UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

DOCKET NO. 9297

IN THE MATTER OF

SCHERING-PLOUGH CORPORATION,

UPSHER-SMITH LABORATORIES, INC.

and

AMERICAN HOME PRODUCTS CORPORATION

MOTION OF WASHINGTON LEGAL FOUNDATION FOR LEAVE TO FILE BRIEF AS *AMICUS CURIAE*

[PUBLIC]

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Dated: September 30, 2002

Pursuant to 16 C.F.R. § 3.52(j), the Washington Legal Foundation (WLF) respectfully moves for leave to file an *amicus curiae* brief in this matter in support of Respondents. In support of that motion, WLF states as follows:

(1) WLF is a nonprofit public interest law and policy center with supporters in all 50 states. WLF devotes a substantial portion of its resources to promoting economic liberty, free enterprise principles, and a limited and accountable government. To that end, WLF has appeared in numerous federal and state courts in cases related to health care delivery. For example, WLF recently successfully challenged the constitutionality of Food and Drug Administration (FDA) restrictions on speech relating to off-label uses of FDA-approved products. *Washington Legal Found. v. Friedman,* 13 F. Supp. 2d 51 (D.D.C. 1998), *appeal dismissed,* 202 F.3d 331 (D.C.Cir. 2000). WLF also filed an *amicus curiae* brief in *Abbott Laboratories v. Louisiana Wholesale Drug Co.,* No. 02-12091-J (11th Cir., dec. pending), urging the U.S. Court of Appeals for the Eleventh Circuit to overturn a district court decision that settlement agreements entered among three pharmaceutical companies engaged in patent litigation amounted to a *per se* violation of the antitrust laws.

2. WLF believes that both "innovator" and generic manufacturers play an important role in providing quality health care to the American public. If advances in health care are to continue, it is vital that innovator companies that develop new drugs and medical devices, or new methods of using those products, be afforded periods of patent protection, during which potential competitors are not permitted to market the same product. Patents provide an economic incentive for new product development by ensuring that pharmaceutical companies that gamble the substantial sums necessary for research and development of new

therapies will be able to realize a return on their investment when their research and development expenditures bear fruit. On the other hand, once an appropriate period of patent exclusivity has expired, consumers are well served by government policies that encourage other companies to market generic versions of the new drug, thereby ensuring the competition necessary to produce lower prices.

3. Competition between innovator and generic producers inevitably will lead to disagreements regarding precisely how long the legally-mandated exclusivity period for an innovator company's products should last. Those disagreements often will result in litigation, which usually is extremely time-consuming and expensive and diverts the attention of pharmaceutical executives away from finding ways to provide the public with innovative, low-cost pharmaceutical products. Accordingly, WLF believes that the law should provide strong incentives for parties to pharmaceutical patent litigation to settle their disagreements as quickly as possible.

4. WLF is concerned that the position espoused by Complaint Counsel in this case will, if adopted by the Commission, provide precisely the wrong incentives. Complaint Counsel appears to view litigation as just another forum within which innovator and generic companies can carry out their competition, and that litigation is to be encouraged as a means of ensuring that every potentially invalid patent is challenged in court. WLF is filing this brief because it strongly disagrees with that view. WLF believes that the settlement of litigation in most instances is pro-competitive. WLF also believes that Complaint Counsel's position, by calling into question the legality of virtually all patent settlements, will actually discourage meritorious challenges by generic companies who are reluctant to undertake an

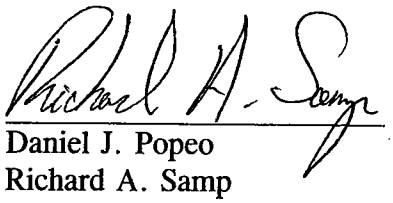
expensive battle of indeterminate duration and outcome knowing that pre-trial settlement may not be an option.

5. WLF has not fully reviewed the entire trial record and thus takes no position on the merits of the underlying antitrust dispute. WLF principal purpose in filing is to disagree with Complaint Counsel's view that a "reverse payment" settlement of a pharmaceutical patent dispute is *per se* illegal. Rather, any such settlement ought to be evaluated under a rule-of-reason analysis. Moreover, a rule-of-reason analysis must include an examination of the likely outcome of the patent litigation; in the absence of such an examination, it is impossible to determine whether the settlement has actually restrained any competition.

6. WLF seeks to file this brief solely because of its interest in promoting the efficient settlement of patent disputes, including but not limited to, settlements between innovator and generic drug companies in the pharmaceutical industry. It has no direct interest, financial or otherwise, in the outcome of this case.

WHEREFORE, the Washington Legal Foundation respectfully requests that the Commission grant its motion for leave to file the attached *amicus curiae* brief.

Respectfully submitted,



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BRIEF OF WASHINGTON LEGAL FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENTS

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BRIEF OF WASHINGTON LEGAL FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENTS

INTERESTS OF *AMICUS CURIAE*

The Washington Legal Foundation (WLF) is a public interest law and policy center located in Washington, D.C., with supporters in all 50 states. The interests of WLF are set out more fully in the accompanying motion for leave to file this brief.

WLF has no direct interest, financial or otherwise, in the outcome of this case. It is filing this brief solely because of its interest in promoting the efficient settlement of patent disputes, including but not limited to, settlements between innovator and generic drug companies in the pharmaceutical industry.

STATEMENT OF THE CASE

In the interests of brevity, WLF hereby adopts by reference the Statement of Facts contained in the briefs of Schering-Plough Corporation ("Schering") and Upsher-Smith Laboratories, Inc.

The Commission issued its complaint in this matter on March 30, 2001. The complaint charged that Schering, Upsher-Smith, and American Home Products Corporation ("AHP") violated § 5 of the Federal Trade Commission Act, 15 U.S.C. § 45, by entering into agreements designed to delay the entry of low-cost generic competition to Schering's K-Dur 20. The complaint alleged that the $60 million payment by Schering to Upsher-Smith in return for six product licenses was a sham transaction, and that substantially all of the $60 million was paid in return for Upsher-Smith's 34-month delay (from November 1998 to September 2001) in marketing its generic version of K-Dur 20.

