UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

In the Matter of	)	
Schering-Plough Corporation, a corporation,	)	Docket No. 9297
Upsher-Smith Laboratories, Inc. a corporation,	)	
and	)	
American Home Products Corporation, a corporation.	)	

AMERICAN HOME PRODUCTS CORPORATION'S
STATEMENT OF THE CASE

Pursuant to the Scheduling Order dated May 3, 2001, American Home Products

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along with company organizational charts, and has received from complaint counsel no specific objection to the scope of the company's search or request to search additional personnel. Late yesterday, counsel for AHP received complaint counsel's motion to compel the production of documents, which seeks to compel AHP to produce all documents by

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2001, responses to interrogatories 1, 2, 5, 6, 9, 13, and 14. Commission Rule of Practice

[redacted]

complaint counsel, objecting to the deposition on the grounds that the deposition was unnecessary and, at best, premature. For nearly two months, complaint counsel did not press to pursue that deposition. It was AHP's understanding that complaint counsel was at least postponing its request for the deposition. Accordingly, counsel for AHP were surprised to receive, late yesterday, complaint counsel's motion to compel that deposition, to which AHP will respond promptly.

Second, complaint counsel noticed a Rule 3.33(c) deposition concerning a number of documents. The documents are protected by the attorney-client and work product privileges, and were inadvertently produced to the FTC by AHP during the pre-complaint investigation. AHP requested the return of the documents, but complaint counsel have refused to return them. Complaint counsel have demanded that a deposition on the documents go forward, but AHP has declined to produce a witness to testify about them. The documents and the Rule 3.33(c) deposition will be the subject of a motion for a protective order, which AHP expects to file as soon as the Court rules on AHP's request to file the motion under seal.

Finally, complaint counsel have noticed three additional depositions to take place in October [redacted]

III. LEGAL AND FACTUAL MATTERS TO BE DECIDED BY THE COURT

In this section, we first describe the facts that the evidence will reveal. We then discuss the principal legal issues to be decided by the Court.

A. The Facts

In 1996, Schering sued ESI Lederle (ESI), now a business unit of an AHP subsidiary,

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(ANDA) for a generic potassium chloride product infringed Schering's patent 4,863,743

settlement agreement, Schering did not expect that it would have to pay ESI any additional amount beyond $5 million, because it expected that ESI would not receive FDA approval.

At the same time the parties entered into the settlement agreement, they entered into a

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of the judge himself), and became involved in fashioning and commenting on terms of the settlement. Moreover, the magistrate judge was made aware that compliance with the antitrust laws is an important consideration in the settlement of patent infringement litigation

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generally, and specifically in this litigation.

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Noerr-Pennington immunity protects from antitrust challenges not only the filing of litigation itself, but also "those acts reasonably and normally attendant upon effective litigation." Coastal States Mktg., Inc. v. Hunt, 694 F.2d 1358, 1367 (5th Cir. 1983); see also McGuire Oil Co. v. Mapco, Inc., 958 F.2d 1552, 1558-60 (11th Cir. 1992); Barq's Inc. v. Barq's Beverages, Inc., 677 F. Supp. 449, 453 (E.D. La. 1987); Aircapital Cablevision, Inc. v. Starlink Communications Group, Inc., 634 F. Supp. 216, 226 (D. Kan. 1986). The immunity

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also extends to a "decision to accept or reject an offer of settlement." Columbia Pictures

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D. The Agreement Between AHP and Schering Licensing AHP under Schering's '743 Patent Does Not Unreasonably Restrain Commerce

The Court will need to decide whether the AHP/Schering agreement unreasonably

- the scope of the relevant market in which Schering competes;

[redacted]

- whether AHP is a "competitor" of Schering's;
- whether AHP was paid a share of the "monopoly profits"; and, most importantly,
- whether Schering paid AHP to "delay its entry" into competition with a monopolist.

In particular, complaint counsel have acknowledged that they can prevail in this case only if they prove that Schering's payments to AHP were for "delay." During the pretrial hearing on July 25, the Court asked complaint counsel: "Then are you saying the

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Complaint counsel thus must demonstrate what the "but for" world would have looked like; they must show what would have happened in the absence of the agreement. This is the essence of what a rule of reason case is about: proof that the world absent the agreement likely would have been more competitive than the world with the agreement.

