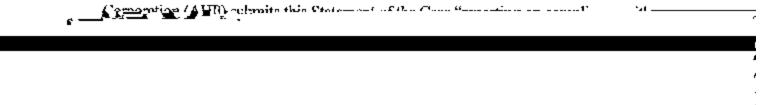
# UNITED STATES OF AMERICA BEFORE FEDERAL TRADE COMMISSION



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

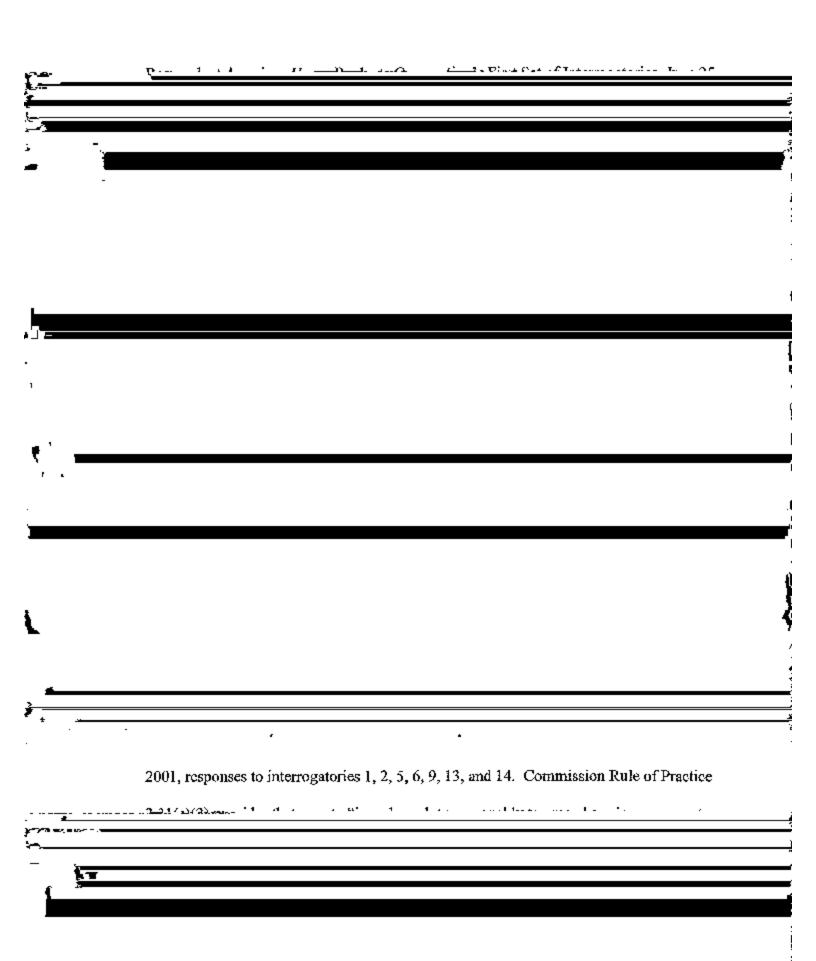
# AMERICAN HOME PRODUCTS CORPORATION'S STATEMENT OF THE CASE

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



<b>T</b>	*I.	-				
		Incorre				
<b>*</b>						
•						
			,			
•						
. 1						
1						
, y -						
3.4						
			;			
			آر آد			
			آلا			
4						
			•			
Ĺ			•			
4_			:			
			•			
			:			
			·			
-			<del></del>			
			į			
	1					

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



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 AIIP'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

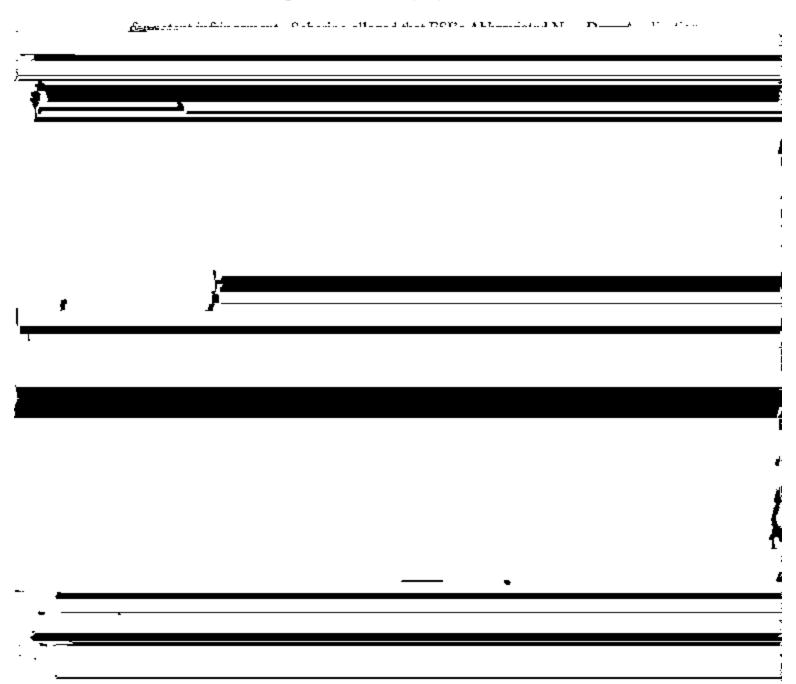
	<u> Qutaber</u>					
<b>-</b>		4				
25	ACF 127462-01-11					
<b>4.</b> -						
7		Ŷ				

