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 Corporation (AHP) submits this Statement of the Case "reporting on compliance with discovery and settlement negotiations and identifying the legal and factual matters to be decided by the Administrative Law Judge."

I. COMPLIANCE WITH DISCOVERY

A. Document Discovery

AHP received document requests from complaint counsel on May 22, 2001 and August 3, 2001. To date, AHP has produced on a rolling basis approximately 37 boxes of documents in response to those requests. AHP anticipates that it will produce an estimated 35 additional boxes of documents and told complaint counsel last week that it will produce substantially all of the documents no later than September 28, 2001. AHP has provided

complaint counsel with the list of personnel searched in response to the document requests, 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 October 3, several days after the date by which AHP had already indicated it expected to produce substantially all documents. AHP believes complaint counsel's motion is unfounded, and AHP will promptly file its response.

AHP served a document request on complaint counsel on June 1, 2001, and has to date received approximately 2 boxes of documents in response, apart from documents produced by respondents and third parties during the course of the Commission's pre-complaint investigation in this matter. Complaint counsel have not produced any additional documents following issuance of the Court's September 7, 2001 Order granting in part and denying in part AHP's Motion to Compel. Discovery into complaint counsel's compliance with that ruling may be necessary.

AHP has served subpoenas duces tecum on two third parties and anticipates serving additional such subpoenas before the deadline for issuance of subpoenas.

B. Interrogatories

AHP served 16 interrogatories on complaint counsel on June 1, 2001 and received complaint counsel's responses on June 25, 2001. Complaint counsel objected to many of AHP's interrogatories on the grounds that the interrogatories were "premature to the extent that [they] ask[], prior to the close of discovery, for complaint counsel to describe in detail the basis for its contention." See Complaint Counsel's Responses and Objections to

Respondent American Home Products Corporation's First Set of Interrogatories, June 25, 2001, responses to interrogatories 1, 2, 5, 6, 9, 13, and 14. Commission Rule of Practice 3.31(c)(2) provides that a party "is under a duty seasonably to amend a prior response to an interrogatory . . . if the party learns that the response is in some material respect incomplete or incorrect." 16 C.F.R. § 3.31(e)(2)(2001). AHP expects that complaint counsel will comply with their duty and respond fully to the interrogatories before the close of discovery. If complaint counsel fail to respond fully to the interrogatories, as required, AHP anticipates that it will confer with complaint counsel, pursuant to Rule 3.22(f), and that it may be forced to file a motion to compel responses to its interrogatories or for other appropriate relief. AHP anticipates that it will serve additional interrogatories before the deadline for service of interrogatories.

C. Requests for Admissions

AHP served its first set of requests for admissions on complaint counsel on August 30, 2001, and expects to receive complaint counsel's responses on September 19, 2001. AHP anticipates serving additional requests for admissions before the deadline for issuance of such requests.

D. Depositions

Complaint counsel have noticed a substantial number of depositions of AHP, Schering-Plough Corporation (Schering), and Upsher-Smith Corporation (Upsher) employees and of third parties. We focus here on the deposition notices directed to AHP.

First, on July 11, complaint counsel noticed a deposition for a custodian of records to describe the process by which AHP compiled and produced documents in response to complaint counsel's first request for production of documents. On July 19, AHP wrote to

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.

AHP anticipates that it will conduct at least one and possibly more fact witness depositions before the close of fact discovery.

II. SETTLEMENT NEGOTIATIONS

AHP has not engaged in discussions with complaint counsel about possible terms of a consent order to settle this matter.

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, for patent infringement. Schering alleged that ESI's Abbreviated New Drug Application (ANDA) for a generic potassium chloride product infringed Schering's patent 4,863,743 ('743 patent). Due to various factors, ESI's position in the patent litigation was not strong. In 1998, following a hearing in which the federal judge presiding over the case gave indications that ESI's chances of success were not strong, ESI, AHP, and Schering entered into a settlement agreement.

If ESI had not settled and had lost the patent infringement case, it would have been barred from marketing its generic potassium chloride product until Schering's patent expired in September 2006. Moreover, whether ESI settled or not, the earliest time at which ESI could have begun to market its product, in the unlikely event that it was held not to have infringed Schering's patent, would have been March 2002. (This date is based on the effect of a previous agreement between Schering and Upsher, combined with the provisions of the Hatch-Waxman Act.) Under the terms of the settlement agreement, ESI obtained a royalty-free license to market its generic, allegedly infringing product beginning in January 2004, nearly three years before Schering's patent was due to expire in September 2006.

The settlement agreement provided for a payment from Schering to ESI of $5 million. The agreement also provided for an additional potential payment from Schering to ESI of no more than $10 million, depending on if and when ESI received Food and Drug Administration (FDA) approval to market its generic product. At the time it entered into the

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 license agreement granting Schering rights to market in Europe two generic drugs for which ESI had submitted ANDAs. ESI itself did not intend to market the products in Europe, in large part because it did not have a European generic marketing or distribution arm. In contrast, the license agreement stated that "Schering and its affiliates have networks, systems, and personnel" for marketing generic drugs in Europe. In consideration for the license, Schering agreed to pay ESI $5 million upon execution of the agreement, and an additional $10 million in installment payments spread out over the years 1999 through 2004.

The complaint does not allege that the rights Schering received under the license agreement were not worth the money that Schering paid for them. The evidence will show that Schering in fact valued the rights it received at $35 million. And, while complaint counsel have served a lengthy report of an expert who questions the reasonableness and legitimacy of the fee Schering paid to Upsher for the rights to five generic products, complaint counsel have not produced an expert report opining on the value of the rights that Schering received from AHP under the license agreement.