Following a two-month trial in early 2002, Administrative Law Judge (ALJ) D.

Michael Chappell dismissed the complaint on June 27, 2002. The ALJ found that $60 million was a fair price in 1997 for the licenses Schering received from Upsher-Smith. Initial Decision ("ID") 31-64. He rejected Complaint Counsel's argument that "reverse payment" patent litigation settlements (whereby the party receiving a patent license on a future date also receives a substantial cash payment) should be deemed *per se* illegal as horizontal market allocation agreements. ID 96-100. Applying a rule-of-reason analysis, the ALJ determined that Complaint Counsel had failed to demonstrate that the two settlement agreements constituted unfair trade practices in violation of § 5 of the FTC Act. ID 101-114. In particular, he determined that Complaint Counsel had failed to demonstrate that the agreements restricted competition. *Id.*

ARGUMENT

I. COMPLAINT COUNSEL DO NOT CHALLENGE PAYMENTS FOR WHICH PATENT HOLDERS RECEIVE FAIR MARKET VALUE, AND THERE IS SUBSTANTIAL EVIDENCE THAT SCHERING RECEIVED FAIR VALUE FOR ITS PAYMENT TO UPSHER-SMITH

The Schering/Upsher-Smith patent litigation settlement agreement is a particularly poor vehicle for Complaint Counsel to pursue their theory that "reverse payment" patent litigation settlements are *per se* illegal. The ALJ made findings of fact that the fair market value of the licenses granted by Upsher-Smith to Schering was $60 million. ID 64, 107-111. Thus, unless the Commission is convinced that those findings are clearly erroneous, the Schering/Upsher-Smith agreement simply is not a "reverse payment" settlement.

Complaint Counsel made clear at trial that they do not object to patent settlements that do no involve "reverse payment":

This case does not challenge the settlement of patent disputes by an agreement on a

> date of entry, standing alone, or the payment of fair market value in connection with "side deals" to such an agreement. Rather, our challenge is to a substantial payment by the patent holders to the alleged infringer in consideration of a settlement agreement with delayed entry.

Complaint Counsel's Trial Brief at 43. Thus, Complaint Counsel's entire case against Upsher-Smith is premised on a contention that Schering paid more than fair market value for the licenses it received. In light of the ALJ's findings of fact, Complaint Counsel face an exceedingly difficult task in proving their case.

Although Complaint Counsel challenge those factual findings in their appeal brief, they do so without ever attempting to place a dollar value on the licenses. Indeed, Complaint Counsel's own experts conceded that the licenses likely had some considerable positive value. Tr. 5:948-57 (Bresnahan). Complaint Counsel insist, based on the language of the settlement agreement, that some portion of the $60 million payment must have been in return for Upsher-Smith's agreement not to enter the market until September 2001. Br. 29-32. But that argument makes no sense in the absence of evidence that the licenses were worth less than $60 million because -- under the "reverse payment" theory as explained by Complaint Counsel -- a patent litigation settlement is unobjectionable unless any "side deal" payments tendered by the patent holder exceed the fair market value of the goods or services received in exchange.

In support of their contention that Schering was not really paying $60 million to license products from Upsher-Smith, Complaint Counsel note that the settlement agreement required Schering to make full payment even if the licenses later declined in value. Br. 31-32. That argument says nothing about the fair market value of the licenses in June 1997, when Schering and Upsher-Smith reached their settlement agreement; the parties reached a

good-faith agreement on that date that the licenses were worth $60 million. Complaint Counsel now ask the Commission to second-guess not only the parties' but also the ALJ's determination regarding the value of licenses conveyed by Upsher-Smith; in the absence of any attempt by Complaint Counsel to undertake its own valuation, such second-guessing is wholly inappropriate.[1]

Finally, Complaint Counsel suggest that the legitimacy of the licensing "side deal" is suspect because throughout the negotiations process, Upsher-Smith stated that it wanted a cash payment as part of any litigation settlement. Br. 26-29. But even assuming that Complaint Counsel's characterization of the testimony is accurate, that does nothing to undermine the legitimacy of the licensing payment. To the contrary, it demonstrates the importance of side deals in facilitating litigation settlements: by agreeing to purchase assets from Upsher-Smith for fair market value, Schering provided Upsher-Smith a return on a significant R & D investment and helped to bring together parties who had been at each other's throats during two years of antagonistic litigation.[2] These types of value-creating, pro-competitive agreements should be embraced, not condemned.

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[1] Surely, the ALJ's numerous credibility determinations regarding this issue should be given considerable deference.

[2] There is no basis for Complaint Counsel's repeated insinuation that side deals entered into in connection with litigation settlements are inherently suspect. Indeed, there are numerous reasons for the prevalence of side deals entered into in connection with litigation settlements, quite apart from their tendency to provide negotiators with a good "exit strategy" to break negotiation impasses. For example, the transactional costs of entering into a business deal are often reduced in the context of settlement negotiations, when top officials of the affected companies are already readily available. Moreover, the antagonism associated with litigation finally comes to an end during a successful settlement, thus facilitating the types of licensing deals that had been a practical impossibility during the litigation.

In sum, Complaint Counsel's failure to demonstrate that the licenses conveyed to Schering by Upsher-Smith were worth less than $60 million is by itself a sufficient reason to sustain the ALJ's dismissal of the complaint as it relates to the Schering/Upsher-Smith settlement agreement. Initial Decision Findings ("IDF") 290-300. That agreement should not cause the Commission to examine the legality of "reverse payment" patent settlement agreements because Complaint Counsel have failed to demonstrate that any "reverse payment" took place.

II. THE COMMISSION SHOULD NOT EMPLOY THE *PER SE* RULE IN EXAMINING "REVERSE PAYMENT" SETTLEMENTS

Although Complaint Counsel failed to demonstrate any "reverse payment" in connection with the Schering/Upsher-Smith agreement, some of the payments made by Schering to ESI bring the Schering/ESI agreement within Complaint Counsel's definition of a "reverse payment" patent litigation settlement agreement. The Commission nonetheless should reject Complaint Counsel's call to apply *per se* antitrust analysis to such agreements.

