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

BRIEF OF *AMICUS CURIAE* NATIONAL ASSOCIATION OF CHAIN DRUG STORES

[PUBLIC]

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IDENTITY AND INTEREST OF *AMICUS CURIAE*

National Association of Chain Drugs Stores, Inc. ("NACDS") is a tax exempt association of nearly 200 chain community pharmacies that operate over 34,000 pharmacies throughout the United States.[1] Chain operated community retail pharmacies fill over seventy (70) percent of the three (3) billion prescriptions that are dispensed annually in the United States. Anticompetitive practices by drug manufacturers, such as the practices at issue in this appeal, harm NACDS members and their customers by maintaining artificially high prices for prescription drugs. NACDS believes that its industry-wide perspective on this important problem will be of assistance to the Commission, and, accordingly, NACDS moves for leave to file this *amicus curiae* brief pursuant to 16 C.F.R. § 3.52(j).

ISSUE URGED

It is *per se* unlawful for a patent holder to pay an alleged infringer to stay out of the market.

SUMMARY OF ARGUMENT

In enacting the Hatch-Waxman Amendments, Congress intended to create a system that would facilitate the entry of generic drugs into the marketplace for the benefit of consumers. As part of this system, Congress encouraged generic drug manufacturers to challenge weak patents. Generic manufacturers are natural competitors of brand-name pharmaceutical manufacturers and are uniquely situated to launch and maintain such challenges. The system enacted by Congress would be

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[1] Several private antitrust cases have been brought against Schering, Upsher, and ESI relating to the agreements at issue here. Many NACDS members have an interest in the outcome of those cases as members of the putative classes or as individual plaintiffs.

turned on its head if generic manufacturers were permitted to conspire with brand name manufacturers to eliminate competition between them. Unless agreements like those at issue here are summarily condemned under the antitrust laws, drug companies will be able to extract billions of dollars in overcharges from consumers in the coming years.

Courts have held that payments by patent holders to alleged infringers to acknowledge validity and infringement of the patent and/or to stay off of the market for a defined period of time are *per se* illegal. *See In re Terazosin Hydrochloride Antitrust Litigation*, 164 F. Supp. 2d 1340 (S.D. Fla. 2000), *appeal filed* No.02-10171-5 (11th Cir.); *In re Cardizem CD Antitrust Litigation*, 105 F. Supp. 2d 682 (E.D. Mich. 2000), *appeal filed* No.00-2483 (6th Cir.); *see also Andrx Pharmaceuticals, Inc. v. Biovail Corp. Int'l*, 256 F.3d 799 (D.C. Cir. 2001); *Eon Labs Mfg., Inc. v. Watson Pharmaceuticals, Inc.*, 164 F. Supp. 2d 350 (S.D.N.Y. 2001); *Biovail Corp. v. Hoechst AG*, 49 F. Supp.2d 750 (D.N.J. 1999). That conclusion has been endorsed by respected commentators. *See, e.g.*, II H. Hovenkamp, et al., IP AND ANTITRUST: AN ANALYSIS OF ANTITRUST PRINCIPLES APPLIED TO INTELLECTUAL PROPERTY LAW § 33.2, at 33-13 to 33-14 (2002); Balto, *Pharmaceutical Patent Settlements: The Antitrust Risks*, 55 Food Drug L.J. 321 (2000) [hereinafter "*Balto*"]; Leffler, *Want to Pay a Competitor to Exit the Market? Settle a Patent Infringement Case*, 2 ABA Antitrust Sec. Econ. Comm. Newsl. 26 (2002) [hereinafter "*Leffler*"]; Brodley, *Patent Settlement Agreements*, 16 Antitrust 53 (2002); Feinstein, Testimony before the Joint DOJ/FTC Hearings on Competition and Intellectual Property Law & Policy in the Knowledge-Based Economy (May 2, 2002).

The Initial Decision rendered by the ALJ in this matter ("Initial Decision"), however, rejected application of the *per se* rule. We will demonstrate in this brief that the ALJ's rejection of the

per se rule rests upon a fundamental misunderstanding of the nature of both a patent and the *per se* rule itself. Specifically, we will show

- A finding of *per se* unlawfulness here would not require the Commission to adopt a "new" *per se* rule. Since the enactment of the Sherman Act, it has always been *per se* unlawful, absent integrative efficiencies, for one competitor to pay another not to compete. The agreements at issue here are unusual only in their brazenness.

- The decisions in *Cardizem* and *Terazosin* are not distinguishable on the grounds articulated by the ALJ. One of the agreements in *Terazosin*, like the agreements here, involved a final and not an interim settlement. Moreover, a final settlement in which a patent holder pays the alleged infringer not to contest validity and infringement is more, not less, pernicious than an interim settlement.

- Per se invalidity does not require an antitrust plaintiff to first demonstrate that the challenged patent would have been found to be invalid or not infringed but for the unlawful agreement. The reward granted by Congress to patent holders for innovation is a patent that enjoys only a rebuttable, not a conclusive, presumption of validity (and no presumption at all of infringement). The unlawful payment by the patent holder to the alleged infringer eliminates the probability that the patent will be found to be invalid or not infringed and eliminates along with it the consumer benefit that the probability creates. The unlawful payment destroys the alignment of interests between consumers and the generic manufacturer in using that probability to bring a generic product onto the market.

- Schering's payment of $90 million to its generic competitors clearly allowed it to exert exclusionary power beyond that resulting from the patent itself. Schering

confronted its competitors not only with the "stick" of the power of the patent, but also with the "carrot" of tens of millions of dollars. There cannot be a clearer case of an exclusion beyond that effected by the patent itself.