AHP and Schering and their counsel were not the only participants in the negotiations that eventually led to the settlement and license agreements. A critical third party was involved: the federal magistrate judge overseeing the case. Over the course of many months, the magistrate judge, acting at the direction of the judge to whom the case was assigned, presided over settlement conferences, was made aware of settlement proposals exchanged between the parties outside his presence, exhorted the parties to settle (at the frequent behest

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 generally, and specifically in this litigation.

The basic terms of the eventual settlement and license agreements were arrived at during a court-ordered settlement negotiation session that took place on a Friday night at the federal courthouse with the magistrate judge, and the magistrate was well aware of those terms. The presiding judge was then immediately made aware of the settlement. On the Monday following the Friday night negotiating session, the judge sua sponte dismissed the patent infringement litigation, resolving claims, defenses, and potential counterclaims. This settlement process and the result provided certainty to the parties and consumers and reduced burdens on the court system.

B. The Agreement at Issue Here is Immune from Challenge Under the Antitrust Laws Because It Was Approved by a Federal Magistrate Judge Who Had Knowledge of the Antitrust Issues Implicated by Settlements of Patent Infringement Litigation

One of the principal legal issues for the Court to decide is whether the AHP/Schering agreement is immunized from challenge under Section 5 of the FTC Act because of the active involvement of, and implicit approval by, a federal magistrate judge.

Under the Noerr-Pennington doctrine, "where a restraint upon trade or monopolization is the result of valid governmental action, as opposed to private action," the restraint cannot be challenged under the antitrust laws. Eastern R.R. Presidents Conference v. Noerr Motor Freight, Inc., 365 U.S. 127, 136 (1961); see United Mine Workers v. Pennington, 381 U.S. 657 (1965); see also California Motor Transp. Co. v. Trucking Unlimited, 404 U.S. 508, 510-11 (1972) (extending the doctrine to judicial proceedings).

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. 316, 326 (D. Kan. 1986). The immunity also extends to a "decision to accept or reject an offer of settlement." Columbia Pictures Indus., Inc. v. Prof'l Real Estate Investors, Inc., 944 F.2d 1525, 1528 (9th Cir. 1991), aff'd, 508 U.S. 49 (1993).

The Noerr-Pennington immunity doctrine and the cases establishing the parameters of that doctrine compel a finding that the AHP/Schering agreement cannot be challenged under the antitrust laws.

C. A Cease and Desist Order is Inappropriate Because Complaint Counsel Cannot Prove a Cognizable Danger of Recurrent Violation in Light of AHP's Exit from the Oral Generics Business

AHP will offer undisputed evidence that it is exiting from the oral generic drug business, which is the business that engaged in the conduct challenged in the complaint. In these circumstances, courts have ruled that a Commission cease and desist order is inappropriate unless complaint counsel can prove that there is a cognizable danger of recurrent violation. See, e.g., Borg-Warner Corp. v. FTC, 746 F.2d 108, 109-10 (2d Cir. 1984); National Lead Co. v. FTC, 227 F.2d 825, 839-40 (7th Cir. 1955), rev'd on other grounds, 352 U.S. 419 (1957). We do not believe that complaint counsel will be able to satisfy its burden of proof on this issue, and the complaint against AHP accordingly must be dismissed. The Court will need to resolve this issue.

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 restrains commerce in violation of Section 5 of the FTC Act.

The complaint does not allege that the AHP/Schering settlement agreement is per se unlawful. Complaint counsel nevertheless have indicated that that they will be advancing the theory that the agreement is unlawful "under a per se standard and a rule of reason standard."[1] Under well-established case law, however, the AHP/Schering agreement can not be assessed under a per se standard of illegality. The rule of reason applies. Moreover, complaint counsel have implicitly conceded that they cannot, as is usual in a per se case, rely on a conclusive presumption of anticompetitive effect; as described below, they have effectively conceded that they bear the burden of proving anticompetitive effect.

The complaint does not allege that AHP engaged in any conduct that has traditionally been deemed per se unlawful. It does not allege that AHP and Schering fixed prices, rigged bids, or allocated markets. Instead, the theory of the complaint, as repeatedly stated by complaint counsel, is that Schering is a monopolist and that it paid a share of its monopoly profits to a competitor to delay the competitor's entry. See, e.g., Complaint Counsel's Response to Schering's Motion for Partial Dismissal of the Complaint, Jun. 25, 2001, at 9 (patent settlement violates the antitrust laws when "the patent-holder entices its competitor to delay entry or withdraw its challenge to the patent in exchange for a share of the monopoly profits"). This theory requires complaint counsel to prove, and the Court to decide:

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[1] Transcript of Prehearing Conference, May 1, 2001, at 12 (statement of complaint counsel Karen Bokat).

- the scope of the relevant market in which Schering competes;
- whether Schering was, at all pertinent times, a monopolist;
- 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 Government has to prove the payment was for delay in order to win this case?" Complaint counsel responded: "Absolutely." Transcript of Prehearing Conference, Jul. 25, 2001, at 34 (statement of complaint counsel Michael Kades). See also id. at 47 (statement of complaint counsel that "[w]hat we have to prove, however, is the agreement was anticompetitive, and what that rests on is what that payment was for . . . this case comes down to whether we can prove that the agreement – that the payment was for delay, . . . and yes, that is the central focus of this case.").

The "delay" element of complaint counsel's theory takes this case out of the realm of conduct that is judged by a per se standard. The concept of "delay" is a relative concept; a delay in an event means a postponement of that event from an earlier time at which it otherwise would have occurred. Thus, complaint counsel have conceded that they must prove that the AHP/Schering agreement, which licensed AHP under Schering's patent to begin marketing AHP's generic version of K-Dur 20 on January 1, 2004, postponed AHP's marketing to a point later than it would have occurred in the absence of the agreement.

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.