The Supreme Court has made clear that *per se* treatment should be applied with great caution and only in the few cases where sufficient experience has shown that the conduct "always or almost always tend[s] to restrict competition and decrease output." *Northwest Wholesale Stationers, Inc. v. Pacific Stationery & Printing Co.*, 472 U.S. 284, 289-90 (1985) (quoting *Broadcast Music, Inc. v. Columbia Broadcasting Sys.*, 441 U.S. 1, 19-20 (1979)). Indeed, only three years ago the Court warned that "the plausibility of competing claims about the effects of the [conduct at issue] rules out the indulgently abbreviated review." *California Dental Ass'n v. FTC*, 526 U.S. 756, 778 (1999).

The reason for this caution is clear. When the *per se* rule is applied to an agreement,

a claimant need not prove: that a relevant market exists; that the accused parties have market power; that the accused parties' purpose is anticompetitive; or that the agreement has actual anticompetitive effects. Equally important, particularly in the context of these agreements, the defendant may not offer any explanation of the rationale for entering into the challenged agreement. The agreement is *presumed* to be illegal with limited inquiry into the exact type of harm caused. *Northwest Wholesale Stationers*, 472 U.S. at 289. Because the *per se* rule categorically condemns business arrangements, courts have explained that "a presumption exists that the circumstances of a case will be looked at in light of the rule of reason standard and will not be deemed per se unreasonable." *All Care Nursing Serv., Inc. v. High Tech Staffing Servs., Inc.*, 135 F.3d 740, 746 (11th Cir. 1998).[3]

The *per se* rule should thus only be invoked when its application would generate a low risk of error – *i.e.*, to circumstances in which the courts have consistently found unambiguously anticompetitive conduct after applying the rule of reason to nearly identical conduct in prior cases:

> The object is to see whether the experience of the market has been so clear, or necessarily will be, that a confident conclusion about the principal tendency of a restriction will follow from a quick (or at least quicker) look, in place of a more

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[3] Indeed, in recent years, the Supreme Court has specifically disapproved the application of *per se* rules in cases involving activity that in an earlier era might have been analyzed as *per se* unlawful. *See, e.g., Broadcast Music*, 441 U.S. at 24 (blanket license agreement with price fixing effects not *per se* unlawful); *NCAA v. Board of Regents*, 468 U.S. 85, 103 (1984) (*per se* rule not applied to plan for televising college football games that included horizontal price fixing and output restrictions); *Northwest Wholesale Stationers*, 472 U.S. at 294 (appeals court's application of *per se* rule to concerted refusal to deal held inappropriate). Moreover, the Supreme Court has even reversed its own precedent in rejecting application of the rule to conduct previously considered to be *per se* unlawful. *See State Oil v. Kahn*, 522 U.S. 3, 7 (1997) (reversing Court's previous application of the *per se* rule to agreements to fix maximum resale prices).

> sedulous one. And of course what we see may vary over time, if rule-of-reason analyses in case after case reach identical conclusions.

California Dental, 526 U.S. at 780-81; *FTC v. Indiana Federation of Dentists*, 476 U.S. 447, 458 (1986) (refusing to force alleged conduct "into the 'boycott' pigeonhole" to resolve claim under *per se* rule); *Cha-Car, Inc. v. Calder Race Course, Inc.*, 752 F.2d 609, 613 (11th Cir. 1985) ("[A]ny departure from the rule of reason standard must be based upon demonstrable anti-competitive economic effect, rather than formalistic line drawing.").

Application of the *per se* rule here is inconsistent with this well established "practice makes perfect" approach. It took the Supreme Court more than half a century of experience with group boycotts before the Court was willing to apply the *per se* rule to that type of conduct.[4] And since then, the Supreme Court has, on at least two occasions, further refined and narrowed its application of the *per se* rule in that context. *See Indiana Federation of Dentists*, 476 U.S. at 458-49; *Northwest Wholesale Stationers,* 472 U.S. at 294.

The Court's experiment with condemning vertical territorial restraints as *per se* illegal is similarly instructive of its caution. *Compare White Motor Co. v. United States*, 372 U.S. 253, 261-63 (1963) (reversing district court finding that vertical non-price restraints were illegal *per se* because "[w]e need to know more than we do about the actual impact of [vertical restraints] on competition to decide whether they ... should be classified as per se violations of the Sherman Act") *with United States v. Arnold, Schwinn & Co.*, 388 U.S. 365, 379 (1967) (applying *per se* treatment, noting that territorial "restraints are so obviously

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[4] Arguably, the first significant boycott case heard by the Supreme Court was *W.W. Montague & Co. v. Lowry*, 193 U.S. 38 (1904). The Court did not formally declare group boycotts *per se* illegal under the Sherman Act until its decision in *Klor's, Inc. v. Broadway-Hale Stores, Inc.*, 359 U.S. 207 (1959).

destructive of competition that their mere existence is enough") *and Continental T.V., Inc. v. GTE Sylvania Inc.*, 433 U.S. 36, 48-50, 58-59 (1977) (describing *Schwinn* as "formalistic line drawing" and emphasizing that "[p]er se rules of illegality are appropriate only when they relate to conduct that is manifestly anticompetitive").

