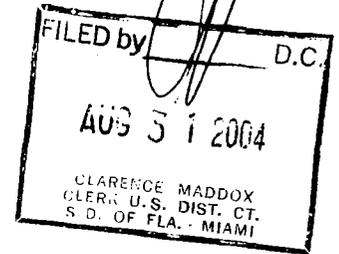


UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF FLORIDA  
CASE NO. 99-MDL-1317-SEITZ/KLEIN-(ALL CASES)



IN RE: TERAZOSIN HYDROCHLORIDE  
ANTITRUST LITIGATION

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**ORDER**

**(1) GRANTING DEFENDANT ABBOTT LABORATORIES' MOTION FOR SUMMARY JUDGMENT ON SHERMAN ACT SECTION 2 (AND ANALOGOUS) CLAIMS; AND (2) DENYING PLAINTIFF KAISER FOUNDATION HEALTH PLAN INC.'S MOTION FOR SUMMARY JUDGMENT ON SHAM LITIGATION<sup>1</sup>**

THIS CAUSE is before the Court on Defendant Abbott Laboratories' ("Abbott") Motion for Summary Judgment on Sherman Act Section 2 (and Analogous) Claims and Kaiser Foundation Health Plan Inc.'s ("Kaiser") Motion for Summary Judgment on Sham Litigation. These are essentially cross motions for summary judgment. The Court has considered the motions, responses, replies, supporting exhibits, and oral argument of counsel. Having considered the undisputed material facts<sup>2</sup> in the light most favorable to Plaintiffs, the Court concludes that no genuine issue of material fact exists for trial on the Section Two and analogous claims. Therefore, on these claims, Defendant Abbott is entitled to summary judgment as a matter of law, and Plaintiff Kaiser's Motion must be denied.

There are five grounds for granting Abbott's motion. First, Plaintiffs have failed to show that any of the seventeen patent infringement lawsuits in question was objectively baseless. Second, even

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<sup>1</sup> Because Defendant's Motion on the Section Two and analogous claims is granted, it is not necessary to determine whether Abbott possessed monopoly power. Thus, Kaiser Foundation Health Plan Inc.'s Motion for Summary Judgment on Monopoly Power and Individual Sherman Act Plaintiffs' Motion for Summary Judgment on the Issue of Monopoly are denied as moot.

<sup>2</sup> On July 16, 2004, the parties submitted a Joint Statement of Facts Not in Dispute. [D.E. 1386]. For the purposes of conciseness and clarity, references to that Statement will be indicated as "S. ¶ \_\_\_\_." In addition, references to the Federal Food, Drug, and Cosmetics Act, 21 U.S.C. § 301, *et. seq.*, included in that Statement will be omitted.

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assuming that Plaintiffs could establish that some of these actions were objectively baseless, they did not, and apparently cannot, proffer any admissible evidence of a subjective bad-faith intent to abuse the judicial process in violation of the Sherman Act. Third, even viewing the seventeen lawsuits as a serial pattern of baseless anti-competitive actions filed automatically and without probable cause, the Court must find as a matter of law, based on the record evidence, that Defendant did not lose its Noerr-Pennington<sup>3</sup> immunity because there was a legal basis for filing each of these lawsuits and a significant percentage of the suits were successful. Fourth, excluding the patent infringement lawsuits related to the '207 patent, the remaining lawsuits concluded prior to the generic drug competitor receiving tentative Food and Drug Administration ("FDA") approval for its generic bioequivalent drug. Thus, there is only speculation, rather than evidence, that Abbott's filing of these lawsuits caused the alleged antitrust injury, namely, the prevention of generic market entry. Finally, in connection with the Walker Process<sup>4</sup> claim regarding the allegedly fraudulent procurement of the '207 patent, there is no record evidence of fraud or an attempt to commit fraud to procure the patent. Therefore, the Court will grant summary judgment in favor of Defendant Abbott on the Section Two and analogous state claims.

## **Factual Background**

### **I. Nature of the Action**

This multi-district antitrust litigation ("MDL") originates at the intersection of antitrust and patent law. At its core, this case revolves around Abbott's attempts to protect its patents' exclusivity with respect to the brand name drug Hytrin, and the competing efforts of generic manufacturers to

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<sup>3</sup> See E. R.R. Presidents Conference v. Noerr Motor Freight, Inc., 365 U.S. 127 (1961); United Mine Workers of Am. v. Pennington, 381 U.S. 657 (1965).

<sup>4</sup> See Walker Process Equip.Inc., v. Food Mach. and Chem. Corp., 382 U.S. 172 (1965).

develop and launch bio equivalent drugs for entry in the terazosin hydrochloride market. Between May 31, 1977, and August 13, 1999, pursuant to several patents, Abbott exclusively manufactured and marketed terazosin hydrochloride under the brand name of Hytrin. Hytrin is a drug prescribed for the treatment of high blood pressure and benign prostatic hyperplasia (“BPH”), an enlargement of the prostate gland that surrounds the urinary canal. Hytrin proved to be a lucrative drug for Abbot; for example, in 1998, Hytrin generated \$540 million in sales which accounted for more than twenty percent of Abbott’s sales of pharmaceutical products in the United States that year. Geneva Pharmaceuticals Inc. (“Geneva”), Zenith Goldline, Inc. (“Zenith”) – now known as IVAX Pharmaceuticals, Inc. (“IVAX”) – and other generic drug manufacturers developed generic versions of Hytrin for sale in the United States to compete for the Hytrin market. Whereas the first generic drug manufacturer, Geneva, began the regulatory process to enter the market in January 1993, generic entry only occurred in August 1999. Generic market entry not only provides less expensive drugs for consumers, but also eliminates a brand name drug company’s patent monopoly.

Plaintiffs Kaiser, Individual Direct Purchasers, Indirect Purchaser Class Plaintiffs, and State Plaintiffs (collectively, “Plaintiffs”)<sup>5</sup> sued Defendant Abbott alleging, *inter alia*, claims under Section Two of the Sherman Act (“Section Two”)<sup>6</sup> and analogous state laws for monopolization and attempted monopolization. Plaintiffs’ Section Two claims have two bases. The first basis is the

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<sup>5</sup> The Individual Direct Purchasers are large entities (e.g., Walgreens, Shop-Rite) that purchased Hytrin directly from Abbott. The Indirect Purchaser classes are seventeen certified state classes of end payers for Hytrin consisting of Third Party Payers (e.g., insurance companies) and individual consumers. See In re Terazosin Hydrochloride, 220 F.R.D. 672 (S.D. Fla. 2004). Kaiser’s action was transferred to this Court for consolidated MDL proceedings from the Central District of California. The State Plaintiffs represent the consumers from the states of Florida, Colorado, and Kansas.

<sup>6</sup> Section Two of the Sherman Antitrust Act makes it a felony for any “person [to] monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the Several States . . . .” 15 U.S.C. § 2.

allegation that Abbott filed seventeen “sham” patent infringement lawsuits to delay market entry of competing generic bioequivalent drugs for Hytrin and thus illegally maintained Abbott’s patent monopoly beyond the life of its patents. Second, Plaintiffs claim that Abbott fraudulently procured one of its Hytrin patents, the ‘207 patent, which allowed it to maintain a monopoly on the terazosin hydrochloride market.

To place the patent infringement litigation at issue in context, it is necessary to set out the pertinent framework for drug regulation in the United States and then discuss the parties’ undisputed underlying material facts as to Abbott’s patents, the generic drug manufacturers’ applications to market their generic bioequivalent drugs, and the patent lawsuits themselves.

## **II. The FDA Regulatory Framework Under Hatch-Waxman**

A drug patent gives its owner the right to exclude others from making, using, or selling the drug in the United States for the duration of the patent. However, the FDA regulates the sale of drugs in the United States pursuant to the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301, *et seq.* Thus, drug companies must apply for and obtain approval from the FDA before they can sell a drug in the United States. S. ¶¶ 1-2. To secure FDA approval to market a new drug, a pharmaceutical company must first file a New Drug Application (“NDA”) with the FDA and may not market a new drug until the NDA is approved. S. ¶ 3. The NDA applicant must demonstrate to the FDA that the new drug is safe and effective for its proposed use(s). S. ¶ 3. New drugs that are approved and marketed through the NDA-approval process, such as Hytrin, are generally referred to as “brand-name” or “pioneer” drugs. S. ¶4. The pharmaceutical companies that develop new drugs, such as Abbott, are generally referred to as “brand name,” “innovator,” or “pioneer” companies. S. ¶ 4.

In 1984, Congress amended the laws governing pharmaceutical sales and enacted what is

commonly known as the Hatch-Waxman Act (“Hatch-Waxman”).<sup>7</sup> S. ¶5. This Act established an abbreviated process that shortened the time and effort needed to obtain FDA market approval for generic copies of previously approved pioneer drug products, yet also sought to guard against infringement of patents relating to pioneer drugs. As part of the legislative scheme to balance these competing interests, Hatch-Waxman provides that once the FDA approves a new drug, it is listed in a FDA publication called the “Orange Book” which identifies both the brand name and the chemical or generic name for the drug. S. ¶6. The FDA also lists in the Orange Book any patents owned by the innovator that “claim the drug” or “which claim a method of using such drug” and “with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug,” along with the expiration date of such patent(s). S. ¶ 6.

On the other side of the balance, Hatch-Waxman provides that five years after the FDA has approved a new drug, a generic pharmaceutical company may seek approval to sell a generic version of the drug by filing an Abbreviated New Drug Application (“ANDA”). S. ¶ 7. A generic pharmaceutical manufacturer, such as Geneva, may not market a generic drug until the FDA approves the ANDA for that company’s generic drug and must also meet certain validation requirements before it can legally market its product. S. ¶ 7. To secure FDA approval for an ANDA, a generic manufacturer must demonstrate that the proposed generic drug is the bioequivalent of the corresponding brand-name drug. S. ¶ 8.

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<sup>7</sup> The legislative policy behind Hatch-Waxman was to balance the need to preserve the incentive for brand name drug companies to develop new drugs with the public’s interest in buying less expensive generic bioequivalent drugs. See Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration: An FTC Study* (July 2002) (noting that as of 2002, generics comprised 47% of the prescriptions filled in the United States, up from 19% in 1984) [hereinafter “FTC Study”].

When filing an ANDA, FDA regulations require the ANDA applicant to certify that either: (I) no patent is listed in the Orange Book relevant to its ANDA; or (II) the patent listed in the Orange Book has expired; or (III) the listed patent will expire on a particular date, and the ANDA filer does not seek FDA approval before that date (a “Paragraph III Certification”); or (IV) the listed patent is invalid or will not be infringed by the manufacture, use, or sale of the proposed generic drug (a “Paragraph IV Certification”). S. ¶9. If the ANDA filer makes a Paragraph III Certification, the ANDA cannot receive final approval until the expiration of the relevant patent(s). S. ¶ 10. If the ANDA filer makes a Paragraph IV Certification, however, it is required to provide a notice to the innovator company of the certification, including “a statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed.” S. ¶ 11. The Hatch-Waxman and FDA regulations do not require the ANDA applicant to provide a sample of its proposed generic product. S. ¶ 11.

During the time period at issue in this case, if the generic company filed a Paragraph IV Certification and the innovator company filed a patent infringement lawsuit in federal court within forty-five days of the innovator company's receipt of the generic company's Paragraph IV Certification, such a lawsuit would trigger a “30 month stay” provision. S. ¶ 12. Under this provision, the FDA was prohibited from granting final approval for the ANDA until: (1) the thirty (30) months elapsed or (2) a “court decision” relating to the specific ANDA held the patent invalid or un infringed, whichever occurred first. S. ¶ 12. Until July 2000, FDA regulations provided that a “court decision,” in the context of the 30 month stay, meant a decision of an appellate court or a decision of a district court from which no appeal was taken. S. ¶ 15. However, during the 30 month stay period, the FDA may grant “tentative approval” to an ANDA applicant if the FDA determines

that the ANDA would otherwise receive final approval but for the 30 month stay. S. ¶ 14. District courts are authorized to extend or shorten the 30 month stay under certain circumstances. S. ¶ 12. A dismissal of the Hatch-Waxman infringement lawsuit lifts the 30 month stay. A patent infringement action filed after the Act's forty-five day window does not trigger a 30 month stay.