- A finding of *per se* illegality does not depend upon the plaintiff demonstrating that any anticompetitive harm actually resulted from the unlawful restraint. Market division

agreements like those at issue here hold a great potential to cause competitive harm, and that potential is sufficient to warrant *per se* condemnation. Whether harm actually results is a question of causation, not violation.

This brief addresses the *per se* illegality of the agreements on the ground that the payments were made in exchange for market exclusion, *i.e.*, our analysis assumes that the ALJ erroneously concluded that the payments were in bona fide exchange for licenses. In order to enhance

understanding, the brief first demonstrates that a payment by a patent holder to a challenger in exchange for market exclusion is *per se* unlawful. We then show that the conclusion does not change where, as here, the patent holder combines the payment of cash with the granting of a limited license.

ARGUMENT

I. CONDEMNING THESE AGREEMENTS *PER SE* DOES NOT REQUIRE ADOPTION OF A NEW RULE.

In exchange for the payment of $60 million, Upsher agreed that it would "not market in the United States its KLOR CON M 20 potassium chloride product, or any other sustained release microencapsulated potassium chloride tablet, prior to September 1, 2001." (Agreement ¶ 3.) In exchange for the payment of $30 million, ESI agreed that it would not "prior to January 1, 2004, sell, offer to sell or market in the United States any Referencing Product, or from and after January 1, 2004 and until September 5, 2006, sell, offer to sell or market in the United States more than a single Referencing product." (Agreement ¶ 3.1(a)(iii).) Under any reasonable definition, these are horizontal market allocation agreements.

For more than a century, agreements between actual or potential competitors to allocate territories or customers have been considered unreasonable *per se* under Section 1 of the Sherman Act. *See, e.g., United States v. Addyston Pipe & Steel Co.*, 85 F. 271, 293-94 (6th Cir. 1898), *aff'd*, 175 U.S. 211 (1899); *see also Palmer v. BRG of Georgia, Inc.*, 498 U.S. 46, 49-50 (1990); *Copperweld Corp. v. Independence Tube Corp.*, 467 U.S. 752, 768 (1984); *United States v. Topco Associates, Inc.*, 405 U.S. 596, 608 (1972). By insulating the conspirators from competition, this sort of scheme "interfere[s] with the setting of price by free market force." *United States v. Container Corp.*, 393 U.S. 333, 337 (1969). Within its allocated sphere, each conspirator

unilaterally sets output and price, which "naturally" inflates the price. *Addyston Pipe* & *Steel*, 175 U.S. at 241.

The Initial Decision nevertheless asserts that courts and enforcement agencies should be slow to "adopt" a *per se* rule until they have experience with a particular fact pattern that has been vetted in the "economic literature." (Initial Decision at 96, 98.) Under this approach, *United States v. Socony-Vacuum Oil Co.*, 310 U.S. 150 (1940), would have been a rule-of-reason case, since courts and academicians had not previously considered the legality of a horizontal agreement among competing oil producers to restrict supply; and the same is true of *Palmer v. BRG of Georgia, Inc.*, 498 U.S. 46 (1990), since courts and academicians in 1990 were completely unfamiliar with horizontal market-allocation agreements between providers of bar-review courses that divide up the United States.

The flawed reasoning of the Initial Decision was rejected in *Arizona v. Maricopa County Medical Society*, 457 U.S. 332, 349-51 & n.19 (1982), where the Court emphasized that "the argument that the *per se* rule must be rejustified for every industry that has not been subject to significant antitrust litigation ignores the rationale for *per se* rules, which in part is to avoid 'the necessity for an incredibly complicated and prolonged economic investigation into the entire history of the industry involved, as well as related industries, in an effort to determine at large whether a particular restraint has been unreasonable -- an inquiry so often wholly fruitless when undertaken.'" (quoting *Northern Pacific R. Co. v United States*, 356 U.S. 1, 5 (1958)). Thus, applying an ***existing*** *per se* rule to a new fact pattern must be distinguished from creating a ***new*** *per se* rule. *Id.* at 349 n.19.[2]

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[2] Similarly, the existence of scholarly disagreement about the applicability of a *per se* rule has (continued...)

It is *per se* unlawful (absent integrative efficiencies) for one competitor to pay another not to enter the market. That result does not change merely because the payment was less than it otherwise would have been absent the payor's ownership of a patent. Reaching that conclusion does not require adoption of a new *per se* rule; it requires only the application of the existing rule after parsing the defendants' pleas for an exception.

As we demonstrate next, no exception is justified here.

II. THE AGREEMENTS ARE AT LEAST AS PERNICIOUS AS THOSE CONDEMNED IN *CARDIZEM* AND *TERAZOSIN*.

The Initial Decision asserts that the district court decisions in *Cardizem* and *Terazosin* are distinguishable because they involved only "interim" settlements rather than the final settlements at issue here. (Initial Decision at 97.) That assertion is wrong both factually and legally.[3]

In *In re Terazosin Hydrochloride Antitrust Litigation*, 164 F. Supp. 2d 1340 (S.D. Fla. 2000), the court held that two separate agreements were *per se* unlawful. The agreement between Abbott and Zenith, like the agreements here, called for the complete settlement of a lawsuit in exchange for cash paid by the patent holder. The generic manufacturer, Zenith, brought a declaratory judgment action against Abbott, asserting that Abbott had improperly listed two patents with the FDA and that Zenith therefore should be entitled to market its generic product immediately. *Id.* at 1344. Abbott

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[2](...continued)
never been considered grounds for declining to apply it. *See FTC v. Superior Court Trial Lawyers Ass'n*, 493 U.S. 411, 421-22 (1990).