In contrast to these examples, all that Complaint Counsel have to point to are two interim federal district court decisions, both of which are under appeal. *In re Cardizem CD Antitrust Litig.*, 105 F. Supp. 2d 618 (E.D. Mich. 2000); *In re Terazosin Hydrochloride Antitrust Litig.*, 164 F. Supp. 2d 1340 (S.D. Fla. 2000). As the *first* district courts to consider the antitrust standards that should be applied to patent settlement agreements reached in the Hatch-Waxman context, the *Cardizem* and *Terazosin* opinions do not remotely resemble the substantial experience that the Supreme Court envisioned as a precursor to the application of the *per se* rule. Indeed, the two district courts did not even purport to fully assess the competitive impact of the patent settlements at issue therein, but rather, blindly condemned the conduct as *per se* anticompetitive.[5]

More importantly, the two district courts' application of the *per se* rule flies in the

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[5] In addition to being at odds with existing Supreme Court precedent, *Cardizem* and *Terazosin* are both factually distinguishable in significant respects. In particular, both cases involved "reverse payments" from patent holders to generic drug companies in the absence of final litigation settlement agreements. Without doubt, the most pro-competitive aspect of the agreements being challenged herein is that they resulted in *final* settlements of lengthy, contentious litigation. The absence of such final settlements in *Cardizem* and *Terazosin* thus significantly affected the antitrust analysis applicable to the agreements reached in those cases. Complaint Counsel are correct that the agreements challenged in *Terazosin* did, in fact, include a final settlement with one of the two generic manufacturers involved, Br. 43 n.40; but the district court's failure to separately analyze the effects on competition of the two agreements entered into in that case -- one of which involved a final settlement of litigation and the other of which did not -- serves only to highlight the superficial nature of the *Terazosin* analysis.

face of the experience of those courts that have actually assessed the competitive impact of patent litigation settlements. Before *Cardizem* and *Terazosin,* courts universally applied a rule of reason analytical framework to evaluate the legality of patent litigation settlements.[6] The only exception to this approach was where the agreements were found to mask an industry-wide price-fixing conspiracy.[7]

Complaint Counsel contend that *United States v. Masonite Corp.,* 316 U.S. 265, 282 (1942), stands for the proposition that even when the patent at issue is valid, patent settlements are *per se* illegal when a competitor abandons its own products and in return receives a share of the patentee profits. Br. 41-42. That is a misreading of the case. While it is true that Masonite Corp. possessed a legitimate patent and decided to license it to a group of manufacturers, it is also true that Masonite fixed the prices at which the licensees could sell the licensed products and allocated certain markets in which the licensees could sell the products. It was this price fixing, not the actual licensing, that the Supreme Court deemed *per se* illegal.[8] Accordingly, *Masonite* is wholly inapposite in the absence of any

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[6] *See, e.g., Standard Oil Co. (Indiana) v. United States,* 283 U.S. 163 (1931); *Hartford-Empire Co. v. United States,* 323 U.S. 386, 400, *clarified,* 324 U.S. 570 (1945); *Clorox Co. v. Sterling Winthrop, Inc.,* 117 F.3d 50 (2d Cir. 1997) (applying rule of reason in trademark case even though the settlement resembled a market allocation agreement).

[7] *See Noll v. O.M. Scott & Sons Co.,* 467 F.2d 295, 301 (6th Cir. 1972); *United States v. New Wrinkle,* 342 U.S. 371, 374 (1952); *see also Duplan Corp. v. Deering Milliken, Inc.,* 540 F.2d 1215, 1220 (4th Cir. 1976) ("it is only when settlement agreements are entered into in bad faith and are utilized as part of a scheme to restrain or monopolize trade that antitrust violations may occur").

[8] Masonite executed agency contracts with the licensees. In the contracts:

> The "agent" expressly acknowledged the validity of Masonite's hardboard patents so long as the agreement remained in force. The "agent" agreed to promote the sale of

allegation or finding that Schering, Upsher-Smith, or ESI ever conspired to fix prices. Two other cases relied on by Complaint Counsel -- *United States v. New Wrinkle Inc.*, 342 U.S. 371 (1952); and *United States v. Line Material Co.,* 333 U.S. 287 (1948) -- are similarly inapposite. Both cases involved use of patent licenses to set minimum prices. *New Wrinkle,* 342 U.S. at 372; *Line Material,* 333 U.S. at 290-299.

A fourth case relied on by Complaint Counsel in support of their *per se* argument, *United States v. Singer Mfg Co.,* 374 U.S. 174 (1963), is similarly unhelpful to their position. In *Singer,* the patent holder and licensee were found to have conspired to exclude another competitor from the market. In contrast, the ALJ explicitly held that no similar conspiracy existed in this case. ID at 121. Moreover, it is important to note what *Singer*

> Masonite hardboards. Masonite agreed to manufacture designated hardboard products in specified sizes and to ship on orders and specifications from the "agent" to any place within the continental United States or Hawaii. Masonite agreed to designate from time to time the minimum selling price and the maximum terms and conditions of sale at which the "agent" might sell Masonite's products. The list prices and terms of sale were to be the minimum prices and maximum terms of sale at which Masonite was either offering or making sales to its customers. The right to change the list prices and terms of sale was vested solely in Masonite and might be exercised on 10 days notice. It was agreed that Masonite was bound to adhere to the prices, and terms and conditions of sale which it fixed for its "agents." In case the "agent" sold for less than the minimum price it was obligated to pay liquidated damages at a specified rate. On direct shipments to the "agent" the hardboards "shall be received and held on consignment" and "title thereto shall remain" in Masonite until sold by the "agent." The minimum prices were f.o.b. Masonite's factory, the "agent" paying freight and transportation costs and sales and other taxes. The "agent" also agreed at its expense to carry insurance on all products consigned to it. The "agent's" compensation was fixed by way of specified commissions on each sale. The "agent" was prohibited from making sales (except for offsized boards) to any person other than specified classes. Those provisions permitted the "agent" to sell only to the construction industry, the industrial market being reserved for Masonite.

Masonite, 316 U.S. at 271.

does *not* stand for:

> [I]t may be helpful to set out what is not involved in this case. There is no claim by the Government that it is illegal for one merely to acquire a patent in order to exclude his competitors; or that the owner of a lawfully acquired patent cannot use the patent laws to exclude all infringers of the patent.

Singer, 374 U.S. at 189.