### **III. Abbott's Patents for Terazosin Hydrochloride**

Abbott holds a number of patents permitting it to manufacture and market drugs containing the chemical compound terazosin hydrochloride, and there are no crystalline forms of terazosin hydrochloride other than those claimed or disclosed in the Abbott patents. S. ¶ 50. These patents include the following:

#### **A. '894 Patent**

Abbott is the assignee<sup>8</sup> of the 4,026,894 ('894) patent for terazosin hydrochloride. The '894 application was filed on October 14, 1975. The patent was issued on May 31, 1977, was listed in the Orange Book prior to 1993, and expired on May 31, 1994. Abbott's Hytrin tablets contain terazosin hydrochloride dihydrate, which means the crystalline arrangement contains two water molecules for every terazosin molecule.<sup>9</sup> No generic pharmaceutical company has challenged the validity of the '894 patent or sought to market a generic terazosin hydrochloride product before the expiration of the '894 patent. S. ¶ 41.

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<sup>8</sup> Often, an Abbott scientist or researcher would create the patented invention and then assign the patent rights to Abbott.

<sup>9</sup> Terazosin hydrochloride also exists in an anhydrous (meaning without water) crystalline form. This fact becomes significant after 1989.

### **B. '097 Patent**

Abbott is also the assignee of the 4,112,097 ('097) patent which covers a pharmaceutical composition of dihydrate terazosin hydrochloride for treating hypertension and a method for treating hypertension with terazosin hydrochloride. The application for this patent was filed on January 21, 1977, and was a divisional of the application for the '894 patent. The '097 patent issued on September 5, 1978, and was originally set to expire on September 5, 1995. However, on November 16, 1995, in patent infringement litigation, Abbott asserted that the Uruguay Round Agreements Act ("URAA") extended the term of the '097 patent through January 21, 1997. On March 14, 1996, the Northern District of Illinois held that the URAA extended the term of the '097 patent only through October 14, 1995. See Abbott Labs. v. Zenith Labs. Inc., No. 96 C. 611, 1996 WL 131498 (N.D. Ill. Mar. 14, 1996). The Federal Circuit affirmed the lower court decision that the '097 patent expired on October 14, 1995. See Abbott Labs. v. Geneva Pharms. Inc., 104 F.3d 1305 (Fed. Cir. 1997). No generic pharmaceutical company challenged the validity of the '097 patent or sought to market a generic terazosin hydrochloride product before October 14, 1995. However, Geneva, Novopharm, and Warner-Chilcott ("Warner") sought approval for their generic products and filed ANDAs before January 21, 1997, the date which Abbott claimed to be the expiration date of the '097 patent. S. ¶¶ 42-44.

### **C. '532 Patent**

The 4,251,532 ('532) patent, which is also assigned to Abbott, covers not only the dihydrate of terazosin hydrochloride, but also the pharmaceutical composition containing the dihydrate of terazosin hydrochloride, and a method of treating hypertension with the dihydrate of terazosin hydrochloride. The application for the '532 patent was filed on September 24, 1979. The patent

issued on February 17, 1981, and it expired on February 17, 2000. The '532 patent was listed in the Orange Book prior to 1993, and no generic pharmaceutical company challenged the validity of the '532 patent. S. ¶ 45.

**D. '615 Patent**

Abbott's 5,294,615 ('615) patent is for an anhydrous crystalline polymorph of terazosin hydrochloride with a certain x-ray diffraction pattern (Form II), a pharmaceutical composition comprising a therapeutically effective amount of the crystalline polymorph in combination with a pharmaceutically acceptable carrier, and methods of treating hypertension and BPH. The application for the '615 patent was filed on July 13, 1993, the patent issued on March 15, 1994, and it expires on March 15, 2011. The '615 patent was listed in the March 1995 supplement to the Orange Book. S. ¶ 46.

**E. '095 Patent**

Abbott is the assignee of the 5,412,095 ('095 patent) patent on an anhydrous crystalline polymorph of terazosin hydrochloride with a certain x-ray diffraction pattern (Form III), and a methanol solvate of terazosin hydrochloride. This methanol solvate can be used as an intermediate in producing Form IV terazosin hydrochloride (claimed by the '207 patent described below). The application for the '095 patent was filed on May 20, 1994, it issued on May 2, 1995, and it expires on April 29, 2013. The '095 patent was listed in the Orange Book on May 8, 1995. S. ¶¶ 47-48.

**F. '207 Patent**

Lastly, Abbott is the assignee of the 5,504,207 ('207) patent which claimed an anhydrous crystalline polymorph of terazosin hydrochloride with a certain x-ray diffraction pattern (Form IV) and a process for the preparation of terazosin hydrochloride dihydrate using Form IV terazosin

hydrochloride as an intermediary. The application for the '207 patent was filed on October 18, 1994, it issued on April 2, 1996, and it was submitted to the FDA for listing in the Orange Book on April 2, 1996. S. ¶ 49.

#### **IV. ANDAs for Terazosin Hydrochloride Products**

Generic drug manufacturers filed ANDA certifications challenging some of these patents. These companies included: Geneva, Novopharm, Zenith, Invamed, Lemmon, Warner, and Mylan. The ANDAs these companies filed were the only ones filed for generic terazosin hydrochloride products. S. ¶ 28.

##### **A. Geneva**

Geneva filed ANDA 74-315 on January 12, 1993 for terazosin hydrochloride tablets using Form II anhydrous terazosin. It later switched to Form IV anhydrous terazosin. Geneva obtained tentative approval on June 17, 1997, and final approval on December 31, 1998. Geneva came to market with its tablet product in May 2001. S. ¶ 29. Geneva also filed ANDA 74-823 on December 29, 1995, for terazosin hydrochloride capsules employing Form IV anhydrous terazosin and obtained final approval on March 30, 1998. Geneva came to market with its generic capsules on August 13, 1999. S. ¶ 30.

##### **B. Novopharm**

Novopharm filed ANDA 74-446 on December 16, 1993, for terazosin hydrochloride tablets, and obtained tentative FDA approvals on November 26, 1996, and December 29, 1999. It received final approval on May 18, 2000. Novopharm never came to market with a terazosin hydrochloride product and did not file any other ANDAs for terazosin hydrochloride. S. ¶ 31.

### **C. Zenith**

On August 1, 1994, Zenith filed ANDA 74-530 for terazosin hydrochloride tablets. The proposed product used anhydrous Form II terazosin. Zenith refused to provide certifications to Abbott's '095 and '207 patents on the ground that the patents had not been properly listed in the Orange Book. Zenith received a letter from the FDA dated July 8, 1997, stating that the FDA could not approve Zenith's application because of the absence of those certifications. Zenith subsequently provided those certifications and received tentative approval on August 14, 1998, and final approval on April 21, 2000. It never came to market with its tablet product. S. ¶ 32.

Later, Zenith filed ANDA 75-614 on April 7, 1999, for terazosin hydrochloride capsules and obtained final FDA approval on January 30, 2001. Zenith, which by that time had changed its name to IVAX, came to market with terazosin hydrochloride capsules in February 2001. S. ¶ 33.

### **D. Invamed**

On April 8, 1995, Invamed filed ANDA 74-657 for terazosin hydrochloride tablets. The proposed product used anhydrous Form IV terazosin. Invamed received tentative FDA approval on March 13, 1997, and final approval on April 28, 2000. However, it never came to market with a terazosin hydrochloride tablet product. S. ¶ 34. Invamed also filed ANDA 75-667 for terazosin hydrochloride capsules on July 8, 1999, received tentative FDA approval on August 20, 1999, and final approval on July 28, 2000. Similarly, it never came to market with a terazosin hydrochloride capsule product. S. ¶ 35.

### **E. Lemmon**

Lemmon filed ANDA 74-651 on May 3, 1995, for terazosin hydrochloride tablets, but Lemmon's ANDA has not received either tentative or final FDA approval. S. ¶ 36. The proposed

product used Form II anhydrous terazosin.

**F. Warner-Chilcott**

Warner filed ANDA 74-763 on September 29, 1995, for terazosin hydrochloride tablets, and this tablet ANDA has not received tentative or final FDA approval. S. ¶ 37. The proposed product used Form II anhydrous terazosin. Warner filed ANDA 75-317 on or about January 16, 1998 for terazosin hydrochloride capsules using Form IV terazosin. As with its proposed tablets, Warner's capsule ANDA has not received tentative or final FDA approval. S. ¶ 38.

**G. Mylan**

On June 6, 1997, Mylan filed ANDA 75-140 for a 5 mg terazosin hydrochloride capsule only, and later amended its ANDA on February 6, 1998, to include 1, 2, and 10 mg terazosin hydrochloride capsules. S. ¶ 39. Mylan obtained tentative FDA approval on September 28, 1998, and received final approval on all dosage forms on February 11, 2000. It came to market with its generic terazosin hydrochloride capsule in all four strengths on February 17, 2000. S. ¶ 39.

After being notified of each of these ANDA filings, Abbott filed seventeen patent infringement lawsuits against these companies which form the basis for Plaintiffs' Section Two claims. The lawsuits are described below in chronological order.

**V. The Terazosin Hydrochloride Patent Infringement Lawsuits**

**A. Geneva '532 Lawsuit**

On January 12, 1993, Geneva notified Abbott of a Paragraph IV Certification with respect to the '532 patent and asserted that its proposed generic product did not infringe the patent because the active ingredient in its product was anhydrous ("without water") terazosin hydrochloride, while the '532 patent claimed dihydrate ("with water") terazosin hydrochloride. S. ¶ 51. Thereafter, on

February 26, 1993, Abbott sued Geneva in the Northern District of Illinois alleging infringement of the '532 patent under 35 U.S.C. § 271(e)(2)(A). S. ¶ 52. Geneva's process for manufacturing its anhydrous generic tablet product initially used water; after Abbott received and tested samples of Geneva's product, Abbott informed Geneva that it had detected the presence of the dihydrate terazosin claimed by the '532 patent. S. ¶ 53. On August 27, 1993, Geneva's counsel informed Abbott's counsel that to end the controversy between the parties relating to the alleged infringement of the '532 patent, Geneva had modified the process for manufacturing Geneva's generic tablet product so it would no longer use water. S. ¶ 54. Geneva provided new samples of its generic product, which Abbott then tested. S. ¶ 54. On November 16, 1993, Abbott voluntarily dismissed its complaint without prejudice. S. ¶ 55.

**B. Geneva '615 Lawsuit**

Based on the samples it received in the '532 litigation, described above, on September 15, 1994, Abbott sued Geneva for the alleged infringement of the '615 patent, which had issued in March 1994. S. ¶ 56; Tabacchi Aff. at ¶ 4. Geneva did not dispute that its proposed generic tablet product contained Form II terazosin hydrochloride claimed by the '615 patent, but denied that the patent was valid or enforceable because the Form II had been on sale more than a year before Abbott applied for the '615 patent. S. ¶ 57. In June 1995, Geneva informed Abbott that it had switched from Form II terazosin hydrochloride (the form claimed by the '615 patent) to Form IV terazosin hydrochloride (the form which would be claimed by the '207 patent), which was then unpatented. S. ¶ 58. On July 17, 1995, after testing samples of Geneva's tablet product and confirming that the samples did not contain Form II terazosin hydrochloride, Abbott voluntarily dismissed its complaint without prejudice. S. ¶ 59.

### **C. Zenith '615 Lawsuits**

On August 1, 1994, Zenith filed a Paragraph IV Certification ANDA for a generic terazosin hydrochloride tablet. On November 14, 1994, Abbott sued Zenith for infringement of the '615 patent. S. ¶ 60. In response, Zenith moved to dismiss the action under Fed. R. Civ. P. 12(b)(6) on the ground that Abbott had not listed the '615 patent in the Orange Book and, therefore, could not have a basis for an infringement action under 35 U.S.C. § 271(e)(2)(A). S. ¶ 61. Abbott countered that nothing in § 271(e)(2)(A) required a patent to be listed in the Orange Book before an infringement action could be brought. S. ¶ 62. On March 15, 1995, the district court granted Zenith's motion and dismissed the case. S. ¶ 63; see Abbott Labs. v. Zenith Labs. Inc., 35 USPQ 2d 1161 (N.D. Ill. 1995).

