wages, claiming that if his pay were divided by the number of hours he worked and reduced to an hourly rate, his hourly rate was not much higher that, or, in some cases, even lower than, that of the team members. The Fourth Circuit performed no such mathematical gymnastics in deciding *Jones*, however. *Jones* simply compared the manager's weekly salary with the highest possible non-exempt weekly wage, concluding that the pay differential was sufficient to render the manager exempt. 69 Fed.Appx. at 639.

Application of each factor indicates that Plaintiff's primary duty was management within the meaning of the regulations Plaintiff is exempt from FLSA overtime provisions by virtue of the executive exemption, and Defendant is entitled to summary judgment on this basis. The potential application of the administrative exemption is thus moot, and the Court declines to address it.

IV. *CONCLUSION*

THE COURT, having considered the pertinent portions of the record and having heard oral argument from the parties, hereby

ORDERS AND ADJUDGES that Defendant Tractor Supply Company's Motion for Summary Judgment, filed October 8, 2004 is GRANTED. Final judgment shall be entered by separate order.

In re: TERAZOSIN HYDROCHLORIDE ANTITRUST LITIGATION

No. 99–MDL–1317.

United States District Court,
S.D. Florida.

Jan. 5, 2005.

Background: Direct and indirect purchasers of patented drug and three states brought consolidated antitrust suits against patentee and manufacturer of generic version of patented drug, alleging that defendants' agreement not to compete violated the Sherman Act. The United States District Court for the Southern District of Florida, No. 99-01317-MD-PAS, Patricia A. Seitz, J., 164 F.Supp.2d 1340, ruled that agreement was per se unlawful, and appeal was taken. The Court of Appeals, 344 F.3d 1294, reversed and remanded. On remand, parties moved for summary judgment.

Holdings: After granting the motions in part, 335 F.Supp.2d 1336, the District Court, Seitz, J., held that:

(1) generic manufacturer was likely to prevail on claim that drug patent was invalid under the on-sale bar;

(2) agreement exceeded exclusionary scope of the patent; and

(3) agreement was horizontal restraint of trade that was per se violation of the Sherman Act.

Ordered accordingly.

1. Patents ⚿191

Right to exclude others is granted to allow the patentee to exploit whatever de-

gree of market power it might gain thereby as an incentive to induce investment in innovation and the public disclosure of inventions. 35 U.S.C.A. §§ 271(a), 283.

2. Patents ⚿191

Patent's exclusionary right cannot be exploited in every way; patent holder's protections are limited by the precise terms of the patent grant, and cannot be extended by agreement. 35 U.S.C.A. §§ 271(a), 283.

3. Patents ⚿191

Intellectual property law does not offer pharmaceutical patentees a guaranteed insulation from competition, without the risk that the patent later will be held invalid; rather than providing such unconditional protection from generic competition, legitimate exclusion value of a pharmaceutical patent is the power it actually confers over competition, which is in turn a function of the scope of the patent and its chance of being held valid. 35 U.S.C.A. §§ 271(a), 283.

4. Patents ⚿169

Exclusionary value of pharmaceutical patent cannot be defined by looking at the patent terms in a vacuum; instead, when litigation is pending as to the validity of the patent, the chances that the patent will be held valid must be considered as part of the analysis. 35 U.S.C.A. §§ 271(a), 283.

5. Patents ⚿165(2)

The legal scope of patent is measured by its numbered claims.

6. Monopolies ⚿12(15)

Agreement between patentee and manufacturer of generic version of patented drug, under which the generic manufacturer agreed to keep generic drug off the market pending final appellate resolution of patent infringement litigation, was not immune from antitrust scrutiny because the patent was not set to expire while agreement was in affect, where there was significant likelihood that generic manufacturer would prevail and that the patent would be held invalid on appeal. Sherman Act, § 1, as amended, 15 U.S.C.A. § 1.

7. Patents ⚿169

Any definitive construction of the exclusionary scope of a patent requires at least a limited assessment of the underlying patent infringement case. 35 U.S.C.A. §§ 271(a), 283.

8. Injunction ⚿138.1

In the Federal Circuit, the party seeking the extraordinary relief of a preliminary injunction must demonstrate: (1) a reasonable likelihood of success on the merits; (2) irreparable harm if the injunction were not granted; (3) the balance of the hardships; and (4) the impact of the injunction on the public interest.

9. Patents ⚿295, 298

In the patent context, a "reasonable likelihood of success" required for preliminary injunction requires a showing of validity and infringement.

10. Patents ⚿295

If the alleged infringer raises a substantial question concerning patent's validity, i.e., asserts a defense that the patentee cannot show lacks substantial merit, preliminary injunction should not issue.

11. Patents ⚿295

Validity questions during preliminary injunction proceedings in patent infringement case can be successful, that is, they may raise substantial questions of invalidi-

ty, on evidence that would not suffice to support a judgment of invalidity at trial; vulnerability is the issue at the preliminary injunction stage, while validity is the issue at trial.

12. Patents ⚿303

Presumption that patent is valid does not relieve a patentee who moves for preliminary injunction from carrying the normal burden of demonstrating that it will likely succeed on all disputed liability issues at trial, even when the issue concerns the patent's validity. 35 U.S.C.A. § 282.

13. Patents ⚿76

The "on-sale bar" to patent validity does not require sustained commercial activity, advertising, or displays; on the contrary, a single sale or even a single offer to sell is sufficient to trigger the statutory bar. 35 U.S.C.A. § 102(b).

See publication Words and Phrases for other judicial constructions and definitions.

14. Patents ⚿76

Sale or offer for sale need not be made by the inventor or by the patent owner for on-sale bar to apply; a sale or offer for sale by a third party is just as effective a bar as a sale or offer by the inventor. 35 U.S.C.A. § 102(b).

15. Patents ⚿295

Alleged infringer was likely to prevail on claim that drug patent was invalid under the on-sale bar, for purposes of issuing preliminary injunction prohibiting infringement while appeal in infringement action was pending; patentee had made three sales of the drug more than a year before obtaining patent and parties knew that the sale embodied a form of the drug that was later patented. 35 U.S.C.A. § 102(b).

16. Patents ⚿76

The four policies underlying the on-sale bar to patent validity 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 invention beyond the statutorily prescribed time. 35 U.S.C.A. § 102(b).

17. Federal Courts ⚿684.1

The standard for obtaining a stay pending appeal is essentially the same as that for obtaining a preliminary injunction, only the movant is required to demonstrate a strong showing that he is likely to succeed on the merits.

18. Monopolies ⚿12(15)

Agreement under which alleged infringer agreed to keep its generic drug off the market pending final appellate resolution of patentee's infringement action exceeded exclusionary scope of the patent, in determining whether the agreement violated antitrust law; agreement did not resolve the litigation, but instead tended to prolong that dispute to patentee's advantage, delaying generic entry for a longer period of time than its drug patent or any reasonable interpretation of the patent's protections would have provided. Sherman Act, § 1, as amended, 15 U.S.C.A. § 1.

19. Monopolies ⚿12(1)

Although settlements are favored over litigation because they allow litigants to avoid risk and uncertainty, this alone can-

not insulate a settlement agreement from antitrust scrutiny.

20. Monopolies ⚿12(15)

While reducing risk and uncertainty is a legitimate benefit of settlements, antitrust tribunals reviewing settlements in patent disputes cannot simply rubberstamp the parties' accords because they are in line with the litigants' own self-interest; there is nothing magical about a settlement that immunizes an agreement that may otherwise violate the antitrust laws.

21. Monopolies ⚿28(8)

Although applying any particular method of antitrust analysis may involve fact questions, the selection of a mode of analysis is entirely a question of law for the Court to decide.

22. Monopolies ⚿12(1.10)

In assessing whether an agreement unreasonably restrains trade such that it violates Sherman Act, courts generally apply one of three modes of antitrust analysis: (1) the per se rule, for obviously anticompetitive restraints; (2) the quick look approach, for those restraints with some procompetitive justification; or (3) the full "rule of reason," for restraints whose net impact on competition is particularly difficult to determine. Sherman Act, § 1, as amended, 15 U.S.C.A. § 1.

23. Monopolies ⚿12(1.2)

In all cases, the criterion to be used in judging the validity of a restraint on trade is its impact on competition. Sherman Act, § 1, as amended, 15 U.S.C.A. § 1.

24. Monopolies ⚿12(1.10)

"Per se analysis" permits courts in antitrust cases to make categorical judgments that certain practices, including price fixing, horizontal output restraints, and market-allocation agreements, are illegal without the need for any elaborate inquiry as to the precise harm they have caused or the business excuse for their use. Sherman Act, § 1, as amended, 15 U.S.C.A. § 1.

See publication Words and Phrases for other judicial constructions and definitions.

25. Monopolies ⚿12(1.10)

Although courts are reluctant to apply the per se approach with regard to restraints whose economic impact is not immediately obvious, it is the appropriate mode of analysis in an antitrust case when experience with a particular kind of restraint enables the court to predict with confidence that the rule of reason will condemn it. Sherman Act, § 1, as amended, 15 U.S.C.A. § 1.

26. Monopolies ⚿12(1.10)

Under the "rule of reason," the test of legality under antitrust laws is whether the restraint imposed is such as merely regulates and perhaps thereby promotes competition or whether it is such as may suppress or even destroy competition; therefore, the rule of reason requires a plaintiff to prove the anticompetitive effect of the challenged conduct on the relevant market, and that the conduct has no procompetitive benefit or justification. Sherman Act, § 1, as amended, 15 U.S.C.A. § 1.

See publication Words and Phrases for other judicial constructions and definitions.

27. Monopolies ⚿12(1.10)

"Quick look approach" for assessing whether an agreement unreasonably re-

strains trade in violation of the Sherman Act falls somewhere in continuum between the per se rule and the rule of reason, and applies to those intermediate cases where the anticompetitive impact of a restraint is clear from a quick look, as in a per se case, but procompetitive justifications for it also exist; only if an observer with even a rudimentary understanding of economics could conclude that the arrangements in question would have an anticompetitive effect on customers and markets would summary review under the quick look be proper. Sherman Act, § 1, as amended, 15 U.S.C.A. § 1.

See publication Words and Phrases for other judicial constructions and definitions.

28. Monopolies ⚿12(15)

Agreement between patentee and manufacturer of generic version of patented drug, under which generic manufacturer agreed not to market its drug until final appellate resolution of infringement action in exchange for payments from the patentee, was horizontal restraint of trade that was per se violation of the Sherman Act; agreement guaranteed patentee that its only potential competitor at the time would, for a substantial price, refrain from marketing its FDA-approved generic version of drug even after an adverse district court ruling as to patent's validity, and had additional effect of delaying entry of other generic competitors. Sherman Act, § 1, as amended, 15 U.S.C.A. § 1.

29. Monopolies ⚿12(1.14)

Horizontal agreements between competitors are antitrust's most suspect" classification, which as a group provoke closer scrutiny than any other arrangement. Sherman Act, § 1, as amended, 15 U.S.C.A. § 1.

30. Monopolies ⚿12(1.16)

As a general class, agreements between competitors to allocate markets are clearly anticompetitive, with the obvious tendency to diminish output and raise prices. Sherman Act, § 1, as amended, 15 U.S.C.A. § 1.

31. Monopolies ⚿12(1.14)

A particular horizontal agreement is defined as a "naked restraint" if it is formed with the objectively intended purpose or likely effect of increasing price or decreasing marketwide output in the short run, with output measured by quantity or quality. Sherman Act, § 1, as amended, 15 U.S.C.A. § 1.

See publication Words and Phrases for other judicial constructions and definitions.

32. Monopolies ⚿12(1.14)

If agreement is one that presents a naked restraint of trade with no purpose except stifling competition, it qualifies for per se treatment. Sherman Act, § 1, as amended, 15 U.S.C.A. § 1.

33. Monopolies ⚿12(1.8)

Restraint of trade is "ancillary" if its objectively intended purpose or likely effect is lower prices or increased output as measured by quantity or quality. Sherman Act, § 1, as amended, 15 U.S.C.A. § 1.

See publication Words and Phrases for other judicial constructions and definitions.

34. Monopolies ⚿12(1.2, 1.10)

If a restraint of trade is defined not as naked but rather as ancillary, the plaintiff acquires the burden of showing both power and anticompetitive effect, and a broader range of defenses are countenanced.

Sherman Act, § 1, as amended, 15 U.S.C.A. § 1.

35. Monopolies ⚿12(15)

Agreement between patentee and manufacturer of generic version of patented drug, under which generic manufacturer agreed not to market its drug until final appellate resolution of infringement action in exchange for payments from the patentee was a naked restraint of trade subject to per se treatment, rather than an ancillary restraint subject to rule of reason analysis; agreement extended the protections of the patent beyond district court's ruling on issue of validity, and permitted patentee to continue to exploit its patent protections irrespective of whether the patent was declared valid. Sherman Act, § 1, as amended, 15 U.S.C.A. § 1.

36. Monopolies ⚿12(1.14)

Once a naked restraint of trade is found, any alleged procompetitive justifications are irrelevant and should not be considered. Sherman Act, § 1, as amended, 15 U.S.C.A. § 1.

37. Health ⚿319

Hatch–Waxman Act does not indicate congressional intent to delay market entry of generic version of patented drug beyond the 30 months provided for in the statute, even in the face of continuing litigation. Federal Food, Drug, and Cosmetic Act, § 505(j)(5)(B)(iii), 21 U.S.C.A. § 355(j)(5)(B)(iii).

38. Monopolies ⚿12(1.2)

True ancillary restraints of trade only escape the per se rule because they are counterbalanced by otherwise unattainable procompetitive benefits from some joint integrated activity. Sherman Act, § 1, as amended, 15 U.S.C.A. § 1.

39. Monopolies ⚿12(1.2)

Presumption that naked restraint of trade has anticompetitive effects dispenses with the need to define a relevant market and assess other factors such as barriers to entry that might bear on the defendant's ability to profit by raising price above cost. Sherman Act, § 1, as amended, 15 U.S.C.A. § 1.

Patents ⚿328(2)

5,504,207. Cited.

Mitchell Wayne Berger, Rene Devlin Harrod, Berger Singerman, Fort Lauderdale, FL, Daniel Berger, David Sorensen, Eric L. Cramer, Berger & Montague, P.C., Philadelphia, PA, Richard Drubel, Samuel D. Heins, R. Bryant McCulley, Boies Schiller & Flexner, Hanover, NH, Bruce E. Gerstein, Garwin Bronzaft Gerstein & Fisher LLP, New York, NY, Aubrey B. Calvin, The Calvin Law Firm, Houston, TX, Cory A. Johnson, Attorney General Office Department of Legal Affairs, Tallahassee, FL, for Plaintiffs.

Pamela B. Slate, Slate Kennedy, Kimberly R. West, Matthew D. Fridy, Wallace Jordan Ratliff & Brandt, Birmingham, AL, Monica L. Rebuck, Steve D. Shadowen, Hangley Aronchick Segal & Pudlin, Harrisburg, PA, Joseph T. Lukens, Hangley Aronchick Segal & Pudlin, Philadelphia, PA, Michael D. Hausfeld, Daniel A. Small, Cohen Milstein Hausfeld & Toll, W. Scott Simmer, Andrew Craig Udin, Robins Kaplan Miller & Ciresi, Washington, DC, Elwood S. Simon, John Zuccarini, Elwood S. Simon & Associates, Birmingham, MI, David Scott Mandel, Mandel & Cale, Miami, FL, Stephen Lowey, Richard W. Co-

hen, Geoffrey M. Horn, Lowey Dannenberg Bemporad & Selinger, White Plains, NY, Scott Ray Strand, Robins Kaplan Miller & Ciresi, Minneapolis, MN, for Defendants.