As have the courts, individual Commissioners and Commission personnel have repeatedly expressed the view that the Commission should proceed under a rule of reason theory in its enforcement actions in this context.[9] FTC Commissioner Leary has explained that "the issues in these patent settlements are difficult and individual facts are important[,]" noting that "it is not at all easy to distinguish between the [settlement agreements] that are pernicious and those that are not - particularly, when the uncertain outcome of patent litigation is factored in."[10] A former FTC official responsible for several investigations of these agreements also has suggested that even if the agreements "appear to be anticompetitive

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[9] For example, a 1999 FTC Staff Report examining competition in the pharmaceutical industry concludes that "antitrust authorities need to apply the standard case-by-case approach to antitrust analyses of vertical and horizontal issues that arise in this industry." Roy Levy, Bureau of Economics, Federal Trade Commission, *The Pharmaceutical Industry: A Discussion of Competitive and Antitrust Issues in an Environment of Change*, Bureau of Economics Staff Report at xii (March 1999). The Staff Report also identified the enormous significance of intellectual property rights in the pharmaceutical industry as an important issue for the FTC's consideration. *Id.* at 180.

[10] Thomas B. Leary, *Antitrust Issues in the Settlement of Pharmaceutical Patent Disputes* at 1, 6 (Nov. 3, 2000), *available at* www.ftc.gov/speeches/leary/learypharma.htm; *see also* Thomas B. Leary, *Pharmaceutical Patent Dispute II Address Before the Sixth Annual Antitrust Healthcare Forum*, Northwestern University School of Law (May 17, 2001) ("It should be evident that the issues involved in pharmaceutical patent settlements are complex. My personal views have evolved considerably in the last eight months . . .").

arrangements . . . [they] are not as simple as they may appear."[11]

Recognizing the novelty of the issues raised by Hatch-Waxman agreements, the Commission in 2001 initiated an extensive investigation of such agreements and the role they play in the pharmaceutical industry.[12] Conceding that the competitive impact of Hatch-Waxman agreements is far from clear, the Commission has expressly noted that the results of the investigation may reveal that "there may be circumstances where the agreements between innovator and generic drug companies are pro-competitive."[13]

Thus, Complaint Counsel's condemnation of "reverse payment" settlements as *per se* unlawful stands in direct contrast to judicial precedent and agency experience suggesting that

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[11] Richard Gilbert & Willard K. Tom, *Is Innovation King at the Agencies? The Intellectual Property Guidelines Five Years Later*, 69 Antitrust L.J. 43, 76-77 (2001). Will Tom was Deputy Director of the Bureau of Competition at the FTC. Gilbert and Tom were also involved in drafting the U.S. Department of Justice and Federal Trade Commission Antitrust Guidelines for the Licensing of Intellectual Property, *reprinted in* 6 Trade Reg. Rep. (CCH) ¶ 13,132 (Apr. 6, 1995).

[12] FTC, Agency Information Collection Activities, Comment Request, 66 Fed. Reg. 12512, 12516 (Feb. 27, 2001).

[13] *Id.* at 12516. A speech by FTC Commissioner Thomas B. Leary expressly addressed the competitive effects of a payment from an IP owner to an alleged infringer: "Presumptively strong suspicion of reverse payments may be justified, but at this stage I would hesitate to make the presumption conclusive." *See* Leary, *supra* note 10 at 8; *see also* Timothy J. Muris, *The Federal Trade Commission and the Rule of Reason: In Defense of Massachusetts Board,* 66 ANTITRUST L.J. 773, 800 (1998) ("[O]nly after considerable judicial experience with a category of practices, such as price fixing and market division, will a decision be reached regarding whether suspicion is warranted. Restraints novel in form or industry application will not be reviewed as suspicious on their face."). Mary L. Azcuenaga, *Recent Issues in Antitrust and Intellectual Property*, 7 B.U.J. Science & Tech. Law 1, 22 (2001) ("[These cases] are not easy. Unless the enforcement agencies know more about the validity of particular patents than the Patent and Trademark Office does, the cases run the risk of being counter productive.").

aspects of such agreements may in fact prove to be pro-competitive.[14]

III. COMPLAINT COUNSEL'S POSITION UNDERMINES THE PATENT STATUTE'S GUARANTEE OF A PRESUMPTION OF VALIDITY

Not only does Complaint Counsel's position contravene established antitrust precedent, its characterization of patent settlements as market allocation agreements also directly undermines fundamental concepts of patent law. In treating the Schering agreements as *per se* unlawful, Complaint Counsel rely heavily on their presumption that Upsher-Smith and ESI are potential competitors of Schering that agreed not to enter the relevant market while the '743 patent remained in force. By employing this presumption, however, Complaint Counsel desecrate the explicit guarantee of the patent statute that "[a] patent shall be presumed valid." 35 U.S.C. § 282.

For the parties to a horizontal property settlement agreement to be horizontal competitors -- a prerequisite to establishing a *per se* unlawful market allocation agreement -- both parties must have the legal right to compete in the relevant market without the intellectual property at issue in the agreement. Because the patent laws expressly endow a patent owner with the right to exclude others from his or her inventions,[15] an alleged

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[14] The unsettled nature of this area is evidenced by the wide spectrum of viewpoints that have been offered about Hatch-Waxman Act agreements in the numerous articles published on the topic during 2001 and 2002. *See, e.g.*, James R. Atwood, *Securing and Enforcing Patents: The Role of Noerr/Pennington*, 83 J. Pat. & Trademark Off. Soc'y 651 (September 2001); James B. Kobak, *The Federal Circuit as a Competition Law Court*, 83 J. Pat. & Trademark Off. Soc'y 527 (August, 2001); Carole E. Handler, *Antitrust Implications of Settlement and Patent Disputes*, 658 PLI/Pat 483 (2001); Azcuenaga, *supra* note 13; Willard K. Tom, *The 1975 Xerox Consent Decree: Ancient Artifacts and Current Tensions*, 68 Antitrust L.J. 967 (2001).

[15] 35 U.S.C. § 154; *see Dawson Chemical Co. v. Rohm & Haas Co.*, 448 U.S. 176, 215 (1980) ("[T]he essence of a patent grant is the right to exclude others from profiting

infringer may be a potential competitor *as a factual matter* (by virtue, for example, of his or her ability and intent to manufacture products embodying the invention), but not necessarily *as a legal matter.*[16] A court should consider an alleged infringer to be an actual or potential competitor of a patent holder *as a legal matter* only if, at the time of the settlement agreement, the parties knew the patent was invalid, not infringed, or otherwise not enforceable.[17] Any other conclusion would obliterate the statutory right of patent holders to operate under the presumption that their patents are valid.