### 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.

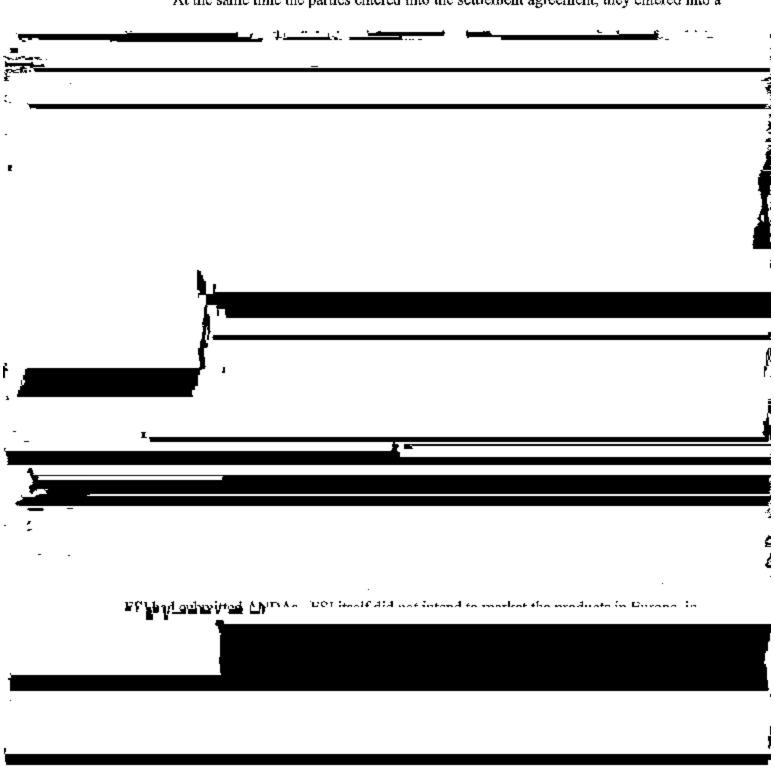
### A. The Facts

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



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



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 natent infringement litigation generally, and specifically in this litigation. 1

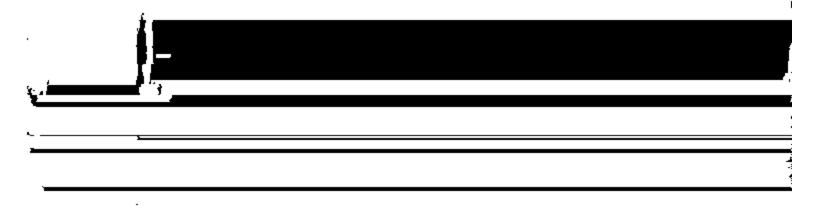
Noerr-Pennington immunity protects from antitrust challenges not only the filing of litigation itself, but also "those acts reasonably and normally attendant upon effective litigation."

Coastal States Mktg., Inc. v. Hunt, 694 F.2d 1358, 1367 (5<sup>th</sup> Cir. 1983); see also McGuire Oil

Co. v. Mapco, Inc., 958 F.2d 1552, 1558-60 (11<sup>th</sup> Cir. 1992); Barg's Inc. v. Barg's

Beverages, Inc., 677 F. Supp. 449, 453 (E.D. La. 1987); Aircapital Cablevision, Inc., v.