[3] We address below (*see infra* pp. 23-25) the Initial Decision's assertion that the *Cardizem* decision is distinguishable because it did not involve the payment of cash *plus* the granting of a license.

counter-claimed for patent infringement. *Id.* In exchange for substantial cash payments, Zenith, like Upsher and ESI here, agreed to dismiss its claims and not to enter the market. *Id.* at 1346.

The *Terazosin* court had no trouble concluding that the Abbott/Zenith agreement "forestall[s] competition in the United States for sales of [prescription] drugs" and is "one of the classic examples of a *per se* violation" of the Sherman Act. *Id.* at 1349. Rejecting many of the same "defenses" raised by the defendants here, the court concluded that the agreement "resulted in a cooperative agreement to forestall competition, not to enhance it." *Id.* at 1351. Thus, the Initial Decision's assertion that *Terazosin* involved only interim settlements is simply wrong.[4]

Two of the three agreements at issue in *Terazosin* and *Cardizem* involve only "interim" settlements. While the Initial Decision correctly held that those two agreements were factually distinguishable from the agreements at issue here, the Initial Decision did not properly analyze the legal significance of that distinction. The Initial Decision asserts that final as opposed to interim settlements are entitled to more lenient antitrust treatment because there is a public interest in the settlement of litigation. (Initial Decision at 99-100.) That analysis is wrong in at least two respects.

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[4] This latest rash of unlawful agreements in the pharmaceutical industry is not the first occasion for the courts and enforcement agencies to condemn payments by a patent holder to forestall a challenge to the patent. *See, e.g., United States v. Singer Mfg. Co.*, 374 U.S. 174, 199-200 (1963) (White, Jr., concurring) (agreement to settle a patent interference case "at least in part, to prevent an open fight over validity" was unlawful because "the patent laws do not authorize, and the Sherman Act does not permit, such agreements between business rivals to encroach upon the public domain and usurp it to themselves"); *American Cyanamid Co.*, 72 F.T.C. 623, 1967 FTC LEXIS 43, 71 (1967) (competitor's agreement to withhold potentially invalidating information from patent office, in exchange for license, is unlawful), *aff'd sub nom. Charles Pfizer & Co. v. FTC*, 401 F.2d 574 (6th Cir. 1968). *See generally Andrx Pharms., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 813 n.15 (D.C. Cir. 2001) (discussing *Singer* and *American Cyanamid*). These cases are themselves merely applications of the century-old proposition that a patent holder is subject to the ordinary antitrust strictures when he exerts exclusionary power beyond that conferred by the patent. (*See infra* pp. 14-15)

First, while there is generally a public interest in the final settlement of litigation, it is not obvious why there is any less of a public interest in the interim settlement of litigation. Each avoids transaction costs resulting from litigation. The magnitude of transaction costs associated with each type of settlement is presumably commensurate with the magnitude of the litigation proceeding foregone and, indeed, the absolute magnitude of transaction costs associated with particular preliminary injunction proceedings (avoided by an interim settlement) will in some instances be larger than those associated with a final settlement. The courts in both *Cardizem* and *Terazosin* nevertheless held that interim settlements were *per se* unlawful.

Second, and more importantly, the Initial Decision assumes without analysis that a final settlement in which the challenger agrees to stay out of the market is less anticompetitive than an interim settlement in which the challenger agrees to stay out of the market only pending resolution of the litigation but preserves his right to challenge validity or non-infringement.

That assumption is wrong. The efficiency of settling litigation depends upon the nature of the litigation that is settled. Where, as here, the challenger's purpose in launching a challenge to patent validity or infringement is to bring a competing product onto the market, "there is a public interest favoring the judicial testing of patent validity and the invalidation of specious patents." *United States v. Glaxo Group, Ltd.*, 410 U.S. 52, 69 (1973) (Rehnquist, C.J. dissenting); *see also id.* at 58 ("it is as important to the public that competition should not be repressed by worthless patents, as that the patentee of a really valuable invention should be protected in his monopoly. . . .") (majority decision); *Blonder-Tongue Laboratories, Inc. v. University of Illinois Foundation*, 402 U.S. 313, 343 (1971).

The Initial Decision made a profound error in failing to recognize that the purpose of this type of patent challenge is to bring a competing product onto the market. Society has an interest in avoiding transaction costs whenever a new entrant attempts to unseat an incumbent rival: a new supermarket chain entering a local geographic area incurs substantial expenses in attempting to enter successfully against the incumbent supermarket chains; electronics manufacturers incur substantial development costs in attempting to design around existing patents. But society has a far more pressing interest in preserving incentives for would-be entrants to incur those costs (and to inflict corresponding costs on the incumbents) when, in their judgment, those costs are justified by the probability-adjusted expected profits from successful entry. For that reason, it has long been *per se* unlawful for incumbents to pay potential entrants to cease their entry efforts, and it is simply irrelevant that the pay-off would have avoided significant transaction costs. The *per se* rule should apply in the same way when the means of entry is a potentially successful patent challenge. (*See infra* pp. 19-21)

III. THE ANTITRUST PLAINTIFF NEED NOT ESTABLISH THAT THE PATENT WOULD HAVE FOUND TO BE INVALID OR NOT INFRINGED.

The Initial Decision seems to suggest that a payment from the patent holder to the challenger should be unlawful only if the antitrust plaintiff first proves that the patent is invalid.[5] (Initial Decision at 99.) The rationale for this proposed rule appears to be the notion that such a payment

[5] For ease of reference here, we analyze the issue in terms of whether the patent is valid versus invalid instead of whether it is infringed versus not infringed. The same essential analysis applies to either situation.

causes no harm to consumers if the patent is valid, and therefore the payment should be deemed lawful unless the antitrust plaintiff first demonstrates that the patent is invalid.