In the month of the dismissal, Abbott listed the '615 patent in the Orange Book and later, on June 5, 1995, sued Zenith again in the same court, alleging infringement of the '615 patent. This new case was assigned to the same judge who heard the prior '615 case against Zenith. S. ¶ 64. As it had done a year earlier, Zenith again moved to dismiss this action under Fed. R. Civ. P. 12(b)(6) arguing, *inter alia*, that the patent listing was untimely. On September 28, 1995, the district court agreed, granted the motion, and dismissed the case. S. ¶¶ 65-66. However, the district court denied Geneva's motion for attorney's fees against Abbott. S. ¶ 67. The effect of the district court's order was that Abbott could not sue Zenith for infringement of the '615 patent until Zenith marketed a terazosin hydrochloride tablet containing Form II terazosin hydrochloride. Zenith never marketed a terazosin hydrochloride tablet. S. ¶ 68.

#### **D. Invamed '532/'615/'095 Lawsuit**

Invamed notified Abbott on April 29, 1995, of a Paragraph IV Certification with respect to the '532 patent and asserted that the active ingredient in its generic product was anhydrous terazosin, while the '532 patent claimed dihydrate terazosin; thus, its generic product did not infringe on the '532 patent. S. ¶ 69. However, Invamed did not certify with respect to the '615 patent and prior to Abbott's filing suit, Invamed had not provided Abbott with product samples for testing, despite Abbott's request. S. ¶¶ 69-70.

On June 13, 1995, Abbott sued Invamed alleging infringement of the '532, '615 and '095 patents. S. ¶ 71. Abbott also sought to compel Invamed to certify with respect to the '615 and '095 patents, which had issued by that time. S. ¶ 71. On July 25, 1995, Invamed provided Abbott with samples of its proposed product, and Abbott tested the samples. S. ¶ 72. On September 12, 1995, Abbott proposed that the parties could resolve the suit if Invamed agreed to provide certifications with respect to the '615 and '095 patents, and Invamed agreed. S. ¶ 73. Thereafter, on October 17, 1995, Abbott voluntarily dismissed its complaint without prejudice. S. ¶ 74.

#### **E. Lemmon '532 Lawsuit**

On May 3, 1995, Lemmon notified Abbott of its Paragraph IV Certification with respect to the '532 patent, asserting, like Invamed, that its proposed generic product did not contain water and, therefore, did not infringe the '532 patent. S. ¶ 75. Abbott asked, on May 10, 1995, for a sample of Lemmon's product, but did not receive one. Thus, on June 22, 1995, Abbott sued Lemmon for infringement of the '532 patent. S. ¶¶ 76-77. After Abbott filed suit, Lemmon provided product samples and stated that it would "not engage in the commercial manufacture, use or sale of generic terazosin hydrochloride as long as [the '615] patent had not been found invalid or not enforceable."

S. ¶¶ 78-79. Therefore, on July 12, 1995, Abbott voluntarily dismissed its complaint without prejudice. S. ¶ 80.

**F. Geneva '097/'095 and Novopharm '097 Lawsuits**

Geneva provided Abbott with a notice, dated October 5, 1995, of its Paragraph IV Certification on the '097 patent and stated that it would seek approval to sell its proposed generic drug after October 14, 1995 (the date on which Geneva believed the patent expired), but before January 21, 1997 (the date on which Abbott contended the patent expired). S. ¶ 81. Also on October 5, 1995, Geneva notified Abbott of a Paragraph IV Certification with respect to the '095 patent and stated that its product did not infringe the '095 patent because it was using an anhydrous form of terazosin hydrochloride other than the form claimed in the '095 patent (Form III). S. ¶ 82. In response, on November 16, 1995, Abbott sued Geneva for infringing both the '097 and '095 patents. However, on February 15, 1996, Abbott voluntarily dismissed its claim as to the '095 patent. S. ¶¶ 83-84.

Novopharm also provided Abbott with a notice dated December 20, 1995, of a Paragraph IV Certification with respect to the '097 patent and claimed that the patent had expired. S. ¶ 85. On February 1, 1996, Abbott sued Novopharm for infringement of the '097 patent. This case was consolidated with the Geneva '097 suit on February 15, 1996. S. ¶ 86; Def.'s Tab B. Ex. 45 (Docket sheet for Novopharm '097 case).

The issue in the consolidated action was the expiration date of the '097 patent. Abbott's '097 patent was originally scheduled to expire on September 5, 1995 (17 years from its date of issuance). However, as a result of the Uruguay Round Agreements Act of 1994 ("URAA"), the duration of American patents was extended from 17 years from date of issuance to 20 years from the date of

filing of the patent application. S. ¶ 87. For patents already issued, such as the '097 patent, the URAA provided that such patents would expire either 17 years from issuance or 20 years from filing, whichever patent period was longer. S. ¶ 87.

The application for the '097 patent was filed on January 21, 1977, and, thus, Abbott argued that the '097 patent expired on January 21, 1997. S. ¶ 88. The URAA provided, however, that if a patent application referred to an earlier application, the 20-year term would run from the filing date of that earlier application. Geneva and Novopharm argued that because the '097 patent application referred to the application for the '894 patent which was filed on October 14, 1975, the '097 patent expired on October 14, 1995. Abbott asserted that under the relevant effective date provision (URAA § 534(b)(3)), the rule concerning reference to an earlier-filed application did not apply to applications filed before January 1, 1996. S. ¶ 89.

On March 14, 1996, the district court granted Novopharm's and Geneva's motions to dismiss Abbott's claim for infringement of the '097 patent and held that the patent had expired on October 14, 1995. S. ¶ 90; see Abbott Labs. v. Novopharm, Ltd., No. 96-C-611, 1996 WL 131498 (N.D. Ill. Mar. 14, 1996). Abbott appealed this decision. Novopharm sought expedited consideration of the appeal saying that it would suffer "irreparable harm" if it came to market before the Federal Circuit considered the issue and possibly reversed. S. ¶¶ 91-92. Abbott stipulated to an expedited appeal. S. ¶ 92. On January 14, 1997, the Federal Circuit affirmed the district court. S. ¶ 93; see Abbott Labs. v. Novopharm, Ltd., 104 F.3d 1305 (Fed. Cir. 1997).

### **G. Invamed '095 Lawsuit**

On October 31, 1995, in connection with its April 8, 1995, ANDA, Invamed notified Abbott of a Paragraph IV Certification with respect to the '095 patent, asserting that it did not infringe the

'095 patent because it was using an anhydrous form of terazosin hydrochloride other than the one claimed in the '095 patent (Form III). S. ¶ 94. In response, on December 7, 1995, Abbott sued Invamed for infringement. S. ¶ 95. In April 1996, Invamed provided Abbott with a sworn statement that the active ingredient used in Invamed's proposed product would be manufactured outside the United States. On May 10, 1996, Abbott voluntarily dismissed its complaint without prejudice. S. ¶¶ 96-97.

#### **H. Warner '615/'097 Lawsuits**

Warner notified Abbott on December 15, 1995, of a Paragraph IV Certification with respect to the '097 and '615 patents. In the notice, Warner claimed that the '097 patent had expired, and that Warner's proposed tablet product contained an anhydrous form of terazosin hydrochloride other than the form claimed in the '615 patent. S. ¶ 98. On January 26, 1996, Abbott filed suit against Warner for infringement of both the '097 and '615 patents. In June 1996, Warner changed its Paragraph IV Certifications as to both the '097 and '615 patents to Paragraph III Certifications. S. ¶¶ 99-100. On August 9, 1996, Abbott voluntarily dismissed its complaint. S. ¶ 101.

#### **I. Geneva Capsule '615 Lawsuit**

Next, Geneva provided Abbott with a February 16, 1996, notice of a Paragraph IV Certification with respect to the '615 patent and asserted that its proposed generic capsule product would not infringe the '615 patent because it contained Form IV terazosin hydrochloride rather than the Form II claimed in the '615 patent. S. ¶ 102. On March 27, 1996, Abbott sued Geneva for patent infringement. S. ¶ 103. After Abbott filed suit, Geneva provided Abbott with additional information regarding its terazosin hydrochloride capsules, and Abbott agreed to postpone Geneva's time to answer while it considered this new information. S. ¶¶ 104-105. On May 8, 1996, Abbott voluntarily

dismissed its complaint without prejudice. S. ¶ 106.

**J. Geneva, Novopharm, and Invamed '207 Lawsuits**

Abbott was issued the '207 patent on April 2, 1996, and listed it in the Orange Book that same month. Geneva provided Abbott with two notices, both dated April 29, 1996, of Paragraph IV Certifications with respect to the '207 patent which asserted that claims 1 through 3 of the patent were not infringed and that claim 4 of the patent was invalid under 35 U.S.C. § 102(b) (“on-sale bar”). S. ¶ 107. On June 4, 1996, Abbott sued Geneva regarding its tablet ANDA alleging infringement. S. ¶ 109. But Abbott failed to institute any litigation challenging Geneva’s capsule product. S. ¶ 108. While Geneva conceded that its terazosin hydrochloride tablet product contained Form IV terazosin hydrochloride as claimed by the '207 patent, it denied that the patent was valid or enforceable. S. ¶ 110.

Similarly, Novopharm notified Abbott in an August 8, 1996, notice of a Paragraph IV Certification with respect to the '207 patent and stated that the patent was invalid under the on-sale bar. S. ¶ 111. On September 13, 1996, Abbott sued Novopharm for infringement of the '207 patent. This case was consolidated with the Geneva '207 suit. S. ¶¶ 112-13. As with Geneva, Novopharm admitted that its product contained Form IV terazosin hydrochloride but denied that the '207 patent was valid or enforceable. S. ¶ 113.

On January 15, 1997, Geneva moved for summary judgment (as did Novopharm on January 22, 1997). Geneva and Novopharm argued that claim 4 of the '207 patent (the only claim of the patent asserted) was invalid under the on-sale bar, relying on sales of anhydrous terazosin from the early 1990s which allegedly contained Form IV terazosin hydrochloride. These sales occurred more than one year before Abbott filed its application for the '207 patent and involved anhydrous terazosin

that Byron Chemical Company (“Byron”) bought from its overseas supplier and then sold to Geneva in the United States. The summary judgment motion was fully briefed by April 22, 1997. Abbott did not contest that these prior purchases included the same Form IV terazosin hydrochloride that Abbott claimed in its ‘207 patent. However, Abbott argued that the buyers’ and seller’s alleged lack of knowledge of the existence of Form IV terazosin hydrochloride prevented the triggering of the on-sale bar. S. ¶¶ 114-115.

While the Geneva/Novopharm lawsuits and motions for summary judgment were pending, Invamed provided a September 25, 1997, notice to Abbott of a Paragraph IV Certification with respect to the ‘207 patent asserting, *inter alia*, that the on-sale bar invalidated the patent. S. ¶ 116. Abbott sued Invamed for patent infringement on October 28, 1997, in the same district court, and this case was consolidated with the Geneva and Novopharm ‘207 suits. *Id.* at ¶ 117. Like the other generic manufacturers, Invamed did not dispute that its product contained Form IV terazosin hydrochloride claimed by the ‘207 patent but denied the validity or enforceability of the ‘207 patent. S. ¶ 118.

On September 1, 1998, the district court granted summary judgment for Geneva, Novopharm and Invamed and held claim 4 of the ‘207 patent (claiming Form IV terazosin hydrochloride ) invalid because of the “on-sale” bar. Abbott Labs. v. Geneva Pharm. Inc., No. 96-C-3331, 1998 WL 566884, at \*5 (N.D. Ill. Sept. 1, 1998). The remaining claims of the ‘207 patent have not been challenged and remain in force. S. ¶ 119. Abbott appealed the district court’s decision to the Federal Circuit. After Abbott filed its appeal, the Supreme Court, on November 10, 1998, issued its opinion in Pfaff v. Wells Elec. Inc., 525 U.S. 55 (1998). On July 1, 1999, a panel of the Federal Circuit affirmed the district court and cited Pfaff in its opinion; it also cited several pre-Pfaff Federal Circuit

decisions. S. ¶ 122; see Abbott Labs. v. Geneva Pharm. Inc., 182 F.3d 1315 (Fed. Cir. 1999). Rehearing was denied on August 6, 1999, the Federal Circuit's mandate issued on August 12, 1999, and the United States Supreme Court denied certiorari on January 10, 2000. S. ¶ 122.