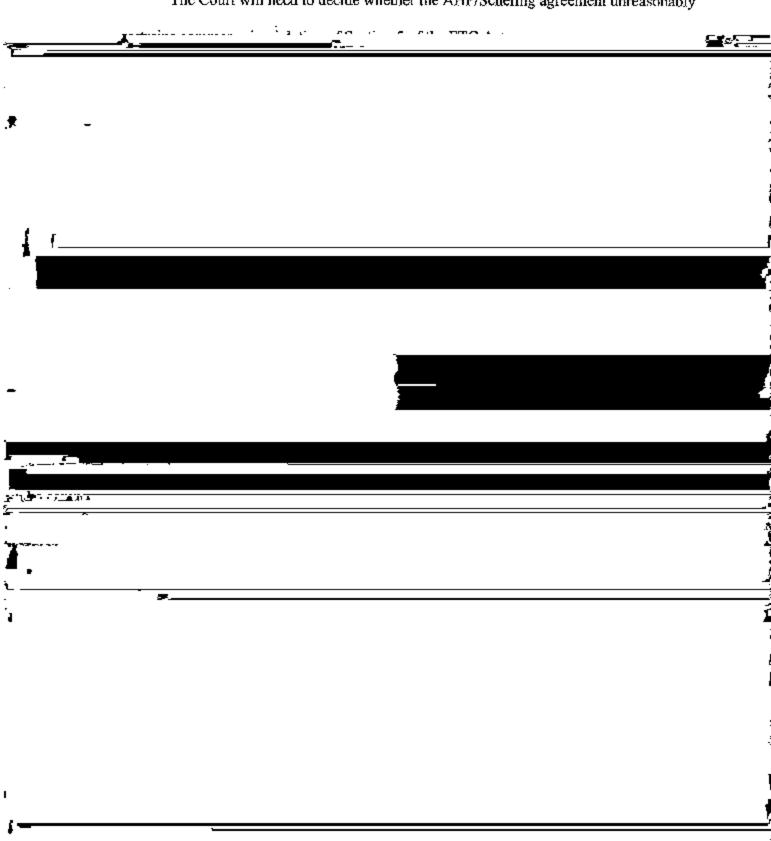
Opening Communications Crown In \_ 624 0 C ..... 216 226 (D. Wa\_\_1006) The immunity



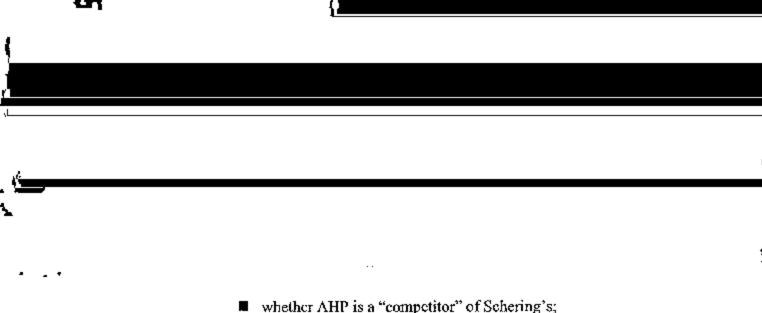
also extends to a "decision to accept or reject an offer of settlement." Columbia Pictures

## 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

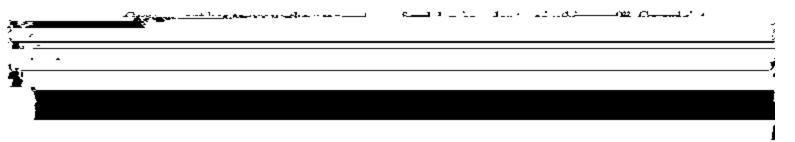


the scope of the relevant market in which Schering competes;



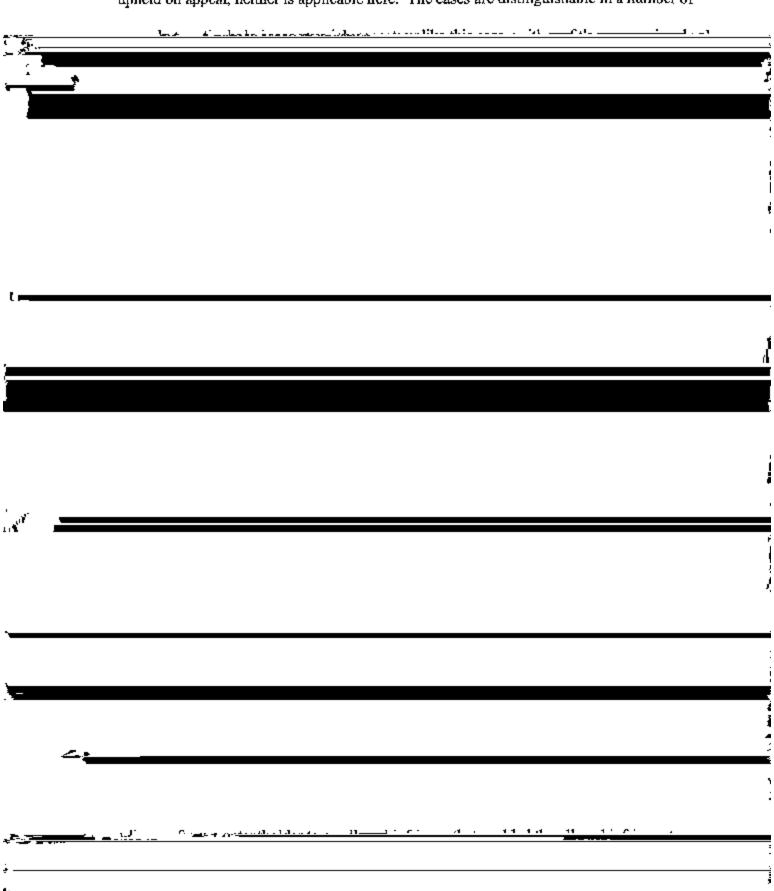
- whether AHP is a "competitor" of Schering's;
- whether AHP was paid a share of the "monopoly profits"; and, most importantly,
- whether Schering paid AHP to "delay its entry" into competition with a monopolist.