Complaint counsel will not be able to satisfy this burden of proof, because they will not be able to demonstrate that absent the settlement agreement, it is more likely than not that AHP and Schering would have continued litigating and that AHP would have won the patent litigation and would have been able to enter the market before January 2004. It appears that complaint counsel hope to prove their case simply by having an economist opine that one can infer, from the fact that Schering paid AHP money as part of the settlement agreement, that the payment delayed AHP's entry. Even under this theory – which we do not believe is sufficient to prove a violation of Section 5 – complaint counsel will have to prove, and the Court will have to decide, that in fact AHP received the net value flowing between the parties in the settlement and license agreements, apart from the consideration expressed in terms of time to enter. We believe the evidence will demonstrate the opposite.

Complaint counsel have repeatedly argued that the AHP/Schering agreement is similar to agreements that were held per se unlawful in In re Terazosin Hydrochloride Antitrust Litig., No. 99-MDL-1317 (S.D. Fla. Dec. 13, 2000) (attached as Exhibit 1) and In re Cardizem CD Antitrust Litig., 105 F. Supp. 2d 682 (E. D. Mich. 2000). We question whether those cases were correctly decided, and indeed, the Cardizem court certified the decision for interlocutory appeal to the Sixth Circuit because it found that the case presented questions "as to which there is substantial ground for difference of opinion." 28 U.S.C. § 1292(b)(1994). But even if one assumes those cases were correctly decided and will be

upheld on appeal, neither is applicable here. The cases are distinguishable in a number of ways, but particularly in one crucial respect: unlike this case, neither of those cases involved a license from a patentholder to an alleged infringer that enabled the alleged infringer to begin marketing on a date certain before patent expiration.

Finally, the complaint challenges certain ancillary restraints contained in the settlement agreement between AHP and Schering. See Complaint ¶ 55 (allegations about provisions of agreement under which AHP agreed not to market any generic version of Schering's product before January 2004, not to market more than one generic version of the product prior to expiration of the patent, and not to conduct, sponsor, file or support a study of the bioequivalence of any product to K-Dur 20 before patent expiration). These restraints, however, were legitimately ancillary to the procompetitive agreement that enabled AHP to enter the market before the expiration of Schering's patent and must therefore be judged by the rule of reason. The restraints served to ensure that Schering would not be forced to litigate against AHP again about the same patent, if AHP were to make insignificant changes to its product to avoid the literal terms of the agreement. Moreover, the evidence will demonstrate that AHP would not in any event have been in a position to market any other generic version of Schering's product, and that no third party asked AHP to sponsor or support a bioequivalence study. Thus, complaint counsel will not be able to demonstrate that the ancillary restraints were anticompetitive in purpose or effect.

E. The Agreement Between AHP and Schering Licensing AHP under Schering's '743 Patent Does Not Constitute a Conspiracy to Monopolize

Finally, the complaint alleges that the AHP/Schering agreement constitutes a conspiracy to monopolize under Section 5 of the FTC Act. To prove this claim against AHP, complaint counsel will have to prove, among other things, and the Court will have to decide,

that AHP had a specific intent that Schering monopolize the relevant market. See International Distribution Ctrs., Inc. v. Walsh Trucking Co., 812 F.2d 786, 796 (2d Cir. 1987) (holding that plaintiff's conspiracy to monopolize theory failed because it did not "reasonably establish that any individual defendant except [one] intended to create a monopoly; a plurality of actors sharing such an intent is required under section 2."); Belfiore v. New York Times Co., 826 F.2d 177, 183 (2d Cir. 1987) ("Even if the Times did possess the requisite intent to achieve a monopoly in any market, . . . [the conspiracy to monopolize] claim would fail for lack of evidence that the intent was shared by agreement with another party."); CDC Techs., Inc. v. Indexx Labs., Inc., 7 F. Supp. 2d 119, 131 (D. Conn. 1998) ("If one party's intent to monopolize is not shared by another party, there can be no conspiracy to monopolize."), aff'd, 186 F.3d 74, 81 (2d Cir. 1999) (affirming district court's dismissal of conspiracy to monopolize claim).

The evidence will not support this element of the complaint's conspiracy to monopolize claim. There is no direct evidence that AHP possessed the requisite specific intent. Moreover, the circumstantial evidence leads one to conclude that AHP did not have the requisite intent. AHP was not the first ANDA filer for a generic version of K-Dur 20. Pursuant to the Hatch-Waxman Act, because of the previous settlement agreement between Schering and Upsher, AHP would not have been able to enter the market until six months after Upsher had already started marketing a generic version of K-Dur 20. The Commission's complaint alleges that "generic entry generally leads to a significant erosion of the branded drug's market share and unit and dollar sales within the first year." Complaint ¶ 17. Thus, under the theory of the complaint, Schering's alleged monopoly would already have largely dissipated as a result of Upsher's entry. The unlikelihood of Schering being

able to re-achieve its alleged monopoly through any agreement with AHP demonstrates that AHP could not have and did not have any specific intent that Schering monopolize the alleged market. See, e.g., Bailey's, Inc. v. Windsor Am., Inc., 948 F.2d 1018, 1032 (6th Cir. 1991) (finding it "wildly improbable" that defendant could have specific intent to monopolize where its products accounted for a small share of the market); Hudson Valley Asbestos Corp. v. Tougher Heating & Plumbing Co., 510 F.2d 1140, 1144 (2d Cir. 1975) ("the absence of any likelihood of success is certainly some evidence on the question of whether such specific intent existed," and where evidence showed "the futility of any effort to monopolize," the court of appeals upheld the district court's finding of no conspiracy to monopolize); Apex Oil Co. v. DiMauro, 713 F. Supp. 587, 600 (S.D.N.Y. 1989) (in case where "the unlikelihood of achieving a monopoly . . . [was] manifest," the court found no triable issue of fact on specific intent to monopolize, stating "the likelihood of success of acquiring and/or maintaining monopoly power is an appropriate consideration on the question of specific intent"); Optivision, Inc. v. Syracuse Shopping Ctr. Assocs., 472 F. Supp. 665, 680 (N.D.N.Y. 1979) ("The absence of any serious likelihood of successfully achieving monopolization is evidence that can be used to support a finding of lack of specific intent.").