Robert Alexander Milne, Wayne A. Cross, Paul Olszowka, Brendan G. Woodard, White & Case, New York, NY, Paul Alan Shelowitz, Candace Dohn Banks, Akerman Senterfitt, Jon W. Zeder, Ferrell Schultz Carter & Fertel, Miami, FL, Stuart N. Senator, Rohit K. Singla, Munger Tolles & Olson, Los Angeles, CA, Jeffrey I. Weinberger, David M. Rosenzweig, Samuel N. Weinstein, Munger Tolles & Olson, San Francisco, CA, for Plaintiffs and Defendants.

OMNIBUS ORDER ON SIX MOTIONS FOR SUMMARY JUDGMENT RE: PLAINTIFFS' SECTION ONE (AND ANALOGOUS) CLAIMS [1]

SEITZ, District Judge.

THIS MATTER is before the Court on six summary judgment motions relating to the Sherman Act Class Plaintiffs and Plaintiff Kaiser Foundation Health Plan, Inc.'s ("Kaiser") claims arising under Section One of the Sherman Antitrust Act, 15 U.S.C. § 1. This Court previously concluded that the April 1, 1998, agreement between Defendants Abbott Laboratories ("Abbott") and Geneva Pharmaceuticals ("Geneva") (collectively, "Defendants")—by which Geneva agreed to delay marketing its generic competitor to Abbott's brand name pharmaceutical terazosin hydrochloride product, Hytrin—was a *per se* violation of Section One. The Eleventh Circuit reversed that ruling in September 2003, finding the Court's *per se* condemnation of the Agreement to be "premature" and remanding the case to this Court for consideration of the exclusionary potential of Abbott's '207 patent. The Sherman Act Class Plaintiffs, Kaiser, and Defendants have each filed motions seeking a declaration from the Court as to whether the challenged provision of the Abbott–Geneva Agreement exceeded, or was within, the exclusionary scope of Abbott's patent protections. The Sherman Act Class Plaintiffs also seek rulings that the Agreement violates Section One under either a *per se* or "quick look" antitrust analysis, and that they may prove their Section One claims using direct evidence of actual anticompetitive effects in lieu of a detailed market power analysis.

The Court has considered the Motions, the responses and replies thereto, the applicable case law, all supporting exhibits,

1. Specifically, this Order: (1) grants the Sherman Act Class Plaintiffs' Motion for Partial Summary Judgment Declaring that the Abbott–Geneva Agreement Exceeded the Exclusionary Potential of the 207 Patent [D.E. 1192]; (2) grants Plaintiff Kaiser's Motion for Summary Judgment on Section One Claims [D.E. 1161]; (3) denies Defendants' Motion for Summary Judgment on Sherman Act Section One (and Analogous) Claims [D.E. 1188]; (4) grants the Sherman Act Class Plaintiffs' Motion for Partial Summary Judgment for a Finding that the Abbott–Geneva Agreement Violates Section One of the Sherman Act [D.E. 1190–1]; (5) denies as moot the Sherman Act Class Plaintiffs' alternative Motion for Partial Summary Judgment for a Finding that a Quick–Look Analysis Applies to the Agreement [D.E. 1190–2]; and (6) denies as moot the Sherman Act Class Plaintiffs' Motion for Partial Summary Judgment for a Ruling that Proof of Actual Anticompetitive Effects is Sufficient to Establish a Violation of Section One of the Sherman Act [D.E. 1194]. Although the parties filed five summary judgment motions as to the Section One claims, because the motion regarding the appropriate antitrust scrutiny has two alternative requests for relief, this Court's ruling effectively relates to six separate motions.

and the oral argument of counsel at the July 2, 2004, and August 3, 2004, hearings. Having considered the undisputed material facts [2] in the light most favorable to the non-moving parties, the Court concludes that: (1) the exclusionary effects of the challenged provision of the Abbott–Geneva Agreement exceeded the exclusionary potential of the '207 patent; and (2) the Agreement is *per se* unlawful under Section One of the Sherman Act. Therefore, the Sherman Act Class Plaintiffs and Kaiser are entitled to summary judgment as a matter of law on their Section One and analogous claims, and Defendants' Section One Motion must be denied.

I. *FACTUAL BACKGROUND*

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 develop and launch bioequivalent 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 Abbott; 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, Zenith Goldline Pharmaceuticals, Inc. ("Zenith"),[3]—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 bioequivalent drugs for consumers, but also eliminates a brand name drug company's patent monopoly.

Plaintiffs Kaiser, the Sherman Act Class Plaintiffs, Individual Direct Purchasers, Indirect Purchaser Class Plaintiffs, and State Plaintiffs (collectively, "Plaintiffs") [4] sued Defendants alleging, *inter alia*, claims under Section One of the Sherman Act ("Section One") [5] and analogous state

2. On July 16, 2004, the parties submitted their Joint Statement of Facts Not in Dispute. [DE–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.

3. Zenith settled this action and is no longer a party to this multi-district litigation.

4. 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.

5. Section One of the Sherman Antitrust Act prohibits "[e]very contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the

laws for conspiracy to restrain trade. Essentially, Plaintiffs contend that Defendants violated Section One by entering into an agreement in April 1998 that resulted in delayed domestic competition for the sale of terazosin hydrochloride, thus constituting an unreasonable restraint of trade. More specifically, Plaintiffs argue that Abbott's agreement to pay Geneva $4.5 million per month to keep its generic terazosin hydrochloride product off the market pending final appellate resolution of the '207 patent infringement litigation resulted in reduced output, artificially inflated prices, and eliminated competition in the market for terazosin hydrochloride. Defendants respond that the Agreement was a permissible exercise of Abbott's rights under the '207 patent, and that their accord represented a reasonable interim settlement of a genuine intellectual property dispute.

To place the '207 patent infringement litigation in context, it is necessary to set out the pertinent framework for drug regulation in the United States and then discuss the parties' undisputed material facts as to Abbott's '207 patent, the '207 patent litigation, and the Abbott–Geneva Agreement upon which Plaintiffs' Section One claims are based.

A. *The FDA Regulatory Framework Under Hatch–Waxman*

A drug patent gives its owner the right to attempt to exclude others from making, using, or selling the drug in the United States for the duration of the patent. Before a drug company can sell a drug in the United States, it must apply for and obtain approval from the Food and Drug Administration ("FDA"), which regulates the domestic sale of drugs pursuant to the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301, *et seq.* 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 the Drug Price Competition and Patent Term Restoration Act, 21 U.S.C. § 355, commonly known as the Hatch–Waxman Act ("Hatch–Waxman").[6] 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

several States, or with foreign nations . . . .'' 15 U.S.C. § 1. It is understood, however, that the ban on ''contract[s] in restraint of trade'' means only unreasonable restraints, that is, restraints that impair competition.'' *Valley Drug Co. v. Geneva Pharms., Inc.,* 344 F.3d 1294, 1303 (11th Cir.2003) (internal citations omitted).

6. 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).

products, yet also sought to protect 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 product, 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.

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 relevant to 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, the filing of such a lawsuit would trigger a "thirty month stay" of final FDA approval. S. ¶ 12. Under Hatch–Waxman's stay provision, the FDA is prohibited from granting final approval for the ANDA until *the earlier of:* (1) thirty (30) months after the date of the innovator company's receipt of the generic's notice regarding its Paragraph IV Certification; or (2) issuance of a "court decision" [7] relating to the specific ANDA that holds the

7. 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 (citing 21 C.F.R. § 314.107(e) (1989)).

patent invalid or uninfringed. S. ¶ 12. However, during the thirty 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 thirty month stay. S. ¶ 14. District courts are authorized to extend or shorten the thirty month stay where either party to the action fails to reasonably cooperate in expediting the litigation. S. ¶ 12. A dismissal of the Hatch–Waxman infringement lawsuit lifts the thirty month stay. Although a patent holder can file a patent infringement action against an alleged infringer after that forty-five day period following receipt of the Paragraph IV Certification, such an action does not trigger a thirty month stay.

B. *Abbott's '207 Patent and the '207 Patent Litigation*

Of Abbott's numerous terazosin hydrochloride patents, only the 5,504,207 patent ("the '207 patent") is directly relevant to the instant motions. Abbott is the assignee of the '207 patent on a crystalline polymorph of anhydrous terazosin hydrochloride with a certain x-ray diffraction pattern (Form IV) and a process for the preparation of terazosin hydrochloride dihydrate using Form IV as an intermediary. S. ¶ 49. The application for the '207 patent was filed on October 18, 1994. *Id.* The patent issued on April 2, 1996, and was submitted to the FDA for listing in the Orange Book on the same day. *Id.*

Geneva filed two ANDAs for terazosin hydrochloride. It filed ANDA 74–315 on January 12, 1993, for terazosin hydrochloride tablets using Form II anhydrous terazosin. S. ¶ 29. In June 1995, it switched to Form IV anhydrous terazosin. S. ¶ 58. Geneva obtained tentative approval for its tablet ANDA on June 17, 1997, and final approval on December 31, 1998. S. ¶ 29. Geneva came to market with its tablet product in May 2001. *Id.* 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.

In connection with these two ANDAs, Geneva provided Abbott with two notices, both dated April 29, 1996, of Paragraph IV Certifications with respect to the '207 patent. These certifications 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) (the "on-sale bar"). S. ¶ 107. On June 4, 1996, Abbott sued Geneva regarding its tablet ANDA alleging infringement. S. ¶ 109. Abbott failed, however, 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.

On January 15, 1997, Geneva moved for summary judgment [8] on the grounds that claim 4 of the '207 patent (the only claim of the patent asserted against Geneva) was

8. The Geneva litigation was consolidated with a case in which Abbott sued Novopharm—another generic drug manufacturer—also for infringement of the '207 patent. 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. Within a week of one another, both Geneva and Novopharm filed motions for summary judgment in their respective litigation with Abbott, on the same grounds. S. ¶¶ 114–15. Nearly ten months later, in October 1997, Abbott sued a third generic drug manufacturer, Invamed,

invalid under the "on-sale bar," relying on sales of anhydrous terazosin from the early 1990s which 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. In its opposition to the summary judgment motion, 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 at the time of the sales prevented the triggering of the "on-sale bar." S. ¶¶ 114–115.

On September 1, 1998, the district court granted Geneva's summary judgment motion, finding claim 4 of the '207 patent (claiming Form IV terazosin hydrochloride) invalid because of the "on-sale bar." *Abbott Labs. v. Geneva Pharms., Inc.,* No. 96–C–3331, 1998 WL 566884, at *5 (N.D.Ill. Sept.1, 1998). In so finding, the district court relied on the Federal Circuit decision in *J.A. LaPorte, Inc. v. Norfolk Dredging Co.,* 787 F.2d 1577 (Fed.Cir. 1986), *cert. denied,* 479 U.S. 884, 107 S.Ct. 274, 93 L.Ed.2d 250 (1986). *Id.* 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 it opinion in *Pfaff v. Wells Elecs., Inc.,* 525 U.S. 55, 119 S.Ct. 304, 142 L.Ed.2d 261 (1998) (rejecting the "totality of the circumstances" test for determining whether an invention was on sale before the critical date). 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, including *LaPorte.* S. ¶ 122; *see Abbott Labs. v. Geneva Pharms., 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 U.S. Supreme Court denied certiorari on January 10, 2000. S. ¶ 122.

C. *The Abbott–Geneva Agreements*

On April 1, 1998, when Geneva's motion for summary judgment had been fully briefed for nearly one year, Abbott and Geneva entered into the agreement that is the subject of Plaintiffs' claims ("Agreement" or "Abbott–Geneva Agreement"). S. ¶ 178. The Agreement provided, in relevant part, that:

> Geneva shall not sell, offer for sale, donate, or otherwise distribute in the United States any Terazosin Hydrochloride Product until after the earlier of (1) the Generic Entry Date, or (2) the Appellate Judgment.

S. ¶ 179. The term "Generic Entry Date," as used in the Agreement, was defined as the earlier of the date of sale of generic Hytrin by a third party, or the expiration date of Abbott's '532 patent for dihydrate terazosin hydrochloride—February 18, 2000. S. ¶ 180. In turn, the term "Appellate Judgment" referred to the conclusion

for infringing the '207 patent. S. ¶ 117. That suit was also consolidated with those against Geneva and Novopharm. In the interest of clarity, the Court will refer to Geneva only as the Defendant in the underlying patent infringement action, as Geneva is the only one of the three defendants in the patent litigation that is a party to the instant case.

of the pending '207 litigation, and meant a final, unappealable judgment, including any appeal or petition for certiorari to the United States Supreme Court. S. ¶ 181.

The Agreement provided, *inter alia*, that Abbott would pay Geneva $4.5 million per month beginning on April 30, 1998. The Agreement also provided that in the event of "Final Judgment in Geneva's Favor," [9] Abbott's monthly payments to Geneva would stop and Abbott would pay into escrow $4.5 million per month until the earlier of the "Generic Entry Date," the "Appellate Judgment," or the date of "Final Judgment in Abbott's Favor." [10] The Agreement further provided that Geneva would receive the amount in escrow if Geneva prevailed in any appeal. Otherwise, the amount in escrow would be returned to Abbott. Under the Agreement, upon a Final Judgment in Abbott's favor, Abbott would have no obligation to make any payment to Geneva. S. ¶ 182. Finally, the Agreement provided that Abbott had the option to terminate payments if the Generic Entry Date had not occurred on or before February 18, 2000. S. ¶ 183.

In August 1999, Abbott and Geneva terminated the Agreement. As of the date of termination, Abbott had paid a total of $49.5 million into escrow. As part of the termination agreement, $45 million in escrow funds were returned to Abbott. Had Geneva launched on August 13, 1999, without first having terminated the Agreement, Abbott would have asserted that Geneva was in breach of the Agreement. S. ¶ 186. Geneva launched its generic product on August 13, 1999. S. ¶ 187. Since going to market with a generic form of terazosin hydrochloride in August 1999, Geneva has been an actual competitor of Abbott. S. ¶ 188. The activities of Abbott and Geneva being challenged in this action have occurred in, and have had a substantial effect on, interstate commerce. S. ¶ 189.

D. *The December 2000 Per Se Ruling and the Eleventh Circuit's Reversal*

On December 13, 2000, this Court granted Plaintiffs' motion for partial summary judgment, concluding that the Abbott–Geneva Agreement was a *per se* violation of Section One. *See In re Terazosin Hydrochloride Antitrust Litig.*, 164 F.Supp.2d 1340 (S.D.Fla.2000). In making that determination, the Court characterized the Agreement as a geographic market allocation arrangement between horizontal competitors, essentially allocating the entire United States market for terazosin drugs to Abbott. *Id.* On September 15, 2003, the Eleventh Circuit Court of Appeals reversed, finding that this Court's condemnation of the Abbott–Geneva Agreement as a *per se* violation of Section One was "premature." *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1304 (11th Cir.2003). The Eleventh Circuit premised its ruling on the fact that Abbott, as owner

9. "Final Judgment in Geneva's Favor" was defined as "the entry pursuant to Federal Rule of Civil Procedure 79(a) by the United States District Court for the Northern District of Illinois in Case No. 96 C 3331 of a final, appealable judgment that Geneva's Terazosin Hydrochloride Products do not infringe or would not infringe any valid and enforceable claim of the '207 patent." S. ¶ 185.