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upheld on appeal, neither is applicable here. The cases are distinguishable in a number of

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International Distribution Ctrs., Inc. v. Walsh Trucking Co., 812 F.2d 786, 796 (2d Cir.

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able to re-achieve its alleged monopoly through any agreement with AHP demonstrates that

Respectfully submitted,

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Dated: September 18, 2001

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paper copy and an electronic copy of American Home Product Corporation's Statement of the Case to be filed with the Secretary of the Commission, that two paper copies were served by hand delivery upon the Honorable D. Michael Chappell, Administrative Law Judge, and that the following persons were served with one paper copy by hand delivery:

Karen G. Bokat, Esq.

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA
SOUTHERN DIVISION

CASE NO. 99-MDL-1317-SEITZ/GARBER
ALL SHERMAN ACT CASES

In re TERAZOSIN HYDROCHLORIDE
ANTITRUST LITIGATION
_____/

ORDER GRANTING PLAINTIFFS' MOTION FOR PARTIAL SUMMARY JUDGMENT AND DENYING DEFENDANT

After defendant Zenith Goldline Pharmaceuticals, Inc. ["Zenith"] moved for summary judgment on the plaintiffs' federal antitrust complaints [D.E. No. 77, Civ. No. 98-3125; D.E. No. 45, Civ. No. 99-1938], the Sherman Act Plaintiffs[1] sought a partial summary judgment [D.E. No. 21, Civ. No. 99-MDL-1317] that defendant Abbott Laboratories ["Abbott"] contracted with defendants Zenith and Geneva Pharmaceuticals, Inc. ["Geneva"], to secure the entire domestic market for prescription drugs containing terazosin hydrochloride in violation of section one of the Sherman Antitrust Act, 15 U.S.C. § 1. The undisputed facts in this case demonstrate that Abbott's agreements with its horizontal competitors would

and sought the Food and Drug Administration's ["FDA"] approval to market the drug by filing a New Drug Application ["NDA"]. Pursuant to the Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-91 ("FDCA"), FDA examined terazosin hydrochloride's safety and efficacy and approved it for human consumption, publishing three of Abbott's claimed patents in the publication, "Approved Drug Products with Therapeutic Equivalence Evaluations," affectionately known as the "Orange Book."

In 1987, Abbott began exclusively marketing terazosin hydrochloride under the trademark "Hytrin" in tablet and capsule forms. Hytrin has been lucrative for Abbott. According to the Federal

When Abbott received notice of Geneva's "paragraph IV certifications" challenging its patents, it exercised its statutory right to sue Geneva within forty-five days for patent infringement under 21 U.S.C. § 355(j)(5)(B)(iii) by instituting several actions in the United States District Court for the Northern District of Illinois. By statute, these suits effectively prevented FDA from approving Geneva's disputed ANDAs for 30 months unless Abbott's Hytrin patents were declared "invalid or not infringed." *Id.* §

Abbott retained right to sue Zenith for patent infringement "upon the commencement of marketing . . .

Pharm. Corp. v. Shalala, 955 F. Supp 128, 131-32 (D.D.C. 1997); *id* at 130 (enjoining FDA from enforcing regulation against plaintiff because underlying statute "does not include a 'successful defense' requirement"). FDA briefly ceased enforcing its regulation "in order to promote administrative uniformity and to avoid [judicial] forums shopping problems," but on July 3rd, Judge Boyle of the United States District Court for the Eastern District of North Carolina upheld the validity of the successful

favorable court ruling." (Walgreen Pls.' Opp'n, Nov. 8, 1999, Ex. 3 (Letter from Jason A. Gross, Director, Zenith Regulatory Affairs, to Douglas L. Sporn, Director, FDA Office of Generic Drugs (Feb. 27, 1998) (previously filed under seal)).)

In late March, 1998, both Geneva and Zenith were poised to market generic versions of Hytrin in the United States. Geneva received final FDA approval for its generic capsule in March subject to "validation,"[4] and the 30-month stay on its generic tablet proposal was set to expire in October. Zenith declared that it was ready to market a generic tablet upon receipt of a favorable decision from the Federal Circuit and final FDA approval.[5] But competition between Abbott, Geneva, and Zenith for the United States market for sales of terazosin hydrochloride drugs did not materialize.