Respectfully submitted,

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Dated: September 18, 2001

CERTIFICATE OF SERVICE

I hereby certify that this 18th day of September, 2001, I caused an original, one 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:

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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 ZENITH'S MOTION FOR SUMMARY JUDGMENT

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 tend to impair domestic competition and restrain the trade of terazosin hydrochloride products. American courts have long condemned such agreements as illegal *per se* under the Sherman Act. Accordingly, the Court will grant the requested partial summary judgment to the plaintiffs, deny defendant Zenith's motion for summary judgment without prejudice, and allow the parties to conduct full discovery on the issues of causation and damages.

BACKGROUND

1. Stirrings of a Competitive Market for Terazosin Hydrochloride

Abbott developed terazosin hydrochloride for the treatment of hypertension and enlarged prostate

[1] The term "Sherman Act Plaintiffs" refers to all plaintiffs who allege violations of the Sherman Antitrust Act in the individual and class cases consolidated before the Court.

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 Trade Commission, Hytrin generated $540 million in sales in 1998, accounting for more than twenty percent of Abbott's net sales of pharmaceutical products in the United States.[2]

Beginning in 1990, generic drug maker Geneva took steps to compete with Abbott by developing a generic terazosin hydrochloride drug that could contain different inactive ingredients and be sold without a brand name in tablet and capsule forms. Taking advantage of the "Hatch-Waxman Amendments" to FDCA that streamlined the evaluation process for proposed generic drugs,[3] Geneva applied for FDA approval by submitting four Abbreviated New Drug Applications ["ANDAs"] between 1993 and 1996. Geneva's ANDAs relied on data concerning Hytrin's safety and efficacy, asserted that the proposed generic drug was "bioequivalent" to Hytrin, and certified under paragraph IV of 21 U.S.C. § 355(j)(2)(A)(vii) that the proposed drug did not infringe any *valid* patent claimed by Abbott for Hytrin.

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[2] (*See* Compl., *Abbott Labs.*, No. C-3945, at ¶ 10 (FTC May 22, 2000), *available at* http://www.ftc.gov/os/2000/05/abbottgenevacomp.htm *and reprinted in* Zenith Notice, Ex. B, Civ. No. 99-MDL-1317, Mar. 20, 2000); *see also* FEDERAL TRADE COMMISSION, ANALYSIS TO AID PUBLIC COMMENT (2000), *available at* http://www.ftc.gov/os/2000/05/abbottgenevaanalysis.htm ["ANALYSIS"]. The Federal Trade Commission recently concluded an investigation into the Abbott-Geneva accord by entering a consent decree prohibiting similar accords. *See* ANALYSIS ¶ 21. That decree does not govern the Court's decision.

[3] Drug Price Competition & Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355). The declared purpose of this legislation was to "make available more low cost generic drugs." H.R. REP. NO. 98-857, pt. 1, at 14 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647.

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.* § 355(j)(5)(B)(iii)(I).

The Hatch-Waxman Amendments to FDCA furnished a significant incentive for Geneva to raise the first challenge to Abbott's Hytrin patents, namely, exclusive marketing rights to the first generic version of Hytrin for 180 days. *Id.* § 355(j)(5)(B)(iv). Under the "successful defense" regulation that FDA promulgated to implement this statutory incentive, however, Geneva needed to obtain a final decision of non-infringement from either the trial court or the Court of Appeals for the Federal Circuit in order to perfect its entitlement to the 180-day exclusive marketing period. *See* Abbreviated New Drug Application Regs., 54 Fed. Reg. 28,872, 28,894 (July 10, 1989); Abbreviated New Drug Application Regs., Patent and Exclusivity Provisions, 59 Fed. Reg. 50,338, 50,350-55 (Oct. 3, 1994). If another generic drug maker, such as Zenith, challenged Abbott's patents and successfully defended its ANDA first, Geneva would not be entitled to this statutory incentive. Zenith would be able to market the first generic terazosin hydrochloride drug, albeit without exclusive marketing rights to delay its competitors from entering the marketplace.

In June, 1994, Zenith joined the race to bring the first generic terazosin hydrochloride drug to market by filing an ANDA featuring a paragraph IV certification on one of Abbott's Hytrin patents. (Zenith Mem., Oct. 22, 1999, Ex. 6, at 11.) Abbott brought two unsuccessful infringement suits against Zenith for infringement of this patent, which was not timely included in the Orange Book. *See Abbott Labs. v. Zenith Labs., Inc.*, 934 F. Supp. 925, 939 (N.D. Ill. 1995) (dismissing case and observing that

Abbott retained right to sue Zenith for patent infringement "upon the commencement of marketing . . . of the generic copy"). Abbott then submitted two additional patents to FDA for inclusion in the Orange Book, U.S. Patents 5,412,095 ["'095 patent"] and 5,504,207 ["'207 patent"]. In March, 1996, FDA informed Zenith that it would have to amend its ANDA to certify with respect to those patents. Zenith balked at amending its ANDA, however, because Abbott then could institute another infringement suit and trigger a new 30-month stay of FDA approval (absent an intervening judicial determination of non-infringement) of Zenith's proposed generic tablet. On April 15, 1996, Zenith sued Abbott for improperly listing the '095 and '207 patents, and requested injunctive relief delisting them from the Orange Book. Abbott counterclaimed, alleging that Zenith had infringed those patents.

