this Commission decision. *Parker v. Bowen*, 788 F.2d 1512 (11<sup>th</sup> Cir. 1986), is similarly distinguishable. *See* Upsher Br. 11. The *Parker* panel expressly held that the reviewing agency "is not bound by the ALJ's

credibility findings, but when it rejects such findings, it should ordinarily do so expressly, articulating the reasons for its conclusion.” 788 F.2d at 1520. That is exactly what the Commission did in this case.<sup>14</sup>

Thus, the Commission’s findings of fact – even when different from the ALJ’s – were carefully considered, amply supported by the record, and are therefore conclusive.<sup>15</sup>

---

<sup>14</sup> The facts of the other cases cited by the petitioners on the issue of “credibility” highlight their misconstruction of the term in this case. *United States v. Ramirez-Chilel*, 289 F.3d 744 (11<sup>th</sup> Cir. 2002), *cert. denied*, 537 U.S. 1114, 123 S. Ct. 850 (2003), was a criminal case that required the court’s judgment on the *contradictory testimonies* of the officers and the defendant, while *CFTC v. Wellington Precious Metals, Inc.*, 950 F.2d 1525 (11<sup>th</sup> Cir. 1992), concerned civil contempt stemming from an investment fraud and disgorgement order where the contemnor’s *truthfulness* was at the heart of the proceeding. Similarly, petitioners’ invocation of *Equifax*, *see* Upsher Br. 25, is inapposite because of “the peculiar circumstances of [that] case.” 678 F.2d at 1052. The *Equifax* court found that a key Commission inference “flies squarely in the face of *the Commission’s own findings*.” *Id.* (emphasis added). The Commission’s challenged inferences here contradict *the ALJ’s findings*, not with its own.

<sup>15</sup> Schering’s assertion that 12 citations in the Opinion are to matters not in the record, Schering Br. 56 n.26, reflects some confusion. For example, CX 1529 at 101-02 was admitted at Tr. 8625. Similarly, Schering itself read CX 1495 at 96-97 into the record at Tr. 1419-21. More important, even aside from those 12 citations, there is ample support in the record for each of the propositions in the Commission’s opinion for which the referenced materials were cited. *Compare* CX 1508 at 42 *with* Hoffman, Tr. 3563; CX 1529 at 101-02 *with* Troup, Tr. 5439; CX 1532 at 30 *with* CX 1531 at 88-89, CX 1532 at 25-28; CX 1531 at 67-68 *with* CX 1531 at 54, CX 1532 at 17-18; CX 1495 at 128-29 *with* CX 558; CX 1495 at 96 *with* CX 558, CX 577, CX 1484 at 45, 57, 59; CX 1484 at 76-77 *with* Audibert, Tr. 4111; CX 1495 at 123-24 *with* CX 1494 at 84-85; CX 1483 at 109-10 *with* SPX 5; CX 1515 at 103 *with* Lauda, Tr. 4383; CX 1483 at 95-96 *with* Audibert, Tr.

## **II. SUBSTANTIAL EVIDENCE SUPPORTS THE COMMISSION'S FINDING THAT SCHERING PAID UPSHER TO DELAY GENERIC ENTRY**

The primary factual question at issue in this appeal is whether Schering's large payments to Upsher were a *quid pro quo* for the generic competitor's promise to defer introduction of its lower-cost generic version of K-Dur, or whether, as petitioners claim, these payments were entirely up-front royalties for licenses of other products. Based on "the cumulative impact of the extensive record evidence in this case," Op. 41, the Commission rejected petitioners' claim, finding instead a direct nexus between Schering's payments and the agreed entry date of September 2001. *See* Op. 39-79.

### **A. The Commission Found Substantial Evidence That Schering Paid for Upsher's Deferred Entry**

The Commission began its analysis with the parties' agreement. It found that the agreement's express terms indicated "that at least part of the consideration for the \$60 million payment was Upsher's commitment to delay entry." Op. 41. Paragraph 3 of the agreement (which sets forth Upsher's obligation not to market its generic before September 2001, CX 348), is one of the *quids pro quo* for Schering's payments. Schering's own in-house counsel conceded this point at trial. Hoffman, Tr. 3565-67. Moreover, the \$60 million payments were

---

4172-76; CX 1483 at 50-52 *with* Audibert, Tr. 4177-78.

guaranteed. The substantial payments, supposedly for product licenses, were not dependent on the development, regulatory approval, or marketability of these products. Instead, they were tied solely to Upsher's agreement to defer its generic K-Dur 20 entry. If Schering did not pay the \$60 million, then Upsher would be free to market its generic product before the agreed-upon date. CX 348 ¶¶ 3, 12.

Upsher's attempts to construe the agreement differently only highlight the true nature of the contracting parties' deal. Upsher Br. 21-23. As an initial matter, merely calling the payments "upfront royalty payments" cannot alter the true nature of the agreement's *quid pro quo*,<sup>16</sup> especially given the context of this case where Schering was aware of the antitrust risks of the payments. Hoffman, Tr. 3541. Similarly, the fact that the named payor was formally a different corporate entity than Schering is immaterial because the entity, by the terms of the agreement itself, was merely a *designated affiliate* of Schering. CX 348 ¶ 7.

More important, however, Upsher's argument highlights the fact that in reality, Schering did not pay \$60 million for the licenses. Upsher argues that it had additional obligations under the agreement, such as manufacturing. But very few, if any, of those tasks were performed, Op. 71-72, and *none* of them constituted a condition on Schering's payments. CX 348. Indeed, not only did Schering fail to

---

<sup>16</sup> Cf. *Yarn Processing Patent Validity Litigation*, 541 F.2d 1127, 1135-37 (5<sup>th</sup> Cir. 1977) ("royalty" label doesn't alter anticompetitive purpose and effect).

insist on performance, but it continued to make payments – *without any protests* – despite Upsher’s failure to perform and, indeed, its slowdown and eventual cancellation of the Niacor program. Op. 72, 78.<sup>17</sup>

The Commission also relied on substantial evidence from the settlement negotiations that demonstrated that Schering was paying Upsher to compensate it for deferring its generic K-Dur 20 entry, not for product licenses. Op. 44-52.<sup>18</sup> For example, testimony from petitioners’ own witnesses showed that:

- Upsher insisted from the very first negotiation session that any settlement must include cash payments to compensate it for staying off the market, Op. 44; CX 1494 (Driscoll IH) at 65-66; CX 1495 (Driscoll Dep.) at 58-59; CX 1511 (Kapur Dep.) at 19-20; indeed, “throughout the settlement negotiations, Upsher made the connection

---

<sup>17</sup> Niacor was the principal Upsher product in the licensing component of the Schering-Upsher agreement, with the other licenses essentially added for lagniappe. *See* Op. 53 n.83 (summarizing record evidence).