The syllogism appears to be this:

- For purposes of antitrust analysis, patents are appropriately categorized as being either valid or invalid;
- A payment to recognize the validity of a valid patent is not anticompetitive;
- Therefore, a payment to recognize the validity of a patent can be anticompetitive only if the patent is invalid.

This argument rests on a false, black-and-white worldview in which patents are categorized as being either valid or invalid. The reality is that there exists a third category: patents whose validity is subject to challenge. And it is precisely this real-world category that is the relevant one here. Manufacturers enter into these agreements when they are disputing *whether* the patent is valid or invalid and before the patent court has removed that uncertainty. It is in this *real* context -- not some hypothetical context in which patents are *known* to be valid or *known* to be invalid -- that the lawfulness of such agreements must be judged. The law is abundantly clear that the legality of an agreement under the antitrust laws is determined based on the circumstances as they existed at the time of the agreement. *See, e.g.*, XI Hovenkamp, *ANTITRUST LAW* ¶ 1901, at 185-86 (1998); *SCM Corp. v. Xerox Corp.*, 645 F.2d 1195, 1207 (2d Cir. 1981); *Taylor Publ'g Co. v. Jostens Inc.*, 216 F.3d 465, 475 (5th Cir. 2000).[6]

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[6] The courts in both *Cardizem* and *Terazosin* held the agreements there *per se* unlawful without regard to whether the patents were valid or infringed. *See Cardizem*, 105 F. Supp. 2d at 699; *Terazosin*, 164 F. Supp. 2d at 1348-50. And the court in *Terazosin* held that the agreement to terminate Zenith's challenge to the patent listing was *per se* unlawful regardless of whether that lawsuit

(continued...)

In this relevant context, it is clearly anticompetitive for a patent holder to pay a potential competitor to drop a challenge to the patent. The "right" granted by Congress to a patent holder is the right to ask a federal court to exclude competitors under the procedures dictated by Congress. As the Supreme Court famously held in *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100 (1969): "The heart of [the patent owner's] legal monopoly is the right *to invoke the State's power* to prevent others from utilizing his discovery without his consent". *Id.* at 135 (emphasis added). Congress provided that in patent litigation the patent shall enjoy only a *rebuttable* presumption of validity. 35 U.S.C. § 282. Congress did *not* provide, as it might have, that a patent once issued is conclusively presumed to be valid. And, of course, contrary to the Initial Decision, there is no presumption at all that a patent has been infringed. (*Contra* Initial Decision at 104.)

Challengers thus have an incentive to litigate validity or infringement whenever the potential profit from selling the product, discounted by the probability of losing the lawsuit, exceeds the costs of the litigation. Thus, "the patent rules provide an economic incentive for alleged infringers to seek a judicial finding of invalidity or non-infringement." *Leffler*, at 30.

Moreover, Congress designed the patent litigation system in such a way that consumers can reap the benefits of this possibility that a patent will be invalidated.[7] For example, if there is a 10%

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[6](...continued)
was meritorious -- indeed, the district court hearing the Zenith/Abbott delisting case had denied Zenith's motion for preliminary injunction. *Terazosin*, 164 F. Supp. 2d at 1345.

[7] Although there is a statutory presumption that a patent is valid, 35 U.S.C. § 282, patents are issued in *ex parte* proceedings and it is not at all uncommon for them to be held invalid. *See* Allison and Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185, 205 (1998) (concluding that almost half of all patents that are fully litigated are found to be invalid). If there were not some probability that the patent court would have found the patent to be invalid or not
(continued...)

probability that a particular patent will be found to be invalid, consumers will benefit from that probability if either of two events occurs. *First*, consumers will benefit if the litigation continues and the patent is invalidated. That is why the Supreme Court has repeatedly held that there is a vital public interest in having invalid patents exposed as such through litigation. (*See supra* at 9-10.)

Second, consumers will benefit if the challenger uses the leverage provided by that 10% probability to procure a license from the patent holder. As the court noted *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 166 F. Supp. 2d 740, 749 (E.D.N.Y. 2001),

"If in fact Bayer would have licensed or authorized Barr to distribute ciprofloxacin rather than risk the loss of its patent, plaintiffs would have benefited from the resulting competition . . . ."[8] *Id.* at 749. The consumer benefit results from the fact that the license royalty rate will be discounted to reflect the litigants' views of the probability that the patent will be invalidated. *Leffler*, at 32.

Thus, absent a payment from the patent holder to the challenger, the challenger's interests are aligned with those of consumers: the challenger can make profits only by selling the generic product to consumers, and he can make those sales by invalidating the patent or using the threat of

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[7](...continued)
infringed, Schering would not have been willing to pay Upsher and ESI more than Schering's future litigation costs in order to drop the patent challenge.

[8] An alleged infringer can use the leverage provided by such a threat to negotiate a license to market the patented goods. *See C.R. Bard Inc. v. Cordis Corp.*, 1996 U.S. Dist. LEXIS 6374, at *5 (D. Mass. Mar. 4, 1996) ("Parties to a patent infringement suit commonly settle litigation with an agreement granting a license to the alleged infringer."); *In re Mahurkar Double Lumen Hemodialysis Catheter Patent Litig.*, 831 F. Supp. 1354, 1378 (N.D. Ill. 1993) *aff'd sub nom. Quinton Instruments Co. v. Impra, Inc.*, 71 F.3d 1573 (Fed Cir. 1995) (noting that "the settlement of patent litigation . . . often includes an explicit license").

invalidation to obtain a license from the patent holder. *See id.* at 31 ("The self interest of the challenger . . . motivates it to take actions benefiting consumers.").