Later that month, on April 29, 1996, Geneva renewed its drive to market the first generic tablet and capsule versions of Hytrin by filing an ANDA featuring a new paragraph IV certification with respect to Abbott's recently-listed '207 patent. Abbott launched an infringement action to stop Geneva's new generic tablet proposal, but inexplicably failed to protest Geneva's new generic capsule proposal. FDA continued to evaluate the safety and efficacy of Geneva's proposed capsule while the automatic 30-month stay for approval of Geneva's proposed tablet took effect.

1. The Survival of the "Successful Defense" Requirement

In 1997, two federal courts rendered conflicting decisions on the validity of the successful defense requirement, temporarily throwing into question which drug maker would market the first generic version of Hytrin. On January 23rd, the United States District Court for the District of Columbia strongly questioned the validity of the successful defense regulation and concluded that the first drug maker to file an ANDA for a generic micronized glyburide product, Mova Pharmaceutical Corp., was entitled to exclusive marketing rights to that product for 180 days despite the fact that one of its competitors, Mylan Pharmaceuticals, Inc., filed a micronized glyburide ANDA later and successfully defended it first. *Mova*

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] forum 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 defense regulation and enjoined FDA from *refusing* to enforce it. *See Granutec, Inc. v. Shalala*, 1998 WL 153410, at *1 (4th Cir. Apr. 3, 1998) (recounting history of unreported District Court case). The Court of Appeals for the Fourth Circuit promptly stayed this injunction pending appeal. *Id.* at *5.

On November 5, 1997, FDA announced that it would enforce the successful defense regulation and await the decision of the appellate courts before revising its standards. Policy on 180-Day Marketing Exclusivity for Drugs Marketed under Abbreviated New Drug Applications; Clarification, 62 Fed. Reg. 63,268, 63,269 (Nov. 28, 1997). Thus, despite the decision of the United States District Court for the District of Columbia in the *Mova* case, Geneva would have to successfully defend its ANDA against Abbott's infringement suit before Zenith successfully defended its ANDA in order to market the first generic version of Hytrin.

While *Mova* and *Granutec* were pending before the federal Courts of Appeal, Zenith's campaign to beat Geneva to the market also suffered a setback. On October 1, 1997, the United States District Court for the District of New Jersey rejected Zenith's complaint for injunctive relief to delist Abbott's '095 and '207 patents, at least temporarily blocking final FDA approval of Zenith's ANDA. *See Zenith Labs., Inc. v. Abbott Labs.*, Civ. No. 96-1661, slip. op. at 26-27 (D.N.J. Oct. 1, 1997). Zenith appealed this decision to the Court of Appeals for the Federal Circuit. Then, on February 27, 1998, Zenith asked FDA to develop "a plan of action . . . to expedite final approval of Zenith's ANDA upon the delisting of Abbott's patents," so Zenith could "immediately bring [its] product to market should [it] receive a

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 word that FDA had approved Geneva's generic terazosin hydrochloride capsule. During the following two days, Abbott entered into separate confidential agreements with Zenith and Geneva to alter each company's rights and responsibilities.

Under its March 31, 1998, "Settlement Agreement," Zenith agreed to accept $3 million to join Abbott in dismissing the disputes before the District of New Jersey and the Federal Circuit, and to accept

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[4] "Validation" refers to the process by which a drug maker produces three commercial-size batches of the approved drug to prove that its product meets the technical specifications contained in the relevant ANDA. *See* FOOD & DRUG ADMIN., GUIDELINE ON GENERAL PRINCIPLES OF PROCESS VALIDATION (1987), *reprinted in* Geneva Opp'n, Ex. 3-A, Mar. 21, 2000; *see also* 21 C.F.R. § 211.110; (Geneva Opp'n, Ex. 3, at 3 (Aff. of Joan Fiore, Geneva Project Manager)).

[5] (*See* Walgreen Pls.' Opp'n, Ex. 4 (Declaration of Karen Rucci, Associate Director, Zenith Regulatory Affairs, at ¶ 5).) According to the defendants, by filing the first ANDA on Abbott's patents, Geneva precluded Zenith from introducing the first generic version of Hytrin. (*E.g.*, Abbott Statement, Mar. 20, 2000, at 14.) This statement draws a legal conclusion and conflicts with the state of the Law at the time of the defendants' agreements. *See infra* note 12 and accompanying text.

an additional $6 million per quarter (or a prorated sum for a shorter period) to "not sell, offer for sale, donate, or otherwise commercially distribute in the United States any [t]erazosin [h]ydrochloride [p]roduct" until another drug maker sold a generic version of Hytrin in the United States. Abbott elected to "allow[] Zenith to enter the market," or Abbott's patents expired. (*See* Pl.'s Mem., Feb. 18, 2000, Ex. 1, at 2, 3, 5 (Zenith-Abbott Agreement (Mar. 31, 1998)) ["Zenith Agreement" or "Z.A."].)[6] Zenith also promised "not [to] aid or assist any person or entity to gain FDA approval to market a [t]erazosin [h]ydrochloride [p]roduct," and obtained Abbott's permission to market such products once generic competition began. (*Id.* at 7, 4.)

On April 1, 1998, Geneva agreed to accept $4.5 million per month from Abbott (or a prorated sum for a shorter period) to refrain from marketing any generic terazosin hydrochloride drug, including its FDA-approved capsule, until another drug maker sold a generic version of Hytrin in the United States or Geneva received a final, unappealable judgment that its proposed generic tablet did not infringe Abbott's patents. (*See* Pl.'s Mem., Ex. 2, at 2-5 (Geneva-Abbott Agreement (Apr. 1, 1998)) ["Geneva Agreement" or "G.A."].)[7] Geneva and Abbott agreed to continue their court battle over the proposed generic terazosin hydrochloride tablet. Geneva promised to "join and support any motion filed by Abbott . . . in the Northern District of Illinois" seeking an extension of FDA's 30-month stay on approval of its proposed tablet. (*Id.* at 5.) If Geneva successfully defended Abbott's suit before the trial court, Abbott would pay subsequent monthly payments into an escrow fund payable to the final prevailing party on

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[6] Zenith would receive only $3 million for the first quarter that it refrained from marketing a generic version of Hytrin, (*id.* at 3), but if Geneva ultimately enjoyed exclusive marketing rights by statute for 180 days, Abbott would pay Zenith three million dollars during that period as well. (*Id.* at 4.)