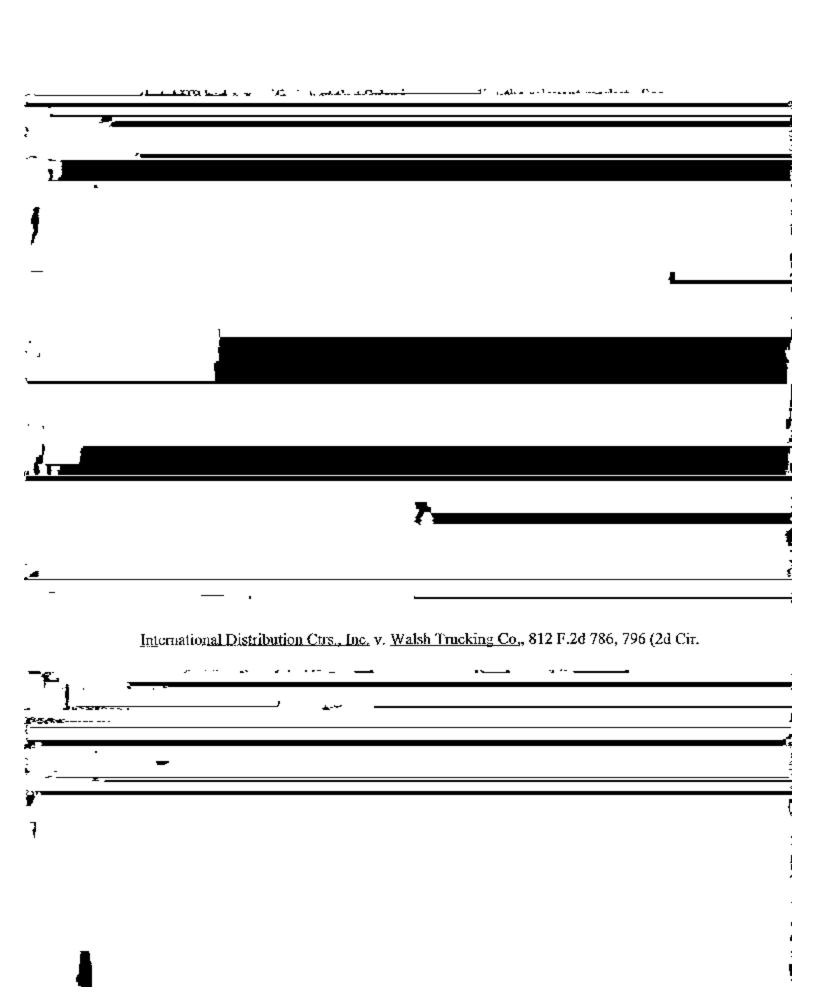
In particular, complaint counsel have acknowledged that they can prevail in this case only if they prove that Schering's payments to AHP were for "delay." During the pretrial hearing on July 25, the Court asked complaint counsel: "Then are you saying the