#### **K. Mylan '207 Lawsuits**

Mylan also gave Abbott a Paragraph IV Certification with respect to the '207 patent on July 11, 1997. This notice was limited to a 5 mg capsule product. S. ¶ 123. On August 1, 1997, Abbott sued Mylan for patent infringement. Mylan responded that its generic contained Form IV terazosin hydrochloride but argued that the '207 patent was not valid or enforceable due to the on-sale bar. S. ¶¶ 124-25. On February 9, 1998, Mylan informed Abbott that it had submitted an amendment to its ANDA to provide for the addition of three new dosage strengths and incorporated its prior Paragraph IV Certification by reference. S. ¶ 126. In response, on March 2, 1998, Abbott sued Mylan for patent infringement covering the new dosage strengths, and this case was consolidated with the pending Mylan '207 suit regarding the 5 mg capsule. S. ¶ 127.

After the district court in the Geneva, Novopharm, and Invamed suits held the '207 patent invalid, Mylan moved for summary judgment arguing that Abbott was collaterally estopped from relitigating the issue of validity. S. ¶ 128. The Mylan '207 district court agreed and, on March 4, 1999, granted Mylan's motion for summary judgment. S. ¶ 128. Abbott appealed, but on October 4, 1999, the Federal Circuit affirmed the district court's decision. S. ¶ 128.

#### **L. Warner '207 Lawsuit**

Abbott also challenged Warner's '207 Paragraph IV Certification ANDA. S. ¶ 129. On March 12, 1998, Warner informed Abbott of this ANDA, and asserted, as did the other generic manufacturers, that the '207 patent was invalid under the on-sale bar. S. ¶ 129. Abbott sued this

generic competitor on April 6, 1998, for patent infringement, and like the other generic manufacturers, Warner admitted that its generic product contained Form IV terazosin hydrochloride but claimed that the '207 patent was invalid and unenforceable. S. ¶¶ 130-31.

Following the Geneva/Invamed/Novopharm district court's holding that the '207 patent was invalid, Warner moved for summary judgment based on collateral estoppel as to the issue of the '207 patent's validity. S. ¶ 132. The district court granted Warner's motion on November 19, 1998; Abbott appealed and, on November 24, 1999, the Federal Circuit affirmed. S. ¶ 132.

#### **M. Abbott's Motive for the Lawsuits**

Plaintiffs sought discovery of the evidence and facts Abbott considered before filing these lawsuits, but Abbott refused to disclose such information based on the attorney-client privilege. Plaintiffs have asked the Court to draw a negative inference of Abbott's intent based on the invocation of the attorney-client privilege. In the Summer of 1999, Abbott's CEO circulated an internal memorandum which stated: "I'd like to take this opportunity to recognize the truly outstanding work of our legal team, which successfully defended Hytrin's patent protection against challenge for nearly four years." Def.'s Ex. Tab C-27. Plaintiffs claim that this statement is evidence that the purpose of the lawsuits was to extend illegally Abbott's patent monopoly by instituting sham lawsuits solely to trigger the Hatch-Waxman 30 month stays.

#### **VI. Facts Regarding Walker Process Claim**

Apart from the "sham litigation" claim, Plaintiffs have also sued Abbott for fraud on the United States Patent and Trademark Office ("PTO") in the procurement of the '207 patent. In March 1993, the Sumika Fine Chemical Co. published a Japanese Patent Application, No. 08-78352 (the "Sumika reference") which disclosed seven crystal forms of terazosin hydrochloride. S. ¶ 133. On

November 1, 1994, during the prosecution of an earlier filed terazosin hydrochloride patent, the '095 patent (Form III), an in-house attorney for Abbott, Jerry F. Janssen, submitted the complete Sumika reference and a complete English translation to the PTO examiner who was considering the application. S. ¶ 134. His submission described the Sumika reference as follows:

Japanese KoKai Patent (published patent application filed December 31, 1990), published March 30, 1993 to Sumika Fine Chemicals, Ltd., which discloses seven crystalline modifications of terazosin hydrochloride and their preparation. S. ¶ 134.

The same attorney, Janssen, prosecuted the '207 patent. S. ¶ 135. On March 6, 1995, Janssen filed with the PTO an Information Disclosure Statement ("IDS") with respect to the application for the '207 patent, identifying several prior art references, including:

Published Japanese Patent Application 05-0789,382 to Sumika Fine Chemical Co., Ltd., which discloses and claims crystalline modifications of anhydrous terazosin hydrochloride. S. ¶ 135.

That '207 patent IDS included a completed Form PTO 1449, which set forth the numbers of all the submitted references, including the Sumika reference. Next to the Sumika reference, a check mark indicated that an English translation of the reference had been included in the submission. S. ¶ 136. When the examiner reviewed the references, he made the following notation next to the checkmark by the Sumika reference: "(Abstract Only)." S. ¶ 137. In the '207 litigation, when asked about the missing complete English-language translation of the Sumika reference, Janssen testified that he intended to submit the translation and thought he did. S. ¶ 138. He had provided the full translation of the Japanese patent as part of the application for the '095 patent. S. ¶ 139. Mr. Wong, the assistant patent examiner in the '207 patent application, testified that he saw the "full English language translation of" the Japanese patent "during the pendency of the ['207] application." S. ¶ 140.

Later, in December 1995, Janssen filed an IDS and a Supplement to Information Disclosure Statement (“Supplement to IDS”) to the patent examiner. Those submissions disclosed two prior public sales of Form IV terazosin hydrochloride—a July 1990 sale from Byron to Geneva, and a December 1991 sale from Byron to Geneva. S. ¶ 141. In the IDS, Janssen argued that those two sales did not bar patentability for the same reasons expressed in a summary judgment brief that Abbott had filed in litigation. S. ¶ 142. Janssen did not prepare the summary judgment brief, although the language Janssen used in the IDS is similar to the language used in the Abbott summary judgment brief. However, Janssen’s IDS submission does not include the footnote from the brief that discusses the LaPorte<sup>10</sup> case. S. ¶ 142. The 1986 LaPorte case held that the on-sale bar should apply when a third-party sale relates to a device which “embodies” the invention. 787 F.2d at 1583. Kaiser contends that citing this case to the PTO during the pendency of the ‘207 application would have prevented the ‘207 patent from being issued to Abbott. According to Kaiser, LaPorte would have demonstrated to the PTO that the on-sale bar applied as to the Form IV terazosin hydrochloride claimed by the ‘207 patent.

## **VII. Parties’ Motions**

Based on these undisputed facts, Defendant Abbott moves for summary judgment on Plaintiffs’ Section Two sham litigation and Walker Process claims and argues that : (1) Abbott had an objectively legitimate basis for filing these lawsuits; (2) even assuming that some of these lawsuits are objectively baseless, Plaintiffs have proffered no admissible evidence that demonstrates a subjective, bad-faith effort to interfere with the generic competitors’ business; (3) alternatively, Abbott did not engage in a serial pattern and practice of filing automatic and baseless lawsuits; (4)

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<sup>10</sup> J.A. LaPorte, Inc. v. Norfolk Dredging Co., 787 F.2d 1577 (Fed. Cir. 1986).

after excluding the '207 patent litigation, the remaining patent infringement lawsuits concluded before the generic manufacturers received tentative FDA-approval for their ANDAs, and thus, no antitrust injury flowed from the filing of these lawsuits; and finally, (5) on the Walker Process claim, Plaintiffs have come forward with no evidence of fraud or attempted fraud.

The Individual Sherman Act Plaintiffs<sup>11</sup> respond that: (1) they have shown a single serial pattern of sham lawsuits filed without probable cause and they need not show objective baselessness and subjective motive; (2) even if Abbott's lawsuits are analyzed under a two-prong objective/subjective test,<sup>12</sup> the lawsuits were objectively baseless and Abbott's invocation of the attorney-client privilege and Abbott's CEO's internal memo satisfy the subjective prong of the standard; and (3) they need not demonstrate that tentative FDA approval was received before the patent lawsuits concluded to establish antitrust injury and standing. Separately, Kaiser argues that Abbott is not entitled to summary judgment on the Walker Process claim because disputed issues of material fact remain as to whether Abbott withheld the complete English-translation of the Sumika reference and failed to cite the LaPorte decision to the '207 patent examiner. The Court turns to these arguments.

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<sup>11</sup> The State Plaintiffs and Indirect Purchaser Class Plaintiffs join the arguments of both Kaiser and the Individual Sherman Act Plaintiffs.

<sup>12</sup> The Kaiser and Individual Direct Purchasers state two different standards on sham litigation. Kaiser agrees with Abbott that the objective-subjective PRE standard should apply, and that the Court should determine, as a matter of law based on the underlying undisputed material facts, whether Abbott engaged in sham litigation. See Kaiser Mot. for Summ. J. at 2-3. However, the Individual Direct Purchaser Plaintiffs argue that PRE should not apply to a series of lawsuits as opposed to a single allegedly sham lawsuit. See Individual Pls.' Opp'n to Def. Abbott's Mot. for Summ. J. at 14-17.

## **Discussion**

### **I. 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 the record 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).

### **II. Section Two and Noerr-Pennington Immunity**

Plaintiffs assert both Section Two monopolization and attempted monopolization claims. To establish a violation under Section Two of the Sherman Act for monopolization, a plaintiff must show: “(1) the possession of monopoly power in the relevant market and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident.” United States v. Grinnell Corp., 384 U.S. 563, 570-71 (1966). To prove a claim for attempted monopolization, a plaintiff must establish: “(1) that defendant has engaged in predatory or anticompetitive conduct with (2) a specific intent to monopolize and (3) a dangerous probability of achieving monopoly power.” Spectrum Sports, Inc.

v. McQuillan, 506 U.S. 447, 456 (1993).

Plaintiffs claim that Abbott engaged in sham litigation by filing seventeen baseless patent infringement lawsuits in response to generic manufacturers' notification of ANDA applications. This conduct, Plaintiffs assert, satisfies the predatory/anticompetitive conduct element of both a monopolization and attempted monopolization claim. See generally Robert H. Bork, The Antitrust Paradox: A Policy at War with Itself, 347-59 (The Freedom Press 1993) (1978) (explaining development of case law on sham litigation theory). Plaintiffs' allegations require the Court to analyze: (1) the Noerr-Pennington doctrine of antitrust immunity including whether Plaintiffs have successfully demonstrated that a sham litigation exception strips Abbott of that immunity; and (2) the intersection of the sham litigation exception with the public interest in protecting an innovator drug company's intellectual property rights.

Generally, under the Noerr-Pennington doctrine, private citizens may exercise their First Amendment rights to petition the government with immunity from antitrust liability. See Baltimore Scrap Corp. v. David Joseph Co., 237 F.3d 394, 398 (4th Cir. 2001) (citing Noerr, 365 U.S. at 136-39 and Pennington, 381 U.S. at 669). The Noerr Court emphasized that it is "neither unusual [n]or illegal for people to seek action on laws in the hope that they may bring about an advantage to themselves and a disadvantage to their competitors . . . ." 365 U.S. at 139. In fact, the "federal anti-trust laws do not regulate the conduct of private individuals in seeking anti-competitive action from the government." McGuire Oil Co. v. Mapco, Inc., 958 F.2d 1552, 1558 (11th Cir. 1992) (internal quotations and citations omitted). Although the Noerr-Pennington doctrine was created to immunize petitioning of administrative and legislative officials, the Supreme Court has extended the immunity to attempts to seek judicial relief. Id. at 1558-59 (citing Cal. Motor Transp. Co. v. Trucking

Unlimited, 404 U.S. 508 (1972)).