[7] Abbott reserved the right to suspend its payments to Geneva, promising "not to sue it for patent infringement . . . of the '207 patent," if no drug maker introduced a generic version of Hytrin by February 18, 2000. (*Id.* at 4.) For its part, Geneva promised "to use its best efforts to oppose any attempts by any ANDA applicant that is a party to litigation involving terazosin hydrochloride patents to assert that it is entitled to approval of its ANDA . . . prior to the date currently determined pursuant to 21 C.F.R. § 314.107." (*Id.* at 5.)

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 hydrochloride drug available in the United States.

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 these arguments and others to establish that it is entitled to summary judgment on the plaintiffs' complaints. Leaving aside the defendants' assertions regarding causation and damages until the parties have had a full opportunity to conduct discovery,[1] the Court will examine the parties' contentions *seriatim*.

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[1] On February 14, 2000, the Court stayed all discovery unrelated to class issues until the parties' cross motions for summary judgment were fully briefed and resolved. Since the parties have not conducted full discovery on the issues of causation and damages, those questions presently are not ripe for summary judgment.

Zenith protests that *Atlantic Richfield Co. v. USA Petroleum Co.*, 495 U.S. 328 (1990), bars this tribunal from considering whether the defendants committed a *per se* violation of the Sherman Act until the plaintiffs prove that they have suffered an "antitrust injury" under the Clayton Antitrust Act, 15 U.S.C. §§ 12-27(a). As the Supreme Court observed in that case, however, "proof of a *per se* violation and of antitrust injury are distinct matters that must be shown independently." 495 U.S. at 344 (citation omitted). Accordingly, today's decision draws no conclusion regarding whether the plaintiffs have suffered an antitrust injury.

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. Liberty Lobby, Inc.*, 477 U.S. 242, 247 (1986). Once the moving party demonstrates the absence of a genuine issue of material fact, the non-moving party must "come forward with 'specific facts showing that there is a genuine issue for trial.'" *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986) (quoting FED. R. CIV. P. 56(e)). Accepting this evidence as truthful, the Court must view the record and all factual inferences therefrom in the light most favorable to the non-moving party and decide whether "'the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law.'" *Allen v. Tyson Foods, Inc.*, 121 F.3d 642, 646 (11th Cir. 1997) (quoting *Anderson*, 477 U.S. at 251-52).

2. The Sherman Antitrust Act and Illegality *Per Se*

Congress designed the Sherman Antitrust Act of 1890 as a "consumer welfare prescription" to protect free enterprise and competition. *Reiter v. Sonotone Corp.*, 442 U.S. 330, 343 (1979) (citation omitted). Although section one of the Sherman Act literally bans every agreement "in restraint of trade," 15 U.S.C. § 1, this provision has been interpreted to prohibit only those contracts involving interstate commerce that "unreasonably" restrain competition. *Standard Oil Co. v. United States*, 221 U.S. 1, 55-60 (1911). Applying the "rule of reason," courts conduct an extensive and complex investigation into "the facts peculiar to the business in which the restraint is applied, the nature of the restraint and its effects, and the history of the restraint and the reasons for its adoption" to determine whether the challenged contract unreasonably restrains competition. *United States v. Topco Assocs., Inc.*, 405 U.S. 596, 606 (1972) (citation omitted). Only blatantly anti-competitive agreements that predictably "tend to restrict competition and decrease output" may be condemned as unreasonable and illegal *per se* "without

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. United States*, 356 U.S. 1, 5 (1958) (Black, J.).

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." *NCAA v. Board of Regents*, 468 U.S. 85, 103 (1984) (footnote omitted); *see also* 7 PHILLIP E. AREEDA, ANTITRUST LAW ¶ 1503a, at 372 (1986) ("Every antitrust suit should begin by identifying the ways in which a challenged restraint might possibly impair competition."). The defendants' agreements contain numerous covenants inimical to free enterprise.

In its agreement with Abbott, Geneva promised to withhold its FDA-approved capsule from the United States market, to refrain from selling its rights to that capsule and its tablet ANDAs, to oppose any attempts by other ANDA applicants to enter the market early, and, in the event that Geneva "successfully defended" its tablet ANDA before the Federal Circuit and secured a 180-day exclusivity period, to forgo marketing that tablet until Abbott exhausted any appeals before the Supreme Court. *See supra* pages 7-8. Similarly, in its accord with Abbott, Zenith agreed to dismiss its efforts to delist Abbott's Hytrin patents, to rebuff other entities' requests for help in challenging those patents, and, with the assurance of continued payment during any period of exclusivity enjoyed by a rival generic drug maker, to refrain from marketing the first generic terazosin hydrochloride product unless Abbott authorized Zenith to enter the market, or Abbott's patents elapsed. *See supra* pages 6-7.