<sup>18</sup> Remarkably, Schering now claims that the Upsher settlement negotiation evidence sheds no light on whether Schering paid Upsher for delay or for product licenses. Schering Br. 56 n. 27. Throughout the administrative hearing, however, Schering’s counsel had argued, in the context of the AHP agreement, that this type of evidence was “crucial,” Tr. 2508, and that examining it was the “central way” to “find out what the parties said about various offers and counteroffers ... what the parties agreed to and what they didn’t agree to.” Tr. 2501-02.

between delayed entry and the payment of money by Schering,” Op. 52;

- the \$60 million amount of Upsher’s demand was specifically tied to what Schering could lose in K-Dur 20 sales if Upsher entered, CX 1494 (Driscoll IH) at 66-67, and to what Upsher expected to lose if it deferred its entry, CX 283; Op. 44; and
- the \$60 million figure could not have been based on the value of any product licenses because that amount was chosen before Schering ever evaluated any of Upsher’s products, Op. 44-45; Lauda, Tr. 4342-43; *see also* CX 1516 (Lauda Dep.) at 40.

Finally, Schering’s memorandum to its Board seeking approval for the transaction confirmed that Schering fully understood that Upsher demanded money “to make up for the income that [Upsher] had projected to earn from sales” of Klor Con M20, and that satisfying this demand was a “prerequisite” to the agreement. CX 338 at SP1200270. Because replacing Upsher’s lost sales was a precondition of any settlement, common sense confirms that Schering paid for more than the Niacor license. If the \$60 million were entirely for Niacor, then the settlement would not have met Upsher’s “lost revenue” requirement for settlement.

The Commission also looked to evidence about what Schering and other companies were willing to pay for a sustained-release niacin product license when such a license was not tied to an agreement to defer generic entry. Op. 53. This evidence showed that, when evaluating the prospects for a stand-alone license, not a single company anywhere offered up-front payments. Op. 65 n.85. Schering had refused to offer any guaranteed money for Niaspan, another sustained-release niacin product, CX 554, and just eight days before the Upsher settlement, it decided to terminate discussions. Op. 60; CX 558. Schering's U.K. subsidiary had no interest in the Niacor license when the benefit of delaying Upsher's marketing of a generic K-Dur 20 was not part of the deal. Op. 73 n.96; USX 595 at USL13152. And more than forty other companies that Upsher approached about Niacor either never responded, rejected the license outright, or refused to offer any up-front money. Op. 48 n.81.

This evidence as a whole establishes that Schering did not pay the \$60 million for the Upsher licenses, but instead used the product licenses to provide an ostensible justification for the payments for an agreed entry date.<sup>19</sup>

---

<sup>19</sup> Upsher complains that "Upsher-Smith's liability under the antitrust laws cannot turn solely upon whether the product rights it was licensing to Schering were worth \$60 million *from Schering's standpoint*." Upsher Br. 17 (emphasis is Upsher's). It did not. Upsher's antitrust liability stems, in fact, from its agreement to delay its market entry in exchange for a portion of Schering's supracompetitive rents. And for its part, the record amply shows that Upsher

**B. Petitioners' Alternative Explanations for the \$60 Million Payments Are Contrary to the Record Evidence**

Petitioners' attempts to re-litigate these factual issues in this Court (including claims that their contentions were "undisputed" or "unrebutted") are seriously off the mark. The Court need only examine a few examples:

**Contention:** Schering's assessment of the Niacor opportunity was consistent with and supported by the analysis of a similar product, Niaspan, that the company had just concluded before the Upsher negotiations. Schering Br. 15, 53, 57.

**Response:** In fact, just eight days before the Upsher settlement, Schering had concluded after an extensive analysis over many months that Niaspan did not "represent a large-enough opportunity in the marketplace" to warrant further investigation or investment. Op. 65; CX 558. Schering's lead negotiator, Martin

---

insisted from the very beginning – before its licenses were even on the negotiating table – that it must be paid *for the lost revenue* that it would incur from its delayed entry. CX 338 (Schering's report to its board of Upsher's insistence on getting paid to compensate it for lost revenue); CX 1495 (Driscoll Dep.) at 58-59 (Upsher's demand for payment came in the initial meeting of May 21, 1997); Troup, Tr. 5420 (possibility of Schering licensing some of Upsher's generic products first raised by Raman Kapur, President of Schering's subsidiary, Warrick, at the May 28, 1997, meeting). Moreover, Upsher was well aware from its lack of success shopping Niacor-SR for European distribution that no buyer was likely to make an up-front payment of \$60 million for this product in a legitimate deal. Op. 48 n.81. But even if the Commission had relied on the buyer's perspective in a valuation analysis, that would not be in the least controversial. *See, e.g., Froelich v. Senior Campus Living LLC*, 355 F.3d 802, 813 n.5 (4<sup>th</sup> Cir. 2004).

Driscoll, explained that in light of the growth of statins as a treatment option, “*Niaspan’s market opportunity is narrowing even prior to its introduction*”. CX 558 at 2720 (emphasis added). Kos Pharmaceuticals’ Niaspan had an almost identical pharmacological profile to Upsher’s Niacor,<sup>20</sup> but from the start of its investigation of Niaspan, Schering questioned the product’s safety and efficacy. *E.g.*, CX 1484 (Audibert Dep.) at 39-40; *see* Op. 56-59 (summarizing record evidence). Schering requested but did not receive additional data on safety and efficacy. CX 1484 (Audibert Dep.) at 1-4, 12-25; CX 558 at SP002719. Schering conducted its own market research, which confirmed the limitations of niacin products such as Niaspan and Niacor. CX 576; Op. 58-59.

If anything, Niacor presented an even riskier opportunity than Niaspan. As Upsher’s own economic expert acknowledged, “more than in most other industries, there is a substantial risk that any particular product in the pipeline at any time won't get into the market.” Kerr, Tr. 6316. Niaspan’s FDA medical review had been completed, and Kos was down to discussing labeling with the FDA at the time negotiations with Schering started. CX 543; Audibert, Tr. 4102-05. Niacor’s

---

<sup>20</sup> *See* Op. 61-62 (comparing clinical data of the two products). The comparison shows Niaspan and Niacor are clinically comparable. Both are sustained-release niacins which Schering was interested in as complementary agents to statins, the primary compounds used to treat high cholesterol. CX 1494 (Driscoll IH) at 8-24.

FDA application, on the other hand, had not even been filed when Schering and Upsher executed their agreement. Prospects for the product were dependent, of course, on FDA approval. Thus, Niacor faced even greater hurdles than Niaspan – and Schering knew that when it entered the Upsher agreement.