The patent holder's payment to the challenger deadens his incentive to challenge the patent -- an incentive created and expressly strengthened by Congress. The suppression of that incentive destroys "the alignment of interests between consumers and [generic] manufacturer." *Premier Elec. Constr. Co. v. National Elec. Contr. Ass'n, Inc.*, 814 F.2d 358, 369 (7th Cir. 1987). An agreement among competing manufacturers that destroys that alignment of interests is not only unlawful but "will be illegal *per se*." *Id.*

Such unlawful agreements "depriv[e] [consumers] of their right to a market in which manufacturers and distributors of generic drugs make their decisions about challenging patents and entering markets free from the influence of cash payments. . . ." *In re Ciprofloxacin*, 166 F. Supp. 2d at 749. Rather than using the leverage provided by the patent challenge to enter the market and make profits by selling a product to consumers, Upsher and ESI instead simply accepted the probability-adjusted expected value of those profits from the competitor from whom they would have taken the sales. They entered into classic market allocation agreements.

In sum, the Initial Decision rests on the unspoken but essential premise that, for purposes of antitrust analysis, patents are categorized as either valid or invalid. That premise (1) ignores the real-world fact that Schering agreed to pay $90 million precisely in order to avoid a determination as to patent validity/infringement, and (2) ignores the economic reality that Upsher and ESI could have used the threat of a finding of invalidity/non-infringement to obtain a license from Schering and that consumers would have thus benefited from the *risk* that the patent would be found to

be invalid/non-infringed. A plea that antitrust plaintiffs be required first to prove patent invalidity is a plea to ignore these most salient economic features of the issue.

IV. THE PAYMENT OF $90 MILLION WAS BEYOND THE SCOPE OF THE PATENT.

The Initial Decision acknowledges that the Supreme Court has applied the *per se* rule when the patent holder has exerted exclusionary power beyond that conferred by the patent. (Initial Decision at 100.) But the Initial Decision did not apply such an analysis here because the ALJ concluded that the $90 million payments were in exchange for bona fide licenses rather than in exchange for exclusion. *Id*. Assuming that the Commission finds that the ALJ's factual conclusion was erroneous, the following analysis demonstrates that the payments were beyond the scope of the patent.

The law is well settled that a patent holder who exerts exclusionary power beyond that flowing from the patent is subject to either the *per se* rule or the rule of reason, depending upon the nature of the restraint. If the restraint is one subject to *per se* condemnation under the ordinary antitrust strictures, then that is the rule that will apply. *See Palmer v. BRG*, 498 U.S. at 49-50; *United States v. Glaxo Group, Ltd.*, 410 U.S. at 56; *United States v. Topco Assocs.*, 405 U.S. at 610-11; *United States v. Sealy, Inc.*, 388 U.S. 350, 355 (1967); *United States v. Line Material Co.*, 333 U.S. 287, 308 (1948); *United States v. Masonite Corp.*, 316 U.S. 265, 279 (1942); *In re Yarn Processing Patent Validity Litig.*, 541 F.2d 1127, 1134-36 (5th Cir. 1976); *Terazosin*, 164 F. Supp. 2d at 1349; *Cardizem*, 105 F. Supp. 2d at 699; *United States v. General Electric Co.*, 1997-1 Trade Cas. ¶ 71,765, 1997 WL 269491 (D. Mont. 1997); *Duplan Corp. v. Deering Milliken, Inc.*, 444 F. Supp. 648, 677-78 (D.S.C. 1977), *aff'd in part and rev'd in part on other grounds*, 594 F.2d 979 (4th Cir. 1979); *United States v. Krasnov*, 143 F. Supp. 184 (E.D. Pa. 1956); *United States v.*

Crown Zellerbach Corp., 141 F. Supp. 118, 126-28 (N.D. Ill. 1956); *United States v. Imperial Chem. Indus.*, 100 F. Supp. 504, 592-93 (S.D.N.Y. 1951); *United States v. National Lead Co.*, 63 F. Supp. 513, 523-24 (S.D.N.Y. 1945), *aff'd*, 332 U.S. 319 (1947). Here, the restraint is in the form of a horizontal market allocation agreement; such agreements are clearly *per se* unlawful.

Defendants assert that Schering's patent gave it a "right to exclude" competitors. It is true that some courts, as a short-hand expression, refer to a patent holder's "right to exclude." *See, e.g., Rhone-Poulenc Agro, S.A. v. DeKalb Genetics Corp.*, 271 F.3d 1081, 1088 (Fed. Cir. 2001). But such expressions must be recognized as the short-hand that they are. Properly stated, a patent holder's right is the right to *request a court*, under the procedural rules as determined by Congress, to exclude a competitor. *Zenith Radio Corp. v. Hazeltine Research*, 395 U.S. at 135. It is not a right to pay a competitor to exclude itself.