3. Abbott's Accords with Zenith and Geneva

Abbott and Zenith informed the Federal Circuit on March 20, 1998, that they were settling their dispute and asked the Court to hold Zenith's appeal in abeyance. Then, on March 30th, Abbott received

an additional $6 million per quarter (or a prorated sum for a shorter period) to "not sell, offer for sale, [redacted]

appeal), whether before the Federal Circuit or the Supreme Court. Geneva also pledged not to transfer the rights to its ANDAs or the FDA-approved capsule. If Abbott elected to terminate its payments in February, 2000, Geneva would enjoy the right to market terazosin hydrochloride products in the United States without objection. (*Id.* at 4.)

On April 2, 1998, and for the following sixteen months, Abbott sold the only terazosin

DISCUSSION

As previously mentioned, the Sherman Act Plaintiffs seek a partial summary judgment that the defendants committed a *per se* violation of section one of the Sherman Act by contracting to allocate the United States market for terazosin hydrochloride products, thereby stifling domestic competition and restricting the output and sale of generic versions of Hytrin. The defendants counter that the challenged agreements tended to foster competition, imposed only incidental restraints on generic drug production mirroring those imposed by law, and caused no harm to the plaintiffs. Zenith, in particular, relies on

1. Summary Judgment Standard

Summary judgment is appropriate when "the pleadings . . . show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." *Anderson* v.

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genuine issue of material fact, the non-moving party must "come forward with 'specific facts showing

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elaborate inquiry as to the precise harm they have caused or the business excuse for their use."

Broadcast Music, Inc. v. Columbia Broad. Sys., 441 U.S. 1, 19-20 (1979); *Northern Pac. Ry. Co. v.*

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3. **The Challenged Accords are Illegal *Per Se***

"[W]hether the ultimate finding is the product of a presumption or actual market analysis, the essential inquiry remains the same—whether or not the challenged restraint enhances competition."

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were poised to compete with Abbott at the same level of the market; Geneva had received final FDA approval for its capsule pending validation and Zenith anticipated a favorable ruling that would result in final approval of its tablet proposal. Prices were likely to fall as the output of terazosin hydrochloride drugs climbed. *See generally* 11 HERBERT HOVENKAMP, ANTITRUST LAW ¶ 1902a, at 191 (1998) ["HOVENKAMP"] (noting that horizontal agreements "enable participants to reduce the output of goods in

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territories in order to minimize competition." *Topco Assocs., Inc.*, 405 U.S. at 608.

Such concerted action is usually termed a "horizontal" restraint, in contradistinction to combinations of persons at different levels of the market structure, e.g., manufacturers and distributors, which are termed "vertical" restraints. This Court has reiterated time

not persuasive, and the defendants' evidence does not establish a genuine issue for trial.

A. Economic Justifications for Challenged Accords

1. Pro-Competitive Motives or Provisions

The defendants maintain that their agreements would have tended to advance competition by ending or preventing fractious patent disputes and eliminating obstacles to Geneva and Zenith's entrance into the United States market for terazosin hydrochloride products. Of course, the Supreme Court "has consistently rejected the notion that naked restraints of trade are to be tolerated because they are well intended or because they are allegedly developed to increase competition." *Topco Assocs., Inc.*, 405 U.S. at 610 (citations omitted). Viewed in the light most favorable to the defendants, however, the record does

Court review, even if Geneva obtained a favorable ruling from the Federal Circuit in satisfaction of FDA's successful defense requirement. This design did not enhance competition.[11]

Geneva would have been able to market terazosin hydrochloride products in the United States without objection if Abbott elected to end its payments, (G.A. at 4), but this clause cannot justify the

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promised "not [to] aid or assist any person or entity to gain FDA approval to market a [t]erazosin [h]ydrochloride [p]roduct," but once generic competition began, Zenith could market such products in the United States without objection from Abbott. (*Id.* at 6.) The Zenith Agreement would indefinitely postpone Zenith's entry into the United States market and would permit competition only once Abbott lost its exclusive market. Like its agreement with Geneva, Abbott's agreement with Zenith resulted in a cooperative effort to forestall competition, not to enhance it.