10. "Final Judgment in Abbott's Favor" was defined as "the entry pursuant to the Federal Rule of Civil Procedure 79(a) by the United States District Court for the Northern District of Illinois in Case No. 96 C 3331 of a final, appealable judgment that Geneva's Terazosin Hydrochloride Products infringed or would infringe any valid and enforceable claim of the '207 patent." S. ¶ 184.

of the '207 patent, had "the lawful right to exclude others." *Id.* Recognizing that the patentee's exclusionary right cannot be exploited in every way, the Eleventh Circuit concluded that this Court nonetheless needed to consider the exclusionary scope of the patent before making any determination as to whether the alleged restraint is *per se* illegal. *Id.* at 1306 (citing *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F.Supp.2d 188, 249 (E.D.N.Y. 2003)). The Eleventh Circuit, therefore, remanded the case for further proceedings consistent with its opinion.

E. *The Parties' Motions*

Based on these undisputed facts, the parties collectively filed six motions for summary judgment [11] relating to Plaintiffs' Section One claims. These motions can be divided into two categories: those that relate to the threshold examination of the exclusionary potential of the '207 patent, and those that relate to the subsequent antitrust scrutiny of the anticompetitive impact of the challenged restraint.

Falling into the first category are: (1) the Sherman Act Class Plaintiffs' Motion for Partial Summary Judgment for an Order Declaring that the Abbott–Geneva Agreement Exceeded the Exclusionary Potential of the '207 Patent; (2) Kaiser's Motion for Summary Judgment on Section One Claims [12]; and (3) Defendants' Motion for Summary Judgment on Sherman Act Section One (and Analogous) Claims. In their motions, the Sherman Act Class Plaintiffs and Kaiser argue that the Abbott–Geneva Agreement exceeded the scope of the '207 patent by delaying generic competition for terazosin hydrochloride through the date of a final appellate judgment as to the validity of the '207 patent. Defendants' motion, in turn, contends that the Agreement was within the potential exclusionary power of the patent because: (a) it only limited competition for a small subset of the natural life of the patent, which at the time of the Agreement had not been invalidated and was not set to expire until October 2014; and (b) it was reasonably likely that Abbott could have obtained a preliminary injunction or stay pending appeal to keep Geneva off the market past the date of the district court's order invalidating the patent. These Section One motions require, pursuant to the Eleventh Circuit's opinion and its instructions on remand, the development of an appropriate framework for assessing the exclusionary potential of the '207 patent.

In the second category of motions are: (1) the Sherman Act Class Plaintiffs' Motion for Partial Summary Judgment for a Finding that the Abbott–Geneva Agreement Violates Section One of the Sherman Act or in the Alternative for a Finding that a "Quick–Look" Analysis Applies to the Agreement (hereinafter, "the Quick–Look Motion"); and (2) the Sherman Act Class Plaintiffs' Motion for Partial Summary

11. *See supra* n. 1.

12. The Sherman Act Class Plaintiffs' Motion seeks *partial* summary judgment—specifically, an order declaring that the Abbott–Geneva Agreement exceeded the exclusionary scope of the '207 patent—while Kaiser captioned its motion as one for summary judgment on the Section One claims, without any limitations. However, upon review of the Motions, it is apparent that the Sherman Act Class Plaintiffs and Kaiser all seek the same relief: a ruling, in accordance with the Eleventh Circuit's directions on remand, that the challenged provision of the Abbott–Geneva Agreement delayed generic entry longer than the '207 patent would otherwise permit, and that the Agreement cannot be justified by the likely outcome of the '207 patent litigation.

Judgment for a Ruling that Proof of Actual Anticompetitive Effects is Sufficient to Establish a Violation of Section One of the Sherman Act (hereinafter, "the Direct Evidence Motion"). In the former motion, the Sherman Act Class Plaintiffs argue that the Agreement's restraint on generic competition in the terazosin hydrochloride market constitutes a *per se* violation of Section One, as it is a horizontal market allocation that has the great tendency to diminish output and increase prices. As an alternative motion, the Sherman Act Class Plaintiffs argue that the Agreement should be evaluated under a "quick look" approach in lieu of a full-blown "rule of reason" analysis. Finally, in the event that the Court does not apply a truncated analysis that presumes the Agreement's anticompetitive impact, the Sherman Act Class Plaintiffs ask the Court to rule that it may establish the actual anticompetitive effects of the Agreement through direct evidence, thus eliminating the need for an extensive, time-consuming analysis of market power.

The Court will begin with the first category of motions, addressing the exclusionary potential of the '207 patent, in Section III of this Order. The latter category of motions will be considered in Section IV, below.

II. SUMMARY JUDGMENT STANDARD

Summary judgment is appropriate, in accordance with Fed.R.Civ.P. 56, 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, 106 S.Ct. 2505, 91 L.Ed.2d 202 (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., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 587, 106 S.Ct. 1348, 89 L.Ed.2d 538 (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, 106 S.Ct. 2505). The moving party is entitled to summary judgment where the "record taken as a whole could not lead a rational trier of fact to find for the non-moving party." *Matsushita*, 475 U.S. at 587, 106 S.Ct. 1348.

These standards apply equally to antitrust cases, where "the usual entanglement of legal and factual issues ... may be particularly well-suited for Rule 56 utilization." *Thompson Everett, Inc. v. Nat'l Cable Adver., L.P.*, 57 F.3d 1317, 1322 (4th Cir.1995); *see also Bayou Bottling, Inc. v. Dr. Pepper Co.*, 725 F.2d 300, 303 (5th Cir.1984) (citing *Aladdin Oil v. Texaco, Inc.*, 603 F.2d 1107, 1111 (5th Cir.1979)) [13] ("simply because a case is based upon the antitrust laws does not suspend the application of Rule 56."). Because " '[t]he very nature of antitrust litigation encourages

13. The Eleventh Circuit adopted as precedent decisions of the former Fifth Circuit rendered prior to October 1, 1981. *See Bonner v. City of Prichard*, 661 F.2d 1206, 1209 (11th Cir. 1981).

summary disposition of such cases when permissible,' " courts have recognized that "summary judgment is an important tool for dealing with antitrust cases." *Oksanen v. Page Mem'l Hosp.*, 945 F.2d 696, 708 (4th Cir.1991) (quoting *Collins v. Associated Pathologists, Ltd.*, 844 F.2d 473, 475 (7th Cir.1988)). As the instant motions are not ones in which "motive and intent play important roles in determination of factual issues," but rather involve legal questions for the Court to decide as a matter of law, disposition of these matters on summary judgment is appropriate. *See Doctor's Hosp. of Jefferson, Inc. v. Southeast Med. Alliance, Inc.*, 897 F.Supp. 290, 292 (E.D.La.1995) (citing *Aladdin Oil*, 603 F.2d at 1111).

III. THE EXCLUSIONARY POTENTIAL OF THE PATENT

The Eleventh Circuit found this Court's characterization of the Abbott–Geneva Agreement as a *per se* violation of Section One to be "premature" absent consideration of the protections afforded by the '207 patent. *Valley Drug Co.*, 344 F.3d at 1304. This patent, the Eleventh Circuit held, "gave Abbott the right to exclude others from making, using, or selling anhydrous terazosin hydrochloride until October of 2014, when it is due to expire." *Id.* at 1305. Because "[t]he effect of the Geneva Agreement on the production of Geneva's infringing generic terazosin product may have been no broader than the potential exclusionary effect of the '207 patent," the Eleventh Circuit directed this Court to evaluate the protections afforded by the '207 patent in determining whether the Agreement constitutes a violation of Section One. *Id.* at 1305, 1310; *see also United States v. Studiengesellschaft Kohle, m.b.H.*, 670 F.2d 1122, 1128 (D.C.Cir.1981) (holding that "the protection of the patent laws and the coverage of the antitrust laws are not separate issues."). Specifically, the Eleventh Circuit held that "[t]he appropriate analysis on remand will likely require an identification of the protection afforded by the patents and the relevant law and consideration of the extent to which the [Geneva Agreement reflects] a reasonable implementation of these." *Id.* at 1312. After such an analysis has been completed, "[a]ny provisions of the Agreement[ ] found to have effects beyond the exclusionary effects of Abbott's patent may then be subject to traditional antitrust analysis to assess their probable anticompetitive effects in order to determine whether those provisions violate § 1 of the Sherman Act." *Id.* (citing *Standard Oil Co. v. United States*, 283 U.S. 163, 175, 51 S.Ct. 421, 75 L.Ed. 926 (1931)).

Although earlier in this case, Plaintiffs challenged several provisions of the Abbott–Geneva Agreement, since the Eleventh Circuit's decision they have narrowed their Section One claims to a single provision of the Agreement—the prohibition of Geneva's marketing its generic terazosin products between the September 1, 1998, district court judgment in the '207 patent litigation and the Federal Circuit's mandate on August 12, 1999 (hereinafter, "the challenged provision" or "the appellate-stay provision").[14] With regard to that provision, the Eleventh Circuit considered

14. In their Motion for Partial Summary Judgment, the Sherman Act Class Plaintiffs acknowledge that "[s]ince the Eleventh Circuit's ruling ... Plaintiffs have focused their case (with respect to alleged actual anti-competitive effects) on the Agreement's prohibition on Geneva's entering the market regardless of whether the district court presiding over the '207 litigation found the patent invalid on summary judgment." *See* DE–1192 at n. 14.

that "[t]he '207 patent may have allowed Abbott to obtain preliminary injunctive relief or a stay of an adverse judgment pending appeal, which also would have prevented Geneva from marketing its terazosin hydrochloride products during this period." *Id.* at 1305. In so ruling, the Eleventh Circuit did not articulate any particular legal framework for this Court's analysis of the Geneva Agreement on remand. It did note, however, that to evaluate the legality of the Agreement, its provisions "should be compared to the protections afforded by the preliminary injunction and stay mechanisms and considered in light of the likelihood of Abbott's obtaining such protections." *Id.* at 1312.

In the absence of an articulated analytical framework from the Eleventh Circuit, the Court finds guidance in the writings of Professor Herbert Hovenkamp. In a recent article on the antitrust implications of settlements in intellectual property ("IP") disputes, Professor Hovenkamp addresses the complex issues that arise when parties enter into a settlement agreement that would potentially constitute an antitrust violation in the absence of claimed IP rights. In such a situation, "once conduct is found that would likely be an antitrust violation in the absence of a settlement, some care must be taken to ensure (1) that the parties did have a bona fide dispute, (2) that the settlement is a reasonable accommodation, and (3) that the settlement is not more anticompetitive than a likely outcome of the litigation." *See* Herbert Hovenkamp, Mark D. Janis & Mark A. Lemley, *The Interface Between Intellectual Property Law and Antitrust Law: Anticompetitive Settlement of Intellectual Property Disputes*, 87 Minn. L.Rev. 1719, 1727 (2003). Like the Eleventh Circuit's decision, Professor Hovenkamp's three-part test urges this Court to consider the likely outcomes of the underlying patent litigation, and in so doing, requires at least a limited inquiry into the merits of the parties' respective positions regarding the application of the "on-sale bar" and the validity of the '207 patent, viewed as of the date on which the Agreement was entered into.

Taking into account both the Eleventh Circuit's opinion and Professor Hovenkamp's analytical approach, the Court has adopted a three-part test to evaluate whether the challenged provision of the Abbott–Geneva Agreement was a reasonable implementation of the exclusionary potential of the '207 patent. First, the Court will examine the exclusionary scope of the '207 patent, and determine the extent of the protections afforded to Abbott by its patent and the relevant law. Because this determination, as discussed more fully below, requires an analysis of the underlying patent litigation and the potential for Abbott to extend its terazosin monopoly by requesting a preliminary injunction, step two requires an evaluation of the likely outcomes of the '207 patent litigation, including the likelihood of Abbott obtaining injunctive relief to keep Geneva off the market pending appeal of the patent validity issue, judged as of April 1, 1998. Finally, once the likelihood of such relief has been addressed, the Court next must determine whether the settlement represented a reasonable implementation of the protections afforded by the '207 patent, in light of the applicable law, the

At the July 2, 2004, Oral Argument, counsel for the Sherman Act Class Plaintiffs further confirmed that their only challenge to the Agreement, for purposes of these Motions, is the provision that provided for a restraint on competition going beyond the September 1998 date when the patent was found invalid. *See* Tr. [DE–1385] at 149–151.

then-pending litigation, and the general policy justifications supporting settlements of intellectual property disputes. Ultimately, if the challenged provision of the Agreement is deemed to have effects that exceed the exclusionary potential of the patent or any reasonable implementation of the patent's protections, the challenged provision can be subjected to traditional antitrust analysis in accordance with the Eleventh Circuit's decision.

A. The Exclusionary Scope of the '207 Patent

[1] The starting point for the Court's analysis on remand is to define the exclusionary scope of the '207 patent. As a basic matter of patent law, the '207 patent granted Abbott the lawful right to exclude others. *See Valley Drug,* 344 F.3d at 1304 (citing 35 U.S.C. §§ 271(a) & 283); *see also Dawson Chem. Co. v. Rohm & Haas Co.,* 448 U.S. 176, 215, 100 S.Ct. 2601, 65 L.Ed.2d 696 (1980) ("[T]he essence of a patent grant is the right to exclude others from profiting by the patented invention."). This exclusionary right is granted to allow the patentee to exploit whatever degree of market power it might gain thereby as an incentive to induce investment in innovation and the public disclosure of inventions. *See id.* (citing *Bonito Boats, Inc. v. Thunder Craft Boats. Inc.,* 489 U.S. 141, 150–51, 109 S.Ct. 971, 103 L.Ed.2d 118 (1989) & *Studiengesellschaft,* 670 F.2d at 1127); *see also Zenith Radio Corp. v. Hazeltine Research, Inc.,* 395 U.S. 100, 135, 89 S.Ct. 1562, 23 L.Ed.2d 129 (1969) (noting that a patentee may lawfully "prevent other[s] from utilizing his discovery without his consent.").