Viewed together and in their factual context, these provisions illustrate that Geneva and Zenith forswore competing with Abbott in the United States market for terazosin hydrochloride drugs and promised to take steps to forestall others from entering that market for the life of their respective

agreements in exchange for millions of dollars in monthly or quarterly payments. Geneva and Zenith 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 some market, thus causing higher prices, inefficient substitutions, and the resultant losses in consumer welfare"). Instead of braving the rigors of competition, or unilaterally avoiding the arena, Geneva and Zenith both made pacts with Abbott to "enhance their collective profits to the detriment of consumers."[9] Abbott disinvited Geneva and Zenith from marketing the first generic terazosin hydrochloride drugs in the United States for an indefinite period, eliminated the risk that either drug maker would sell or purchase the right to introduce such drugs in the interim, and enlisted their potential cooperation in opposing or refusing to support other drug makers' ANDAs. This scheme of agreements clearly "den[ied] to consumers the opportunity to choose among alternative offers without offering the possibility of any joint, efficiency-producing activities." *See United States v. Realty Multi-List, Inc.*, 629 F.2d 1351, 1364 (5th Cir. 1980) (citation omitted).[10] Under this scheme, the defendants would earn their profits by limiting marketwide output and maintaining a higher price for Abbott's product.

Abbott's agreements with Geneva and Zenith to forestall competition in the United States for sales of terazosin hydrochloride drugs confront the Court with "[o]ne of the classic examples of a *per se*

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[9] 7 PHILLIP E. AREEDA, ANTITRUST LAW ¶ 1503a, at 374; *see Palmer v. BRG*, 498 U.S. 46, 49-50 (1990) (per curiam) (observing that plaintiff need not prove that defendants previously competed in relevant market to establish *per se* violation of 15 U.S.C. § 1); In re *Cardizem CD Antitrust Litig.*, 105 F. Supp.2d 618, 677-79 (E.D. Mich. 2000) ["*Cardizem I*"] (same). These agreements did not deprive Geneva or Zenith of the opportunity to sell terazosin hydrochloride drugs outside the United States.

[10] In *Bonner v. City of Prichard*, 661 F.2d 1206, 1209 (11th Cir. 1981), the Court of Appeals for the Eleventh Circuit adopted as binding precedent all decisions that the former Court of Appeals for the Fifth Circuit rendered before October 1, 1981.

violation"—"an agreement between competitors at the same level of the market structure to allocate 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 and time again that "[h]orizontal territorial limitations . . . are naked restraints of trade with no purpose except stifling of competition." Such limitations are *per se* violations of the Sherman Act.

Id. (citations omitted); *see also id.* at 613 (Burger, C.J., dissenting) (observing that *per se* rule rightly condemns horizontal agreements "involv[ing] restraints on interbrand competition or an allocation of markets by [an entity or group] with monopoly or near-monopoly control of the sources of supply"). *See generally* HOVENKAMP, *supra* page 11, ¶ 1902a, at 190 ("Horizontal agreements are antitrust's most 'suspect' classification.").

When presented with a plainly anti-competitive contract, the Court "need not then inquire whether the [defendants] actually possess the power to inflict public injury," or whether "the restraint . . . is justified by any procompetitive purpose or effect." *Realty Multi-List*, 629 F.2d at 1362. Nevertheless, this tribunal will examine the defendants' chief mitigating arguments, mindful that "[t]he probability that anticompetitive consequences will result from a practice . . . must be balanced against its pro-competitive consequences," *Arizona v. Maricopa County Med. Soc.*, 457 U.S. 332, 350 n.16 (1982), and that the defendants must "come forward with 'specific facts showing that there is a genuine issue for trial'" on the potential consequences of their accords. *See Matsushita Elec. Indus. Co.*, 475 U.S. at 587.

4. The Defenses Offered by Defendants are Invalid

The defendants claim immunity from the *per se* rule on several grounds. First, they contend that the challenged agreements tended to foster competition or had no impact on their ability to compete. Second, they argue that the agreements are beyond the scope of the *per se* rule because they were novel, analogous to patent settlements, or designed to influence government organizations. These arguments are

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 not substantiate that the Geneva and Zenith Agreements were reasonably ancillary to pro-competitive activity rather than unreasonable restraints of trade.

The Geneva Agreement did not enhance competition. According to the defendants, Geneva contracted with Abbott to avoid "substantial legal and financial risks" accompanying the introduction of its capsule product, furthering "the public policy preference for deferring generic entry until after the resolution of any patent dispute with respect to any given drug." (Abbott Statement at 7 (citations omitted); *id.* at 13 (citing Decl. of Steven N. Wiggins, Econ. Professor, Texas A&M Univ., at ¶¶ 14-22, 32-48).) Accepting these allegations as true, it is readily apparent that Geneva did *not* have to enter into a contract with Abbott in order to defer its entry into the United States market.

Abbott's confidential agreement with Geneva did not resolve its action before the Northern District of Illinois; in fact, it tended to prolong that dispute to Abbott's advantage. Geneva agreed to accept over a million dollars per week to refrain from marketing any generic terazosin hydrochloride product until another drug maker sold a generic version of Hytrin in the United States, or it received an unappealable judgment that its proposed generic tablet did not infringe Abbott's patents. (G.A. at 3-5.) The latter condition restrained Geneva from marketing its products during the pendency of any Supreme

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 defendants' comprehensive and unreasonable restraints. One could reasonably infer that this clause was a catalyst for competition if Geneva paid Abbott for it, but the suggestion that Abbott handsomely paid Geneva to split competition in its own lucrative domestic market for terazosin hydrochloride products is patently unreasonable. *See* In re *Cardizem CD Antitrust Litig.*, 105 F. Supp. 682, 699 (E.D. Mich. 2000) ["*Cardizem II*"] (concluding that drug makers' alleged agreement to allocate United States market for brand-name drug Cardizem CD provided "an incentive to stay off the market"); *Cardizem I*, 105 F. Supp.2d at 679 (noting that defendant "ignore[d] the reasonable inference that HMRI would not have paid Andrx millions of dollars to stay off the market beyond July 9, 1998, if it was not reasonably probable that Andrx would enter the market"). The Geneva Agreement clearly sought to curtail the domestic sale of generic terazosin hydrochloride drugs.