2. Ineffective Restraints

Next, the defendants contend that their agreements could not unreasonably restrain the domestic market for terazosin hydrochloride products because Geneva was unable to validate its capsule product and legally enter the market until August, 1999, and Zenith was subject to Geneva's 180-day period of exclusivity on March 31, 1998. Although the Court accepts the defendants' allegations of fact as true for purposes of resolving the plaintiffs' motion for partial summary judgment, *Allen*, 121 F.3d at 646, the contention that Zenith could not enter the market in March, 1998, draws a legal conclusion and must be disregarded by the Court under FED. R. CIV. P. 56(c).[12] Indeed, the defendants' allegations are irrelevant, for it is well-settled that

> conspiracies under the Sherman Act are not dependent on any overt act other than the act of conspiring. 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.*

United States v. Socony-Vacuum Oil Co., 310 U.S. 150, 224 n.59 (1940) (citations omitted and emphasis added); *see Maricopa County Med. Soc.*, 457 U.S. at 345 (following *Socony-Vacuum Oil Co.* decision);

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B. Similarity of Accords to Contracts Beyond the Scope of the *Per Se* Rule

Having failed to identify a genuine issue of fact concerning the anti-competitive potential of their agreements to allocate the United States market for terazosin hydrochloride products to Abbott, the defendants attempt to redraw their accords as novel compacts, patent settlements, or petitions not subject to the *per se* rule. These efforts are also unpersuasive.

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Zenith, Geneva, and Abbott assert that the impact of their agreements "is not immediately obvious" because the judiciary lacks experience with "agreement[s] between brand[ed] and generic drug manufacturers . . . to settle novel delisting claims and patent litigation and [to] speed introduction of the generic . . . product into the market." (Zenith Opp'n at 12; see Geneva Opp'n, Mar. 21, 2000, at 8 ("[n]ot a single court has evaluated whether agreements such as these . . . are anticompetitive"); Abbott Opp'n, Mar. 20, 2000, at 20.) This assertion is incorrect. American courts have extensive experience with

Trading Corp. v. Jerrico, 924 F.2d 1555,-1567 (11th Cir. 1991), but the rule need not "be rejustified for every industry that has not been subject to significant antitrust litigation." *See Maricopa County Med. Soc.*, 457 U.S. at 350-51. The Sherman Act "establishes one uniform rule applicable to all industries alike." *Socony-Vacuum Oil Co.*, 310 U.S. at 222. Contrary to the defendants' assertions, this case does

U.S. 657 (1965); *Eastern R.R. Presidents Conference v. Noerr Motor Freight*, 365 U.S. 127, 137-38 (1961). The *Noerr-Pennington* doctrine "protect[s] those acts reasonably and normally attendent upon effective litigation," including threats of suit, and demand letters, *Mapco*, 958 F.2d at 1560 (citation omitted), but does not condone contracts bearing a "resemblance to the combinations normally held

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U.S. at 528; *see Allied Tube & Conduit Corp. v. Indian Head, Inc.*, 486 U.S. 492, 507 (1988). Consequently, the challenged agreements are not entitled to refuge under this doctrine.

Abbott's confidential agreements with Geneva and Zenith were not legitimate efforts to influence public officials; rather, they implemented the defendants' scheme to restrain the domestic sale of generic terazosin hydrochloride products without government scrutiny. *Noerr-Pennington* immunity does not apply to restraints adopted by private entities; it extends only when "the alleged restraint of trade [is] the intended consequence of public action." *FTC v. Superior Court Trial Lawyers Ass'n*, 493 U.S. 411, 424-25 (1990). Further, clandestine restraints of trade are not "normally attendant upon" patent litigation.

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tend to inhibit domestic output and price competition without creating efficiencies for American consumers, and the defendants have not adduced sufficient facts to place the illegality of their restraints in genuine dispute. Therefore, for the reasons stated in the foregoing opinion, it is hereby

ORDERED that the Sherman Act Plaintiffs' motion for partial summary judgment [D.E. No. 21, Civ. No. 99-MDL-1317] is GRANTED, and it is

ORDERED that defendant Zenith Goldline Pharmaceuticals, Inc.'s motion for summary judgment [D.E. No. 77, Civ. No. 98-3125; D.E. No. 45, Civ. No. 99-1938] is DENIED without prejudice to its arguments regarding causation and damages, which may be renewed at the close of Phase II discovery.

DONE and ORDERED in Miami, Florida, this 13th day of December, 2000.

PATRICIA A. SEITZ
UNITED STATES DISTRICT JUDGE

Copies to:
The Honorable Barry L. Garber, United States Magistrate Judge
All Counsel on Attached Service List
J. S. Milford, Esq.