Similarly, Schering's attempt to equate Niaspan's projected market (U.S.) with Niacor's (mainly Europe), Schering Br. 58-59, is undermined by the *contemporaneous documentary* evidence. The reports of the Niaspan negotiations revealed that Schering (and Kos) viewed the European and Japanese markets for sustained-release niacins as limited. *See, e.g.*, CX 1470 at SP002748; Op. 58, 66-67. Schering's own market research confirmed that the European market preferred fibric acids to niacins. Op. 59; CX 576 at SP020710. That view was confirmed by the lack of interest from European companies, including one of Schering's own European subsidiaries, which had already rejected offers for Niacor directly from Upsher. USX 595 at USL13150. *See also* CX 854, CX 857, CX 875.<sup>21</sup>

The investigation of Niaspan was actually never completed and significant additional information would have had to be considered, such as a review of patent

---

<sup>21</sup> Moreover, Schering's statement that "the worldwide cholesterol market Schering acquired rights to was as big as, or bigger than, the U.S. market" is misleading. Schering Br. 58. The relevant market is not the one for cholesterol-reducing drugs *in general*, but rather the specific market for *sustained-release niacins*, such as Niaspan and Niacor.

status, regulatory labeling, manufacturing capabilities, and product liability. CX 546 at SP002770. Schering had seen enough, however, to refuse to offer any money up-front for Niaspan. Op. 60; CX 1495 (Driscoll Dep.) at 122; CX 554.

In contrast, Schering's consideration of Upsher's Niacor was, at best, cursory. *See* Op. 61-69 (summarizing record evidence). Audibert completed his work in a "little bit more" than a day. Audibert, Tr. 4164. *See* Op. 62-64 (summarizing methodology). Schering conducted this assessment without any of the due diligence it ordinarily requires when evaluating a licensing opportunity (*e.g.*, patent status, finalized labeling, product liability), *see* CX 546, and without resolving the safety and efficacy issues which Niacor shared with Niaspan. *See* Op. 61-62, 66. Nevertheless, Schering committed to make \$60 million in unconditional up-front payments, significantly more than it had *ever* committed up-front in a license, only days after rejecting Niaspan, for a product with comparable clinical limitations, riskier prospects for FDA approval, and a less desirable commercial market. Op. 59-60.

**Contention:** The \$60 million figure was based on the parties' internal forecasts concerning Niacor and the market valuation of Kos based on Niaspan. Schering Br. 53-64; Upsher Br. 20, 27, 29.

**Response:** That figure was already on the table before any “side deal” entered the discussions, based on Upsher’s demand for payment for “lost revenue.” Op. 44-45; CX 1494 (Driscoll IH) at 65-66 and CX 1495 (Driscoll Dep.) at 58-59 (Upsher’s demand for payment came in the initial meeting of May 21, 1997); Troup, Tr. 5413-14, 5416-17, 5420 (possibility of Schering licensing some of Upsher’s generic products first raised by Schering at May 28, 1997, meeting). This demand was based both on an assessment of Schering’s potential lost K-Dur 20 profits as well as Upsher’s projected lost sales of Klor Con M20. Op. 44.<sup>22</sup> This target, in turn, was passed on to Thomas Lauda, who was ultimately responsible for the valuation of Niacor. Lauda testified he was told that the negotiators “were looking to have a value of about \$60 [million].” CX 1516 (Lauda Dep.) at 40; CX 1515 (Lauda IH) at 85-86; Op. 61.

Without purporting to confirm or reject Audibert’s sales projections, the Commission could nevertheless readily find that this analysis did not support a corporate decision to put \$60 million down for Niacor. Op. at 40. The limitations

---

<sup>22</sup> The \$60 million equaled approximately 8 months of Schering’s profits, Bresnahan, Tr. 607-08; *see also* Tr. 532-33, but four years of Upsher’s forecasted lost profits. CX 283. These facts illustrate the fundamental economic incentives at play: the incumbent can well afford to compensate would-be competitors for sitting back and not upsetting the status quo. For this reason the Commission gives close scrutiny to settlement agreements that provide for substantial payments from the pioneer drug manufacturer to the generic competitor.

of a straight sales projection are manifest.<sup>23</sup> Neither Audibert nor anyone else at Schering analyzed or incorporated the risks involved in purchasing the rights to Niacor. Among other things, neither Audibert nor anyone else at Schering evaluated the likelihood of Niacor's obtaining regulatory approval in the United States or in Europe, or whether Upsher could in fact grant Schering an exclusive license outside the United States. Op. 69-70.

Audibert's calculations, which were the only forecast in support of Schering's payments, predicted losses for the first five years of the deal. CX 338. His positive valuation of Niacor depended entirely on the profits generated in the later years, those most difficult to forecast. Mr. Lauda himself explained that such a forecast has little use in determining whether to license a product, let alone how much to pay for it: "Well, you know, if I'm losing money the first five years, I may not want to do the deal anyway, because my risk is I'm going to make money ten years from today." CX-1515 (Lauda IH) at 105.

As for Upsher, after one optimistic forecast in March 1994, the five most recent Upsher projections in 1996 and 1997 estimated annual Niacor sales at no

---

<sup>23</sup> A sales forecast (particularly for a product in development) is "a lot of guess work," CX 1494 (Driscoll IH) at 42-43, depends heavily on assumptions, and is only "part of the economic profile of the [licensing] opportunity." CX 1550 (Poorvin Dep.) at 79. Licensing decisions are based on "a lot of reasons," CX 1515 (Lauda IH) at 106 – a sales forecast being but "*one of the many considerations that are used.*" CX 1550 (Poorvin Dep.) at 79 (emphasis added).

more than \$25 million. CX 234 at USL12785; CX 321 at USL 05248; CX 322 at USL05287; CX 778 at USL15531; CX 1094 at USL11935; *see also* Troup Tr. 5533-541.

**Contention:** The Schering Board was asked to approve the Niacor license only if it was sufficiently valuable to Schering apart from the litigation settlement agreement (which specified a generic entry date). Schering Br. 15, 61.

**Response:** Not so. In fact, in the memorandum to the Board seeking approval of the agreement, Schering's managers told the Board that the agreement's payment terms were dictated by Upsher's insistence on a guaranteed "income stream to replace the income that Upsher-Smith had anticipated earning" and now expected to forgo by agreeing to stay off the market until 2001. CX 338 at SP1200268; Op. 44 n.78. The sentence in the Board memorandum cited by Schering merely recounts what Schering purportedly told Upsher during the negotiations ("... we informed them that any such deal should stand on its own merit independent of the settlement"). CX 338 at SP1200268. The Board members never saw a copy of the agreement and had no independent basis for evaluating the Niacor license, assuming instead (incorrectly) that management had done the necessary due diligence. CX 1485 (Becherer Dep.) at 13-14, 34, 40-41.

Schering management withheld critical information from the Board – in particular, that Schering’s U.K. subsidiary had previously rejected an opportunity to license Niacor. *See* Op. 48 n.81, 78 n.96; USX 595 at USL13150. At least one director thought that information was relevant. CX 1485 (Becherer Dep.) at 32-33.

**Contention:** The reason Schering and Upsher never proceeded to bring Niacor to market was the poor showing of Kos’s product Niaspan after the parties executed their settlement agreement. Schering Br. 20, 60; Upsher Br. 28-29.

**Response:** Schering had *already* discounted Niaspan’s chances in the course of its own analysis of the product – this was one of the primary reasons Schering itself discontinued negotiations with Kos. CX 558; Op. 60, 78 n.100. Indeed, Schering showed little interest in pursuing Niacor after signing the agreement with Upsher. Op. 71, 78. Upsher, for its part, had already begun to shut down work on Niacor, without telling Schering, before the Kos results were announced. *See* Op. 70-73; Lauda, Tr. 4377-78; CX 963 at 12581-83; CX 1357. Upsher explained to Schering on October 6, 1998, that its abandonment of Niacor was based “[f]irst and foremost” on concerns the FDA had raised concerning a pharmacokinetic study for Niacor. CX 1111.