[2–4] However, the patent's exclusionary right cannot be exploited in every way. *Id.* (citations omitted); *see also* Carl Shapiro, *Antitrust Limits to Patent Settlements,* 34 RAND J. Econ. 391, 395 (2003) (theorizing that a patent "does not give the patentee 'the right to exclude' but rather the more limited 'right to *try* to exclude' by asserting its patent in court"). It is well-settled that a patent holder's protections are limited by the precise terms of the patent grant, and cannot be extended by agreement. *See Valley Drug,* 344 F.3d at 1312 (citing *United States v. Line Material,* 333 U.S. 287, 300, 68 S.Ct. 550, 92 L.Ed. 701 (1948) ("the precise terms of the grant define the limits of a patentee's monopoly and the area in which the patentee is freed from competition of price, service, quality or otherwise")); *see also United States v. Masonite Corp.,* 316 U.S. 265, 277, 62 S.Ct. 1070, 86 L.Ed. 1461 (1942) ("The owner of a patent cannot extend his statutory grant by contract or agreement. A patent affords no immunity for a monopoly not fairly or plainly within the grant."). Further, intellectual property law does not offer pharmaceutical patentees a guaranteed insulation from competition, without the risk that the patent later will be held invalid. *See* Hovenkamp, *et al.,* 87 Minn. L.Rev. at 1761. Rather than providing such unconditional protection from generic competition, "[t]he legitimate exclusion value of a pharmaceutical patent [like the '207 patent] is the power it actually confers over competition, which is in turn a function of the scope of the patent and its chance of being held valid." *Id.; see also* Shapiro, 34 RAND J. Econ. at 395 (noting that "the patentholder's rights are calibrated according to the likelihood that the patentholder would win the patent litigation, and the extent of exclusion that such a victory would permit."). The exclusionary value of the patent, therefore, cannot be defined by looking at the patent terms in a vacuum; instead, when litigation is

pending as to the validity of the patent, the chances that the patent will be held valid must be considered as part of the analysis. *Id.*

[5] The legal scope of the '207 patent, like that of any patent, is measured by its numbered claims.[15] *See Merck & Co., Inc. v. Teva Pharms. USA, Inc.*, 347 F.3d 1367, 1374 (Fed.Cir.2003); *see also Motion Picture Patents Co. v. Universal Film Mfg. Co.*, 243 U.S. 502, 510, 37 S.Ct. 416, 61 L.Ed. 871 (1917) ("The patent law simply protects [the patent holder] in the monopoly of that which he has invented and has described in the claims of his patent."). However, in this case, the Court need not define the legal scope of the patent by analyzing the terms of the patent's numbered claims and assessing whether the patent's protections extended to the Agreement's prohibition of marketing all forms of terazosin hydrochloride.[16] Instead, because the only provision of the Agreement that Plaintiffs challenge is the prohibition of Geneva's marketing its generic product until after appellate resolution of the '207 patent litigation, in analyzing the exclusionary scope of the '207 patent in accordance with the Eleventh Circuit's instructions, the relevant issue is the temporal breadth of the patent's protections. The focus of this analysis, therefore, is on the period of time for which the patent would continue to protect Abbott from generic competition.

As their summary judgment submissions reflect, the parties disagree as to whether the temporal scope of the patent's exclusions may be defined merely by reference to its expiration date, or whether a more searching analysis of the strength of the patent in the face of validity challenges is required. Defendants argue that the exclusionary scope of the patent permitted Abbott to keep Geneva's generic product off the market through appellate review of the District Court's patent validity ruling by virtue of the fact that the patent was not set to expire until October 2014. Abbott notes that "the '207 patent had the potential 'to exclude others from making, using or selling anhydrous terazosin hydrochloride until October of 2014, when it [was] due to expire.' " *See* Defs.' Sect. One Brief at 7 (citing *Valley Drug Co.*, 344 F.3d at 1305). As of April 1, 1998—the date of the Agreement—the '207 patent had never been held invalid and, therefore, still enjoyed the presumption of validity.

15. Although the '207 patent includes four claims, in the underlying patent litigation, Abbott only asserted infringement of claim 4, which defines the claimed crystalline form of anhydrous terazosin hydrochloride (Form IV) in terms of an analytical method called x-ray powder diffractometry.

16. The Agreement prevented Geneva from selling, offering for sale, donating or otherwise distributing in the United States "any Terazosin Hydrochloride Product" until after the earlier of the Generic Entry Date or the Appellate Judgment (as both terms are defined in Section I.C., above). *See* Ex. 1, Tab A at ¶ 20, Exs. to Defs.' Mot. for Summ. J. on Sherman Act Section One (and Analogous Claims). In turn, "Terazosin Hydrochloride Product" is defined as "any pharmaceutical product, regardless of formulation or dosage form (tablet, capsule, etc.) containing terazosin hydrochloride." Although the restriction on Geneva's marketing of *any* terazosin hydrochloride product appears to extend well beyond the protections of the patent, this issue is not before the Court at this time given Plaintiffs' narrowing of their Section One claims. *See supra* n. 14. However, because the Eleventh Circuit directed the Court to assess whether the challenged provision may be justified as ancillary to another agreement (which, together with the challenged provision, could have the overall effect of enhancing competition), the Court will briefly address this issue later in its analysis.

Abbott concludes, therefore, that as of April 1, 1998, the exclusionary scope of the patent protected it from generic competition up to and including October 2014, without regard to the patent validity issues being litigated in the Northern District of Illinois. As further support for construing the patent as protecting Abbott from generic competition through the patent's natural expiration date, Abbott notes that the patent examiner at the United States Patent and Trademark Office ("PTO") had already considered and rejected the very argument regarding the "on-sale bar" on which Geneva based its only validity challenge. *Id.* Plaintiffs, in turn, respond that Defendants' approach would render the Eleventh Circuit's instructions on remand inconsequential, as there would be no need to analyze the exclusionary potential of the patent and consider the likelihood of Abbott obtaining injunctive relief if the matter were as simple as looking at the patent's expiration date.

[6] Defendants' argument, however facially appealing, represents an overly simplistic approach to the Eleventh Circuit's opinion. It fails to take into account the advanced stage of the underlying patent litigation and the substantial questions that Geneva had asserted regarding the '207 patent's validity. At the time that the Agreement was entered into, Defendants were nearly two years into their patent infringement litigation, and Geneva's Motion for Summary Judgment—in which it asserted a strong legal challenge to the validity of the '207 patent under the "on-sale bar"—had been fully briefed for approximately one year. As will be addressed more fully in step two of the Court's analysis, Geneva's challenge to the patent represented a substantial question as to validity, and was premised on solid legal precedent in the Federal Circuit. The chance that the '207 patent would be held valid—an essential part of the equation for defining the legitimate exclusionary value of the patent—was not high as of April 1, 1998. Given the significant likelihood that Geneva would prevail and that the patent would be held invalid, the mere fact that the patent was, at the time, not set to expire until October 2014 cannot immunize Defendants from antitrust scrutiny of their Agreement. Indeed, any construction of the patent's exclusionary scope as of April 1, 1998, that fails to take into account the chances of the patent being held invalid would essentially afford pioneer drug manufacturers an unbridled power to exclude others without regard to the strength of their patent rights. Such an interpretation would give the patent holder rights beyond those granted by the Patent Act, and beyond the structure contained in the Hatch–Waxman Act.

Further, Abbott's reliance on the PTO examiner's prior rejection of Geneva's "on-sale bar" argument is unpersuasive. First, "the question whether the on sale bar applies is a question of law, *UMC Elecs. Co. v. United States*, 816 F.2d 647, 657 (Fed.Cir.1987). The Patent Office's decisions on questions of law are reviewed 'without deference to the views of the Agency.'" *Abbott Labs. v. Geneva Pharms., Inc.*, No. 96 C 3331, 1998 WL 566884, at *5 n. 9 (N.D.Ill. Sept.1, 1998) (citing *In re Brana*, 51 F.3d 1560, 1568 (Fed.Cir.1995)). Therefore, the Court need not attribute any particular weight to the PTO examiner's analysis of this legal question. Second, as addressed in the Court's Order on Plaintiffs' Section Two

claims,[17] the PTO Examiner's review of the '207 patent was based on a one-sided, *ex parte* presentation of the issue; Geneva was not given the opportunity to present the PTO with its position on the validity of the '207 patent, and Abbott's patent lawyer did not provide the PTO examiner with the citation to *LaPorte,* which was relied on by the District Court in ruling the patent invalid. *See* DE–1419 at 24. Although this Court, in its Section Two Order, concluded that there was insufficient evidence that the failure to cite *LaPorte* was knowing or willful—such that it could rise to the level of *Walker Process* [18] fraud or attempt to defraud the PTO—this failure does substantially undermine Defendants' reliance on the PTO's decision. Further, the *ex parte* nature of the process renders its ultimate result, particularly on questions of law, unworthy of deference. *See In re Brana,* 51 F.3d at 1568. The Court, therefore, must reject Defendants' argument that further analysis of the scope of the patent's protections is unnecessary in light of the patent's October 2014 expiration date and the PTO's rejection of the "on-sale bar" challenge.

B. The Likely Outcomes of the Patent Litigation

[7] For the reasons stated above, it is clear that any definitive construction of the exclusionary scope of the patent requires at least a limited assessment of the underlying patent infringement case. Therefore, the second step of the Court's analysis focuses on the likely outcomes of the patent litigation that was pending at the time the parties entered into the Agreement. *See Valley Drug,* 344 F.3d at 1312. By exploring the likely outcomes of the litigation, the Court can delineate the protections afforded by the patent with due consideration for the significant challenge to the '207 patent's validity that Geneva raised in the infringement action.

1. *The Preliminary Injunction Analogy*

To evaluate the likely outcomes of the patent infringement litigation, the Eleventh Circuit specifically directed this Court to consider the analogy of the Agreement being like a preliminary injunction or stay pending appeal. Specifically, the Eleventh Circuit considered that "the '207 patent may have allowed Abbott to obtain preliminary injunctive relief or a stay of an adverse judgment pending appeal, which also would have prevented Geneva from marketing its terazosin hydrochloride products during [the relevant] period." *Valley Drug,* 344 F.3d at 1305.

17. On August 31, 2004, this Court granted Defendants' Motion for Summary Judgment on Sherman Act Section Two (and Analogous) Claims, and denied Kaiser's Motion for Summary Judgment on Sham Litigation. *See In re Terazosin Hydrochloride Antitrust Litig.,* 335 F.Supp.2d 1336 (S.D.Fla.2004). 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. In its Order, the Court concluded that Plaintiffs failed to show that any of Abbott's seventeen patent infringement lawsuits were objectively baseless or that Abbott had a subjective bad-faith intent to abuse the judicial process in violation of the Sherman Act. *Id.* In connection with the '207 patent, this Court held that there was no record evidence of fraud or an attempt to commit fraud to procure the '207 patent. *Id.* Of course, that holding does not preclude a finding here that the PTO's conclusions are not entitled to deference because the examiner did not have before him one of the key cases upon which the "on-sale bar" issue hinged.

18. *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.,* 382 U.S. 172, 86 S.Ct. 347, 15 L.Ed.2d 247 (1965).

The Eleventh Circuit was careful to note the significance of the word "may" in this comment; in so doing, the Court emphasized that it did "not hold that the '207 patent *would* have allowed Abbott to obtain a preliminary injunction or a stay of an adverse judgment pending appeal. [The Eleventh Circuit meant] only that these are among the considerations that the district court should address on remand." *Id.* at n. 17.

As discussed above, Defendants theorize that the Court need not reach this preliminary injunction analogy because the temporal scope of the patent's protections extended through its expiration date in October 2014, without regard to the pending infringement action. Having already considered and rejected that argument, the Court turns to Defendants' alternative theory, that Abbott could have obtained a preliminary injunction or stay pending appeal to keep Geneva's product off the market until after an appellate court ruling on the patent's validity. Defendants argue that such provisional relief would have had an exclusionary effect reasonably equivalent to that of the Geneva Agreement and, therefore, the challenged provision of the Agreement should not be subject to antitrust analysis. Plaintiffs, however, argue that at the time the Agreement was entered into, Abbott had no chance of obtaining a preliminary injunction to keep Geneva off the market even if the district court in the '207 patent case later held the patent invalid on summary judgment.

As a threshold matter, the parties fundamentally disagree as to what degree of certainty is required for Abbott to establish that it could have obtained a preliminary injunction. Central to their arguments is the language from the Eleventh Circuit's opinion suggesting that the challenged provision "should be compared to the protections afforded by the preliminary injunction and stay mechanisms and considered in light of *the likelihood* of Abbott's obtaining such protections." *Valley Drug Co.*, 344 F.3d at 1312 (emphasis added). From the word "likelihood," Plaintiffs infer that the Agreement will be found to exceed the exclusionary potential of the '207 patent unless Defendants show that it was *more probable than not* that Abbott would have obtained an injunction with exclusionary effects equal to the restraints in the Agreement. Plaintiffs cite both Webster's New Collegiate Dictionary and Black's Law Dictionary for the proposition that "the plain meaning of 'likelihood' is 'probability.' " Next, Plaintiffs note that Black's Law Dictionary further defines "probability" as "a condition or state created when there is more evidence in favor of the existence of a given proposition than there is against it." *See Turnpike Nissan, Inc., v. Nissan Motor Corp.*, 150 B.R. 345, 346 (Bkrtcy.M.D.Pa.1992).

Defendants, on the other hand, interpret the Eleventh Circuit's opinion to require only that provisional relief be a "reasonable possibility" in the '207 litigation. Defendants base their interpretation, in part, on a section of the Hovenkamp treatise cited in the Eleventh Circuit's opinion. In section 2046 of *Antitrust Law: An Analysis of Antitrust Principles and their Application* (1999), Hovenkamp began with the premise that the legal system encourages settlement of conflicting intellectual property claims, especially "where the settlement is certainly no more anti-competitive than [a] possible outcome" of the litigation and where "each party's claim seemed reasonably legitimate but also seemed subject to a reasonable risk of failure—that is, each party was in a posi-

tion where settlement seemed to be a reasonable act." *Id.* at 262–64. Because Hovenkamp focused on the reasonableness of the settlement and the *possible* outcomes of litigation, Defendants conclude that the appropriate interpretation of the Eleventh Circuit's decision is whether injunctive relief is a reasonable possibility.

There is some degree of ambiguity in the word "likelihood," and there is no clear guidance in the Eleventh Circuit's opinion as to which of the parties' interpretations is more accurate. The Court therefore looks to prior opinions of this Circuit for guidance on the appropriate use of the word "likelihood." The Eleventh Circuit and the former Fifth Circuit [19] have previously held, albeit in different contexts, that "the word likelihood is synonymous with probability." *Shatel Corp. v. Mao Ta Lumber & Yacht Corp.,* 697 F.2d 1352, 1356 n. 2 (11th Cir.1983); *see also Faciane v. Starner,* 230 F.2d 732, 738 (5th Cir.1956) (using the words "likelihood" and "probability" coextensively in addressing the degree of consumer confusion necessary to support a trademark infringement action). However, in defining the word "probability," the Eleventh Circuit has recognized that it is capable of two definitions: a lower "reasonable probability" standard, or a higher "more likely than not" standard. *Johnson v. Singletary,* 938 F.2d 1166, 1200 n. 6 (11th Cir.1991). But ultimately, the definition most often applied in this Circuit's precedent is the "more likely than not" standard. *See Mercantile Tex. Corp. v. Bd. of Governors of Fed. Reserve Sys.,* 638 F.2d 1255, 1268 (5th Cir.1981) ("A probability signifies that an event has a better than fifty percent chance of occurring"). Although support exists for both interpretations, it is the Plaintiffs' proposed definition that is best suited for this Court's analysis on remand. Therefore, in assessing the likelihood that Abbott could have obtained a preliminary injunction or stay pending appeal, the Court must determine whether it was more probable than not that Abbott would be entitled to such relief.