The Zenith Agreement also sought to restrain domestic competition. Zenith confidentially agreed to terminate its potentially meritorious challenge to Abbott's Hytrin patents in the District of New Jersey and the Federal Circuit in exchange for three million dollars. Thereafter, in a separate series of transactions, Zenith would receive millions of dollars to "not sell, offer for sale, donate, or otherwise commercially distribute in the United States any [t]erazosin [h]ydrochloride [p]roduct" until another drug maker sold a generic version of Hytrin in the United States, among other things. (G.A. at 3.) Zenith also

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[11] *See* 59 Fed. Reg. at 50,354 ("The likelihood of an appellate court decision being heard and overruled by the Supreme Court is too remote to warrant delaying marketing and exclusivity pending resolution of a petition for writ of certiorari."). Further, Geneva also promised to "join and support any motion filed by Abbott . . . in the Northern District of Illinois" seeking an extension of FDA's 30-month stay on approval of its proposed tablet, potentially delaying the proceedings even further. (G.A. at 5.)

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(e).[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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[12] (*E.g.*, Zenith Opp'n, Mar. 20, 2000, at 5 (drawing legal conclusion)); *see Beard v. Annis*, 730 F.2d 741, 743 (11th Cir. 1984) (rejecting statements of law as inadmissible); 10B CHARLES ALAN WRIGHT, ARTHUR R. MILLER & MARY KAY KANE, FEDERAL PRACTICE AND PROCEDURE § 2738, at 346-56 (1998). The defendants' legal allegation pointedly ignores FDA's November 5, 1997, pronouncement that the agency would continue to enforce the successful defense regulation. (*See* Walgreen Pls.' Reply to Zenith, Apr. 3, 2000, at 2.) That was the state of the law on March 31, 1998.

see also AMERICAN BAR ASS'N, ANTITRUST LAW DEVELOPMENTS 79 (4th ed. 1997).

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.

1. Novel Agreements

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 horizontal market allocation agreements and their foreseeable anti-competitive effects.

Without belaboring the point, the undisputed record and the plain text of Abbott's agreements with Geneva and Zenith bespeak the defendants' intent to eliminate domestic competition for sales of terazosin hydrochloride products in the short run and delay the onset of generic competition. Such horizontal agreements to allocate territories remain illegal *per se* under section one of the Sherman Act even if they involve complex disputes involving pharmaceutical companies. *See Maricopa County Med. Soc.*, 457 U.S. at 349 (rejecting argument that Supreme Court "should not apply the *per se* rule in this case because the judiciary has little antitrust experience in the health care industry"); *Cardizem II*, 105 F. Supp.2d at 705-06 (declaring defendants' horizontal market allocation agreement illegal *per se*); *Cardizem I*, 105 F. Supp.2d at 676-77 (rejecting "novelty" arguments raised by drug makers HMRI and Andrx to dismiss consolidated Sherman Act challenges). Certainly, the *per se* rule must be "applied

infrequently and with caution" to avoid "mislabeling procompetitive activity as *per se* illegal," *Seagood 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 not involve "the 'mere attachment of a *per se* label . . . to defendants' conduct,'" or an attempt to "'throw labels . . . around loosely.'" (Zenith Opp'n at 13 (citation omitted).) The defendants' confidential and comprehensive allocation of the United States market for the sale of terazosin hydrochloride products should be denounced under the *per se* rule.

2. Patent Settlements

Zenith and Abbott claim that the challenged accords are analogous to patent settlement agreements and that the *per se* rule does not apply to such settlements. (Zenith Opp'n at 12; Abbott Opp'n at 26-27 ("antitrust cases considering settlements of patent . . . disputes are consistently evaluated under the rule of reason").) Again, the defendants are mistaken. Abbott's agreement with Geneva did not resolve its infringement suit in the Northern District of Illinois, and while Zenith agreed to dismiss its appeal before the Federal Circuit in exchange for three million dollars, this exchange was part of a larger scheme to restrain the domestic sale of generic terazosin hydrochloride products. Furthermore, the Supreme Court has reviewed patent settlements under the *per se* rule. *E.g., United States v. New Wrinkle, Inc.*, 342 U.S. 371, 377 (1952). The *per se* rule applies to the defendants' conduct.

3. Efforts to Influence Government Action

Lastly, Abbott seeks the shelter of the *Noerr-Pennington* doctrine, which shields legitimate efforts to influence public officials from potential antitrust liability. (*See* Abbott Opp'n at 27-29 (citing *McGuire Oil Co. v. Mapco*, 958 F.2d 1552, 1560 (11th Cir. 1992).) *See generally California Motor Transp. Co. v. Trucking Unlimited*, 404 U.S. 508, 513 (1972); *United Mine Workers v. Pennington*, 381

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 violative of the Sherman Act, [including] . . . market-division agreements." *Noerr Motor Freight*, 365 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. Contrary to Abbott's assertion, the Court of Appeals' *Mapco* decision does not "flatly contradict [that] position," or hold that price-fixing stipulations adopted by opposing parties in ongoing litigation are entitled to *Noerr-Pennington* immunity. *See Mapco*, 958 F.2d at 1561-62 (rejecting defendant's narrow argument that plaintiffs' "concerted threats [of suit] and institution of litigation . . . violated the Sherman Act"). Abbott's efforts to parlay its patents into agreements with its competitors to limit the domestic sale of generic terazosin hydrochloride drugs is exactly "the type of commercial activity that has traditionally had its validity determined by the antitrust laws." *Allied Tube & Conduit Corp.*, 486 U.S. at 505.

CONCLUSION

Both the Geneva Agreement and the Zenith Agreement warrant condemnation as *per se* violations of section one of the Sherman Antitrust Act. This tribunal's extensive review of the undisputed record has validated the presumption that the defendants' horizontal market allocation agreements would

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.