By focusing solely on whether the parties understood the generic companies to be potential competitors as a *factual* – rather than legal – matter at the time of the settlement agreements, Complaint Counsel and *amicus* National Association of Chain Drug Stores ("NACDS") engage in a *post hoc* determination of the validity of the patents involved in the settlements. If adopted by the Commission, such a rule could condemn as a market allocation agreement *any* IP settlement where one party agrees not to sell or manufacture a product, including, in the most extreme case, a settlement in which the alleged infringer acknowledges infringement and therefore agrees to forgo manufacturing or selling the infringing product. Thus, Complaint Counsel's and NACDS's position is so overbroad that it can subject all parties to patent settlements and, indeed, many otherwise unobjectionable or

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from the patented invention.").

[16] *See B. Braun Medical, Inc. v. Abbott Labs.*, 124 F.3d 1419, 1426-27 & n.4 (Fed. Cir. 1997) (rejecting defendant's contention that patent owner's restrictions on defendant's sales constituted a *per se* illegal horizontal restraint because patent owner has the right to exclude competition in the relevant sales market).

[17] *See* 35 U.S.C. § 282.

demonstrably procompetitive patent licenses, to antitrust liability merely upon a showing that one party contemplated selling products in competition with the other without regard to the status of any potentially infringed patents.

Complaint Counsel and NACDS ask the Commission to confine application of the *per se* rule to instances in which a "reverse payment" is made by the patent holder to the licensee. But they have been unable to articulate any coherent rationale for drawing the line in that manner. Complaint Counsel argue that no such payments should be permitted because "if parties can pay for an entry date, the incumbent will pay more money for a later date." Br. 68. But because, under Complaint Counsel's logic, every generic manufacturer that is capable of becoming a competitor should be deemed a potential competitor, Complaint Counsel could just as easily argue that parties should *never* be permitted to agree among themselves that the generic firm's entry is to be delayed until a specified date, regardless whether either party pays cash in connection with the settlement. While "reverse payments" may increase suspicions that a settlement is anti-competitive, there is no logical basis for treating "reverse payment" payment settlements as being different in kind from other types of settlements. In both instances, declaring the settlements to be *per se* illegal would undermine the presumption that the patent at issue is valid.

Just last spring, a unanimous Supreme Court warned against the adoption of bright-line rules that undermine the settled rights of patent owners. *Festo Corp. v. Shoketsu Kinzoko Kogyo Kabutshiki Co.,* 122 S. Ct. 1831, 1841 (2002). In *Festo,* the Court instructed lower courts to "be cautious before adopting changes that disrupt the settled expectations of the inventing community." *Id.* (citing *Warner-Jenkinson v. Hilton Davis Chem. Co.,* 520

U.S. 17, 28 (1997)). The Court explained, in the context of the patent doctrine of equivalents, that the temporary monopoly granted by a patent is a property right and that a patent owner is entitled, at all times, to understand the boundaries of its property. *Id.* at 1837. Thus, the Court once again rejected attempts to disturb settled patent law principles, concluding that "[f]undamental alterations in these rules risk destroying the legitimate expectations of inventors in their property." *Id.* at 1841. And it did so by rejecting a lower court's attempt to adopt a bright-line rule that, like the *per se* rule, would avoid the uncertainty "that may lead to wasteful litigation," *id.* at 1837, opting instead for a more flexible cases-by-case rule and explicitly acknowledging "this uncertainty as the price of ensuring the appropriate incentives for innovation. . ." *Id.* at 1838.

Complaint Counsel's disregard for the presumption of validity should be treated similarly here. Complaint Counsel has adopted a far-reaching position that would ultimately "disrupt the settled expectations of the inventing community" by rejecting the flexible rule of reason test in favor of a rigid *per se* rule.

IV. COMPLAINT COUNSEL'S POSITION WILL DISCOURAGE THE LEGITIMATE SETTLEMENT OF PATENT DISPUTES

Largely for the reasons noted above, application of the *per se* rule in this case would have significant harmful consequences by discouraging patent settlements. The public policy favoring settlements is so well established that one author has deemed it a "truism." Stephen Bundy, *The Policy in Favor of Settlement in an Adversary System*, 44 HASTINGS L.J. 1, 48 (1992); *see, e.g.*, *Marek v. Chesny*, 473 U.S. 1, 10 (1985) ("settlements rather than litigation will serve the interests of plaintiffs as well as defendants"); *Williams v. First Nat'l Bank*, 216 U.S. 582, 592 (1910) ("compromises of disputed claims are favored by the courts").

These considerations are magnified in the patent context:

> Settlement is of particular value in patent litigation, the nature of which is often inordinately complex and time consuming. Settlement agreements should therefore be upheld wherever equitable and policy considerations so permit. By such agreements are the burdens of trial spared to the parties, to other litigants waiting their turn before over-burdened courts, and to the citizens whose taxes support the latter. An amicable compromise provides the more speedy and reasonable remedy for the dispute.

Aro Corp. v. Allied Witan Co., 532 F.2d 1368, 1372 (6th Cir. 1976) (citing *D.H. Overmeyer Co. v. Loflin*, 440 F.2d 1213 (5th Cir. 1971)). Indeed, studies show that patent litigation tends to be extraordinarily complex and expensive.[18] In addition, patent cases pose significant risks for both an intellectual property owner and an alleged infringer. An alleged infringer faces the potential of enormous damages awards,[19] while an intellectual property owner faces the possibility of its patents being found invalid or unenforceable.[20]

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[18] John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185, 187-88 (1998) ("patent litigation tends to be exceptionally costly, with legal expenses often exceeding one million dollars per party"); Steven C. Carlson, *Patent Pools and the Antitrust Dilemma*, 16 Yale J. on Reg. 359, 380 (1999) ("Roughly $1 billion dollars is spent annually in the United States on patent litigation"); Tom Arnold, *Suggested Form of Contract to Arbitrate a Patent or Other Commercial Dispute*, 2 Tex. Intell. Prop. L.J. 205, 208 (Spring, 1994) (asserting that it takes "an average of more than six years for patent cases to make their way through the trial and appeal process").