2. *The Federal Circuit's Standard for Injunctive Relief*

[8] Having resolved the meaning of the word "likelihood" in the Eleventh Circuit's opinion, the Court turns to one of the primary issues presented on remand: whether it was more likely than not that Abbott could have obtained a preliminary injunction or stay pending appeal to keep Geneva off the market until after the Federal Circuit had reviewed the District Court's invalidity decision. Because any motion for injunctive relief would have been reviewed by the Federal Circuit, it is undisputed that Federal Circuit law provides the appropriate precedent for this analysis. In the Federal Circuit, the party seeking the "extraordinary relief" of a preliminary injunction must demonstrate: (1) a reasonable likelihood of success on the merits; (2) irreparable harm if the injunction were not granted; (3) the balance of the hardships; and (4) the impact of the injunction on the public interest. *Reebok Int'l Ltd. v. J. Baker, Inc.,* 32 F.3d 1552, 1555 (Fed.Cir.1994) (citing *Hybritech, Inc. v. Abbott Labs.,* 849 F.2d 1446, 1451 (Fed. Cir.1988)); *see also Helifix Ltd. v. Blok–Lok, Ltd.,* 208 F.3d 1339, 1350–51 (Fed.Cir. 2000). Although Plaintiffs generally dispute Abbott's ability to demonstrate any of the four requisite elements for obtaining injunctive relief, the dominant focus of the parties' briefs is the requirement that the

19. *See supra* n. 13.

movant establish a reasonable likelihood of success on the merits.

a. *Likelihood of Success on the Merits for Patent Injunctions*

[9–11] In the patent context, "a reasonable likelihood of success" requires a showing of validity and infringement. *Reebok,* 32 F.3d at 1555 (citing *Hybritech,* 849 F.2d at 1451). Thus, Abbott had to show that, in light of the presumptions and burdens that will inhere at trial on the merits, (1) it will likely prove that Geneva's ANDA infringes the '207 patent, and (2) its infringement claim will likely withstand Geneva's challenges to the validity of the '207 patent. *Genentech, Inc. v. Novo Nordisk, A/S, et al.,* 108 F.3d 1361, 1364 (Fed.Cir.1997) (citing *New England Braiding Co. v. A.W. Chesterton Co.,* 970 F.2d 878, 882–83 (Fed.Cir.1992)). In the '207 litigation, it was undisputed that Geneva's proposed generic product infringed the '207 patent. Thus, the case presented none of the complicated claims construction issues that mark some patent infringement actions. The focus, instead, was on a single legal issue regarding the validity of the '207 patent in light of Geneva's challenge based on the "on-sale bar." In such cases, if the alleged infringer—here, Geneva—raises a "substantial question" concerning validity (*i.e.,* asserts a defense that the patentee cannot show "lacks substantial merit") the preliminary injunction should not issue. *Id.; see also Helifix,* 208 F.3d at 1351. For Geneva to raise a "substantial question" on validity for injunctive purposes, it need not demonstrate to a legal certainty that it would ultimately win at trial. Indeed, "[v]alidity questions during preliminary injunction proceedings can be successful, that is, they may raise substantial questions of invalidity, on evidence that would not suffice to support a judgment of invalidity at trial .... Vulnerability is the issue at the preliminary injunction stage, while validity is the issue at trial." *Amazon.com, Inc. v. Barnesandnoble.com, Inc.,* 239 F.3d 1343, 1358–59 (Fed.Cir.2001) (citations omitted).

[12] Abbott argues, however, that if it alleges irreparable harm that is "sufficiently serious, it is only necessary that there be a fair chance of success on the merits." *See Standard Havens Prods. v. Gencor Indus., Inc.,* 897 F.2d 511, 513 (Fed.Cir. 1990) (citing *William Inglis & Sons Baking Co. v. ITT Cont'l Baking Co.,* 526 F.2d 86, 88 (9th Cir.1975)). It is true that a patent is presumed valid, 35 U.S.C. § 282 (1994), and a party challenging validity must prove invalidity by clear and convincing evidence. "However, the presumption does not relieve a patentee who moves for preliminary injunction from carrying the normal burden of demonstrating that it will likely succeed on all disputed liability issues at trial, even when the issue concerns the patent's validity." *Helifix,* 208 F.3d at 1351 (citing *New England Braiding,* 970 F.2d at 882). Therefore, had it moved for a preliminary injunction to keep Geneva off the market pending appeal of the district court's invalidity ruling, Abbott would still have been held to the requirement of demonstrating a reasonable likelihood of success on the merits.

An assessment of the likelihood that Abbott could have obtained injunctive relief, therefore, requires that this Court consider the likelihood of Abbott prevailing on the merits of the '207 patent litigation, gauged as of the date on which the Agreement was entered into. *See Valley Drug Co.,* 344 F.3d at 1306 ("We begin with the proposition that the reasonableness of agreements under the antitrust laws are to be judged at the time the agreements are

entered into.") (citations omitted). To situate this analysis in the proper temporal framework, it is important to note that as of April 1, 1998, the '207 patent litigation had been pending for nearly two years, and Geneva's Motion for Summary Judgment had been fully briefed for just short of one year. Geneva, in its summary judgment motion, asserted that the '207 patent was invalid because the claimed invention was "on sale" more than one year prior to the patent's earliest filing date. Abbott challenged the application of the "on-sale bar" on the grounds that "the presence of Form IV anhydrous terazosin hydrochloride in the transactions at issue here was, at most, an unintended accident to which both the buyer and seller were wholly indifferent." *See* Pls.' Mot. for Partial Summ. J., Vol. II, Ex. 5 at AL00019057. Of particular relevance to Abbott's present argument is whether Geneva's "on-sale bar" argument raised a "substantial question" concerning the patent's validity, and whether Abbott could demonstrate that the asserted defense "lacks substantial merit." *See Genentech*, 108 F.3d at 1364; *see also Helifix*, 208 F.3d at 1351.

Because the reasonableness of the Agreement is to be assessed as of the date on which it was entered into, this Court may not rely on the District Court's analysis of the '207 patent or on its ultimate conclusion that the patent was invalid under the "on-sale bar." To a certain extent, this Court is placed in the difficult position of having to "unring the bell"; although the District Court and Federal Circuit decisions in the underlying '207 patent litigation have been scrutinized in relation to other portions of this case, for purposes of this analysis, the Court must, in essence, act as if they had not yet been issued.[20] Indeed, the Court cannot be swayed by the subsequent invalidity of the patent. *See Valley Drug*, 344 F.3d at 1306–07 ("the mere subsequent invalidity of the patent does not render the patent irrelevant to the appropriate antitrust analysis.").[21] However, the analysis that this Court must undertake in deciding whether the "on-sale bar" issue would have entitled Abbott to a preliminary injunction pending appeal is far more limited than that which the District Court, hearing the underlying '207 patent dispute, was required to undertake. There, the Court had to analyze a broad range of cases in the Federal Circuit interpreting the parameters of the "on-sale bar." Here, the relevant issue is simply whether Geneva's "on-sale bar" challenge raised "substantial questions" as to the validity of the '207 patent, and whether Abbott had, as of April 1, 1998, demon-

20. The Court thus rejects Plaintiffs' reliance, in assessing Abbott's chances of obtaining a preliminary injunction pending appeal, on the District Court's decision regarding invalidity. While the decision is strong evidence that the District Court would not have issued a preliminary injunction, the relevant analysis requires this Court to situate itself in the world as it existed on April 1, 1998, when no decision as to validity had been rendered.

21. The Eleventh Circuit went on to explain the justification for its decision that the Court cannot be guided by the subsequent invalidity of the patent. "[E]xposing settling parties to antitrust liability for the exclusionary effects of a settlement reasonably within the scope of the patent merely because the patent is subsequently declared invalid would undermine the patent incentives. Patent litigation is too complex and the results too uncertain for parties to accurately forecast whether enforcing the exclusionary right through settlement will expose them to treble damages if the patent immunity were destroyed by the mere invalidity of the patent." *Valley Drug*, 344 F.3d at 1308. This Court, therefore, is not considering the subsequent invalidity of the patent, but rather is assessing the chances, gauged as of April 1, 1998, of Abbott succeeding in defending its patent.

strated that Geneva's challenge was significantly without merit.

b. *The "On–Sale Bar" Issue in the '207 Suit*

[13–15] The primary issue presented in Geneva's motion for summary judgment in the patent infringement action was whether the "on-sale bar" of 35 U.S.C. § 102(b) invalidated claim 4 of the '207 patent. Under § 102(b), a patent is invalid if the invention it claims was offered for sale or sold in the United States more than one year prior to the filing date of the patent application. The "on-sale bar" does not require sustained commercial activity, advertising, or displays. On the contrary, a single sale or even a single offer to sell is sufficient to trigger the statutory bar. *In re Caveney,* 761 F.2d 671, 676 (Fed.Cir. 1985). Moreover, the sale or offer for sale need not be made by the inventor or by the patent owner. A sale or offer for sale by a third party is just as effective a bar as a sale or offer by the inventor. *Id.; see also LaPorte,* 787 F.2d at 1581 (the "bar is not limited to sales by the inventor or one under his control, but may result from the activities of a third party").

The application for the '207 patent was filed on October 18, 1994. Therefore, the critical date for purposes of the "on-sale bar" was October 18, 1993. Through its summary judgment submissions, Geneva effectively demonstrated that prior to October 18, 1993, there had been at least three sales involving anhydrous terazosin hydrochloride that Byron Chemical Company ("Byron") bought from its overseas supplier and then sold to Geneva in the United States. In light of those sales, it is evident that the "on-sale bar" applied absent some exception to the rule. Once Geneva raised this substantial question regarding the validity of the patent, Abbott—in order to avoid invalidation of the '207 patent—had the burden of challenging the application of the "on-sale bar" based on the pre–1993 sales. In a creative effort to meet that burden, Abbott argued that: (1) application of the bar to this case was not supported by any of the policies underlying § 102(b); (2) the subject matter of the sales did not fully anticipate the claimed invention; and (3) Geneva did not demonstrate that the invention was complete and "known to work for its intended purpose," in accordance with *Seal–Flex, Inc. v. Athletic Track & Court Constr.,* 98 F.3d 1318, 1324 (Fed.Cir.1996).

[16] However, none of Abbott's challenges to the application of the "on-sale bar" in the '207 patent litigation demonstrated that Geneva's position lacked substantial merit. As to the policy issue, the first policy underlying § 102(b)—the only one that was implicated in the '207 patent litigation—clearly supported application of the bar.[22] The first policy underlying § 102(b) is to "discourag[e] removal of in-

22. 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 invention beyond the statutorily prescribed time. *In re Mahurkar Double Lumen Hemodialysis Catheter,* 71 F.3d 1573, 1577 (Fed.Cir. 1995); *see also UMC Elecs. v. United States,* 816 F.2d 647, 652 (Fed.Cir.1987), *cert. denied,* 484 U.S. 1025, 108 S.Ct. 748, 98 L.Ed.2d 761 (1988). At the time of the Agreement, Federal Circuit precedent required an analysis of the totality of the circumstances for application of the § 102(b) bar, considered in view of these underlying policy justifications. *Mahurkar,* 71 F.3d at 1577. It was undisputed in

ventions from the public domain that the public reasonably has come to believe are freely available." *In re Mahurkar Double Lumen Hemodialysis Catheter*, 71 F.3d 1573, 1577 (Fed.Cir.1995). As part of its policy issue argument, Abbott argued that there was no fear that the public would be deprived of Form IV terazosin hydrochloride because neither the buyers nor the sellers were aware that they were purchasing that particular invention. Abbott's contention that the parties to the transaction had to be aware of the particular crystal form of the anhydrous terazosin hydrochloride that was the subject of the sales was weak and contrary to established Federal Circuit precedent.[23] *See LaPorte*, 787 F.2d at 1583 ("it is well settled in the law that there is no requirement that a sales offer specifically identify all the characteristics of an invention offered for sale or that the parties recognize the significance of all of these characteristics at the time of the offer.").[24] Moreover, the reality is that the buyers to the pre–1993 transactions were counting on the continued availability of anhydrous terazosin hydrochloride, and they had specifically requested this anhydrous terazosin in order to avoid infringing Abbott's '532 patent for dihydrate terazosin. Abbott also contended that the invention had not been "disclosed" to the public. However, Federal Circuit precedent held that disclosure of the invention to the public was not required. *See LaPorte*, 787 F.2d at 1583 ("our precedent holds that the question is not whether the sale, even a third party

the '207 patent litigation that the third and fourth justifications were not implicated because the sales at issue were made by a third party and not by the inventor. And further, the second policy justification was not implicated since it was undisputed that Abbott moved promptly to disclose its invention through the patent process. Therefore, the only policy justification that was possibly implicated was the first one.

23. Plaintiffs argue that *LaPorte* barred Abbott's ''conception'' argument in the '207 case. *See* D.E. 1192 at 15 (citing *LaPorte*, 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 his 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 invention had been produced from the embodiment of the original invention (*i.e.*, the photograph). *Id.* at 1583.

24. Indeed, as the Sherman Act Class Plaintiffs note in their Motion for Partial Summary Judgment, acceptance of Abbott's argument—that a sale under § 102(b) must disclose all particulars of an invention, not just the invention itself—not only would have contravened *LaPorte*, but also would have plainly frustrated the first policy underlying 102(b). ''Under Abbott's argument, if Geneva had been buying and using terazosin for ten, fifteen or twenty years, but did not know its x-ray diffraction pattern ... Abbott could still come along one day, snap its special x-ray pictures, file a patent and force Geneva off the market.'' *See* Pls.' Mot. for Part. Summ. J., at 17. Such a result would certainly run afoul of the policy discouraging removal of inventions from the public domain that the public had come to rely upon.

sale, 'discloses' the invention to the public, but whether the sale relates to the device that embodies the invention.").

Second, Abbott's argument that the subject matter of the sales did not fully anticipate the claimed invention was also without significant support. Abbott premised its argument on the fact that the parties to the transactions did not appreciate that Form IV terazosin was involved. However, it is undisputed that the parties knew that the sale embodied, and in fact requested, anhydrous terazosin hydrochloride. Abbott had no persuasive legal support for its argument that the parties had to anticipate the particular crystal form of the anhydrous terazosin hydrochloride.

And third, while Abbott argued that the invention was not complete and "known to work for its intended purpose," the record was undisputed that the lots of terazosin hydrochloride that Geneva purchased were acceptable for "development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs"—the articulated purpose for which Geneva purchased the anhydrous terazosin. Abbott's '207 summary judgment papers, therefore, failed to demonstrate that Geneva's "on-sale bar" challenge was substantially without merit.