**A. Sham Litigation Exception and PRE Objective/Subjective Two-Fold Analysis**

Thus, in challenging actions that ostensibly seek judicial relief, an antitrust plaintiff must demonstrate that Noerr-Pennington immunity is inapplicable before proceeding to the elements of a federal antitrust claim. McGuire, 958 F.2d at 1559 n.9. To meet its burden, a plaintiff must demonstrate that a defendant's use of the judicial process comes within the "sham litigation" exception to Noerr-Pennington. Id. at 1559.

Courts apply a two-part test in a "sham litigation" exception analysis. See Prof'l Real Estate Investors v. Columbia Pictures Indus. Inc., 508 U.S. 49, 60 (1993). First, a court must determine whether a lawsuit is objectively baseless. A lawsuit is objectively baseless when "no reasonable litigant could realistically expect success on the merits." Id. at 60. "If an objective litigant could conclude that the suit is reasonably calculated to elicit a favorable outcome, the suit is immunized under Noerr, and an antitrust claim premised on the sham exception must fail." Id. Second, even if a lawsuit is objectively baseless, a court must also consider the "litigant's subjective motive." Id. Under this second prong, "the court should focus on whether the baseless lawsuit conceals an attempt to interfere directly with the business relationships of a competitor." Id. at 60-61 (internal quotations omitted).

This "two-tiered process requires the plaintiff to disprove the challenged lawsuit's *legal* viability before the court will entertain evidence of the suit's *economic* viability." Id. at 61. In the patent-enforcement context, "whether conduct in procuring or enforcing a patent is sufficient to strip a patentee of its immunity from the antitrust laws is to be decided as a question of Federal Circuit law." Nobelpharma, AB v. Implant Innovations, Inc., 141 F.3d 1059, 1068 (Fed. Cir. 1998). Given

the undisputed facts regarding the seventeen lawsuits, the issues before the Court on the Section Two claims are legal ones: whether the seventeen terazosin hydrochloride patent lawsuits were objectively baseless and, if so, whether there is sufficient evidence to have a jury consider whether the lawsuits attempted to conceal an effort to interfere directly with the generic manufacturers' business relationships.

### **1. Objective First Prong**

Analyzing whether the lawsuits were objectively baseless requires a look at the outcomes of each case. In this regard, the seventeen lawsuits can be divided between the "successful" and the "unsuccessful." In examining the latter category, the issue becomes whether there was a reasonable basis for filing the suit at the time litigation was instituted.

#### **a. "Successful" Lawsuits**

"A winning lawsuit is by definition a reasonable effort at petitioning for redress and therefore not a sham." PRE, 508 U.S. at 61. Here, in seven of the seventeen lawsuits, Abbott dismissed the suit after obtaining the relief or information it sought. First, in the Geneva '532 lawsuit, Geneva agreed to modify its process for manufacturing its generic tablet to avoid infringement, and Abbott voluntarily dismissed its complaint. Second, in the Geneva '615 tablet case, Abbott agreed to dismiss the case after Geneva consented to switch from Form II terazosin hydrochloride to avoid infringement. Third, in the Lemmon '532 action, Lemmon provided product samples and promised "not to engage in the commercial manufacture, use or sale of generic terazosin hydrochloride as long as the ['615] patent had not been found invalid or not enforceable." After receiving that promise and samples, Abbott dismissed that case. Fourth, in the Invamed '532/'095/'615 suit, Invamed agreed to provide certifications on the '615 and '095 patents, which it had previously refused to do, and

Abbott voluntarily dismissed the case. Fifth, in the Warner ‘615/’097 action, after originally asserting Paragraph IV certifications, and after Abbott filed suit, Warner switched to Paragraph III certifications. Abbott dismissed the case. Sixth, in the Invamed ‘095 case, after Invamed provided Abbott with a sworn statement that the active ingredient in Invamed’s proposed product would be manufactured outside the United States, Abbott dismissed the lawsuit. Finally, in the Geneva ‘615 (capsule) case, Abbott sued to obtain additional information about the proposed generic products. After receiving that information, Abbott dismissed the action. See Hoffman-La Roche, Inc. v. Invamed, Inc., 213 F.3d 1359, 1364 (Fed. Cir. 2000) (noting that filing suit to obtain court-supervised discovery after pre-suit investigation had uncovered “neither evidence of infringement nor non-infringement” was not baseless). Thus, in seven of the seventeen allegedly baseless lawsuits, Abbott obtained the relief it sought or additional information, and dismissed the lawsuits. By definition, Abbott “won” seven of these lawsuits because they were “reasonable efforts at petitioning for redress . . .” PRE, 508 U.S. at 61.<sup>13</sup>

**b. “Unsuccessful” Lawsuits**

It is undisputed that Abbott lost the remaining ten lawsuits. Nevertheless, a loss of a patent infringement lawsuit does not end the inquiry. Rather, “the patentee must have the right of enforcement of a duly granted patent, unencumbered by punitive consequences should the patent’s validity or infringement not survive litigation.” C.R. Bard Inc. v. M3 SYS. Inc., 157 F.3d 1340, 1369

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<sup>13</sup> Plaintiffs argue that a party cannot “prevail” unless it receives relief from the court itself. However, the definition of “prevail” used in the context of the Fair Housing Amendments Act, 42 U.S.C. § 3613, and Americans with Disabilities Act, 42 U.S.C. § 12205, as Plaintiffs argue, for determining attorney’s fees is irrelevant to the definition of “win” used for purposes of the PRE analysis. See Buckhannon Bd. and Care Home, Inc. v. W. Va. Dept. of Health and Human Res., 532 U.S. 598, 601 (2001). Moreover, the Court cannot agree with Plaintiffs that a plaintiff who has filed suit and receives the relief sought (e.g., monetary compensation, a change in conduct, etc.) could only have been deemed to have “won” under PRE if it continued to litigate the case and received a favorable judgment from the court.

(Fed. Cir. 1998). “[W]hen the antitrust defendant has lost the underlying litigation, a court must ‘resist the understandable temptation to engage in *post hoc* reasoning by concluding’ that an ultimately unsuccessful action must have been unreasonable or without foundation.” PRE, 508 U.S. at 61 (citation omitted). Even when a pioneer drug maker sues a generic competitor in a patent infringement lawsuit but loses, the suit is not a sham if the state of the law is “uncertain.” Organon Inc. v. Mylan Pharms., Inc., 293 F. Supp. 2d 453, 462 (D.N.J. 2003) (applying PRE sham litigation standard to multiple patent infringement lawsuits filed against multiple defendants).

**i. ‘615 Lawsuit (“Orange Book Listing Requirement”)**

Abbott lost the Zenith ‘615 lawsuits. Abbott sued Zenith for patent infringement pursuant to 35 U.S.C. § 271(e)(2)(A) on the ‘615 patent even though it had not listed it in the Orange Book. Zenith moved to dismiss based on the failure to list, and the district court agreed. Abbott Labs. v. Zenith Labs. Inc., 35 U.S.P.Q. 2d 1161, 1165-67 (N.D. Ill. 1995) (explaining that listing gives notice to an ANDA applicant and is a necessary predicate for a Hatch-Waxman patent infringement lawsuit). Based on that decision, Abbott immediately listed the patent and sued Zenith two months later for infringement on the ‘615 patent. Again, Zenith moved to dismiss, and the district court granted the motion. See Abbott Labs. v. Zenith Labs. Inc., 934 F. Supp. 925, 939 (N.D. Ill. 1995). Although the second Zenith ‘615 suit (“Zenith ‘615 II”) was not barred by *res judicata*, the court held that the listing was untimely because Abbott “did not have the ‘615 patent listed . . . at the time [Zenith] filed its ANDA.” Id. at 936. Nevertheless, the court denied Zenith’s motion for attorney’s fees because the Abbot suit was not “vexatious or unjustified litigation, or a frivolous suit.” Id. at 939 (citation omitted).

Here, the relevant infringement statute, 35 U.S.C. § 271(e)(2)(A), did not expressly state an

Orange Book listing requirement before an infringement action could proceed. Neither court cited any case law that addressed this issue. Both the Zenith '615 I and Zenith '615 II decisions discussed the relevant legislative history and statutory interpretation in detail before concluding that Abbott needed to list the '615 patent before suing for patent infringement. The judge who heard the cases, while deciding against Abbott, did not find Abbott's argument frivolous. Importantly, the Zenith '615 II court expressly found that the suit was not frivolous. Therefore, as a matter of law, the '615 lawsuits were not objectively baseless.

**ii. '097 Lawsuit ("URAA Patent Expiration")**

The next Abbott loss raises the issue of when its '097 patent expired. The '097 patent was originally set to expire on September 5, 1995 (seventeen years after the date of issuance). However, after the Uruguay Round Agreements Act of 1994, the duration of the patent was extended to: (1) seventeen years from the date of issuance or (2) twenty years from filing, whichever expiration date was later. See 35 U.S.C. § 154(c)(1). Abbott argued that the new expiration date for the '097 patent was January 21, 1997, or twenty years from the date the '097 patent was filed (i.e., January 21, 1977). Nevertheless, the URAA also provided that if a patent application referred back to an earlier application, the twenty year period would run from the date of the earlier-filed application. In this case, Geneva and Novopharm argued that the '097 patent referred back to the '894 patent which was issued on October 14, 1975. Thus, Geneva and Novopharm asserted that the '097 patent expired on October 14, 1995, or twenty years from the filing date of the '894 patent. Abbott then argued that the relevant effective date provision of the URAA, § 534(b),<sup>14</sup> did not apply to applications filed

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<sup>14</sup> URAA § 534(b)(3) states: "The term of a patent granted on an application that is filed on or after the effective date and that contains a specific reference to an earlier application . . . shall be measured from the filing date of the earliest application . . ."

before January 1, 1996, *e.g.*, the ‘097 patent. Thus, according to Abbott, the issuance date of the ‘097 patent did not need to refer back to the ‘894 patent’s issuance date. The district court agreed with Geneva and Novopharm and concluded that the ‘097 patent expired on October 14, 1995. See Abbott Labs. v. Novopharm Ltd., No. 96-C-611, 1996 WL 131498 (N.D. Ill. Mar. 15, 1996). Abbott agreed to an expedited appeal of this decision, and ten months later the Federal Circuit affirmed. See Abbott Labs. v. Novopharm Ltd., 104 F.3d 1305, 1308 (Fed. Cir. 1997).

The question as to the ‘097 patent litigation is not whether Abbott lost – for it certainly did – but whether Abbott’s statutory interpretation and argument were objectively baseless. Neither the district court nor the Federal Circuit concluded that this action was frivolous. Moreover, the district court stated that no court had addressed Abbott’s specific argument before. Abbott, 1996 WL 131498 at \* 5. Likewise, the Federal Circuit cited no cases that had addressed this URAA provision. Abbott, 104 F.3d at 1308-09. The treaty was new, the provision had not been the subject of prior interpretation, and the argument, while hypertechnical, passed the “straight face” test. Therefore, although Abbott’s interpretation of the URAA was a stretch, it did not exceed the pale of an aggressive attempt to extend the existing law, and thus was not objectively baseless.

### iii. ‘207 Lawsuits (“On-Sale Bar”)<sup>15</sup>

The remaining lawsuits Abbott lost were the six ‘207 patent lawsuits. Although Plaintiffs allege that the ‘207 lawsuits should be viewed as six separate actions, the ‘207 suits should be treated as one suit for purposes of this analysis because they all involved the same patent and the same underlying legal issue. See FTC Study at 19 (“it would be misleading simply to count the number of

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<sup>15</sup> The analysis of the ‘207 lawsuit for Section Two purposes under the “objectively baseless” PRE standard does not apply to Plaintiffs’ Sherman Act Section One claims. These Section One claims will be addressed by separate order.

decisions in either party's favor, because several of the decisions may be related to the same patent"); see also Twin City Bakery Workers & Welfare Fund v. Astra Aktiebolag, 207 F. Supp. 2d 221, 224 n.2 (S.D.N.Y. 2002) (“[i]t would be unreasonable to expect defendants to initiate litigation against only some of the generic-drug applicants they claim are infringing their patents.”).