### III. IT IS UNDISPUTED THAT SCHERING PAID AHP IN EXCHANGE FOR THE LATTER'S DELAYED ENTRY TO THE MARKET

The Schering agreement with AHP delayed the entry of AHP's generic product until 2004. Here too, Schering entered a side agreement that purported to license from AHP certain products in exchange for payments of \$15 million. Op. 80 n.101. Schering conceded, however, that it paid another \$15 million to induce the settlement, \$5 million up-front and another \$10 million for the agreed entry date, contingent only on the FDA approval of the *AHP generic version* of K-Dur. *Id.* The FDA approval was obtained and the \$10 million was paid. *Id.* There is no question here, therefore, that Schering paid at least \$15 million simply to induce AHP's delay of market entry until 2004.

Here again, as in the Upsher case, Schering seriously misstates the record in its attempt to engage this Court in re-litigating factual issues. Schering claims, for example, that it had an extremely strong patent case against AHP, and that its evidence in this regard was unrebutted. That is wrong. Complaint Counsel *did* have a qualified witness, Dr. Banaker, who *did* testify on the claim interpretation question. *E.g.*, Tr. 6387-89. He agreed with the positions articulated by AHP's experts in the underlying patent case that there was no infringement, and disagreed with the opinions of Mr. Miller and Dr. Banker, Schering's experts in this case. *Compare* Tr. 6387-92 *with* Tr. 6399, 6405, 6472 (*in camera*), 6477 (*in camera*),

6479 (*in camera*), 6485-86 (*in camera*). Moreover, it is apparent from Schering's own exhibit that the judge in the underlying patent case did not believe that Schering had an especially strong case. *See generally* SPX 687 at ESIHRG000127. Even Schering's expert, Mr. Miller, conceded that the judge had commented that the patent could be invalid if it were read as broadly as Schering was advocating. Miller, Tr. 3388-89.

Thus, substantial record evidence supports the Commission's conclusion that Schering made sizable payments to AHP – as it did to Upsher – to delay its entry to the market with a generic equivalent of K-Dur.

#### **IV. THE COMMISSION PROPERLY APPLIED A RULE OF REASON ANALYSIS TO CONCLUDE THAT SCHERING PAID ITS COMPETITORS NOT TO COMPETE**

The Commission's approach to this case was entirely consistent with *Valley Drug*. Both the Commission and the *Valley Drug* panel recognized that the presence of a patent makes *per se* treatment inappropriate. This Court did not purport to define for all cases the method of assessing the "exclusionary power" of the applicable patent, but it observed that the size of the "exit" payments or other circumstances might well "raise[] suspicion that the parties lack[ed] faith" in the strength of their patent. 344 F.3d at 1309-10; *see also id.* at 1308. On the scant

record in that case, the Court found it inappropriate to draw inferences from the size of the payments alone.

The present case is the case foreshadowed by *Valley Drug*. This Court was suspicious of payments to potential competitors but sought additional information – just as the Commission was, and did, in the present case. Such payments can be used to share the supracompetitive returns that would flow when potential competitors defer market entry, thus resulting in less competition than would likely occur absent the payments.<sup>24</sup> On the basis of a fully-litigated record, the Commission was able to conclude that the guaranteed delay in generic entry here did *not* flow from the exclusionary power of Schering’s patent but rather from payments not to compete.

---

<sup>24</sup> See, e.g., Herbert Hovenkamp et al., *Anticompetitive Settlement of Intellectual Property Disputes*, 87 Minn. L. Rev. 1719, 1749-51 (2003); Maureen A. O’Rourke & Joseph F. Brodley, *An Incentives Approach to Patent Settlements: A Commentary on Hovenkamp, Janis and Lemley*, 87 Minn. L. Rev. 1767, 1781-82 (2003); Thomas F. Cotter, *Refining the “Presumptive Illegality” Approach to Settlements of Patent Disputes Involving Reverse Payments: A Commentary on Hovenkamp, Janis & Lemley*, 87 Minn. L. Rev. 1789, 1800-01 (2003); Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 RAND J. Econ. 391, 407-08 (2003).

**A. A Patentee’s “Exclusionary Right Cannot be Exploited in Every Way”<sup>25</sup>**

The Supreme Court has repeatedly held that concerted actions to eliminate or reduce market competition are illegal restraints of trade, whether through market allocation agreements, *e.g.*, *Palmer v. BRG of Georgia, Inc.*, 498 U.S. 46, 111 S. Ct. 401 (1990) (*per curiam*); or by paying a competitor to stay off the market, *e.g.*, *Addyston Pipe & Steel Co. v. United States*, 175 U.S. 211, 20 S. Ct. 96 (1899). After all, “[t]he anti-trust laws are as much violated by the prevention of competition as by its destruction.” *United States v. Griffith*, 334 U.S. 100, 107 S. Ct. 941 (1948), *overruled on other grounds*, *Copperweld Corp. v. Independence Tube Corp.*, 467 U.S. 752, 104 S. Ct. 2731 (1984).<sup>26</sup>

Furthermore, agreements to keep competition out of the market have been condemned even if the entrant’s prospects for successful entry are not assured. *E.g.*, *Blackburn v. Sweeney*, 53 F.3d 825 (7<sup>th</sup> Cir. 1995) (unlawful for attorneys to

---

<sup>25</sup> *Valley Drug*, 344 F.3d at 1304.

<sup>26</sup> Ordinarily, these agreements “are thought so inherently anticompetitive that each is illegal *per se* without inquiry into the harm it has actually caused.” *Copperweld*, *supra*, 467 U.S. at 768, 104 S. Ct. at 2740. As discussed below, the Commission concluded, however, that “*per se*” condemnation is inappropriate in this case. Regardless of the terminology, “[t]he analytic focus should be on what conclusions regarding the competitive impact of a challenged restraint can confidently be drawn from the facts demonstrated by the parties.” *Valley Drug*, 344 F.3d at 1304 (citations omitted).

agree not to advertise in one another's cities); *Engine Specialties, Inc. v. Bombardier Ltd.*, 605 F.2d 1 (1<sup>st</sup> Cir. 1979) (unlawful for maker of snowmobiles and maker of minicycles to agree that the former would not enter the latter's market).<sup>27</sup> As the leading antitrust treatise put it, "the law does not condone the purchase of protection from uncertain competition any more than it condones the elimination of actual competition." XII Phillip E. Areeda, Herbert Hovenkamp, *Antitrust Law* ¶ 2030b at 175 (1999) (hereinafter "*Areeda & Hovenkamp*"). See also *Microsoft*, 253 F.3d at 79 ("it would be inimical to the purpose of the Sherman Act to allow monopolists free reign to squash nascent, albeit unproven, competitors at will").