This is not to say that Abbott's arguments were legally frivolous or in bad faith. To the contrary, in the Order granting Defendants' Motion for Summary Judgment on Section Two of the Sherman Act, the Court found that the undisputed evidence did not support the legal conclusion that the '207 litigation was a sham or that it was objectively baseless. *See supra* n. 17. The focus of the analysis here, however, is not whether the litigation was frivolous and baseless, but rather on whether, upon Geneva's assertion of "substantial questions" regarding the validity of the '207 patent, Abbott was able to demonstrate that Geneva's arguments were substantially without merit. Because the Court concludes that Abbott's challenge to Geneva's "on-sale bar" argument, judged as of April 1, 1998, was weak and unlikely to result in a District Court finding that the '207 patent was valid, it follows that Abbott was unlikely to obtain a preliminary injunction to keep Geneva off the market through appellate resolution of the "on-sale bar" issue.[25]

3. *The Likely Outcomes of the '207 Patent Litigation*

[17] The Eleventh Circuit's focus, with respect to the likely outcomes of the litigation, was on whether Abbott could have obtained injunctive relief. For that reason, the Court has primarily addressed whether Abbott would have been able to meet the exacting requirements for obtaining the "extraordinary relief" of a preliminary injunction at that time. However, the foregoing analysis of the strength of Abbott's position in the underlying patent infringement case also indicates that there was only one likely ultimate outcome of

25. Although there are three other elements that courts examine in deciding whether a preliminary injunction should issue, the failure to demonstrate likelihood of success on the merits is fatal to Abbott's chances of obtaining injunctive relief. *See New England Braiding,* 970 F.2d at 880–85 (Fed.Cir.1992); *Reebok,* 32 F.3d at 1556; *see also Amazon.com. Inc.,* 239 F.3d at 1350–51. The Court, therefore, need not even reach the remaining factors of the injunction test. *Glaxo Group Ltd. v. Ranbaxy Pharms., Inc.,* 262 F.3d 1333, 1339 (Fed.Cir.2001).

the '207 patent litigation: that the patent would be found invalid.[26]

C. The Challenged Provision Was Not a Reasonable Implementation of the Patent's Protections

[18] Having concluded that Abbott was not likely to qualify for a preliminary injunction as of April 1, 1998, the Court must examine whether the settlement, or significant parts of it, was a reasonable implementation of the protections afforded by the '207 patent and the relevant law. *See Valley Drug,* 344 F.3d at 1312 (noting that the appropriate analysis on remand will likely require consideration of the extent to which the Agreement reflects "a reasonable implementation" of the protections afforded by the patent and the relevant law"). It cannot be disputed that settlement in general—as an alternative to protracted and costly litigation—provides a number of private and social benefits. *See generally* Shapiro, 34 RAND J. Econ. at 394. Private benefits include the avoidance of the burdensome litigation costs associated with complex litigation, and the resolution of uncertainty regarding the respective rights and obligations of party litigants. *Id.* Beyond cost savings, settlement of pharmaceutical patent disputes often serves the public interest not only by reducing congestion in the court system, but also by facilitating competition. For instance, the prompt resolution of patent litigation may clear the path for generic drug manufacturers to enter the market earlier than if the litigation were extended until a final court judgment. *See In re Tamoxifen Citrate Antitrust Litig.,* 277 F.Supp.2d 121, 133 (E.D.N.Y.2003) (noting that the settlement resolved the parties' complex patent litigation, and in so doing, "cleared the field" for other ANDA filers). Likewise, those Hatch–Waxman settlements that result in the alleged infringer's purchase of an exclusive or non-exclusive license from the patentee may benefit the public by introducing a new rival into the market, facilitating competitive production, and encouraging further innovation. *See* Hovenkamp, *et al.,* 87 Minn. L.Rev. at 1750–51.

In this case, Abbott has suggested that the Agreement as a whole represented a reasonable implementation of the patent's protections [27] because, *inter alia,* (1) the parties were operating against "a backdrop of mutual risk and uncertainty," as an immediate launch by Geneva of its capsule product would have created substantial legal and financial risks for both Abbott and

26. Further, given the record in the patent infringement action, once the District Court found the patent to be invalid, it was even less likely that Abbott could obtain a stay pending appeal. The standard for obtaining a stay pending appeal is essentially the same as that for obtaining a preliminary injunction, only the movant is required to demonstrate a "strong showing that he is likely to succeed on the merits." *See Standard Havens Prods., Inc. v. Gencor Indus., Inc.,* 897 F.2d 511, 513 (Fed.Cir.1990). Given the weakness of Abbott's challenge to the application of the "on-sale bar," it is highly unlikely that the District or Appeals Court would have granted a stay pending appeal of the invalidation ruling. Indeed, Defendants have not cited any cases in which a stay pending appeal was granted in favor of a patentee whose patent was invalidated before the District Court.

27. Of course, Defendants most prominent argument for the reasonableness of the challenged provision is that injunctive relief was a reasonable possibility in the '207 patent litigation, and that the delay of generic entry through appellate resolution of the infringement action was therefore within the exclusionary potential of the patent. As this argument has been addressed extensively earlier in this Order, it is not repeated here in the third step of the Court's analysis.

Geneva; [28] (2) the challenged provision was ancillary to an Agreement whose overall effect was to efficiently dispose of litigation and thereby maximize competition; and (3) there was a high reversal rate by the Federal Circuit in patent cases. While at first glance, these justifications appear viable, they ultimately fail to establish that the appellate-stay provision represented a reasonable implementation of Abbott's patent protections.

First, most of the private and public benefits that generally come with settlements materialize primarily when the settlement terminates the entire litigation between the parties. *See Tamoxifen*, 277 F.Supp.2d at 133 (examining the settlement in this case and concluding that the Abbott–Geneva agreement "meant that the litigation could drag on without providing other generic manufacturers ... a means by which to enter the market."); *see also In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F.Supp.2d 188, 242–43 (E.D.N.Y.2003) (relying on the fact that the parties' settlement resolved the underlying patent disputes as support for finding that the agreement was reasonable). Thus, any examination of the reasonableness of the settlement that resulted in the Abbott–Geneva Agreement must take into account what the settlement actually resolved.[29] *See In re the Matter of Schering–Plough Corp., et al.*, FTC Docket No. 9297, at 13 n. 26, 2003 WL 22989651 (FTC 2003) (noting the distinction between interim and final settlements). The Abbott–Geneva Agreement here did not settle any hotly contested litigation, whose final outcome was difficult to predict. In fact, unlike the settlement agreements in *Tamoxifen* and *Ciprofloxacin*, the Agreement here settled no litigation at all. At best, the Abbott–Geneva Agreement resolved a hypothetical preliminary injunction motion that Abbott states it intended to, but never did, file.

[19, 20] Second, although settlements are favored over litigation because they allow litigants to avoid risk and uncertainty, this alone cannot insulate a settlement agreement from antitrust scrutiny.[30] It is

28. Expanding on the "backdrop of mutual risk and uncertainty," Defendants state that Abbott's risk was that if it failed to obtain injunctive relief, it would have suffered enormous financial damages at the bands of a small generic company that might well not be able to satisfy a judgment in Abbott's favor if Abbott ultimately prevailed in the litigation. *See* Defs.' Brief at 4. Geneva's risk, in turn, was that if it defeated preliminary injunctive relief and marketed its product, it would have put itself at risk of a ruinous damages award against it in the litigation. And, if Geneva had brought its product to market and subsequently been preliminarily enjoined, it would have lost forever its claim to the 180–day exclusivity period once it had been triggered.

29. Defendants object to the Court's consideration of what the Agreement actually settled, arguing that because the Eleventh Circuit did not identify it as a factor to be addressed on remand, it is inappropriate for this Court to do so. However, the Eleventh Circuit's opinion was not a precise delineation of factors to be considered on remand. In fact, the Circuit noted that its holding at that early stage of the litigation was "appropriately narrow," and it was merely "offer[ing] several observations with respect to the framework to be developed on remand for deciding the appropriate antitrust analysis." *Valley Drug*, 344 F.3d at 1306. The Circuit's decision, therefore, cannot be seen as prohibiting the consideration of other factors, including one—such as the reality of what the agreement actually resolved—that is so central to any discussion of the reasonableness of a settlement agreement.

30. Affording such deference to settlements would ignore the realities of patent litigations and disregard the competitive implications of settlement accords. As Hovenkamp recognized, uncertainty may itself encourage collusive agreements; therefore, where the parties are in a position of uncertainty regarding the

well-known that "parties to an intellectual property dispute have a strong incentive to enter into agreements that maximize their own interests but disserve the public's interest with respect to either competition or innovation." *See* Hovenkamp, *et al.*, 87 Minn. L.Rev. at 1722. Parties to an IP dispute "are more interested in maximizing their own profits than enhancing the public welfare." *Id.* Thus, while reducing risk and uncertainty is a legitimate benefit of settlements, antitrust tribunals reviewing settlements in patent disputes cannot simply rubber-stamp the parties' accords because they are in line with the litigants' own self-interest. Indeed, there is nothing magical about a settlement that immunizes an agreement that may otherwise violate the antitrust laws. *See, e.g., United States v. Singer Mfg., Co.*, 374 U.S. 174, 83 S.Ct. 1773, 10 L.Ed.2d 823 (1963); *United States v. New Wrinkle*, 342 U.S. 371, 72 S.Ct. 350, 96 L.Ed. 417 (1952). Here, the mere fact that the Agreement permitted Defendants to minimize their risk and uncertainty cannot insulate it from antitrust scrutiny, particularly in light of the determination that the challenged provision went beyond Abbott's rightful patent protections.

Third, Defendants' argument that the challenged provision was ancillary to a reasonable, efficiency-enhancing settlement agreement is belied by the realities of what the Agreement actually resolved and the remaining terms of the Agreement. The Eleventh Circuit noted that particular provisions of the Agreement should not be considered in isolation, as "agreements that are anticompetitive when considered in isolation (such as covenants not to compete) can still be lawful, if they are viewed as ancillary to another agreement and, when viewed in combination, will have the overall effect of enhancing competition." *Valley Drug,* 344 F.3d at 1313, n. 31 (citing *Business Elecs. Corp. v. Sharp Elecs. Corp.*, 485 U.S. 717, 729, 108 S.Ct. 1515, 99 L.Ed.2d 808 (1988)). But as the Federal Trade Commission recognized in *Schering–Plough*, where an agreement involves an interim rather than a final settlement, it is far more difficult for the litigants to claim that the agreement was ancillary to an efficient disposition of the litigation. *Schering–Plough*, FTC Docket No. 9297 at 13, n. 26, 2003 WL 22989651. Here, the Agreement did not resolve or even simplify Abbott's patent infringement action against Geneva in the Northern District of Illinois; to the contrary, the Agreement tended to prolong that dispute to Abbott's advantage, delaying generic entry for a longer period of time than the patent or any reasonable interpretation of the patent's protections would have provided. Further, the remaining provisions of the Agreement, rather than being catalysts for competition and resolution of litigation, are comprehensive restraints on Geneva's market entry plans that by their very terms far exceed the legal scope of the patent's provisions. Thus, there is no discernable basis for salvaging the challenged provision as ancillary to an otherwise pro-competitive and efficiency enhancing agreement.[31]

scope and or validity of a patent, there is particular concern that the resulting settlement agreement may represent an unlawful restraint. *See* Hovenkamp, *et al.*, 87 Minn. L.Rev. at 1722 ("Incentives to collude are hardly reduced by the fact that a dispute concerns IP. To the contrary, the uncertain scope and validity of IP rights may encourage a collusive settlement, serving both to remove the uncertainty and to permit the two firms to share monopoly profits.").

31. The question of whether the challenged provision is reasonably ancillary to the Agreement's procompetitive core is more appropriately addressed in Section IV, below, in

And finally, the reversal rate in patent cases cannot protect the Agreement in this case from antitrust scrutiny, particularly in light of the low probability that Abbott would have prevailed on the merits of the '207 patent infringement action. Defendants, relying on Judge Rader's dissent in *Cybor Corp. v. FAS Techs., Inc.,* 138 F.3d 1448 (Fed.Cir.1998), state that the reversal rate by the Federal Circuit, in the same time frame as that in which the Agreement was devised, exceeded 50 percent. *See Cybor Corp.,* 138 F.3d at 1476 (citing the Federal Circuit's 1997 statistics indicating that it reversed 27% of the cases it reviewed in whole, and reversed another 26% in part). That statistic, however, relates to claims construction, in which the trial court, as a prerequisite to determining infringement or validity questions, is called upon to "determin[e] the meaning and scope of patent claims." *Id.; see also Smiths Indus. Med. Sys., Inc. v. Vital Signs, Inc.,* 183 F.3d 1347, 1353 (Fed.Cir. 1999); *see also Markman v. Westview Instruments, Inc.,* 52 F.3d 967, 976 (Fed.Cir. 1995); *see generally* R. Polk Wagner and Lee Petherbridge, *Is the Federal Circuit Succeeding? An Empirical Assessment of Judicial Performance,* 152 U. Pa. L.Rev. 1105 (2004). However, the reversal rate is substantially lower for determinations about patent validity. *See* Arti K. Rai, *Engaging Facts and Policy: A Multi–Institutional Approach to Patent System Reform,* 103 Colum. L.Rev. 1035, 1061 (2003) (noting that from 1983 to 1999, the Federal Circuit affirmed seventy-eight percent of all decisions in which a fact finder made determinations about patent validity). Further, in view of the facts here indicating a strong likelihood of invalidity, there is no support for the argument, based solely on the relatively high reversal rates for other patent cases, that there was a high probability that the District Court of Illinois would be reversed, thus rendering the challenged provision prudent and reasonable.

IV. ANTITRUST ANALYSIS

[21] Having concluded that the appellate-stay provision exceeds the exclusionary scope of the patent, the next step is to define the parameters of the appropriate antitrust analysis. *See Valley Drug,* 344 F.3d at 1312 (citing *Standard Oil,* 283 U.S. at 175, 51 S.Ct. 421) ("[a]ny provisions of the Agreement[ ] found to have effects beyond the exclusionary effects of Abbott's patent may then be subject to traditional antitrust analysis to assess their probable anticompetitive effects in order to determine whether those provisions violate § 1 of the Sherman Act"). Although applying any particular method of analysis may involve fact questions, the selection of a mode of analysis is entirely a question of law for the Court to decide. *See Nat'l Bancard Corp. v. Visa U.S.A., Inc.,* 779 F.2d 592, 596 (11th Cir.1986); *see also* 11 Herbert Hovenkamp, ANTITRUST LAW ¶ 1909b (2d ed.2005) (hereinafter, "Hovenkamp Treatise"). The Court now turns, therefore, to the selection of the appropriate mode of analysis for the antitrust scrutiny of the Abbott–Geneva Agreement.

A. Per Se, Quick Look, and The Rule of Reason

[22, 23] In assessing whether an agreement unreasonably restrains trade such

which the antitrust implications of the Agreement are explored. This issue is raised here because Defendants asserted it in connection with their Motion regarding the exclusionary scope of the patent, but it will be addressed more fully below.

that it violates Section One, courts generally apply one of three modes of antitrust analysis: (1) the *per se* rule, for obviously anticompetitive restraints; (2) the quick look approach, for those restraints with some procompetitive justification; or (3) the full "rule of reason," for restraints whose net impact on competition is particularly difficult to determine. *Cont'l Airlines, Inc. v. United Airlines, Inc.,* 277 F.3d 499, 508–09 (4th Cir.2002); *see* Hovenkamp, *et al.,* 87 Minn. L.Rev. at 1728. The boundaries between these levels of analysis are fluid; "there is generally no categorical line to be drawn between restraints that give rise to an intuitively obvious inference of anticompetitive effect and those that call for more detailed treatment." *Cont'l Airlines,* 277 F.3d at 509 (citing *Cal. Dental Ass'n v. FTC,* 526 U.S. 756, 780–81, 119 S.Ct. 1604, 143 L.Ed.2d 935 (1999)). Instead, these three analytical approaches are best viewed as a continuum, on which the "amount and range of information needed" to evaluate a restraint varies depending on how "highly suspicious" and how "unique" the restraint is. *Id.* (citing 11 Herbert Hovenkamp, ANTITRUST LAW ¶ 1911a (1998)); *see also Nat'l Coll. Athletic Ass'n ("NCAA") v. Bd. of Regents of Univ. of Okla.,* 468 U.S. 85, 104 n. 26, 104 S.Ct. 2948, 82 L.Ed.2d 70 (1984) ("no bright line separat[es] per se from Rule of Reason analysis. Per se rules may require considerable inquiry into market conditions before the evidence justifies a presumption of anticompetitive conduct."). In all cases, however, the "criterion to be used in judging the validity of a restraint on trade is its impact on competition." *Id.* at 104, 104 S.Ct. 2948.