The '207 lawsuits present a closer question because they arose in a different temporal, factual and competitive environment than the earlier lawsuits. Geneva filed the first generic ANDA on January 12, 1993. Over the next two years, Abbott's original dihydrate terazosin patents, the '894 and '097 patents, expired. Also, five more generic manufacturers -- Novopharm, Zenith, Invamed, Lemmon and Warner-Chilcott -- filed ANDAs, thus joining Geneva in the race to bring a generic version of terazosin hydrochloride to market.

Between 1993 and 1995, Abbott undertook efforts to obtain new but related patents. On July 13, 1993, after Geneva's ANDA application, but before any other ANDA application, Abbott applied for the '615 patent which claimed the Form II anhydrous terazosin hydrochloride. The '615 patent issued on March 15, 1994.<sup>16</sup> Two months later, on May 20, 1994, Abbott applied for the '095 patent claiming Form III terazosin hydrochloride, which could be used as an intermediate in producing Form IV terazosin hydrochloride. In November 1994, during the '095 patent prosecution, Abbott filed the English translation of the Sumika reference indicating that in 1990 Sumika applied for a Japanese patent for the seven crystal forms of terazosin hydrochloride and received the patent in March 1993. The '095 patent issued on May 2, 1995, and was listed in the Orange Book on May 8, 1995.

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<sup>16</sup>Abbott failed to submit the patent for listing in the Orange Book until after the district court decisions against it in the Zenith '615 lawsuits. The '615 patent was listed in the March 1995 supplement to the Orange Book.

By August 9, 1996, Abbott had either dismissed all of its earlier lawsuits or had a district court judgment entered against it, as in the Zenith '615 and the Geneva/Novopharm '097 lawsuits. Of significance to the evaluation of the '207 litigation were the dismissals of two lawsuits against Geneva for infringement of the '615 patent. In the first lawsuit, filed in September 1994, Geneva did not dispute that its proposed product contained Form II which infringed the '615 patent, but claimed that this patent was invalid because the product was sold in the United States more than a year before Abbott's application for the patent.<sup>17</sup> This triggered a 30 month stay on Geneva's final approval. In June 1995, Geneva informed Abbott that it had switched from Form II to Form IV, which was then unpatented. Abbott dismissed this first Geneva suit on July 17, 1995, after testing and confirming that the samples did not contain Form II, but did contain Form IV.

Abbott filed the Geneva Capsule '615 suit on March 27, 1996. Geneva had provided a Paragraph IV non-infringement certification stating its proposed generic capsule contained Form IV rather than Form II terazosin hydrochloride. Abbott dismissed the Geneva Capsule '615 lawsuit approximately six weeks later, after Geneva provided it with additional information on its Form IV product. This dismissal ended this 30 month stay clock. However, a month before this dismissal, on April 2, 1996, Abbott not only received the '207 (Form IV) patent but also submitted it for Orange Book listing. Abbott had applied for this patent on October 18, 1994, a month before it filed the Sumika reference in its '095 patent application, and a month after instituting the Geneva '615 tablet infringement suit in which Abbott would confirm that Geneva was using Form IV terazosin. With the listing of the new '207 patent, all terazosin hydrochloride ANDA filings had to file

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<sup>17</sup> Presumably, Geneva's defense was premised on Byron's 1990 and 1991 sales of anhydrous terazosin to Geneva. However, the Parties' Statement of Facts Not in Dispute does not provide such details.

certification as to this patent. The new certification caused Abbott to file the '207 lawsuits and the new 30 month stay to start running.<sup>18</sup>

The provisions of the Hatch-Waxman Act reflect Congress' efforts to balance a drug innovator's patent rights with the public's interest in access to less expensive generic versions of the brand drug as early as possible. Thus, the Paragraph IV certification provisions give a brand name manufacturer the means to protect its patent exclusivity by filing a patent infringement action within 45 days of the certification notice. However, the Act's accompanying 30 month stay of a generic's final approval provides an opportunity to artificially extend the expiring patent monopoly by filing a Hatch-Waxman patent infringement action. In October 1994, Abbott started the '207 patent application process and was aware of the Sumika patent covering its invention. By July 1995, Abbott knew that Geneva was working with Form IV terazosin hydrochloride in its proposed generic product. By April 1996, Abbott's original patents, which had produced significant revenues, had either expired naturally or the district court had ruled that it expired. These facts, plus the fact that five generic manufacturers were seeking approval of products using the same Form IV terazosin hydrochloride, can create the type of pressures to employ the Hatch-Waxman statutory process not to protect legitimate patent rights, but to extend a monopoly in violation of the Sherman Act. Thus, courts must carefully analyze such lawsuits to determine whether at the time of filing there was a legally arguable basis to file the suit, or whether the action was so obviously baseless that it was

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<sup>18</sup> On April 29, 1996, Geneva filed its Paragraph IV certification as to the newly issued '207 patent, and on June 4, 1996, Abbott sued Geneva, triggering the 30 month stay period. Thereafter, on September 13, 1996, Abbott filed suit against Novopharm triggering another 30 month stay. A year later, Abbott sued Mylan and Invamed for infringement of the '207 patent -- in August and October 1997, respectively -- again triggering a 30 month stay of these manufacturers' efforts to enter the market. Abbott sued Mylan again and Warner on the '207 patent for their capsule products on March 2, 1998, and April 6, 1998, respectively. The Parties' Joint Statement of Facts Not in Dispute indicates that Zenith provided a certification as to the '207 patent, S. ¶32, but provides no information as to whether any litigation was instituted against Zenith on the '207 patent.

simply a sham to obtain a 30 month stay.

The focus of the '207 lawsuits was whether the on-sale bar invalidated claim 4 of Abbott's '207 patent for Form IV terazosin hydrochloride. See 35 U.S.C. § 102(b).<sup>19</sup> In these suits, each generic-competitor (Geneva, Novopharm, Invamed, Mylan and Warner) conceded that its proposed generic drug infringed the '207 patent.<sup>20</sup> However, they argued that claim 4 of Abbott's patent was invalid and unenforceable because Form IV terazosin hydrochloride had been on sale in the United States in the early 1990s. Abbott did not dispute that these sales occurred more than one year prior to the date of application for the '207 patent (the "critical date" for purposes of the on-sale bar). See Abbott Labs. v. Geneva Pharm. Inc., No. 96-C-3331, 1998 WL 566884 (N.D. Ill. Aug. 28, 1998). The Form IV terazosin hydrochloride Byron sold to Geneva in the United States was purchased from a German company who purchased it from Sumika. Id. at \*4-5 (describing early 1990s Form IV terazosin hydrochloride sales).

Abbott argued that neither Byron nor Geneva "conceived" or was aware that Form IV terazosin hydrochloride was what was being sold. Thus, Abbott argued, based on the then-applicable "totality of the circumstances test,"<sup>21</sup> the on-sale bar policy regarding "encouraging the prompt and widespread disclosure of inventions" was not implicated because the buyers were not aware of the invention being bought. Id. at \*5. Abbott also argued that because the buyers were not aware of the

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<sup>19</sup> 35 USC § 102(b) reads: "A person shall be entitled to a patent unless the invention was patented or described in a printed publication in [the United States] or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States."

<sup>20</sup> Because the generic competitors admitted that their ANDAs infringed Abbott's patent, such admissions justify the patent infringement lawsuits under Hatch-Waxman.

<sup>21</sup> See, e.g., In re Mahurkar Double Lumen Hemodialysis Catheter Patent Litig., 71 F.3d 1573, 1577 (Fed. Cir. 1995) (describing pre-Pfaff "totality of circumstances" test and stating that on-sale bar was not a mechanical rule but rather required an analysis of the facts in light of the four policy justifications for application of the on-sale bar).

invention being bought, they did not rely on the availability of that invention. Id. The district court disagreed and found that the on-sale bar applied because the buyers had come to rely on Form IV terazosin hydrochloride to meet their needs to create a non-infringing product; the fact that the buyers were not aware at the time of purchase in the early 1990s that it was Form IV terazosin hydrochloride was immaterial. Id. at \*6.

Abbott appealed, and during the pendency of the appeal, on November 10, 1998, the United States Supreme Court issued Pfaff v. Wells Elecs., Inc. 525 U.S. 55 (1998). Providing somewhat greater predictability in the application of the “on-sale” bar, the Pfaff Court diverged from the “totality of circumstances” test and established a two-pronged test: (1) the product must be the subject of a commercial offer for sale; and (2) the invention must be ready for patenting. Id. at 67-68 (invalidating patent because invention had been commercially sold prior to the critical date and was ready for patenting). Relying on Pfaff, the Federal Circuit affirmed the district court’s decision that the on-sale bar invalidated the ‘207 patent. Abbott Labs. v. Geneva Pharms. Inc., 182 F.3d 1315, 1318 (Fed. Cir. 1999) (applying Pfaff two-part test).

Although Abbott had a legal basis to institute suit due to the infringement admissions, the critical issue is whether Abbott’s pre-Pfaff legal argument that the parties must appreciate the subject of the sale to trigger the on-sale bar was objectively baseless, particularly in light of the fact that Abbott could not dispute that a prior sale had occurred. The pre-Pfaff “totality of the circumstances” test examined the particular fact-intensive circumstances of a case against the four policy considerations for the § 102(b) bar, to determine if the bar should be applied.<sup>22</sup> Although the Pfaff

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<sup>22</sup> The four policies underlying § 102(b) are: (1) discouraging removal of inventions from the public domain that the public reasonably has come to believe are freely available; (2) encouraging the prompt and widespread disclosure of inventions; (3) allowing an inventor a reasonable amount of time following sales activity to determine the potential economic value of a patent; and (4) prohibiting an inventor from commercially exploiting his

two-step test simplifies the standard for the application of the on-sale bar, the United States Supreme Court announced that decision *after* the district court ruled and while the appeal was pending in the Federal Circuit. Thus, Abbott could not consider Pfaff before it filed suit.

Pfaff and its application by the Federal Circuit provoked legal commentary as to whether the decision provided much needed predictability in the application of the on-sale bar. The Federal Circuit's decision affirming the '207 suits was one of its first, post- Pfaff opinions regarding the on-sale bar. Three articles, including a student note<sup>23</sup>, commented on the '207 decision. One legal commentary argued that Abbott had a legitimate argument under the pre-Pfaff standard and even under Pfaff itself. That article's two authors suggested that the Pfaff decision allowed the Federal Circuit to sidestep Abbott's "conception/appreciation" argument and permitted it to proceed directly to the much easier question of whether the Form IV terazosin hydrochloride was "ready for patenting." See William C. Rooklidge & Russell B. Hill, The Law of Unintended Consequences: The On Sale Bar After *Pfaff v. Wells Electronics*, 82 J. Pat. Trademark Off. Soc'y 163, 169 (2000). The authors also argued that by skipping Abbott's argument, "the Court avoided a complex and appealing argument that may well have earned the patentee reversal under the pre-*Pfaff v. Wells* [test]." Id. Another legal writer also suggested that Abbott's conception argument might have succeeded even under Pfaff because Form IV terazosin hydrochloride may not have been "read[y] for patenting" if it had not yet been conceived by the parties. See Timothy R. Holbrook, The More Things Change, the More They Stay the Same: Implications of *Pfaff v. Wells Electronics, Inc.*, and

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invention beyond the statutorily prescribed time. Mahurkar, 71 F.3d at 1577. The first policy consideration provided the foundation for the district court's decision to apply the "on-sale" bar in the '207 suits.

<sup>23</sup> Nicole Marie Fortune, Note, Scaltech Inc. v. Retec/Tetra L.L.C. & Abbott Laboratories v. Geneva Pharmaceuticals, Inc., 15 Berkeley Tech. L.J. 185 (2000).

the Quest for Predictability in the On-Sale Bar,” 15 Berkeley Tech. L.J. 933, 958-59 (Fall 2000).

These analyses, however, focus only on the knowledge of Byron and Geneva; they do not address the fact that the original sale was by Sumika, which had not only conceived the product sufficiently to disclose it for patenting in 1990, but was obviously in possession of an operative method of making it.