An allegation of patent infringement creates such uncertainty because a patentee's right to exclude others is – like any other property right – not absolute. See Shapiro, *supra* note 24, at 395. As this Court emphasized in *Valley Drug*, patent litigation is increasingly complex and highly uncertain. 344 F.3d at 1308 &

---

<sup>27</sup> The prospects for successful entry may be a factor in establishing damages, but this case concerns only antitrust liability. See *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100, 130, 89 S. Ct. 1562, 1580 (1969) (Section 16 of Clayton Act authorizes injunctive relief "upon the demonstration of 'threatened' injury. That remedy is characteristically available even though the plaintiff has not yet suffered actual injury") (footnotes omitted), *rev'd on other grounds*, 401 U.S. 321, 91 S. Ct. 725 (1971); *Andrx Pharms., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 806, 808 (D.C. Cir. 2001) (plaintiff need establish only threat of injury for injunctive relief standing); *United States v. Microsoft Corp.*, 253 F.3d 34, 79-80 (D.C. Cir. 2001) (*per curiam*) (distinguishing liability from remedies).

n.20. The fact that a patent has been issued by the Patent & Trademark Office (“PTO”) is no guarantee that the courts will uphold its validity, despite the statutory presumption of validity. *See* Op. 30-31. Nor can it be said with any certainty that a court will find that an allegedly infringing product actually infringes – a matter on which the patent holder has the burden of proof. As commentators have explicated, *and the experts on both sides in this case agreed*, a patent’s exclusionary power is *probabilistic* in nature.<sup>28</sup>

Thus, it is incorrect to start, as petitioners do, from the premise that the patentee could exclude all competitors for the term of the patent. As petitioners’ expert acknowledged, a settlement agreement can be anticompetitive even if it results in entry before the end of the patent term. Willig, Tr. 7243.

A patentee has the right to try to exclude allegedly infringing products by instituting a lawsuit – or even by merely threatening a lawsuit. *Zenith Radio, supra*, 395 U.S. at 135, 89 S. Ct. at 1583 (“The heart of [a patentee’s] legal monopoly is the right *to invoke the State’s power* to prevent others from utilizing his discovery without his consent.”) (emphasis added). But the exercise of that right is entirely different from a patent holder’s decision to avoid risking its patent

---

<sup>28</sup> *See, e.g.*, Shapiro, *supra* note 24, at 395; *see also* Bresnahan, Tr. 522-23; Willig, Tr. 7243.

and buying off a potential challenger by an agreement to share supracompetitive returns.<sup>29</sup>

Courts have long held, accordingly, that a settlement may be unlawful if the patent holder obtains “protection from competition which the patent law, unaided by restrictive agreements, does not afford.” *United States v. Masonite Corp.*, 316 U.S. 265, 279, 62 S. Ct. 1070, 1078 (1942). Thus, the owner of a patent “cannot extend his statutory grant by contract or agreement.” *Id.*, 316 U.S. at 277, 62 S. Ct. at 1077; *see also Singer*, 374 U.S. at 196-97, 83 S. Ct. at 1785; *United States v. Line Material Co.*, 333 U.S. 287, 308, 68 S. Ct. 550, 561 (1948); *Ethyl Gasoline Corp. v. United States*, 309 U.S. 436, 456, 60 S. Ct. 618, 625 (1940).

Thus, as a matter of law and economics, the relevant inquiry is whether this settlement provided less competition than would have been *expected* absent the

---

<sup>29</sup> In an often-cited concurrence in *United States v. Singer Mfg. Co.*, Justice White found a *separate* antitrust violation in “the *collusive termination of a Patent Office interference proceeding* pursuant to an agreement between Singer and [its Swiss competitor].” 374 U.S. 174, 197, 83 S. Ct. 1773 (1963) (White, J., concurring) (emphasis added). The parties entered the agreement, wrote Justice White, “to help one another *to secure as broad a patent monopoly as possible, invalidity considerations notwithstanding.*” *Id.* (White, J., concurring) (emphasis added). Justice White pointed out that “the desire to secure broad claims in a patent may well be unexceptional – *when purely unilateral action is involved,*” but does not justify the collusive agreement to terminate a PTO interference proceeding. 374 U.S. at 199 (emphasis added). Thus, that Schering *might have* won its patent litigations and therefore *unilaterally* precluded Upsher and AHP from entering the market does not justify paying off those competitors to *guarantee* that they remain off the market.

payments. Viewed in this light, Schering's payments to Upsher and AHP *increased in real economic terms* the chances that Schering would be able to exclude Upsher or AHP from entering the market with their competing products. For Schering could then rely not only on its patent's exclusionary power – however strong or weak it may be – but also on the agreements' more certain exclusionary terms that precluded Upsher's entry before September 2001, and AHP's entry before January 2004. Schering thus obtained *additional* ability to exclude Upsher and AHP, not from its patent rights, but rather from *the contractual rights for which it paid* tens of millions of dollars.

**B. The Commission Considered the Exclusionary Power of Schering's Patent, Consistent with *Valley Drug***

Contrary to petitioners' assertions, the Commission properly took into consideration the Schering patent's exclusionary power. Petitioners' assertions apparently are rooted in the mistaken assumption that the exclusionary power of a patent can *only* be assessed by a plenary trial on the issues of patent validity and infringement, including possibly a *Markman* hearing to decide the patent claims' construction.<sup>30</sup> That is simply not true.

---

<sup>30</sup> See *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 116 S. Ct. 1384 (1996).

The Commission’s consideration of the exclusionary power of Schering’s patent began with the simple but fundamental principle that, short of a final court judgment on the issue, the parties’ collective expectation of the outcome of their litigation – as reflected in a genuine, arms-length settlement – represents the most accurate assessment of the subject patent’s exclusionary power. The parties’ litigations in this case would have fixed *only* the time of entry of the alleged infringers, because no money damages were at issue.<sup>31</sup> Therefore, a *hypothetical no-payment compromise* on the entry date would most accurately reflect their collectively expected outcome of litigation – i.e., the exclusionary power of Schering’s patent.<sup>32</sup> See Hovenkamp, *supra* note 24, at 1762.<sup>33</sup>

---

<sup>31</sup> This is common in the context of patent litigation under the Hatch-Waxman Act because the alleged infringer there (*i.e.*, the ANDA applicant) need not enter the market in order to challenge the referenced patent. See *Mylan Pharms., Inc. v. Shalala*, 81 F. Supp. 2d 30, 32 (D.D.C. 2000) (filing of ANDA with Paragraph IV Certification “automatically creates a cause of action for patent infringement”).

<sup>32</sup> Although factors such as the parties’ risk aversion and information asymmetry may, *in theory*, affect whether the parties’ settlement reflects their true expected outcome of litigation, there was no record evidence in this case that those factors played a role in shaping the parties’ agreements.