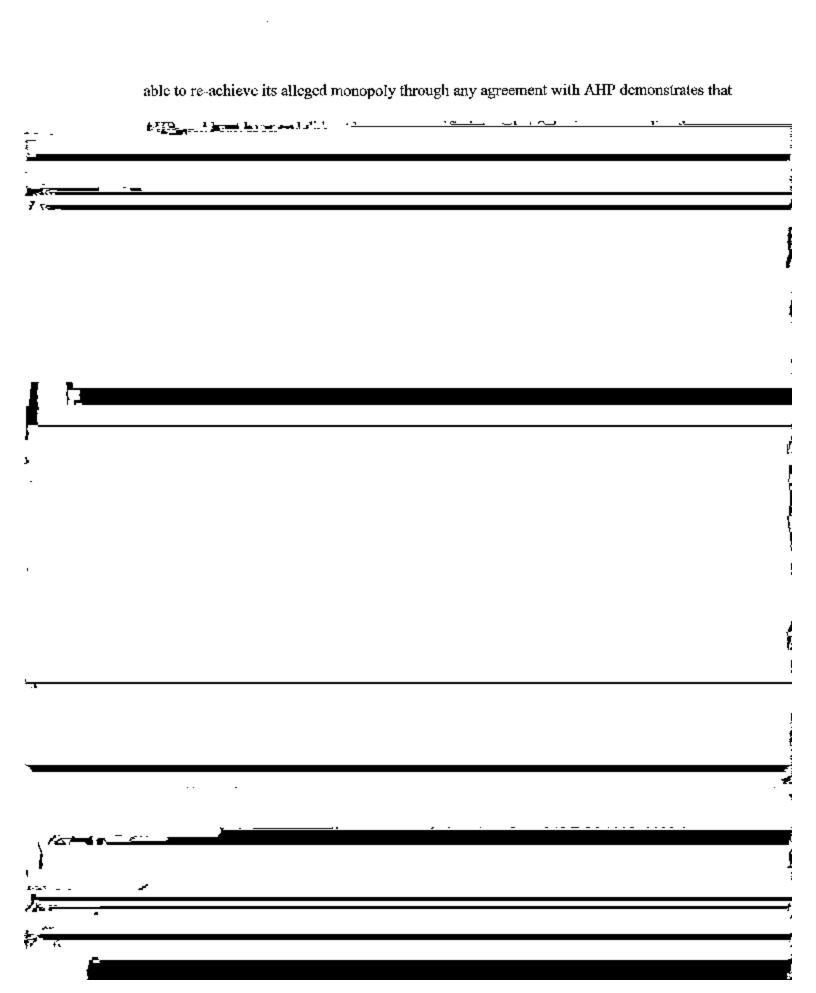


Complaint counsel thus must demonstrate what the "but for" world would have looked like; they must show what would have happened in the absence of the agreement. This is the essence of what a rule of reason case is about: proof that the world absent the agreement likely would have been more competitive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

<u>į̃r• — ,  </u>	<u> </u>	. Product to be as the community of the	
	10		
<u>- 72</u>			
1			
<b>}</b> :			
+=			
	_		
ı			
Tita na	potbo <sub>li</sub> plo <u>fo domonaturto_thu_111</u>	<u> </u>	
-			
12 ° °			







# Respectfully submitted,

Cathy Hoffman flw Michael N. Sohn

Donna Patterson

Cathy Hoffman

David Orta

Anika Cooper

ARNOLD & PORTER

555 Twelfth Street, N.W.

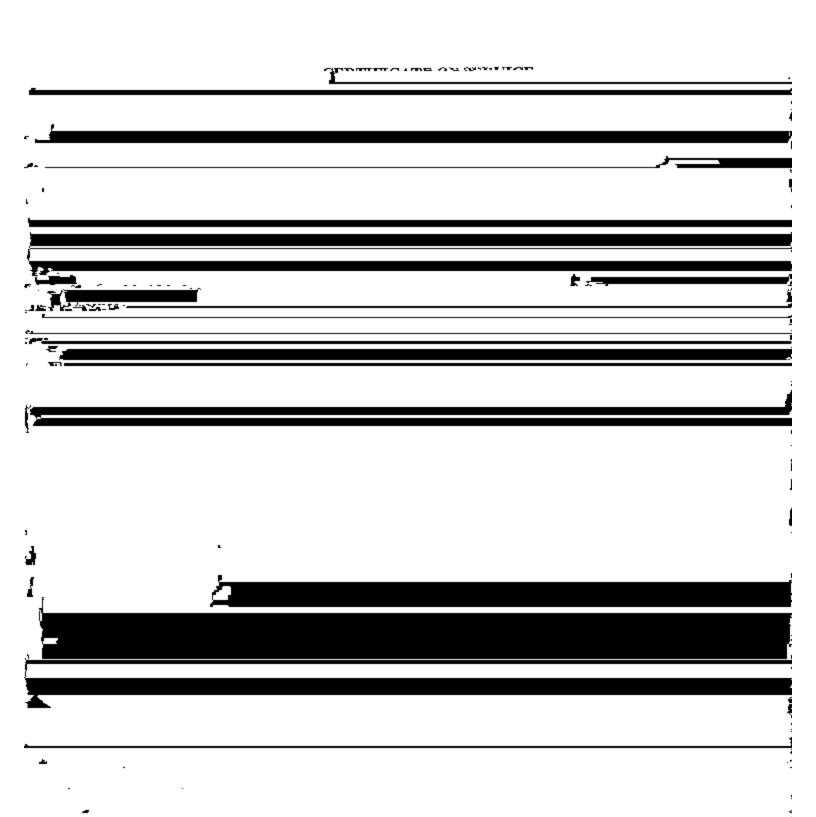
Washington, D.C. 20004-1206

(202) 942-5000

Counsel for American Home Products

Corporation

Dated: September 18, 2001



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:

				:
				. e <sup>eee</sup> 2
·				: :
				: :
				: :
	•			
		-		
				:

#### UNITED STATES DISTRICT COURT SOUTHERN DISTRICT ON PLORIDA SOUTHERN DIVISION

CASE NO. 99-MDL-1917-SETZ/GARBER.
ALL SHERMAN ACT CASES

DEC 1 3 2000

In the TERAZOSIN HYDROCHLORIDE ANTITRUST LITIGATION

ORDER GRANTING PLAINTIPFS' MOTION FOR PARTIAL SUMMARY RUDGMENT AND DENYING DEFENDANT

After defendant Zemith Goldline Pharmaceuticals, Inc. ["Zemith"] moved for summary judgment on the plaintiffs' federal antitrust complaints [D.E. No. 71, Civ. No. 98-3125; D.F. No. 45, Civ. No. 99-1938], the Sherman Act Phrintiffs' sought a partial summary judgment [D.E. No. 21, Qiv. No. 99-MDL-1317] that defendant Abbott Laboratories ["Abbott"] contracted with defendants Zenith and Geneva Pharmaceuticals, Inc. ["Genova"], to secure the entire domestic market for prescription drugs containing tenzonia hydrochloride in violation of scotion 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

to to Teramin Hydrocklaride Antitrust Litig.

and sought the Food and Drug Administration's ["FDA"] approval to market the drug by filing a New Drug Application ["NDA"]. Presease to the Food, Drug, and Cosmotic Act, 21 U.S.C. §§ 301-91 ("FDCA"), FDA examined terazosin hydrochioride'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 hydrochluside under the trademark

"Hytrio" in tablet and capsule forms. Hytrin has been incrative for Abbott. According to the Federal A CORD william in rister in 1000 accounting for a conIn to Teresosin Hydrochloride Antioust Litig.
Fig. 30 Acres 1217

раде 3

When Abbott received notice of Geneva's "paragraph IV certifications" chellenging its patents, if exercised its statutory right to suc Geneva within forty-five days for patent infingement under 21 U.S.C. § 355()(5)(8)(iii) by instituting several actions in the United States District Court for the Northern District of Blimbs. By statute, these suits effectively prevented PDA from approving Geneva's disputed ANDAs for 30 months unless Abbott's Hybrin patents were declared "invalid or not infringed." Id. §

In to Teratoria Hydrochloride Antitrust Littg. Civ. No. 99-MDL 1317 Partial Summary Jodgment Order Abbott retained right to sue Zenith for patent infringement "upon the commencement of marketing . . . 10 to Teramiin Hydrochlaride Authorist Litig. Civ. No. 99-MDL-1317

page 5

Pharm. Corp. v. Shalala. 955 F. Supp. 128, 131-32 (D.D.C. 1997); id at 130 (cajoining FDA from cultoring regulation against plaintiff because underlying statute "does not include a "successful defense" requirement"). FDA briefly ceased enforcing its regulation "in order to promote administrative

States District Court for the Eastern District of North Carolina upbeld the validity of the successful

Partial Summany Judgment Order page 6

favorable court ruling." (Waigrocu Pix.\* Opp'n, Nov. 8, 1999, Fix. 3 (Letter from Jason A. Gross, Director, Zenith Regulatory Affichs, to Douglas L. Sporn, Director, Flin. Office of Generic Drugs-(Feb. 27, 1998) (previously filed under scal)).)

In late March, 1998, both Geneva and Zenith were poised to market generic versions of Hyrrin in the United States. Geneva received final FDA approval for its generic capsule in March subject to "validation," 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 Pederal Circuit and final FDA approval. But competition between Abbott, Geneva, and Zenith for the United States market for sales of tenatosin hydrochloride drugs did not maternalize.

#### 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 aboyance. Then, on March 30<sup>th</sup>, Abbott received

مريني مياني الرياد كالمراجع المراجع ال

to to Teratosia Hydrochloride Antitrust Istig. Civ. No. 99 MDL-1317 Partial Superary Judgment Order an additional \$6 million per quarter (or a protated sum for a shorter period) to "not sell, offer for sale, considering Aberraice commercially distribute in the Thirted States and Etlerance in Thirdwold and A.

In re Teremain Hydrochlarkie Antipust Litig. Cir. No. 99-MDL-1317 Faitlel Summary Judgment Order page 8

appeal, whether before the Federal Circuit or fao 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 terazosia 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 transprin