In any event, at the time the suits were filed, given the right a patentee has to enforce its patent, the Hatch-Waxman regulatory scheme and the state of the law regarding the on-sale bar, it cannot be said that Abbott’s ‘207 lawsuits against Geneva and Novopharm were objectively baseless when filed in 1996.<sup>24</sup> Likewise, the suits as to Mylan, Invamed and Warner were not objectively baseless because of these generic manufacturers’ infringement admissions, even though Abbott’s factual knowledge at the time it instituted these suits (based on discovery in the Geneva/Novopharm cases) made its position increasingly weaker. For these reasons, Abbott’s lawsuits were not sham

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<sup>24</sup> Plaintiffs argue that LaPorte barred Abbott’s “conception” argument in the ‘207 cases. 787 F.2d at 1583. In LaPorte, cutter extensions for hydraulic dredges used to dredge river channel bottoms were invented in 1977. The inventor used the cutter extensions successfully in 1977 and 1978. Id. at 1579. In 1978, a client of the inventor, a consulting engineer, photographed the invention with the inventor’s permission and in the inventor’s presence. Id. In 1979, the consulting engineer gave a copy of the photo to the president of LaPorte, a dredging company. Id.

On November 4, 1980, LaPorte’s president ordered the cutter extension from the consulting engineer; the consulting engineer notified the inventor of this transaction to which the inventor replied: “no problem.” Id. Ultimately, the inventor, the consulting engineer, and LaPorte agreed to seek a patent for the cutter extensions and the application was filed on December 7, 1981. Id. The court held that the on-sale bar applied because: (1) there had been a sale in November 1980, more than one year prior to the patent application date; (2) the fact that the sale occurred between third parties was not relevant; and (3) importantly, the court found that the invention had been produced from the embodiment of the original invention (i.e., the photograph). Id. at 1583. Both the district court in the ‘207 cases and the Federal Circuit cited LaPorte to support the argument for application of the on-sale bar.

In LaPorte, the inventor’s original copy of the cutter extension had been photographed with the inventor’s permission, in his presence, and the inventor consented to sale of the product by the consultant engineer. “*On these facts*, [the court saw] no reason to consider making an exception to the general rule that a third-party sale of a device embodying the claimed invention prior to the critical date invalidates the patent . . .” Id. at 1582 (emphasis added).

In the ‘207 case, as in LaPorte, there was a third-party sale between Byron and Geneva, and the sales occurred more than one year prior to the patent application date. However, none of the parties to the sale conceived or realized what was being sold. Thus, one could argue, if not successfully, that LaPorte did not apply. Moreover, the losses in the courts do not conclusively demonstrate that LaPorte foreclosed Abbott’s argument. See PRE, 508 U.S. at 61 (“[e]ven when the law or the facts appear questionable or unfavorable at the outset, a party may have an entirely reasonable [legal] ground for bringing suit.”) (citation omitted).

lawsuits that would deprive Abbott of Noerr-Pennington immunity. Therefore, Defendant Abbott is entitled to summary judgment in its favor on Plaintiffs' sham litigation and analogous claims.

## **2. Admissible Evidence of Subjective Bad-Faith**

Even if a plaintiff demonstrates that a lawsuit is objectively baseless, under the second prong of PRE, a court must decide whether the evidence establishes that the subjective motive of the litigant was to interfere directly with the business relationships of a competitor. 508 U.S. at 61. A plaintiff has an especially difficult burden in the patent enforcement context because "the law recognizes a presumption that the assertion of a duly granted patent is made in good faith; this presumption is overcome only by affirmative evidence of bad faith." C.R. Bard, 157 F.3d at 1369 (internal quotations and citation omitted); see also Handgards, Inc. v. Ethicon, Inc., 601 F.2d 986, 996 (9th Cir. 1979) (noting that the presumption of patentee's infringement lawsuit being brought in good faith can only be rebutted by "clear and convincing" evidence). Plaintiffs proffer three bases to meet their burden to demonstrate bad faith by clear and convincing evidence.

First, Plaintiffs claim that Abbott knew that filing its lawsuits would trigger a 30 month stay under the Hatch-Waxman Act. Although all of the lawsuits triggered the 30 month stay mechanism, seven of the cases were voluntarily dismissed and, consequently, the stays were lifted within a year of the suit being filed. Moreover, mere knowledge that the filing of a suit may collaterally damage a litigant is not evidence of a bad-faith motive. See PRE, 508 U.S. at 69 (Stevens, J., concurring) ("[w]e may presume that every litigant intends harm to his adversary . . . [but] [a]ccess to the courts is far too precious a right for us to infer wrongdoing from nothing more than using the judicial process to seek a competitive advantage in a doubtful case."). Congress created the regulatory scheme authorizing a patent holder to file suit if the generic company's certification admits

infringement. Because all of the generic companies admitted their product infringed Abbott's '097, '615, and '207 patents, Abbott had the legal right to file suit, and proper exercise of a legal right does not provide evidence of bad faith.

Second, Plaintiffs submit that the internal memorandum that Abbott's CEO circulated in the Summer of 1999 is evidence of bad faith. The memo states: "I'd like to take this opportunity to recognize the truly outstanding work of our legal team, which successfully defended Hytrin's patent protection against challenge for nearly four years." While this memo might suggest one link for a chain of circumstantial evidence of an improper motive, the memo on its face is also a commonly accepted leadership technique to express appreciation for good work done. Here, the work done was what a patent holder has a right to do – protect its patent. The memo says nothing about actions or desires to interfere directly with the business relationships of Abbott's competitors. Therefore, such a memorandum does not begin to provide clear and convincing evidence of bad faith.

Third, Plaintiffs seek to meet their burden by raising a negative inference from Abbott's invocation of the attorney-client privilege regarding the information it had before filing the suits. However, no such negative inference can arise from the assertion of the privilege and, even if it did, such a negative inference cannot substitute for the requisite clear and affirmative evidence of bad faith. See, e.g., Nabisco, Inc. v. PF Brands, Inc., 191 F.3d 208, 225-26 (2d Cir. 1999) ("[w]e are particularly troubled by the court's reliance on Nabisco's assertion of the attorney-client privilege"); Parker v. Prudential Ins. Co. of Am., 900 F.2d 772, 775 (4th Cir. 1990).<sup>25</sup>

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<sup>25</sup> Plaintiffs cite to Kloster Speedsteel AB v. Crucible, Inc., for the proposition that a negative inference can arise from the invocation of the privilege. 793 F.2d 1565, 1579-80 (Fed. Cir. 1986). However, this limited inference arises in the context where "a potential patent infringer has actual notice of another's patent rights, . . . [and] has an affirmative duty to exercise due care to determine whether or not he is infringing." Id. at 1579 (citations omitted). In Kloster, the court permitted an adverse inference against the potential patent infringer because it claimed that it sought the advice of counsel but remained silent and invoked the attorney-client privilege. Id. at 1580. Such a

The CEO's memorandum and these two arguments do not, as a matter of law, provide sufficient evidence to create a jury issue, much less satisfy Plaintiffs' burden to show bad faith by clear and convincing evidence. Thus, Plaintiffs' sham litigation evidence also fails to satisfy the second prong of the PRE test.

### **B. Sham Litigation as Automatic Baseless Petitioning**

The Individual Direct Purchaser Plaintiffs argue that the Court should look at the lawsuits, to which PRE applies,<sup>26</sup> as a serial pattern of baseless lawsuits rather than as individual lawsuits. In a concurrence in PRE, Justice Stevens states that “[r]epetitive filings, some of which are successful and some unsuccessful, may support an inference that the process is being misused.” 508 U.S. at 73 (citing Cal. Motor Transp., 404 U.S. at 508). Under Plaintiffs' theory, when a policy of automatic petitioning is shown, they need not prove objective baselessness and subjective bad faith. They rely on three cases to establish this proposition.<sup>27</sup> However, these authorities do not support Plaintiffs' alternative theory.

In Contra Costa, the plaintiff, a joint venture established by two major steel corporations to renovate a steel mill, sued defendant unions for the defendants' alleged filing of sham lawsuits to

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situation does not exist here. Moreover, the Federal Circuit is currently reviewing whether an adverse inference should arise even in that limited context. See Knorr-Bremse Systeme Fuer Nutzfahrzeuge GmbH v. Dana Corp., 344 F.3d 1336 (Fed. Cir. 2003) (granting en banc review and asking for additional briefing on the following question of “[w]hen the attorney-client privilege and/or work product privilege is invoked by defendant in an infringement suit, is it appropriate for the trier of fact to draw an adverse inference with respect to willful infringement?”).

<sup>26</sup> Federal Circuit law, which governs this issue, applies the PRE objective/subjective test to claims of multiple patent infringement lawsuits. See Globetrotter Software, Inc. v. Elan Computer Group, Inc., 362 F.3d 1367, 1377 (Fed. Cir. 2004); see also Travelers Express Co., Inc. v. Am. Express Integrated Payment Sys. Inc., 80 F. Supp. 2d 1033, 1042 (D. Minn. 1999) (stating that based on established case law, Federal Circuit applies PRE standard on series of allegedly meritless lawsuits).

<sup>27</sup> See Primetime 24 Joint Venture v. Nat. Broad. Co., Inc., 219 F.3d 92 (2d Cir. 2000); USS-POSCO Indus. v. Contra Costa County Bldg. & Constr. Trades Council, AFL-CIO, 31 F.3d 800 (9th Cir. 1994); and Livingston Downs Racing Ass'n, Inc. v. Jefferson Downs Corp., 192 F. Supp. 2d 519 (M.D. La. 2001).

harass plaintiff about employing non-union workers. 31 F.3d at 804. The Contra Costa court suggested that when addressing a series of lawsuits – in contrast to a single lawsuit, as was the case in Contra Costa – the pertinent question is: “whether [the actions] are brought pursuant to a policy of starting legal proceedings without regard to the merits and for the purpose of injuring a market rival.” Id. at 811. The court concluded that the defendants did not have such a policy because fifteen of the twenty-nine actions proved successful; thus, this fact of success in more than half of the lawsuits confirmed that defendants were not filing suits “willy-nilly.” Id. (“[g]iven that the plaintiff has the burden in litigation, a batting average exceeding .500 cannot support” plaintiff’s theory). In the instant suit, Abbott succeeded on seven of the eleven lawsuits it filed: an impressive .636 batting average.<sup>28</sup> Also, none of the lawsuits, individually, can be considered objectively baseless. Therefore, using the Contra Costa standard, Plaintiffs have not demonstrated that Abbott engaged in sham litigation.<sup>29</sup>

Moreover, Primetime 24 is inapplicable to this case. The Primetime 24 Court held that thousands of statutory challenges against a single competitor to raise its expenses of defending litigation stated a claim for sham litigation. 219 F.3d at 101-02; see also Twin City Bakery, 207 F.

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<sup>28</sup> For the reasons described above, in Section II.A.1.b.iii. at supra p.33, the Court has considered the ‘207 lawsuit as one litigation for purposes of this analysis.

<sup>29</sup> The district courts in the Ninth Circuit that have applied Contra Costa have looked at the objective merit of the actions to determine if a pattern and practice of baseless petitioning existed. See, e.g., Avery Dennison Corp v. Acco Brands, Inc., No. CV-99-1877DT(MCX), 2000 WL 986995, at \*22 (C.D. Cal. Feb. 22, 2000) (“[w]ithout any information regarding the merits of the lawsuit,” the court could not conclude that defendant engaged in a “pattern and practice of baseless filings.”); In re Circuit Breaker Litig., 984 F. Supp. 1267, 1273 (C.D. Cal. 1997) (citing Contra Costa and applying objective baselessness standard of PRE to multiple government petitions); Gen-Probe, Inc. v. Amoco Corp. Inc., 926 F. Supp. 948, 959 (S.D. Cal. 1996) (“under either the PRE or USS-POSCO [Contra Costa] test, [plaintiffs] must demonstrate objective baselessness” of lawsuits.).

The same can be said of the Livingston Downs sham litigation case from the Middle District of Louisiana. As in Contra Costa, while the court announced that in the multiple lawsuit context, it would determine whether lawsuits were brought “pursuant to a policy of instituting legal proceedings without regard to the merits . . . ,” the court analyzed the merits of each lawsuit filed. 192 F. Supp. 2d at 538-41.