<sup>33</sup> Contrary to Schering’s and *amicus* Generic Pharmaceutical Association’s (“GPHA”) assertions, the Commission did not assume that “absent the payment, there would have been a different settlement with an earlier entry date.” Schering Br. 44, 52-53; GPHA Br. 19-25. Nor did the Commission assume that the parties could have replaced Schering’s payments with a license. GPHA Br. 4, 26. The comparison that the Commission undertook was between the parties’

Thus, any payment provision in the settlement agreements – beyond the expected savings in litigation costs<sup>34</sup> – will affect the compromise entry date in one direction or another: a payment from the alleged infringer to the patent holder – *i.e.*, a royalty – would be made to gain an earlier entry than a compromise on the date alone. A payment of this kind is unremarkable and indisputably within the limits of a patent’s exclusionary power. A payment in the opposite direction, however – a so-called “reverse payment” – purchases a *later* time of entry than a compromise on the date alone. A patentee would not make a substantial payment if it believed it could exclude the competition for that period solely on the basis of its patent. *Areeda & Hovenkamp, supra*, ¶ 2046 at 349-50 (2004 Supp.). This much more unusual form of payment, *id.* at 338, raises serious antitrust concerns because its effect is to *extend* the patent holder’s expected exclusionary rights, *see Singer*, 374 U.S. at 197 (White, J., concurring); and to delay the entry of low-cost

---

*actual* settlement terms and their expected litigation outcome, *not* with another settlement that the parties would or should have entered. *See* Op. 26 (citing Bresnahan, Tr. 614).

<sup>34</sup> The expected savings in the cost of litigation represent merely the transaction costs of litigation versus settlement and, therefore, do not affect the substantive merits of the dispute (*i.e.*, the expected outcome of litigation). *See Hovenkamp, supra* note 24, at 1750-51.

competitive alternatives.<sup>35</sup> The Commission’s opinion summarizes this sound logic in the following words:

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.

\* \* \*

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, 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.

Op. 25-26 (footnotes & citations omitted).

The foregoing does *not* mean, however, that the Commission condemned Schering’s agreements *solely* because the patentee made a payment to the alleged infringers. In fact, the Commission was careful to emphasize that its analysis did not militate “that all such payments should be viewed as *per se* illegal or ‘inherently suspect.’” Op. 29. Although the Commission viewed the so-called

---

<sup>35</sup> See *Andrx Pharms.*, 256 F.3d at 809 (patentee’s payment to alleged infringer may strongly suggest an anticompetitive agreement) (citing David A. Balto, *Pharmaceutical Patent Settlements: The Antitrust Risks*, 55 Food & Drug L.J. 321, 335 (2000)).

“reverse payments” as raising a “red flag,”<sup>36</sup> that simply meant “a further inquiry” was warranted – an inquiry which the Commission carried out thoroughly. Op. 29.

In this case, there was ample record evidence to support the Commission’s conclusion that the parties expected generic competition to K-Dur 20 well before the agreed entry date, and that the parties negotiated an exchange of money for Upsher’s and AHP’s delayed entry. CX 118; CX 123; CX 150; CX 234; CX 750. In fact, Upsher had represented to the court hearing the patent litigation that the only impediment to its immediate entry was the automatic Hatch-Waxman stay. Op. at 34; Kerr, Tr. 6744-45; CX 1706 at USLPLD004262, 4271 (*in camera*); CX 1705 (*in camera*). As described above, moreover, the Commission found from the parties’ documents and negotiating history that Schering’s payments were in large part consideration for the agreed entry dates and not for more benign purposes.

Moreover, the evidence of the likely and actual impact of generic K-Dur entry allowed the Commission to assess how easy it was for Schering to avoid Upsher’s competition through their agreement. While the *Valley Drug* panel wondered how the payment in that case compared to the parties’ expected lost profits, *see* 344 F.3d at 1310, the Commission in this case was able to answer that question. Schering’s payments were designed to replace Upsher’s lost profits, were

---

<sup>36</sup> This term means essentially the same thing as this Court’s reference to a “suspicion” in *Valley Drug*. 344 F.3d at 1309-10.

calculated based on Upsher's expected lost revenue, and were significantly less than the losses Schering expected from generic competition. In short, Schering made an offer that, regardless of the strength of Schering's patent claim, Upsher could not refuse. *See* note 22, *supra*.

The Commission in this case, for good reasons, did not purport to make an express evaluation of the merits of the underlying patent dispute. Op. 29-35. But that is not the same as ignoring the patent's exclusionary power. Indeed, this Court in *Valley Drug* had before it a final court ruling on the validity of Abbott's patent, but deemed it irrelevant to the antitrust analysis. 344 F.3d at 1306-07 (because agreements are to be judged *ab initio*, "the mere subsequent invalidity of the patent does not render the patent irrelevant to the appropriate antitrust analysis"). This Court's *Valley Drug* decision did not mandate that an antitrust tribunal make the sort of plenary assessment of the underlying merits of the patent dispute that would occur in a patent infringement suit.<sup>37</sup> The method of analyzing the patent's

---

<sup>37</sup> It bears noting here that this Court's decision was focused on the narrow question of whether the challenged agreements – which involved *admittedly infringing* products – should be condemned summarily as illegal *per se*. This Court held that they should not be because they involved patent rights. The Court described its own holding as "appropriately narrow" because it came at an "early stage of the litigation," when many of the critical facts had not yet been established by the district court. *Valley Drug*, 344 F.3d at 1306, 1310. In contrast, the Commission benefitted from a fully developed trial record that established all the facts necessary for its rule of reason analysis and decision.

exclusionary power was left to the district court on remand. Thus, in this case, to the extent assessing the Schering patent's exclusionary power could be made by less speculative means, the substantive issues of the underlying patent dispute need not be tackled.

The Commission's considered approach stands in sharp contrast to that of the *Valley Drug* district court, whose decision lacked *any* consideration of Abbott's patents. The district court had simply characterized the two Abbott agreements as geographic market allocations between horizontal competitors, and declared them *per se* illegal. *Terazosin Hydrochloride Antitrust Litig.*, 164 F. Supp. 2d 1340 (S.D. Fla. 2000). It did not recognize Abbott's status as a patentee or of the effect of its patent rights on the appropriate antitrust analysis. *Valley Drug*, 344 F.3d at 1306. It also rejected out of hand the argument that because the challenged agreements were analogous to patent settlements, they should be subjected to rule of reason antitrust analysis. *Terazosin*, 164 F. Supp. 2d at 1353. This Court's proper rejection of that *per se* decision provides no basis for overturning the Commission's ruling, which expressly rejected a *per se* standard and which took the patent context into account in its rule of reason analysis.