[19] *See, e.g.*, Carlson, *supra* note 18, at 380 ("[P]atent cases have produced some of the largest damages awards in history."); *Jury Finds Infringement of Plane Device Patent*, Nat'l L.J., Feb. 4, 2002, at C13 (verdict of nearly $47 million); John F. Manser, *Connolly Bove Lands $65 Million Verdict in IP Case: Trio Wins Fight Over Corn Gene in N.C. Trial*, Del. L. Wkly., Apr. 27, 1999, at 1 ($15 million in damages and $50 million in punitive damages); Kathleen Hollingsworth, *Federal Circuit: $72 Million in Damages in Hip Replacement Case Affirmed*, West's Legal News, Oct. 4, 1996, at 1996 WL 561184 ($72 million verdict).

[20] *See, e.g.*, *Bet-the-Company Suit Leaves Chip-Maker Afloat*, Nat'l L.J., Feb. 4, 2002, at C29 (ethernet patent found invalid); *Shell Oil Prevails in Suit by Union Carbide*,

Contrary to the strong public policy favoring settlements, Complaint Counsel's position would discourage the orderly resolution of patent disputes. As suggested by Commissioner Thomas B. Leary, application of *per se* treatment will "cast a cloud over all patent settlements"[21] so that patent owners and accused infringers will hesitate before entering into an agreement to resolve a patent dispute in fear that a court will deem their agreement to be *per se* unlawful. Much of this hesitation would flow naturally from the practical implications of the *per se* rule. Categorizing conduct as *per se* unlawful inevitably provides greater incentives for antitrust challenges. At least some of those challenges likely will be directed at conduct that, if analyzed under the rule of reason, would ultimately be found pro-competitive. *See Seagood Trading Corp. v. Jerrico, Inc.*, 924 F.2d 1555, 1567 (11th Cir. 1991) (noting "the potential costs to the marketplace that . . . result[s] from mislabeling procompetitive activity as per se illegal"). In today's technology-based society,[22] where

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Nat'l L.J., Jan. 21, 2002, at C7 (patents covering process of making ethylene oxides found invalid); *Genentech Defeats Huge Claim Over Cancer Drugs*, Jan. 21, 2002, at C7 (method and cell line patent claims found invalid); Margaret C. Fisk, *Company Loses $271 Million Claim Over Wireless Patents*, Del. L. Wkly., Jan. 8, 2002, at 4 (patents for infrastructure equipment used in cellular phone systems found invalid).

[21] Thomas B. Leary, *Antitrust Issues in the Settlement of Pharmaceutical Patent Disputes* at 9 (Nov. 3, 2000), *available at* www.ftc.gov/speeches/leary/learypharma.htm.

[22] There are approximately two million patents in force. *See* U.S. Patent & Trademark Office, *U.S. Patent Statistics, Calendar Years 1963-2000* (2001). The U.S. Patent & Trademark Office ("PTO") received nearly 300,000 patent applications in 2000, an increase of more than 12 percent over the previous year. *See* U.S. Patent & Trademark Office, *A New Organization for a New Millennium: Performance and Accountability Report (Fiscal Year 2000)*, *available at* www.uspto.gov/web/offices/com/annual/2000. The PTO also issued a "record number" of patents in 2000. U.S. Patent & Trademark Office, *Patenting Trends Calendar Year 2000*, *available at* www.uspto.gov/web/offices/ac/ido/oeip/taf/pat_tr00.htm.

prompt, consensual conflict resolution is critical to continued innovation, any increased fear of settlement of patent disputes will have devastating consequences.

The pro-competitive effects of patent litigation settlements, as outlined in *Aro*, are sufficiently obvious that Complaint Counsel readily admit that at least some settlements that provide for delayed entry are nonetheless pro-competitive. Br. 41. Indeed, until the threat of patent infringement liability is lifted, most generic companies are unwilling to compete at all. As the ALJ found, although the Hatch-Waxman Act allows FDA to approve an ANDA 30 months after the applicant has provided notice to the patent holder of its intent to market a generic drug, the threat of ruinous infringement damages leads generic companies to refrain from marketing their products after the 30-month period has expired for so long as patent litigation continues. ID 74. Specifically, he found that Upsher-Smith would not have begun marketing its generic version of K-Dur 20 in November 1998 when it received final approval of its ANDA, and ESI would not have begun marketing its generic product in June 1999 when it received final approval of its ANDA, had the patent litigation initiated by Schering still been ongoing on those dates. *Id.*

The litigation undoubtedly would have been pending on those dates in the absence of the settlements, in light of the uncontested evidence that the parties could reasonably have expected another five years of litigation in the absence of a settlement. IDF 394. In light of the uncertainty regarding when a final judgment could have been rendered in the absence of a settlement, as well as their unwillingness to present any evidence regarding the likely outcome of the litigation, Complaint Counsel have failed to demonstrate that the settlements resulted in *any* delay in generic competition. The only thing that is certain is that the

settlements allowed competition to begin five years earlier than it would have begun if the '734 patent had never been challenged and competition was delayed until after the patent was set to expire in September 2006.

Complaint Counsel seem to suggest that the settlements actually entered into by Schering, Upsher-Smith, and ESI are unreasonable because the parties might have entered into settlement that would have provided for earlier entry dates. While that may be true, the parties were under no obligation to do so. In the absence of evidence that one of the parties suggested a settlement involving an earlier entry date along with a smaller payment from Schering, there is no reason to establish a rule that the actual settlements were *per se* anti-competitive. If a generic company demands a cash payment as the price of a settlement that provides for entry prior to expiration of the patent and the only alternative is to continue with litigation for the indefinite future, there is every reason to conclude that such a settlement may well be pro-competitive.