Thus, for example, a patent holder cannot resort to self-help, destroy his competitors' allegedly infringing goods, and then defend against the resulting criminal charges on the ground that he had a "right to exclude" the infringing goods. *See United States v. Patterson*, 205 F. 292, 299 (S.D. Ohio 1913), *rev'd on other grounds*, 222 F. 599 (6th Cir. 1915). Similarly, a patent holder (except as provided in the Hatch-Waxman Amendments) has no automatic right to exclusion pending resolution of a patent lawsuit, but must satisfy the preliminary injunction criteria just like everybody else. *See, e.g., Illinois Tool Works, Inc. v. Grip Pak, Inc.*, 906 F.2d 679, 684 (Fed. Cir. 1990); *Easter Unlimited Inc. v. Rubie's Costume Co., Inc.*, 2000 U.S. Dist. LEXIS 13337, at *27 (S.D.N.Y. Sept. 15, 2000). Indeed, courts frequently deny preliminary injunctions in patent cases on the very ground that, until a final judicial determination of validity and infringement, the challenger has a "right to compete." *Id.*

Far from giving patent holders any kind of absolute "right to exclude," Congress created economic incentives for alleged infringers to challenge the validity of patents. As noted above, Congress did *not* provide, as it might have, that a patent once issued is conclusively presumed to be valid. This vulnerability of the patent to challenge creates an incentive for potential competitors to litigate validity or infringement rather than knuckle under to the patent holder's alleged "rights." And in the Hatch-Waxman Amendments, Congress increased the incentive to challenge pharmaceutical patents by providing the 180-day exclusivity for the generic "first filer."[9]

The unlawful agreements with Upsher and ESI permitted Schering to obtain the exclusion of those companies from the market other than through the rights granted to Schering by Congress. Schering would have been acting within the scope of its patent rights if it had obtained the exclusion of Upsher and ESI by obtaining or threatening to obtain from the patent court the remedies provided by Congress. For example, Schering could have attempted to convince Upsher and ESI to drop the patent challenge based on the alleged strength of the patent and the prospect that Schering would obtain permanent injunctive relief. Whether that threat would have been sufficient to induce

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[9] Congress also expressly gave generic manufacturers the right to challenge pharmaceutical patents without first entering the market and thus becoming potentially subject to patent damages. In a non-Hatch-Waxman patent litigation in which the challenger has already entered the market, the challenger calculates the probability and potential benefit of a finding of invalidity and weighs that value against (a) the cost of continued litigation *and* (b) the potential damages should the patent be found to be valid.

But Congress substantially altered that calculation in the context of Hatch-Waxman patent litigation: the challenger makes the same calculation as to the probability and potential benefit of a finding of patent invalidity but, because he need not have first entered the market in order to challenge the patent, weighs that value against *only* the future litigation costs. Thus, Congress substantially *increased* the incentive for generic manufacturers to challenge pharmaceutical patents, and concomitantly substantially *increased* the challenger's leverage to obtain a license from the patent holder.

Upsher and ESI to drop the challenge would have depended on Upsher's and ESI's view of the likelihood of succeeding in the case (weighed, of course, against the cost of pursuing the litigation). *Cf*. *Aronson v. Quick Point Pencil Co.*, 440 U.S. 257, 265 (1979) (exclusionary power of pending patent application "depends on how likely the parties consider it to be that a valid patent will issue"); *Clorox Co. v. Sterling Winthrop, Inc.*, 117 F.3d 50, 60-61 (2d Cir. 1997) (where there was no payment by rights holder to alleged infringer, settlement of intellectual property litigation was presumed to flow from "hard-nosed trademark negotiations" and "the result should accord with how the parties view their respective rights").

But here, Schering obtained the exclusion of Upsher and ESI not only by threatening to enforce the statutorily-approved patent rights, *but also by making an extra-statutory payment of $90 million*. Schering confronted its competitors not only with the "stick" of the power of the patent, but also with the "carrot" of millions of dollars.

In obtaining the exclusion of Upsher and ESI other than through the patent rights granted by Congress, Schering subjected itself and its co-conspirators to the ordinary strictures of the antitrust law, including the *per se* rule. The Federal Circuit has explained the principle this way: "On the one hand, the patent owner must be allowed to protect the property right given to him under the patent laws. On the other hand, *a patent owner may not take the property right granted by a patent and use it to extend his power in the marketplace improperly, i.e., beyond the limits of what Congress intended to give in the patent laws." Atari Games Corp. v. Nintendo of America, Inc.,* 897 F.2d 1572, 1576 (Fed. Cir. 1990) (emphasis added). In agreeing to pay Upsher and ESI $90 million to drop the challenge to the patent and to stay out of the market, Schering indisputably acted "beyond the limits of what Congress intended to give." *Id.*

The critical distinction between exerting the exclusionary power of a patent versus exerting extra-patent exclusionary power (such as the power of $90 million) is illustrated by considering two examples:

Example 1: Assume that the alleged infringer has already entered the market and become potentially subject to a claim for patent damages. The patent holder agrees to waive accrued damages in exchange for the challenger's agreement to exit the market. In such a case, the only source of the exclusion is the patent: one of the rights conferred by a patent is the right to seek damages from an alleged infringer. In threatening the challenger with the imposition of patent damages, and in waiving them in exchange for an agreement to exit, the patent holder is merely exercising the exclusionary power of the patent.

The case here is fundamentally different: Schering obtained the exclusion of Upsher and ESI from the market *not* by using the exclusionary power of the patent, but by using that power *plus* the power of $90 million. As explained in one trenchant analysis:

> Procuring a challenger's exit through a cash payment is fundamentally different from convincing the infringer that his expected profit from litigation is negative [*i.e.*, that he will be found liable for patent damages]. Congress has granted the patent holder certain substantive and procedural rights, and it is pro-competitive (because it advances dynamic efficiency) to permit the patent holder to procure the challenger's exit through the threat of the effective use of those rights. In contrast, a patent holder's payment to the challenger to stay out of the market has as its very purpose the creation of a market exclusion beyond that created by the patent rights granted by Congress.

Leffler, at 31.