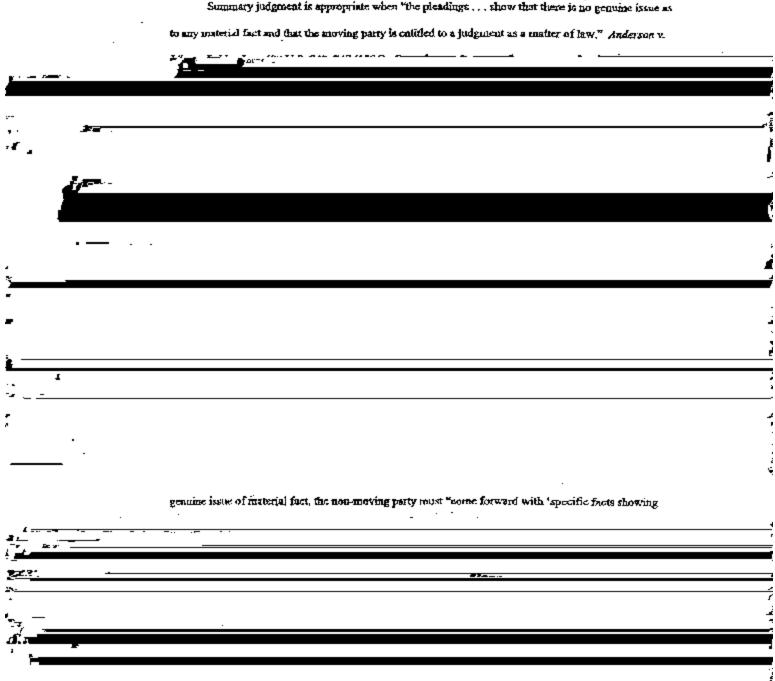
#### DISCUSSION

As previously mentioned, the Sherman Act Flaintiffs seek a partial automaty judgment that the defendants continited a period 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 fluxe imposed by law, and caused no harm to the plaintiffs. Zenith, in particular, relies on

In to Terozonia Hydrockloride Antitrust Litig. Cig. No. 99-MDL-1317 Partial Surnovery Fortgement Order bake a

### . 1. Summery Judgment Standard

Summary judgment is appropriate when "the pleadings . . . show that there is no genuine issue as



In ne Terasosia Hydrochlorida Amiliaust Litig. Civ. No. 99-MDI-1317 Parual Summary Indoment Onler page 10

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

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

### 3. The Challenged Accords are Hiegel Per Sc

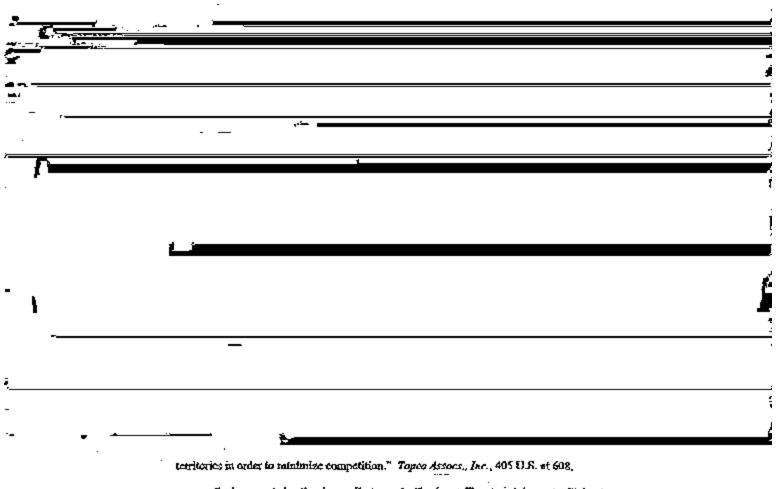
"[W]hether the ultimate finding is the product of a presumption or actual market analysis, the essential inquiry remains the same—whether or not the challenged restraint enhances competition."

In so Terusosia Hydrociderida Aminust Ling. Civ. No. 99-MDL-1317 Parial Summary Indonesia Order page 11

Were poised to compete with Abbott at the same level of the market Kieneva bad received final FDA approval for its expende pending validation and Zenith subseipated a favorable ruling that would result in final approval of its tablet proposal. Prices were likely to fall as the output of terazorin hydrochlorida: drugs climbed. Sea generally 11 Herbert Hovenkamp, Antitikust Law ¶ 1962a, at 191 (1998)

["Hovenkamp"] (noting that horizontal agreements "enable participants to reduce the output of goods in

In to Tenusosin Hydrocklaride Antitrast Litig. Cir. No. 99-MDL-1317 Partial Summary Indoment Order 1985, 12



Such concerted action is usually termed ""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

¶<sup>©</sup>A

In re Termosin Hydrochloride Antitrust Litig. Civ. No. 99-MDL-1317 Partial Summary Indgment Order page 13

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

#### A. Feonomic Justifications for Challenged Accords

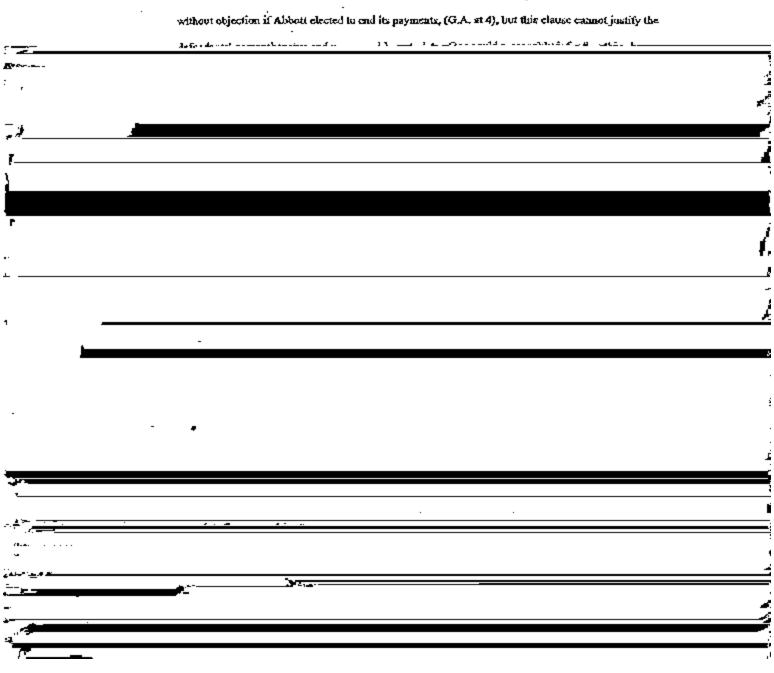
#### 1. Pro-Competitive Matives or Pravisions