### **C. Direct Record Evidence of Anticompetitive Effects Obviates the Need for Indirect Product Market Analysis**

Petitioners complain that the Commission ignored the ALJ’s findings and conclusions to the effect that Complaint Counsel failed to prove a relevant product market and market power. Upsher Br. 42-44. The Commission rejected the ALJ’s view that it was a fatal flaw for Complaint Counsel not to prove their case in the most common way – by defining the “relevant product market” and calculating the various market shares – and for good reason. The Initial Decision failed to take account of the well-established principle that where direct evidence of anticompetitive effect is available, there is no need to engage in the conventional product market analysis. *IFD*, 476 U.S. at 461, 106 S. Ct. at 2019 (“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*”) (emphasis added) (footnotes omitted). *See Palmer v. BRG of Georgia, Inc.*, 874 F.2d 1417, 1437 & n.27 (11<sup>th</sup> Cir. 1989) (Clark, J., dissenting) (“[b]ecause they have shown anticompetitive effects, the plaintiffs would not have to establish a relevant market or that the defendants had market power”), *rev’d*, 498 U.S. 46, 111 S. Ct. 401 (1990) (*per curiam*).<sup>38</sup>

---

<sup>38</sup> *See also 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 of elusive market share figures”); *Toys*

Nor does the lack of “pricing studies,” which had been cited by the ALJ as precluding proof of direct anticompetitive effects, undermine the Commission’s analysis or conclusion, especially when multiple studies confirm what the Commission found here: the first generic entrant takes substantial sales from its branded counterpart at a much lower price. Op. 21-22 (collecting studies). As the Supreme Court stated in *Indiana Federation of Dentists*, when a particular practice “is likely enough to disrupt the proper functioning of the price-setting mechanism of the market ... it may be condemned even absent proof that it resulted in higher prices.” *IFD*, 476 U.S. at 461-62, 106 S. Ct. at 2019. The Commission noted that the justification for use of direct evidence in the absence of pricing evidence is even stronger here 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.” Op. 17. Thus, the Commission’s reliance on direct evidence of anticompetitive effects in lieu of indirect market analysis is consistent with well-established precedent.

---

“R” *Us v. FTC*, 221 F.3d 928, 937 (7<sup>th</sup> 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) (“‘market share is just a way of estimating market power, which is the ultimate consideration,’ and ... ‘when there are better ways to estimate market power, the court should use them’”) (quoting *Ball Mem’l Hosp., Inc. v. Mutual Hosp. Ins., Inc.*, 784 F.2d 1325, 1336 (7<sup>th</sup> Cir. 1986)).

Moreover, there is ample evidence in the record of the agreements' actual anticompetitive effects. Generic entry, the record evidence showed, was a uniquely significant market event for Schering's K-Dur 20. Due to various regulatory and industry factors, the entry of Upsher's generic drug was expected to *and did* cause Schering a *rapid and substantial* loss in the sales volume of K-Dur 20 in favor of the lower-priced generic substitute.<sup>39</sup> Within two months of Upsher's entry, Schering's K-Dur 20 lost more than half its sales to Klor Con M20. *See* Op. 19-23 (summarizing record evidence). The price of the generic, moreover, was approximately 50% of K-Dur 20. Bresnahan, Tr. 474; Rosenthal, Tr. 1559; *see also* CX 1490 (Coleman Dep.) at 26-27 (price of Upsher's Klor Con M20 was approximately 50% less than K-Dur 20); CX 1511 (Kapur Dep.) at 137-138 (Schering's own generic was priced at 40-45% of K-Dur 20). The day of

---

<sup>39</sup> Klor Con M20 would have been – and in September 2001 became – the first “AB-rated” generic counterpart to Schering's K-Dur 20. In other words, it was considered by the FDA to be “bioequivalent” to – and thus substitutable for – its referenced brand-name drug. Hoffman, Tr. 2278; Teagarden, Tr. 197. Most state laws permit a pharmacist to substitute an AB-rated generic drug for its brand-name counterpart, unless directed otherwise by the prescribing physician. Hoffman, Tr. 2278; Teagarden, Tr. 197-98; CX 1493 (Dolan Dep.) at 81; Schering Answer ¶ 18. Some states mandate such substitution if not directed otherwise by the physician. Bresnahan, Tr. 1178; Addanki, Tr. 5998. Moreover, the policies of Medicaid and managed care plans also encourage generic substitution. CX 18 at SP2300044; Goldberg, Tr. 122-24.

reckoning that Schering was able to forestall through these agreements was indeed a devastating one.

As shown above, there was ample evidence in the record – both from historical experience as well as from the actual effects of Upsher’s entry in 2001 – of the anticompetitive effects of the challenged agreements.<sup>40</sup> As discussed below, what was missing in the record, however, was any empirical evidence of the procompetitive effects of those agreements.<sup>41</sup>

---

<sup>40</sup> Although there can be no serious argument on these points, petitioners attempt to obfuscate the issue. Schering’s artful attempt to misconstrue the requirements of *California Dental Association v. FTC*, Upsher Br. 53, is readily exposed, however, by the express language of the Court. 526 U.S. 756, 775 n.12, 119 S. Ct. 1604, 1615 n.12 (1999). The reference to “empirical evidence” in the cited footnote is to the “evidence of *procompetitive* effects” that *petitioners* here must carry – not to Complaint Counsel’s burden of showing the *likely* anticompetitive effects of the agreements. *Id.* (emphasis added). Similarly, the Court’s query “whether the effects *actually* are anticompetitive” refers to the *nature* of the likely effects, rather than to empirical evidence of their existence. *Id.* (emphasis is Schering’s).

<sup>41</sup> Upsher proposes the odd proposition that the Commission should have to find anticompetitive effects of its delayed entry into the market without reference to what happened when Upsher actually did enter the market. *See* Upsher Br. 50. On the contrary, such evidence is highly probative of the competitive conditions the parties preempted through a sharing of supracompetitive profits. *See* ABA Section of Antitrust Law, *Antitrust Law Developments* at 877 (5<sup>th</sup> ed. 2002) (collecting cases).

**D. No Countervailing, Procompetitive Benefits of the Challenged Agreements Were Present in This Case**

The Commission recognized in its decision that “agreements of the kind challenged here can be procompetitive in limited circumstances.” Op. 13. Indeed, the fact that such efficiencies could be even “theoretically possible” led the Commission to decline dealing with the agreements in a summary fashion. *Id.* (citing *California Dental Ass’n*, 526 U.S. at 777-78, 119 S. Ct. at 1616-17). But, as the Commission stated, “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.” Op. 37. Rather, given the evidence that the agreements resulted in less competition than likely would have otherwise occurred, the burden shifted to the petitioners to “demonstrate that these hypothetical circumstances describe the realities of the present case.” *Id.* Petitioners here never did so.

Petitioners hypothesized, for example, that “reverse payments” may enable a cash-starved generic to enter the market earlier than it would have been able to without such payments. Willig, Tr. 7180, 7188, 7258. The Commission agreed that in such *hypothetical* circumstances, reverse payments may be procompetitive. Op. 13. Petitioners here, however, never established that Upsher (or AHP) was so cash-starved that Schering’s payments enabled them to enter earlier than they

would have been able to absent the payments. In fact, as the Commission noted, the evidence showed that Upsher passed the \$60 million payments on to its shareholders. Op. 38 (citing Kralovec, Tr. 5067). Moreover, Upsher stipulated this issue out of the case. CX 1693; *see* Op. 37-38 & n.70.