[24, 25] The first approach, *per se* analysis, permits courts to make "categorical judgments" that certain practices, including price fixing, horizontal output restraints, and market-allocation agreements, are illegal without the need for any elaborate inquiry as to the precise harm they have caused or the business excuse for their use. *Broad. Music, Inc. v. Columbia Broad. Sys.,* 441 U.S. 1, 19–20, 99 S.Ct. 1551, 60 L.Ed.2d 1 (1979); *see also Nat'l Bancard,* 779 F.2d at 597–98. Practices that have been found suitable for *per se* condemnation are those that facially appear to be ones "that would always or almost always tend to restrict competition and decrease output," and that are obviously not "designed to increase economic efficiency and render markets more, rather than less, competitive." *Id.* In such cases, the *per se* approach applies a "conclusive presumption" of anticompetitive effects and illegality to certain types of agreements, with no consideration given to the intent behind the restraint, to any claimed procompetitive justifications, or to the restraint's actual effect on competition. *NCAA,* 468 U.S. at 100, 104 S.Ct. 2948; *see also State Oil Co. v. Khan,* 522 U.S. 3, 10, 118 S.Ct. 275, 139 L.Ed.2d 199 (1997) (holding that restrictions subject to *per se* analysis are those that "have such predictable and pernicious anticompetitive effect, and such limited potential for procompetitive benefit," that no detailed market study or evaluation of actual anticompetitive effects is necessary). Although courts are reluctant to apply the *per se* approach with regard to restraints whose economic impact is not immediately obvious, *State Oil,* 522 U.S. at 10, 118 S.Ct. 275, it is the appropriate mode of analysis when "experience with a particular kind of restraint enables the Court to predict with confidence that the rule of reason will condemn

it." [32] *Arizona v. Maricopa County Med. Soc'y,* 457 U.S. 332, 344, 102 S.Ct. 2466, 73 L.Ed.2d 48 (1982).

[26, 27] At the other end of the spectrum, antitrust tribunals routinely apply the more lenient rule of reason to practices that present some potential for competitive harm but also hold out the promise of social gains. Under the rule of reason, the "test of legality is whether the restraint imposed is such as merely regulates and perhaps thereby promotes competition or whether it is such as may suppress or even destroy competition." *Retina Assocs., P.A. v. S. Baptist Hosp. of Fla.,* 105 F.3d 1376, 1383 (11th Cir.1997) (citing *Chicago Bd. of Trade v. United States,* 246 U.S. 231, 238, 38 S.Ct. 242, 62 L.Ed. 683 (1918)). Therefore, the rule of reason requires a plaintiff to prove the anticompetitive effect of the challenged conduct on the relevant market, and that the conduct has no procompetitive benefit or justification. *See Levine v. Cent. Fla. Med. Affiliates, Inc.,* 72 F.3d 1538, 1551 (11th Cir.1996) (citing *Consultants & Designers, Inc. v. Butler Serv. Group. Inc.,* 720 F.2d 1553, 1562 (11th Cir.1983)); *see also United States v. Topco Assocs., Inc.,* 405 U.S. 596, 606, 92 S.Ct. 1126, 31 L.Ed.2d 515 (1972) (the rule of reason involves a complex investigation into "the facts peculiar to the business in which the restraint is applied, the nature of the restraint and its effects, and the history of the restraint and the reasons for its adoption" to determine whether the challenged contract unreasonably restrains competition). Finally, the quick look approach falls somewhere in the continuum between the *per se* rule and the rule of reason, and applies to those intermediate cases where the anticompetitive impact of a restraint is clear from a quick look, as in a *per se* case, but procompetitive justifications for it also exist. *NCAA,* 468 U.S. at 101, 104 S.Ct. 2948. Only if "an observer with even a rudimentary understanding of economics could conclude that the arrangements in question would have an anticompetitive effect on customers and markets" would summary review under the quick look be proper. *Cal. Dental Ass'n,* 526 U.S. at 770, 119 S.Ct. 1604; *see also Law v. NCAA,* 134 F.3d 1010, 1020 (10th Cir. 1998).

B. The Agreement is Per Se Unlawful

[28] In their Quick–Look Motion, the Sherman Act Class Plaintiffs urge the Court to either condemn the Agreement as a *per se* violation of the Sherman Act, or to apply the quick-look approach as a matter of law.[33] The premise underlying both of

32. The Supreme Court has held that it is the court's experience with the type of restraint that is relevant in applying the *per se* rule, not the industry or the precise factual circumstances of the case. *Arizona v. Maricopa County Med. Soc'y,* 457 U.S. 332, 357, 102 S.Ct. 2466, 73 L.Ed.2d 48 (1982); *see also In re Cardizem CD Antitrust Litig.,* 332 F.3d 896, 900 (6th Cir.2003). Therefore, Defendants cannot avoid the *per se* rule by arguing that courts have not had enough experience with agreements of this kind in the pharmaceutical industry.

33. The Sherman Act Class Plaintiffs ask the Court not only to apply the quick look approach, but also to conclude that the Agreement violates Section One of the Sherman Act under such an analysis. *See* Quick–Look Motion at p. 2. As a fallback approach, if the Court finds that any factual questions preclude summary judgment, the Sherman Act Class Plaintiffs request that the Court merely hold that the quick-look approach applies to the Agreement, leaving the question of whether the Agreement actually violates the Sherman Act under such an analysis to the jury. *Id.* at n. 2.

the Sherman Act Class Plaintiffs' alternative motions is that the anticompetitive nature of Defendants' agreement to forestall generic competition in the domestic market for terazosin hydrochloride is sufficiently obvious as to render a more detailed analysis, under a full rule of reason approach, unnecessary. Disputing the propriety of either of these approaches, Defendants argue that any truncated antitrust scrutiny violates the letter and the intent of the Eleventh Circuit's ruling and further ignores the fact that this case centers on the partial settlement of a patent dispute. Defendants therefore urge the Court to adopt the more lenient rule of reason analysis to the Abbott–Geneva Agreement, and to consider the potential that the Agreement as a whole had to enhance competition.

[29, 30] The Court begins with the recognition that horizontal agreements between competitors are antitrust's most "suspect" classification, which as a group provoke closer scrutiny than any other arrangement. *See* Hovenkamp Treatise ¶ 1902a. Even further, cases such as this—involving settlement agreements with payments from a patentee to a potential competitor to delay market entry—are highly suspicious and require particularly close scrutiny to ensure that firms do not cloak anticompetitive behavior under the guise of a settlement agreement. *See* Hovenkamp, *et al.,* 87 Minn. L.Rev. at 1749. As a general class, agreements between competitors to allocate markets are clearly anticompetitive, with the obvious tendency to diminish output and raise prices. *Valley Drug,* 344 F.3d at 1304. "When a firm pays its only potential competitor not to compete in return for a share of the profits that firm can obtain by being a monopolist, competition is reduced." *Id.* (citing *Palmer v. BRG of Ga., Inc.,* 498 U.S. 46, 49–50, 111 S.Ct. 401, 112 L.Ed.2d 349 (1990) (holding that agreements not to compete within certain territorial limits are obviously anticompetitive)). The Supreme Court has called such horizontal market allocation agreements between competitors "[o]ne of the class examples of a *per se* violation." *United States v. Topco Assocs., Inc.,* 405 U.S. 596, 608, 92 S.Ct. 1126, 31 L.Ed.2d 515 (1972). In explaining the impact of market allocation agreements between competitors, the Supreme Court stated:

> Such concerted action is usually termed a 'horizontal' restraint, in contradistinction to combinations of persons at different levels of the market structure, e.g., manufacturers and distributors, which are termed 'vertical' restraints. This Court has reiterated time and time again that '[h]orizontal territorial limitations . . . are naked restraints of trade with no purpose except stifling of competition.' Such limitations are *per se* violations of the Sherman Act.

Id. (citations omitted).

Because of the obvious anticompetitive tendencies of such arrangements, the Eleventh Circuit, in its remand order, commented that it would "readily affirm" this Court's Order condemning the Agreement as a *per se* violation if it were not for the complicating factor that Abbott owned a then-presumptively valid patent that Geneva's ANDA undisputedly infringed. *Valley Drug,* 344 F.3d at 1304. The Eleventh Circuit further observed that "[c]ourts have not hesitated to apply traditional antitrust principles to agreements not within the scope of the patent protections." *Id.* at 1313 n. 29 (citing *Line Material,* 333 U.S. at 307, 68 S.Ct. 550 (holding a patent pooling agreement that fixed

the prices at which licensees would sell the patented product to be *per se* illegal) and *Masonite,* 316 U.S. at 274, 62 S.Ct. 1070 (holding a price-fixing agreement among patentees and their licensees *per se* illegal)). Therefore, having found that the appellate-stay provision exceeded the statutory grant of patent protections to Abbott, there is no impediment to the Court finding the challenged restraint to be a *per se* violation of the Sherman Act if the circumstances support such a conclusion.

[31–34] In evaluating the question of whether the Agreement here was *per se* illegal, the Court must inquire into whether the restraint, on its face, is a naked restraint of trade that always or almost always tends to restrict output, or an ancillary restraint that results in an efficiency-enhancing integration among the parties to the agreement. *Nat'l Bancard,* 779 F.2d at 603; *see also Polk Bros. v. Forest City Enters.,* 776 F.2d 185, 189 (7th Cir.1985). A particular horizontal agreement is defined as a naked restraint "if it is formed with the objectively intended purpose or likely effect of increasing price or decreasing marketwide output in the short run, with output measured by quantity or quality." *See* Hovenkamp Treatise ¶ 1906a. If the Agreement is one that presents a "naked restraint of trade with no purpose except stifling competition," it qualifies for *per se* treatment. *Consultants & Designers, Inc.,* 720 F.2d at 1561 (citing *White Motor Co. v. United States,* 372 U.S. 253, 263, 83 S.Ct. 696, 9 L.Ed.2d 738 (1963)); *see also* Hovenkamp Treatise ¶ 1906a ("Once a restraint is classified as 'naked,' condemnation follows almost as a matter of course, most often without elaborate inquiry into power or actual effects and with only a several limited recognition of defenses."). By contrast, a restraint is ancillary "if its objectively intended purpose or likely effect is lower prices or increased output as measured by quantity or quality." *See* Hovenkamp Treatise ¶ 1906a. If a restraint is defined not as "naked" but rather as "ancillary," the plaintiff acquires the burden of showing both power and anticompetitive effect, and a broader range of defenses are countenanced. *Id.*

For purposes of this analysis, the following relevant facts are undisputed and dispositive. It is undisputed that Abbott and Geneva were actual or potential competitors [34] at the time the Agreement was executed. It is also undisputed that pursuant to the Agreement, Abbott agreed to pay Geneva $4.5 million per month in exchange for Geneva's agreement not to market its generic terazosin hydrochloride products in the United States until a final appellate judgment on the merits of the '207 patent infringement action. The Agreement, therefore, guaranteed Abbott that its only potential competitor at the time would, for a substantial price, refrain from marketing its FDA-approved generic version of Hytrin even after an adverse district court ruling as to the validity of '207 patent. This restraint exceeded the scope of the '207 patent, and had the effect of keep-

34. There is no question here that this case presents a "horizontal" agreement. For purposes of this analysis, no distinction is made between actual competitors (*i.e.,* those currently competing in the same market) and potential competitors. *See Palmer,* 498 U.S. at 46–48, 111 S.Ct. 401. Further, courts have recognized that the mere filing of an ANDA is sufficient evidence that generic drug companies are competitors of brand-name manufacturers. *See Ciprofloxacin,* 261 F.Supp.2d at 239 (citing *In re Buspirone Patent Litig.,* 185 F.Supp.2d 340, 343 (S.D.N.Y.2002)). Similarly, challenging patents through litigation is a form of competition. *Id.* at 240 (citing *United States v. Line Material Co.,* 333 U.S. 287, 319, 68 S.Ct. 550, 92 L.Ed. 701 (1948)(Douglas, J., concurring)).

ing Geneva's generic capsule product, which had already received final FDA approval on March 30, 1998, off the market until August 13, 1999. Further, because of the regulatory framework under Hatch–Waxman, the Agreement had the additional effect of delaying the entry of other generic competitors,[35] who could not enter the market until the expiration of Geneva's 180–day period of marketing exclusivity, which Geneva (as stated in the Agreement) did not intend to relinquish. As the Sixth Circuit concluded in reviewing a nearly identical agreement, "there is simply no escaping the conclusion that the Agreement ... was, at its core, a horizontal agreement to eliminate competition" in the domestic market for terazosin hydrochloride drugs, a "classic example" of an output-reducing, naked restraint on trade that qualifies for *per se* treatment. *See In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 908 (6th Cir.2003).[36]

C. Defendants' Arguments Against Per Se Treatment are Unavailing

[35] None of Defendants' attempts to avoid *per se* treatment are persuasive. Defendants' primary argument is that *per se* condemnation is inappropriate because the appellate-stay provision, viewed in the context of the entire Agreement, is reasonably ancillary to the Agreement's procompetitive core. Defendants focus on the Eleventh Circuit's direction that any provisions found to have exceeded the exclusionary potential of the patent not be considered "in isolation," but rather in combination with the entire agreement in order to judge the Agreement's overall effect on competition. *Valley Drug*, 344 F.3d at 1313 n. 31. Defendants therefore urge the Court to adopt the rule of reason's balancing approach by which any anticompetitive provisions of the Agreement are weighed against its procompetitive features.

In support of their argument, Defendants identify the following allegedly competition-enhancing qualities of the Agreement to which they contend the appellate-stay provision was "reasonably ancillary": (1) the Agreement maintained the status quo pending appeal, permitting Abbott to

35. Other courts have recognized the negative effect on competition where a settlement creates a "bottleneck" for future ANDA filers. *See Ciprofloxacin*, 261 F.Supp.2d at 242. In *Ciprofloxacin*, the District Court distinguished its case from the case at bar, observing that the Abbott–Geneva Agreement "delayed triggering Geneva's 180–day exclusivity period, effectively holding up FDA approval of other generic manufacturers' ANDA IVs." *Id.* at 243. This was particularly true because Geneva, unlike the generic ANDA applicant in the *Ciprofloxacin* case, did not agree to relinquish its rights to the exclusivity period provided by the Hatch–Waxman Act, but instead indicated, in the Agreement itself, that it intended "to use its best efforts to obtain any statutory period of exclusive marketing to which it may be entitled under 21 U.S.C. § 355(j)(4)(B)(iv)." *See* Ex. 1. Tab A at ¶ 25, Exs. to Defs.' Mot. for Summ. J. on Sherman Act Section One (and Analogous Claims).