Moreover, adopting Complaint Counsel's *per se* rule not only might discourage pro-competitive patent litigation settlements (among parties who fear antitrust liability), but might even discourage patents from being challenged in the first place. A generic company that knows that it would be unable to settle costly and time-consuming patent litigation might well decide not to file an ANDA for FDA-approved products for which a patent is listed in the Orange Book; the company might well decide that the potential rewards of filing are not worth the cost and time necessary to defend a patent infringement suit to final judgment -- even if the company strongly believes that it would win the infringement suit. Consumers and competition in general will suffer if fewer generics are available due to a reduction in

ANDA filings.

In sum, the *per se* rule espoused by Complaint Counsel has little to recommend it. It would decrease competition by discouraging parties from entering into pro-competitive patent litigation settlements.

V. UNDER A RULE OF REASON ANALYSIS, COMPLAINT COUNSEL HAVE FAILED TO INTRODUCE EVIDENCE SUGGESTING THAT THE CHALLENGED SETTLEMENTS ARE ANTI-COMPETITIVE

The June 1997 Schering/Upsher-Smith litigation settlement agreement provided that Upshur-Smith could begin marketing its generic version of K-Dur 20 in September 2001 -- five years earlier than Upsher-Smith could have begun marketing if it had waited until after expiration of the '743 patent but 34 months after FDA authorized Upsher-Smith to begin marketing, by approving Upsher-Smith's ANDA. The June 1998 Schering/ESI litigation settlement agreement provided that ESI could begin marketing its generic version of K-Dur 20 in January 2004 -- 32 months earlier than ESI could have begun marketing if it had waited until after expiration of the '743 patent but 4 1/2 years after FDA authorized ESI to begin marketing, by approving ESI's ANDA.

Accordingly, a key component of any rule of reason analysis must be an examination of the likelihood that Schering would have prevailed in its patent infringement lawsuits if they had not settled. If the '743 patents were highly likely to be deemed valid and Upsher-Smith's and ESI's efforts to market a generic version of K-Dur 20 were highly likely to be deemed to infringe the '743 patent, then any agreement that provided generic marketing prior to September 2006 would be strongly pro-competitive -- because it would allow generic competition earlier than would otherwise have been allowed. If, on the other hand, the '743

patent were likely to be deemed invalid or Upsher-Smith's and ESI's marketing of a generic version of K-Dur 20 were highly unlikely to be deemed to infringe the '734 patent, then any agreement that provided for a delay in generic marketing until after the dates on which final judgments would likely have been entered in Upsher-Smith's and ESI's favor in the patent litigation would be anti-competitive.

Complaint Counsel introduced no evidence whatsoever regarding the validity of the '743 patent or whether Upsher-Smith's and ESI's proposed marketing of a generic version of K-Dur 20 would have infringed the '743 patent. Indeed, Complaint Counsel asserted that it had no means of reliably predicting the outcome of the patent litigation. ID 74. Respondents, on the other hand, introduced evidence that Schering likely would have prevailed at trial. In light of that evidence, there is no reason to conclude that, in the absence of a settlement, any generic K-Dur 20 would have reached the market prior to September 2006. Accordingly, there can be no basis for overturning the ALJ's determination, under a rule of reason analysis, that neither the Schering/Upsher-Smith agreement nor the Schering/ESI agreement was anti-competitive.

WLF recognizes that handicapping the outcome of litigation can be an inexact science. Nonetheless, judges are called upon all the time to engage in that type of analysis. For example, no class action lawsuit filed under Rule 23 of the Federal Rules of Civil Procedure may be dismissed or settled without the approval of the judge overseeing the case (Rule 23(e)), and judges are not to grant such approval without first determining that the dismissal/settlement is fair to the parties -- a determination that requires the judge to assess the strength of the plaintiffs' case. Similarly, if Complaint Counsel wish to convince the

Commission that a particular patent litigation settlement is anti-competitive, it is incumbent on them to provide at least *some* basis for concluding that, in the absence of the settlement, competing products would have entered the market at an earlier date.

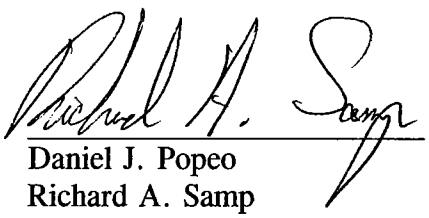
Complaint Counsel ask the Commission to conclude, despite the absence of such evidence, that Schering paid cash not to purchase licenses (in the case of Upsher-Smith) or to facilitate a pro-competitive litigation settlement (in the case of ESI), but rather for the sole purpose of delaying the onset of generic competition. The ALJ found that Complaint Counsel failed to make such a showing, ID 103, and they have pointed to nothing in the record that should cause that finding to be overturned.

Evidence supporting Complaint Counsel's contention would include evidence that the parties bargained back on forth on the amount of cash payments in relation to the date of entry. But there is no such evidence in this case. There is no evidence that any party ever suggested either increasing the cash payments in return for a later entry date, or granting an earlier entry date in return for reducing the cash payments. In the absence of such evidence there is simply no basis for concluding that the entry dates chosen were a function of the amount of money paid by Schering. Rather, there is every reason to accept at face value Respondents' contention that the entry dates were a reasonable compromise based on the parties' good-faith assessments of the relative strength of their litigation claims.

CONCLUSION

Amicus curiae Washington Legal Foundation respectfully requests that the Court affirm the ALJ's dismissal of the complaint.

Respectfully submitted,



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Counsel gratefully acknowledge the assistance of Moin Yahya, a student at George Mason University Law School, for his assistance in the preparation of this brief.

CERTIFICATE OF SERVICE

I hereby certify that on this 30th day of September, 2002, I served copies of the motion for leave to file brief as *amicus curiae* and the accompanying brief of Washington Legal Foundation as follows:

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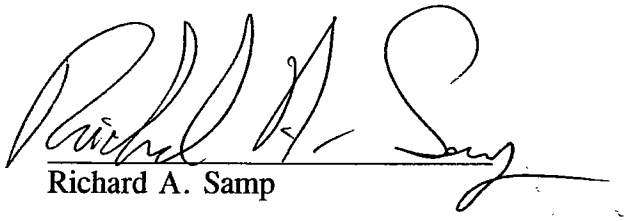

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