Supp. 2d at 224 n.2 (finding that when individual lawsuits are filed against multiple generic drug competitors that file ANDAs rather than a single competitor, a “serial litigation” theory does not apply). Here, Abbott sued seven different generic companies, in seventeen separate lawsuits involving five different patents. Thus, this case does not cast the shadow of “serial litigation” used to injure a single competitor that occurred in Primetime 24. Primetime 24, 219 F.3d at 101 (stating that because thousands of challenges had been filed, it was immaterial that some had merit). Therefore, even under the framework advanced in Contra Costa and Livingston Downs, the Plaintiffs cannot overcome Abbott’s Noerr-Pennington immunity using the sham litigation exception.

### **C. Antitrust Injury / Tentative FDA Approval**

Under either the objective/subjective PRE standard or the Contra Costa standard, the Plaintiffs’ sham litigation claims must fail. Even assuming that Plaintiffs could have successfully overcome Noerr-Pennington immunity, in all but the ‘207 patent suits, the undisputed facts show that Plaintiffs cannot establish antitrust injury -- a critical element in proving a Sherman Act Section Two violation. PRE, 508 U.S. at 61 (“[p]roof of a sham merely deprives the defendant of immunity; it does not relieve the plaintiff of the obligation to establish all other elements of his claim.”).

To establish a Section Two claim, a plaintiff must show that the antitrust “injury [is] of the type the antitrust laws were intended to prevent.” Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc., 429 U.S. 477, 489 (1977). Cognizable antitrust injury is “essential to standing.” Bristol-Myers Squibb Co. v. Copley Pharm. Inc., 144 F. Supp. 2d 21, 22 (D. Mass. 2000) (citation omitted). “Antitrust injury must be caused by the antitrust violation – not a mere causal link, but a direct effect.” City of Pittsburgh v. W. Penn Power Co., 147 F.3d 256, 268 (3d Cir. 1998) (citation omitted).

In a regulated industry, the failure to get needed regulatory approval may “cut[] the causal

chain and convert[] what might have been deemed antitrust injury in a free market into only a speculative exercise.” W. Penn Power, 147 F.3d at 268. Under the specific Hatch-Waxman regulatory system, without tentative FDA approval, a generic manufacturer cannot enter the marketplace, and thus there is no antitrust injury. Copley, 144 F. Supp. 2d at 23.<sup>30</sup>

While the 30 month stay period means that an ANDA applicant cannot begin to receive final FDA approval, the FDA may grant “tentative approval” to an ANDA applicant if the FDA determines that the ANDA would otherwise receive final approval but for the 30 month stay.<sup>31</sup> Thus, if the ANDA applicant has not even received *tentative* FDA approval, there can be no causal connection between these lawsuits and the alleged antitrust injury. See id.; cf. Xechem, 372 F.3d at 902 (noting that plaintiff faced a “difficult task” in establishing injury because while defendant had not listed patent for pioneer drug at issue for two years, plaintiff had still not filed an ANDA).

Here, the ‘532, ‘615, ‘095 and ‘097 patent lawsuits ended before any of the generic manufacturers received tentative FDA approval of its proposed generic drug. The only Lemmon

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<sup>30</sup> Courts differ on whether a generic manufacturer alleging antitrust injury, namely the costs of defending the sham litigation, has antitrust standing to pursue recovery when the lawsuits concluded prior to receiving tentative FDA approval. Compare Copley, 144 F. Supp. 2d at 23 (finding no standing without tentative FDA approval), with Xechem v. Bristol-Myers Squibb Co., 274 F. Supp. 2d 937, 942-43 (N.D. Ill. 2003) (finding that at motion to dismiss stage, plaintiff had raised sufficient allegations of antitrust injury although no ANDA was ever filed), rev’d on other grounds, 372 F.3d 899, 901 (7th Cir. 2004), and Bristol-Myers Squibb v. Ben Venue Lab., 90 F. Supp. 2d 540, 545 (D.N.J. 2000) (ruling that generic competitor defending patent infringement lawsuits could pursue antitrust injury although it had not received tentative FDA approval).

However, in all of these cases, the issue centered on the antitrust injury of plaintiff generic manufacturers and the possible antitrust injury from the costs incurred defending patent litigation. These costs were incurred irrespective of when tentative approval occurred. Here, Plaintiffs, direct and indirect purchasers of Hytrin and generics, have not incurred costs defending any patent litigation.

<sup>31</sup> The Individual Direct Purchaser Plaintiffs argue that “had there been no lawsuits, there would have been no stays” and that tentative approval would have been closely followed by final approval. See Individual Pls.’ Opp’n to Def. Abbott’s Mot. for Summ. J. at 7 (citing Charles Raubicheck, Esq. (Pls.’ App. Tab 14)). However, it is undisputed that the FDA may grant tentative approval even though a pioneer drug company has filed a Hatch-Waxman infringement suit and tentative approval is the essential step before a generic drug can enter the drug market. Given the undisputed facts as to the tentative approval date, the date of final FDA approval -- which is delayed pending suit -- is irrelevant to an analysis of whether the suits caused antitrust injury.

lawsuit ('532) concluded on July 12, 1995, but Lemmon never received tentative approval. The last Warner lawsuit ('615/'097) concluded on August 9, 1996, but Warner never received tentative approval. Abbott voluntarily dismissed its last suit against Invamed ('095) on May 10, 1996, but Invamed did not receive tentative approval until March 13, 1997. The last suit against Zenith ('615) ended on February 7, 1996, but Zenith did not receive tentative approval until August 14, 1998. Geneva received tentative approval on June 17, 1997, for its tablet product, but the last non-'207 suit against it concluded five months before, on January 14, 1997 ('097).

Finally, as to the Novopharm '097 patent litigation, Novopharm received tentative FDA approval on November 26, 1996, and Abbott's last suit against it did not conclude until January 14, 1997 ('097). However, by that time, on September 13, 1996, Abbott had filed an action against Novopharm on the '207 patent which triggered the 30 month stay. Therefore, the '207 Novopharm patent infringement suit would have prohibited Novopharm's entry into the market place even if the '097 case had never been filed.<sup>32</sup>

In sum, Plaintiffs cannot show a causal link between the alleged antitrust violation and the alleged antitrust injury of preventing generic entry into the terazosin hydrochloride marketplace.

### **III. Section Two and Walker Process '207 Prosecution Claim**

As an alternative to the sham litigation exception, a Walker Process fraud claim may provide means of stripping a patentee of antitrust immunity. Nobelpharma, 141 F.3d at 1071. To show Walker Process fraud, a plaintiff must demonstrate that a patentee obtained a patent: (1) by knowingly and willfully misrepresenting the facts to the PTO; (2) with independent and clear evidence of an intent to deceive; and (3) that the patent would not have issued but for the

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<sup>32</sup> Novopharm obtained final approval by May 18, 2000, but never entered the terazosin hydrochloride market.

misrepresentation or omission. Id. at 1069-72. The Kaiser, Indirect Purchaser Class, and State Plaintiffs claim that Abbott committed fraud in obtaining the '207 patent in two ways: (1) by deliberately omitting a full English-language translation of the Sumika reference; and (2) by not citing to the LaPorte case.

First, these Plaintiffs claim that Abbott did not include the English-language translation of the Sumika reference which disclosed seven crystal forms of terazosin hydrochloride. Although Abbott's counsel had indicated that a full English-language translation of the Sumika reference had been enclosed in its PTO filing, only the Abstract was included. Abbott's attorney testified that he intended to include the full-English translation and thought he had. In fact, Abbott's counsel had submitted the full English-language translation in connection with the '095 (Form III) patent, which was issued. Despite this omission, the Assistant Patent Examiner, Mr. King Lit Wong, testified that he saw the "full English translation of" the Japanese patent "during the pendency of the '207 application," and the '207 patent issued anyway. Even assuming Abbott's counsel's conduct was questionable, the uncontroverted evidence is that it did not impede full consideration of the Sumika reference. Plaintiffs have failed to provide evidence which would allow a reasonable person to conclude that there was a willful and knowing misrepresentation of the facts to the PTO. Furthermore, the record is devoid of any evidence of any intent to deceive the PTO. Thus, on these undisputed facts, the Walker Process claim based on the failure to include a complete English-language translation of the Sumika reference must fail as a matter of law.

Next, the Plaintiffs claim that Abbott's failure to cite the La Porte decision in its '207 application constitutes fraud. La Porte, 787 F.2d 1577. In December 1995, Abbott's counsel submitted a Supplement to its Information Disclosure Statement ("IDS") which disclosed prior

United States sales to Geneva of Form IV terazosin hydrochloride in July 1990 and December 1991 by Byron. Abbott's counsel argued that the prior sales should not bar the '207 patent application because the sale of the Form IV terazosin hydrochloride had not been appreciated by any party. The same argument had been made in Abbott's summary judgment brief before the district court, and Abbott cited to La Porte in a footnote in that brief. In the IDS supplement, however, Abbott's counsel did not cite LaPorte.

Here, the failure to cite LaPorte does not rise to the level of Walker Process fraud or an attempt to defraud the PTO. There is no evidence in this record to show that the failure to cite to LaPorte was knowing or willful. Furthermore, Plaintiffs point to no record evidence demonstrating that withholding the citation was done with a clear deceptive intent or that Abbott's citing of LaPorte in the supplement to the IDS would have prevented the '207 patent from issuing. In fact, Abbott made disclosure of the prior sales and made legal arguments that the on-sale bar should not apply. In short, Plaintiffs have not shown that the failure to cite the LaPorte decision or any court decision satisfies any element of Walker Process fraud. Thus, the Plaintiffs have not met their burden on summary judgment because they have not presented any evidence that Abbott acted knowingly and willfully with a clear intent to deceive the PTO, or that the omission of either the complete English-language translation of the Sumika reference or the LaPorte decision would have prevented the PTO from issuing the '207 patent. Therefore, Plaintiffs have failed to strip Abbott of its Noerr-Pennington immunity through a Walker Process fraud theory.

#### **IV. Conclusion**

After careful review of the undisputed material facts in the light most favorable to the Plaintiffs, and analyzing those facts under both the objective/subjective PRE standard and Plaintiffs'

broader theory of “serial” sham litigation, Abbott is entitled to summary judgment as a matter of law on the Section Two and analogous claims. None of these lawsuits was objectively baseless under the PRE standard, and Plaintiffs have failed to proffer any evidence of a bad-faith motivation to interfere with a competitor’s business relationships. Further, there is no serial pattern of baseless petitioning for judicial relief. Plaintiffs have presented no clear and convincing affirmative evidence of fraud in the procurement of the ‘207 patent sufficient to submit this claim to a jury. Therefore, it is hereby

ORDERED that:

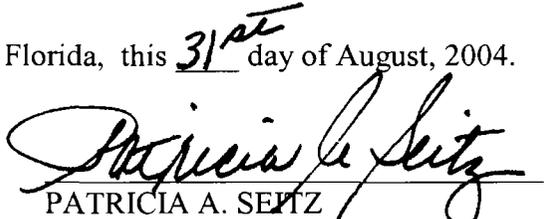
(1) Defendant Abbott Laboratories’ Motion for Summary Judgment on Sherman Act Section Two (and Analogous) Claims **[D.E. 1183]** is GRANTED;

(2) Plaintiff Kaiser’s Motion for Summary Judgment on Sham Litigation **[D.E. 1159]** is DENIED;

(3) Plaintiff Kaiser Motion for Summary Judgment on Monopoly Power **[D.E. 1163]** is DENIED as MOOT; and

(4) Individual Sherman Act Class Plaintiffs’ Motion for Summary Judgment on the Issue of Monopoly Power **[D.E. 1155]** is DENIED as MOOT.

DONE and ORDERED in Miami, Florida, this 31<sup>st</sup> day of August, 2004.

  
PATRICIA A. SEITZ  
UNITED STATES DISTRICT JUDGE

cc: Magistrate Ted Klein  
See attached service list

IN RE TERAZOSIN HYDROCHLORIDE ANTITRUST LITIGATION  
CASE: 99-MDL-1317 SEITZ/KLEIN

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