Exclusion of a competitor based on the power of the patent is efficient because the exclusion is the inventor's reward for innovation; and innovation is vitally important to society. But the

reward that Congress gives to inventors is a patent that carries only a *rebuttable* presumption of validity.[10] Such a vulnerable patent may or may not be sufficient to exclude a potential competitor. To add to the exclusionary power of that patent by paying $90 million to the challenger is to enlarge, by private agreement, the reward that Congress in fact granted. It is to exert exclusionary power that results other than from efficiency. And that is, by definition, anticompetitive. *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585, 605 (1985); Bork, THE ANTITRUST PARADOX, at 264 (Free Press 1993).

Example 2: Company A decides to grant non-exclusive licenses and sets an industry-wide royalty rate of 5%. Company A is advised by Company B that it has done research about inventing around the patent and believes that it has discovered a non-infringing method. Thus, Company B will only agree on a license of less than 5%. Company A grants it a license with a royalty rate of 3%.

This arrangement would not be *per se* unlawful because (a) the license permits the challenger to enter the market and (b) the "consideration" paid by the patent holder -- the waiver of a 2% royalty that otherwise would have been collected -- flows from the patent itself.

But now change the example to invoke the facts here: Company B is attempting to enter the market by developing a non-infringing product. There is some probability that Company B's development efforts will succeed and that it could therefore enter the market royalty-free. That

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[10] Some commentators contend that patent holders should be permitted to pay challengers to drop their challenges because courts and juries can make "mistakes," *e.g.*, they can "erroneously" conclude that a patent is invalid. For purposes of antitrust analysis, however, there are no "mistakes" in patent litigation -- Congress designated the federal courts, in a defined process of patent litigation, as the final arbiters of whether a patent is valid. The reward that Congress gave to innovators was the right to have validity determined in that process.

probability gives Company B leverage to obtain the discounted license from Company A. But now add the critical fact that is different from the preceding example but mirrors what happened here: Rather than using the leverage to enter the market with a discounted license, Company B instead accepts $90 million to stop its design-around efforts.

It clearly is *per se* unlawful for the incumbent to pay the challenger to stop his efforts to develop a product that is designed around the patent. *See, e.g.*, XII Hovenkamp, *Antitrust Law* ¶ 2043, at 237 (1999) (an agreement "not to engage in a certain type of research and development should ordinarily be regarded as a naked output restriction in the market for new innovations, and thus should be illegal per se"); Von Kalinowski, *Antitrust Laws & Trade Regulation* (2d ed.) § 73.02 ("Per se liability will flow from a horizontal agreement among competitors to suppress the use of patents for purposes of restraining trade"); *Engine Specialties, Inc. v. Bombardier Ltd.*, 605 F.2d 1, 11 (1st Cir. 1979) (agreement not to market product in development is *per se* unlawful); *Discovision v. Disc Mfg., Inc.*, 1997 U.S. Dist. LEXIS 7507, at *37-39 (D. Del. Apr. 3, 1997) (agreement that "essentially eliminated any incentive to innovate and design around [defendant's] patents" is *per se* unlawful). Those design-around efforts have only some probability of succeeding -- they might well fail. But *whatever the magnitude of the probability of success*, it is clearly *per se* unlawful for the incumbent to pay the challenger to stop the design-around efforts. Whether the challenger in fact would have successfully designed around the patent is a question of *causation*, not of antitrust violation.

The same analysis applies to Schering's payment to Upsher and ESI to cease their efforts to have the patent declared invalid or not infringed. Invalidating the patent and designing around

it are simply two alternative ways of entering the market in the face of a competitor's patent.[11] The antitrust analysis is the same regardless of which method of entry the challenger pursues: paying a challenger to stop trying to enter the market by *either* method is clearly *per se* unlawful. *See generally Leffler*, at 31 (payment to challenger to stop design-around efforts is *per se* unlawful and "there is nothing different about a payment to drop the challenge to the patent").

V. WHETHER THE AGREEMENTS ACTUALLY CAUSED COMPETITIVE HARM IS A QUESTION OF CAUSATION, NOT VIOLATION.

The Initial Decision is clearly wrong to the extent that it suggests that there is no violation under Section 1 unless plaintiffs prove that the unlawful agreements in fact delayed generic entry. (Initial Decision at 100.) The law is well settled that "the essence of any violation of § 1 is the illegal agreement itself . . . proper analysis focuses, not upon actual consequences, but rather upon the *potential harm* that would ensue *if* the conspiracy were successful." *Summit Health, Ltd. v. Pinhas*, 500 U.S. 322, 330 (1991) (emphasis added); *see also Jefferson Parish Hospital Dist. No. 2 v. Hyde*, 466 U.S. 2, 16 (1984) (*per se* rule is applicable when there is "a substantial potential for impact on competition").

The *per se* rule under Section 1 is "analogous to *per se* restrictions upon, for example, stunt flying in congested areas or speeding;" even if in a particular instance those activities in fact "actually cause no harm," they clearly "pose some threat to the community." *FTC v. Superior Court*

[11] Indeed, the reality is that successfully defending a patent infringement lawsuit is often simply the last step in commercializing a product that has been designed around the incumbent's patent.

Trial Lawyers Ass'n, 493 U.S. 411, 433-34 (1990); *Copperweld v. Independence Tube*, 467 U.S. at 768 ("[c]ertain agreements, such as horizontal price fixing and market allocations, are thought so inherently anticompetitive that each is illegal *per se* without inquiry into the harm it has actually caused"); *FTC v. Indiana Fed. of Dentists*, 476 U.S. at 461-62.