Nor is Schering's complaint that it had to succumb to judicial pressure for settlement sufficient to justify its payment of \$15 million to AHP in exchange for the latter's agreement to stay off the market until 2004. Judicial pressure to settle protracted litigation is not a justification for paying off a competitor not to compete. Moreover, as the Commission pointed out, Schering's purported justification is further undermined by the fact that there was no evidence in the record that Schering even explored other, lawful terms of settlement, Op. 82, despite the fact that it was well aware of its own counsel's reservations regarding a payment for delay. Hoffman, Tr. 3541-42.

Petitioners' and *amicus* GPHA's public policy arguments are equally unconvincing. Schering Br. 47-52; Upsher Br. 53-57; GPHA Br. 26-30. Although public policy certainly favors the private settlement of disputes, patentees have known for more than sixty years that antitrust law imposes limits on the form of settlement. *See Masonite*, 316 U.S. at 277; *Singer*, 374 U.S. at 196-97. Moreover, this Commission ruling in this narrow area has not, and likely will not, deter future

settlements. Just in the last 16 months, Schering itself has entered into at least four settlements with generic competitors in which Schering granted its challenger a license.<sup>42</sup> Indeed, the Commission's considered and thorough approach – and particularly its principled refusal to undertake a mini-trial on the highly complex merits of the patent dispute – likely will provide litigants a higher degree of predictability, and thus facilitate legitimate settlements.

Similarly, the public policy in favor of research and innovation is enshrined in – and thus corollarily limited by – the exclusionary power of the patent which, as shown above, does not extend to paying off potential competitors not to compete. *See* Part IV.A., *supra*. When it enacted the Hatch-Waxman Act, Congress did seek to preserve the incentives for innovative research and development in the pharmaceutical industry,<sup>43</sup> but it also recognized the need to encourage generic entry by encouraging challenges to pharmaceutical patents. *See Areeda & Hovenkamp, supra*, ¶ 2046 at 340 (2004 Supp.). As the Supreme Court recognized in *Masonite*, “[s]ince patents are privileges restrictive of a free

---

<sup>42</sup> *See* Schering news releases at [http://www.schering-plough.com/schering\\_plough/news/release.jsp?releaseID=380214](http://www.schering-plough.com/schering_plough/news/release.jsp?releaseID=380214); *id.* at ID=394601; *id.* at ID=463286; Andrx press release regarding Claritin settlement (Oct. 23, 2003), available at [www.andrx.com](http://www.andrx.com).

<sup>43</sup> *See* H.R. Rep. No. 98-857, pt. 1, at 14-15 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647-48.

economy, the rights which Congress has attached to them must be strictly construed so as not to derogate from the general law beyond the necessary requirements of the patent statute.” 316 U.S. at 280, 62 S. Ct. at 1078. Finally, the existing incentives for innovation are not likely to be unduly affected by the Commission’s ruling, which arose in the relatively unique factual setting of Hatch-Waxman settlements. *Areeda & Hovenkamp, supra*, ¶ 2046 at 338 (2004 Supp.).

*Amicus* GPHA criticizes the Commission’s decision further by asserting that this case “mirrors the situation” in *Verizon Comms., Inc. v. Law Offices of Curtis V. Trinko, LLP*, \_\_\_ U.S. \_\_\_, 124 S. Ct. 872 (2004), and therefore the Commission should keep its hands off settlements such as the ones involved in this case. GPHA Br. 7-16. But the situations in *Trinko* and in this case are nothing alike. First, *Trinko*’s “caution” in applying the antitrust laws concerned markets that are subject to “a regulatory structure designed to deter and remedy anticompetitive harm.” *Trinko*, 124 S. Ct. at 881. The Hatch-Waxman Act does not contain the competition-regulating functions of the 1996 Telecom Act that the *Trinko* Court found significant.<sup>44</sup> GPHA’s argument also ignores the substantial differences

---

<sup>44</sup> Indeed, the need for additional antitrust constraints explains why Congress recently amended the Hatch-Waxman Act to require that settlements like the ones in this case be filed with the government’s antitrust agencies. *See* Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, §§ 1111-1117, 117 Stat. 2461-2463.

between the roles of the FCC under the 1996 Telecom Act and that of the FDA under the Hatch-Waxman Act. The pervasive market regulatory scheme that Congress authorized the FCC to create and implement – including the very type of competitive restraints of which plaintiffs there complained, *id.* at 881-82 – is nothing like the ministerial role that the FDA plays in administering patent-related issues under the Hatch-Waxman Act.

Moreover, GPHA itself acknowledged that competition “costs the brand-name company far more than the generic company gains.” GPHA Br. 4. Accordingly, as the facts of this case illustrate, there is a powerful incentive for pioneers and generics to settle litigation by splitting the supracompetitive profits generated by the pioneers. Unless tempered by antitrust constraints, brand and generic companies will always be better off with the brand paying off the generic. Rather than having generics filing ANDAs and challenging weak patents or designing around narrow ones, generic companies will file ANDAs and be paid not to compete. Such a result would undercut two important benefits of the Hatch-Waxman Act – i.e., encouraging patent challenges and accelerating generic competition. Schering, Upsher, and the GPHA implicitly endorse such a regime: the brand would benefit by having *guaranteed* protection from competition, and the generic would benefit by earning more than it expects from challenging the

patent and competing. Only consumers would suffer, deprived of legitimate competition. This case is not about whether all payments in patent settlements are anticompetitive. If the settlements here are not illegal, however, then no settlements with a payment will be.

### **CONCLUSION**

For the foregoing reasons, the petition for review should be denied and the Commission's Order affirmed.

Respectfully submitted,

WILLIAM E. KOVACIC  
*General Counsel*

SUSAN A. CREIGHTON  
*Director, Bureau of Competition*

BRADLEY S. ALBERT  
ELIZABETH R. HILDER  
MICHAEL B. KADES  
*Attorneys, Bureau of Competition*

FEDERAL TRADE COMMISSION  
600 PENNSYLVANIA AVENUE, N.W.  
WASHINGTON, DC 20580

---

JOHN D. GRAUBERT  
*Principal Deputy General Counsel*

JOHN F. DALY  
*Deputy General Counsel for Litigation*

IMAD D. ABYAD  
*Attorney*

FEDERAL TRADE COMMISSION  
600 PENNSYLVANIA AVENUE, N.W.  
WASHINGTON, DC 20580  
(202) 326-2375

**CERTIFICATE OF COMPLIANCE**

This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because it contains 13,902 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii) and 11<sup>th</sup> Cir. R. 32-4.

\_\_\_\_\_  
Date

\_\_\_\_\_  
Imad D. Abyad

*Attorney for*  
FEDERAL TRADE COMMISSION

**CERTIFICATE OF SERVICE**

I certify that on July 27, 2004, I caused a copy of the foregoing brief to be delivered by overnight courier to each of the following:

John W. Nields  
HOWREY SIMON ARNOLD & WHITE, LLP  
1299 Pennsylvania Avenue, N.W.  
Washington, DC 20004

Christopher M. Curran  
WHITE & CASE LLP  
601 Thirteenth Street, N.W.  
Washington, DC 20005

---

Imad D. Abyad

*Attorney for*  
FEDERAL TRADE COMMISSION