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

In the Terazosia Hydrochloride Antitud Litig. Civ. No. 99-MDL-1317 Partial Summary Judgment Order page 14

- 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.  $^{\rm th}$

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



In re Teracasia Llydrochloride Autimus Lidg. C.v. No. 99-MDL-1317 Partial Summery Judgment Order page 15

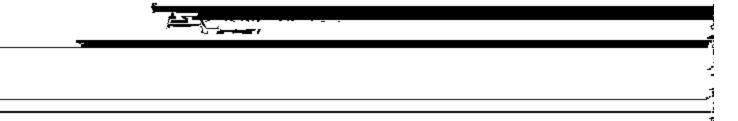
promised "not [to] aid or assist any person or entity to gain FDA approval to market a [t]erazosin [h]ydrochloride [p]roduct," but once generic competition began, Zenith could market such products in the United States without objection from Albert. (Id. at 6.) The Zenith Agreement would indefinitely 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 Rootzwines

Next, the defendants contend that their agreements could not unreasonably restrain the domestic market for termosin 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 logal conclusion and must be disregarded by the Court under PED. R. CIV. P. 56(c). Undeed, the defendants' allegations are irrelevant, for it is well-settled that

conspiracies under the Sherman Act are not dependent on any overt set other than the act of conspiracy, it is the 'contract, combination . . . or conspiracy, in restraint of teads or connected' which § 1 of the Act strikes down, whether the concerted activity be whally nascent or abortive on the one hand, or ruccessful on the other.

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



In it Termusia Hydrochloride Antistust Ling. Civ. No. 99-MDL-1317 Partial Sommany Judgment Order 166-16

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

Having failed to identify a genuine issue of fast concerning the anti-competitive potential of their agreements to allocate the Umbed States market for terazosia hydrochlocale products to Abbott, the defendants attempt to redraw their accords as novel compacts, patent settlements, or politions and subject to the per second. These efforts are also impermissive.

Zenith, Genevi, and Abboti assert that the impact of their ogreements "is not immediately obvious" because the judiciary lacks experience with "agreement(s) between brand(ed) and generic drug manufacturers . . . to sente novel deliating claims and patent lingation 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 ("injot 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

In to Torasosin Hydrochloride Antituot Ling. Civ. No. 99-MDL-1317 Partial Summery Judgment Order page 17

Trading Corp. v. Jerrica, 924 F.26 1555, 1567 (11th Cir. 1994), but the rule need not "be rejustified for every industry that has not been subject to significant entitues litigation." See Maricopa County Med.

Soc., 457 U.S. at 350-51. The Shemman Act "establishes one notions rule applicable to all industries allice." Socony-Vacuum Oil Ch., 310 U.S. at 222. Contrary to the defendants' assertions, this case does

In re Teracosts Hydrockloride Amissost Litig. Civ. No. 29-MDL-1317 Partial Summery Indoment Order page 18

U.S. 657 (1965); Eastern R.R. Presidents Conference v. Noert Motor Freight, 365 U.S. 127, 137-38 (1961). The Noert-Fermington doctains "protect[8] those acts reasonably and normally attendent upon effective litigation," including threats of suit, and domaid letters, Mapon, 958 F.2d at 1560 (citation united), but does not condone contracts bearing a "resemblance to the combinations normally held-

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 cale of generic terezosin hydrochloride products without government scrutiny. Noerr-Pennington irontmity does not apply to restraints adopted by private entition, 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). Purther, claudestine restraints of trade are not "normally attended upon" patent litigation.

In to Terazonia Hydrochloride Antonas Ling, Civ. No. 99-MDL-1317 Partial Summary Indoment Castes page 19

rand to inhibit domestic autput and price competition without creating efficiencies for American
constructed, and the defendants have not addresed 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 Pizimiffs' motion for partial warmary 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 Mismi, Florida, this 13 day of December, 2000.

UNITED STATES DISTRICT TUDGE

Copies to:
The Honorable Bury L. Garber, United States Magistrate Judge
All Counsel on Attached Service List
J. S. Milland, Psq.