The Supreme Court has consistently emphasized that the central focus of the Sherman Act is harm "to the competitive process, *i.e.*, to competition itself." *Nynex Corp. v. Discon*, 525 U.S. 128, 135 (1998). Regardless of whether a particular restraint in fact results in higher prices to consumers -- a question of causation -- a restraint is *per se* unlawful if it is "likely enough to disrupt the proper functioning of the price-setting mechanism of the market. . . ." *FTC v. Indiana Federation of Dentists*, 476 U.S. at 461-62. The very purpose of the Sherman Act is to prevent private parties from "preempt[ing] the working of the market. . . ." *Id.* at 462; *see also Brooke Group Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 220 (1993) (purpose of Sherman Act is to safeguard "the forces of competition"); *Spectrum Sports, Inc. v. McQuillan*, 506 U.S. 447, 458 (1993) (purpose of Sherman Act "is to protect the public from the failure of the market"). The Supreme Court has made this principle perfectly clear:

> Concerted activity inherently is fraught with anticompetitive risk. It deprives the marketplace of the independent centers of decision making that competition assumes and demands. In any conspiracy, two or more entities that previously pursued their own interests separately are combining to act as one for their common benefit. This not only reduces the diverse directions in which economic power is aimed but suddenly increases the economic power moving in one particular direction.

Copperweld Corp. v. Independence Tube, 467 U.S. at 768-69.

The Commission has before it a horizontal agreement in which the incumbent manufacturer has paid its closest possible rivals -- manufacturers that intended to sell at a much lower price the same chemical entity for use in treating the same medical condition -- not to enter the market. This is horizontal, interbrand competition of the most intense kind, and "the primary purpose of the antitrust laws is to protect interbrand competition." *State Oil Co. v. Khan*, 522 U.S. 3, 15 (19997); *see also Business Electronics Corp. v. Sharp Electronic Corp.*, 485 U.S. 717, 724 (1988).

Thus, the courts in both *Cardizem* and *Terazosin* definitively rejected the defendants' attempts to tie a finding of *per se* illegality to a showing of actual harm. The court in *Cardizem* held that whether the defendants' agreement had in fact kept generic competitors out of the market "is not at issue" on the motion for partial summary judgment: "'conspiracies under the Sherman Act are not dependent on any overt act other than the act of conspiracy. . . . It is the contract, combination . . . or conspiracy in restraint of trade or commerce which § 1 of the Act strikes down, whether the concerted activity be wholly nascent or abortive on the one hand, or successful on the other.'" *Cardizem*, 105 F. Supp. 2d at 70 (*quoting Socony-Vacuum Oil*, 310 U.S. at 224 n.9). Relying on the same holding in *Socony-Vacuum Oil*, the court in *Terazosin* reached the identical conclusion. 164 F. Supp. 2d at 1352; *see also Biovail Corp. Int'l v. Hoechst AG*, 49 F. Supp. 2d at 760 (distinguishing question of antitrust violation under Section 1 of the Sherman Act from question of whether plaintiff suffered injury under Section 4 of the Clayton Act).

VI. THE GRANTING OF A LIMITED LICENSE DOES NOT AMELIORATE THE *PER SE* UNLAWFULNESS OF THE AGREEMENTS.

The analysis thus far has focused on the *per se* illegality of the patent holder's payment of cash in exchange for market exclusion. Both the Schering/Upsher and Schering/ESI agreements, however, included the granting by Schering of a royalty-free license to the challengers for a limited period of time in addition to the payment of cash. The granting of this limited license does not vitiate the *per se* illegality of the agreements.

That conclusion results from two interrelated facts. *First*, if the antitrust rules permit the patent holder to give the challenger cash as well as a license, the self-interest of the patent holder and challenger will drive them to shorten the term of the license (or increase the royalty rate) and maximize the amount of the cash payment. In short, permitting cash payments will permit the patent holder and challenger to maximize the shared monopoly profits and then divide them by means of the cash payment. *See generally Leffler*, at 28.

Second, the instances in which a pure licensing settlement is not feasible -- one in which a combination of a license and a payment of a lump sum is necessary in order to reach an efficient settlement -- are exceedingly rare. They have been estimated to be less than 1% of the hypothetical potential cases under reasonable assumptions. *Leffler*, at 28. The witnesses here could not identify *any* circumstances in which such a payment was necessary to an efficient settlement. *See* Complaint Counsel's Proposed Findings of Fact, filed April 15, 2002, Nos. 1413-1427. Identifying any such rare cases would require complex economic evidence and subjective estimations of the probability that a patent would be found to be invalid or not infringed. The potential efficiency losses from an unlikely error of preventing an efficient settlement by proscribing lump sum payments are not likely to outweigh the costs of conducting such analyses. It is clearly appropriate to apply the *per se* rule under these circumstances. *See* Bork, THE ANTITRUST PARADOX, at 269 (Free Press 1993).

Contrary to the Initial Decision's assertion (Initial Decision at 97), the agreement in *Cardizem* involved both the payment of cash and the grant of a pre-patent-expiration license. *See* 105 F. Supp. 2d at 698. The court nevertheless held the agreement to be *per se* unlawful. The Commission should reach the same conclusion here.

CONCLUSION

For the reasons stated above, the agreements at issue are *per se* unlawful, and the Commission should so hold.

Respectfully submitted,

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Dated: August 26, 2002

CERTIFICATE OF SERVICE

I hereby certify that on August 19, 2002, I served a true and correct copy of the MOTION FOR LEAVE TO FILE BRIEF AS *AMICUS CURIAE* and the accompanying BRIEF OF *AMICUS CURIAE* NATIONAL ASSOCIATION OF CHAIN DRUG STORES as follows:

Original (with original signature) and 12 copies by hand deliver, as well as, an electronic version, which is a true and correct of the paper original, to:

Office of the Secretary
Federal Trade Commission - Room H-159
600 Pennsylvania Avenue, N.W.
Washington, D.C. 20580

One copy by hand delivery to the following:

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