36. The Eleventh Circuit disagreed with the Sixth Circuit's approach in *Cardizem*, because that Court did not conduct an analysis of the exclusionary potential of the patent and also placed considerable reliance on the size of the exit payments. Nonetheless, the *Cardizem* court's analysis of the likely anticompetitive effects of the challenged agreement and the application of the *per se* rule remains relevant to this Court's analysis. The agreement in that case, like the Abbott–Geneva Agreement here, did not resolve the underlying patent litigation but rather represented what the parties termed an "interim settlement." Further, the *Cardizem* agreement resulted in a "bottleneck" for future ANDA filers. In these respects, the facts of the *Cardizem* case are factually closer to this case than those that other courts reviewing patent settlements in the pharmaceutical context have addressed. *See Ciprofloxacin*, 261 F.Supp.2d at 242–44; *see also Tamoxifen*, 277 F.Supp.2d at 133.

reasonably exploit its patent rights and allowing the parties to minimize uncertainty regarding the outcome of the patent litigation; (2) the Agreement allowed for Geneva to enter the market long before the October 2014 expiration date of the '207 patent; (3) the Agreement preserved Geneva's opportunity to eliminate the '207 patent altogether—to the benefit not just of Geneva but of all generic companies desiring to sell terazosin hydrochloride; and (4) the Agreement was consistent with the policies underlying the Hatch–Waxman regulatory regime, and the FDA's proposed ANDA regulations. *See* Defs.' Opp'n to the Quick Look Mot. at 13 (citing 54 FR 28892, 1989 WL 281873 (F.R. July 10, 1989) (stating that when the lawsuit is still pending at the expiration of the thirty month stay, "it serves the public interest to permit a prudent ANDA-holder in that situation to stay off the market until the litigation is resolved, thereby minimizing damages")).

[36] Before addressing the merits of these arguments, the Court notes that once a naked restraint of trade is found, any alleged procompetitive justifications are irrelevant and should not be considered. *See Topco,* 405 U.S. at 610, 92 S.Ct. 1126 ("the Court has consistently rejected the notion that naked restraints of trade are to be tolerated because they are well intentioned or because they are allegedly developed to increase competition"); *see also Maricopa Cty.,* 457 U.S. at 351, 102 S.Ct. 2466. Indeed, "the virtue/vice of the *per se* rule is that it allows courts to presume that certain behaviors as a class are anticompetitive without expending judicial resources to evaluate the actual anticompetitive effects or procompetitive justifications in a particular case." *Cardizem,* 332 F.3d at 909. However, a minimal inquiry into the merits of any claimed procompetitive justifications is warranted for the Court to determine whether the Agreement is properly classified as an "ancillary" rather than a "naked" restraint. *See* Hovenkamp Treatise ¶¶ 1907a & 1908a. The Court, therefore, considers Defendants' arguments only in summary fashion, as part of the threshold inquiry of whether the Agreement constitutes a naked restraint of trade.

Defendants' first argument, that the Agreement permitted Abbott to exploit its patent rights and allowed the parties to eliminate uncertainty pending resolution of the '207 litigation, does not remove the challenged portion of the Agreement from the category of naked restraints. As discussed earlier in this Order, while a patent affords the patent holder considerable protections, a patent's exclusionary right cannot be exploited in every way. *See supra* Section III.A. It is well-settled that a patent holder's protections are limited by the precise terms of the patent grant, and cannot be extended by agreement.[37] *Id.* Further, "[t]he legitimate exclusion value of a pharmaceutical patent [like the '207

37. Defendants rely on *Troxel Mfg. Co. v. Schwinn Bicycle Co.,* 465 F.2d 1253, 1255 (6th Cir.1972), to support their contention that Abbott was not "evicted" from its rights under the '207 patent until the Federal Circuit's final appellate resolution of the "on-sale bar" issue. In *Troxel,* the Sixth Circuit held that "a final [appellate] adjudication of invalidity of a licensed patent operates as an eviction from the license, terminating the licensee's obligation to continue making royalty payments after that date by giving no right to recoup royalties already paid." *Id.* at 1255 (citing *Drackett Chem. Co. v. Chamberlain Co.,* 63 F.2d 853, 855 (6th Cir.1933)). However, *Troxel* is not binding precedent in either the Federal or the Eleventh Circuit. Further, *Troxel* dealt with a situation inapposite to the instant case.

patent] is the power it actually confers over competition, which is in turn a function of the scope of the patent and its chance of being held valid." *See* Hovenkamp, *et al.,* 87 Minn. L.Rev. at 1761. In this case, despite the dubious validity of the '207 patent and the advanced stage of the patent infringement litigation, Defendants agreed to extend the protections of the patent beyond the district court's ruling on the validity question, and permitted Abbott to continue to exploit its patent protections irrespective of whether the '207 patent was declared valid. Such a method of "exploitation" of Abbott's patent rights is not supported by the law.

Further, the terms of the Abbott–Geneva Agreement, while analogized by Defendants to a preliminary injunction or stay pending appeal, went beyond what is generally available under a court-ordered injunction. The Agreement: (1) barred Geneva's entry into the market beyond resolution of the patent suit in the district court without any determination of whether Abbott was likely to succeed on the merits of any appeal; (2) provided large interim payments to Geneva—in a sum that exceeded Geneva's total revenues for 1997—that did not have a demonstrable link to the amount of damages that Geneva would incur if Abbott obtained an injunction but was ultimately unsuccessful in the infringement action, as a bond under Fed.R.Civ.P. 65(c) would be measured; (3) and barred Geneva from marketing *any* terazosin hydrochloride product, including those that were not at issue in the patent case. While Defendants could have structured their Agreement in a less restrictive way that reasonably implemented Abbott's patent protections, they instead agreed to a restraint that surpassed that which the patent would have allowed.[38] It cannot be said, therefore, that the Agreement was reasonably ancillary to Abbott's protection of its patent rights.

Similarly, Defendants' second and third arguments fail to establish that the Agreement was reasonably ancillary to an overall procompetitive purpose. The mere fact that the Agreement allowed for generic entry long before the '207 patent's October 2014 expiration date does not render the Agreement procompetitive. This is particularly so given the fact that the patent, judged as of April 1, 1998, was of questionable validity in light of the "on-sale bar" and was likely to be invalidated by the district court. Further, to the extent that the Agreement did not terminate the pending litigation and preserved Geneva's ability to continue its challenge to the '207 patent's validity, Defendants have not demonstrated how or why the appellate-stay provision was essential to achieving this goal. *See* Hovenkamp Treatise ¶ 1908b (in assessing whether a restraint is ancillary, "some determination must be made whether the challenged agreement is an essential part of [the procompetitive] arrangement, or whether it is completely unnecessary," *i.e.* whether it is an "inherent feature" of the procompetitive arrangement or "simply an unnecessary, output-

38. It is also important to note that the Agreement did not "maintain the status quo," but rather provided for a large payment from the patent holder to its competitor to delay generic entry. A true "status quo" situation would have emerged if Geneva, recognizing the potential for a "ruinous" damages award, agreed not to market its generic product until resolution of the '207 appeals without any payments from Abbott. Instead, the parties altered the "status quo" through an agreement that included significant reverse payments.

limiting appendage."). Here, the Court cannot conclude, based on a review of the Agreement as a whole, the parties' arguments, and the record, that the challenged provision was an inherent feature of an otherwise procompetitive arrangement. Instead, all indications are directly to the contrary.

[37] Defendants' fourth argument regarding the Agreement's procompetitive nature also must fail. Defendants contend that the Agreement was consistent with the policies underlying the Hatch–Waxman regulatory regime, and the FDA's proposed ANDA regulations, because it allowed for resolution of the patent infringement action before generic entry. Although the Court recognizes the fiscal prudence of foregoing market entry in the face of uncertainty regarding the legality of a patent, such considerations cannot take precedence over the anticompetitive effect that continued improper exclusion has on the market. *See Valley Drug,* 344 F.3d at 1311 n. 27 ("the anticompetitive effects of exclusion cannot be seriously debated"). Further, the Hatch–Waxman Act itself does not indicate any congressional intent to delay market entry beyond the thirty months provided for in the statute, even in the face of continuing litigation. Indeed, the Act provides for a stay of final FDA approval until *the earlier* of thirty months from the patentee's receipt of the notice accompanying the ANDA-filer's Paragraph IV certification, or the appellate court decision. 21 U.S.C. § 355(j)(5)(B)(iii). This provision, therefore, allows for final approval (and thus opens the door for market entry) *no later than* thirty months from receipt of the Paragraph IV certification. Defendants have not identified any provision of the Act, or of the FDA regulations, that postpones a generic applicant's right to receive final FDA approval, or to enter the market, until after appellate resolution of validity challenges. This argument, therefore, is unavailing.

[38] Finally, under established precedent, true "ancillary" restraints only escape the *per se* rule because they are "counterbalanced by otherwise unattainable procompetitive benefits" from some joint integrated activity. *Nat'l Bancard,* 779 F.2d at 601. Here, Defendants have not offered any evidence or even suggested that the Agreement resulted in an economic integration between Abbott and Geneva. Defendants neither integrated their production or distribution, *Polk Bros.,* 776 F.2d at 189, nor did they create a new product, market or other joint venture for which horizontal restraints were essential, *Broad. Music,* 441 U.S. at 22–23, 99 S.Ct. 1551. Instead, the Abbott–Geneva Agreement clearly denied to consumers the opportunity to choose among alternative terazosin hydrochloride products without offering the possibility of any joint, efficiency-producing activities. The Agreement, therefore, contains a naked, not an ancillary, restraint of trade that is properly condemned under *per se* analysis.[39]

D. Proof of Actual Anticompetitive Effects is Unnecessary

[39] Because the appellate-stay provision evidences a "naked restraint of trade"

39. The Court's focus primarily has been on whether one particular provision of the Agreement, the appellate-stay provision, exceeded the scope of the patent. However, the challenged provision, in accordance with the Eleventh Circuit's opinion, cannot be viewed "in isolation" but rather in the context of the Agreement as a whole. This inclusive approach lends itself to two different possible conclusions: (1) if the larger Agreement as a whole has a procompetitive or efficiency-enhancing purpose, then the challenged provision may be justified as ancillary to such a purpose; or (2) if the Agreement has no over-

subject to *per se* treatment, a "conclusive presumption" of the provision's anticompetitive effects applies. *NCAA,* 468 U.S. at 100, 104 S.Ct. 2948. Application of this presumption "dispenses with the need to define a relevant market and assess other factors such as barriers to entry that might bear on the defendant's ability to profit by raising price above cost." *See* Hovenkamp Treatise ¶ 1910c; *see also State Oil Co. v. Khan,* 522 U.S. 3, 10, 118 S.Ct. 275, 139 L.Ed.2d 199 (1997) (holding that restrictions subject to *per se* analysis are those that "have such predictable and pernicious anticompetitive effect, and such limited potential for procompetitive benefit," that no detailed market study or evaluation of actual anticompetitive effects is necessary). Therefore, the Sherman Act Class Plaintiffs' motion requesting a ruling that proof of actual anticompetitive effects is sufficient for them to establish their Section One claims at trial is moot.[40]

V. CONCLUSION

After careful review of the undisputed material facts in the light most favorable to the non-moving parties, and analyzing those facts under the appropriate legal framework, the Court concludes that the Sherman Act Class Plaintiffs and Kaiser are entitled to summary judgment as a matter of law on the Section One and analogous claims. Judged as of April 1, 1998, the appellate-stay provision of the Abbott–Geneva Agreement exceeded the scope of the protections afforded Abbott under the '207 patent and the applicable law. Further, because horizontal market allocations among competitors have the strong tendency to diminish output and raise prices, the Agreement is so obviously anticompetitive that it violates the Sherman Act under a *per se* analysis. In light of these rulings, the Court will instruct the jury, in accordance with Eleventh Circuit Pattern Jury Instruction No. 3.1, that the Agreement constitutes a *per se* violation of Section One of the Sherman Antitrust Act and is, in and of itself, an "unreasonable" restraint of trade. The trial will proceed, therefore, on the issue of whether the Plaintiffs suffered antitrust injury as a proximate result of Defendants' collusive behavior in violation of Section One. Accordingly, it is hereby

ORDERED that:

(1) The Sherman Act Class Plaintiffs' Motion for Partial Summary Judgment for an Order Declaring that the Abbott–Geneva Agreement Exceeded the Exclusionary

riding procompetitive justification and the restraint is classified as ''naked'' rather than ''ancillary,'' then the Court can declare the Agreement, and not just certain parts of it, to constitute a *per se* violation of the Sherman Act. As the Court has concluded that the Agreement did not have any procompetitive or efficiency-enhancing purpose to which the restraint was ancillary, this case presents the Court with the latter situation.

40. That being said, the Court is persuaded that Abbot has power in the relevant market, which is the market for Hytrin and its generic bioequivalent forms of terazosin hydrochloride. Indeed, in cases such as this, ''[t]he very fact that the pioneer finds it worthwhile to pay a large exclusion payment tends to establish market power.'' Herbert Hovenkamp, Mark D. Janis & Mark A. Lemley, IP AND ANTITRUST: AN ANALYSIS OF ANTITRUST PRINCIPLES APPLIED TO INTELLECTUAL PROPERTY LAW (2004) at 7–37. Although the Court does not find the mere size of the exclusion payment, based on the limited record presented on the issue, to support a finding of illegality, such a significant payment as part of an interim settlement agreement does indicate that the pioneer exercises substantial power in the market. ''It also suggests some inherent uncertainty as to the validity or scope of the patent.'' *Id.*

Potential of the '207 Patent [D.E. 1192] is GRANTED;

(2) Plaintiff Kaiser Foundation Health Plan Inc.'s Motion for Summary Judgment on Section One Claims [D.E. 1161] is GRANTED;

(3) Defendants' Motion for Summary Judgment on Sherman Act Section One (and Analogous) Claims [D.E. 1188] is DENIED;

(4) The Sherman Act Class Plaintiffs' Motion for Partial Summary Judgment for a Finding that the Abbott–Geneva Agreement Violates Section One of the Sherman Act [D.E. 1190–1] is GRANTED;

(5) The Sherman Act Class Plaintiffs' Alternative Motion for Partial Summary Judgment for a Finding that a Quick–Look Analysis Applies to the Agreement [D.E. 1190–2] is DENIED AS MOOT;

(6) The Sherman Act Class Plaintiffs' Motion for Partial Summary Judgment Seeking a Ruling that Proof of Actual Anticompetitive Effects is Sufficient to Establish a Violation of Section One of the Sherman Act [D.E. 1194] is DENIED AS MOOT.

Diana WANZA Plaintiff

v.

AETNA HEALTH INC. Defendant

No. 04–21980–CIV–JORDAN.

United States District Court,
S.D. Florida,
Miami Division.

Jan. 19, 2005.

Background: Beneficiary of employee benefit plan brought action under Employee Retirement Income Security Act (ERISA) alleging that plan administrator improperly failed to pay surgical benefit. Plan administrator moved to dismiss.

Holding: The District Court, Jordan, J., held that beneficiary did not have claim under ERISA for breach of fiduciary duty.

Motion granted.

1. Federal Civil Procedure ⇐673

Complaint is sufficient if it gives defendant fair notice of what plaintiff's claim is and grounds upon which it rests. Fed. Rules Civ.Proc.Rule 8, 28 U.S.C.A.

2. Labor and Employment ⇐630

Beneficiary of group health plan did not have claim under ERISA for breach of fiduciary duty in administration of plan, and thus beneficiary was limited to equitable relief or relief that her contract provided, where objective of suit was to recover surgical benefit for individual beneficiary herself, not to benefit plan as a whole. Employee Retirement Income Security Act of 1974, §§ 409, 502(a)(2), 29 U.S.C.A. §§ 1109, 1132(a)(2).

Kelsay Dayon Patterson, Miami, FL, for Plaintiff.

Andres Gonzalez, Joan Claudia Canal, Steven M. Ziegler Pa, Hollywood, FL, for Defendant.

ORDER ON DEFENDANT'S MOTION TO DISMISS

JORDAN, District Judge.

Diana Wanza brought this action against Aetna Health, Inc. ("Aetna") alleging,