[PUBLISH]

IN THE UNITED STATES COURT OF APPEALS

FOR THE ELEVENTH CIRCUIT

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U.S. COURT OF APPEALS
ELEVENTH CIRCUIT
September 15, 2003
THOMAS K. KAHN
CLERK

No. 02-12091

D. C. Docket No. 99-01317-MD-PAS

VALLEY DRUG COMPANY,
LOUISIANA WHOLESALE DRUG COMPANY, INC.,
et al.,

Plaintiffs-Appellees,

versus

GENEVA PHARMACEUTICALS, INC.,
ABBOTT LABORATORIES

Defendants-Appellants.

Appeal from the United States District Court
for the Southern District of Florida

(September 15, 2003)

Before TJOFLAT and ANDERSON, Circuit Judges, and STAFFORD*, District Judge.

ANDERSON, Circuit Judge:

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*Honorable William H. Stafford, United States District Judge for the Norther District of Florida, sitting by designation.

This case comes to us on interlocutory appeal from the district court's order granting plaintiffs' motion for partial summary judgment. The issue with which we are presented is whether the district court properly determined that two agreements among the defendants were per se violations of § 1 of the Sherman Act, 15 U.S.C. § 1. Because we conclude that the district court incorrectly applied the law, the order below will be reversed and the case remanded for further proceedings consistent with this opinion.

I. BACKGROUND

This is a private antitrust lawsuit, or rather numerous private antitrust lawsuits, brought against three pharmaceuticals manufacturers. The various cases asserting antitrust injury from the actions of the defendants have been consolidated by the Judicial Panel on Multidistrict Litigation in the Southern District of Florida. Plaintiffs basically assert that two agreements, one between defendant-appellant Abbott Laboratories ("Abbott") and defendant-appellant Geneva Pharmaceuticals ("Geneva") and another between Abbott and defendant Zenith Goldline Pharmaceuticals ("Zenith"),[1] entered into in 1998, violated the Sherman Act's

[1] Zenith came to a tentative settlement following the district court's order granting partial summary judgment and is not a party to this appeal.

prohibition against contracts in restraint of trade. Abbott, a manufacturer of the pioneer drug Hytrin, entered separate agreements with generic manufacturers Zenith and Geneva while those companies were pursuing FDA approval of generic versions of Hytrin and while embroiled in patent litigation with those companies. Because the facts of this case took place against a complex regulatory background, we will first describe the relevant regulatory context, then the facts of the case as they appear in the current procedural posture, and then the relevant procedural history.

A. Regulatory Framework

No new drug can be marketed or sold in the United States without approval from the Food and Drug Administration ("FDA"). 21 U.S.C. § 355(a). Applications for FDA approval can be filed in one of two ways: as a new drug application ("NDA") under § 355(b), or as an abbreviated new drug application ("ANDA") under § 355(j). A new drug application must include exhaustive information about the drug, including reports of safety and efficacy studies. See 21 U.S.C. § 355(b)(1).

Prior to 1984, the NDA was the only method of obtaining FDA approval of a new drug. Every applicant had to submit safety and efficacy studies, even if such studies had already been performed for identical drugs or drugs with identical

active ingredients. Adding to this inefficiency was the fact that the conduct of safety and efficacy studies would, if the new drug was the subject of a patent, constitute infringement of that patent under 35 U.S.C. § 271(a).[2] In an effort to eliminate these twin impediments to the introduction of generic drugs to the market, Congress enacted the Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984), commonly known as the Hatch-Waxman Act. The primary accomplishments of the Hatch-Waxman Act were the creation of the ANDA, allowing a new drug applicant to piggyback on the safety and efficacy studies conducted for the pioneer drug, see generally 21 U.S.C. § 355(j); modification of the definition of infringement, so that the conduct of safety and efficacy studies for FDA approval is no longer infringing activity, see generally 35 U.S.C. § 271(e); and allowing the extension of patent terms to compensate for the period when a patented drug could not be marketed because it was undergoing the FDA approval process, see generally 35 U.S.C. § 156.

Several of Hatch-Waxman's additions to 21 U.S.C. § 355 govern FDA approval of ANDAs in the face of patent claims by pioneer drug makers. NDA

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[2] "Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent." 35 U.S.C. § 271(a).

applicants are required to submit the patent number and expiration date of any patent that a generic manufacturer might infringe.[3] If such a patent issues after approval of the NDA, the holder of the application is required to file the patent number and expiration date with the FDA no later than 30 days after the patent issues. See 21 U.S.C. § 355(c)(2). The FDA publishes this patent information, along with other information about the drug, in what is popularly known as the Orange Book. See 21 U.S.C. § 355(j)(7)(A).

An ANDA applicant relying on the safety and efficacy studies filed with the application of a drug listed in the Orange Book must make a certification with respect to each patent claiming the listed drug or a method of using the listed drug of which the applicant is aware. See 21 U.S.C. § 355(j)(2)(A)(vii). The applicant must certify either that (1) the patent information has not been filed with the FDA; (2) the patent is expired; (3) the patent will expire, identifying the expiration date; or (4) the patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug. If the applicant certifies (1) or (2), FDA approval proceeds in regular fashion, see 21 U.S.C. § 355(j)(5)(B)(i); if the applicant certifies (3), the application will not be approved until the date the relevant patent expires, see 21

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[3] Specifically, any patent claiming the drug or method of using the drug that "could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1).

U.S.C. § 355(j)(5)(B)(ii).

If the ANDA applicant certifies that the relevant patents are invalid or will not be infringed, commonly called a "paragraph IV certification," several things happen. First, the applicant must notify the patent holder. 21 U.S.C. § 355(j)(2)(B). If the patent holder brings suit for patent infringement[4] within 45 days of receiving this notice, the FDA automatically delays approval of the ANDA for thirty months. See 21 U.S.C. § 355(j)(5)(B)(iii).[5] If the court hearing the infringement action declares the patent invalid or not infringed, this automatic delay in FDA approval terminates, 21 U.S.C. § 355(j)(5)(B)(iii)(I), or, if the court finds the patent valid and infringed, the approval date will be set for a date on or after the patent's expiration, 21 U.S.C. § 355(j)(5)(B)(iii)(II); 35 U.S.C. § 271(e)(4)(A). If the court grants the patent holder a preliminary injunction prior to

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[4] It shall be an act of infringement to submit an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. § 355(j)] . . . for a drug claimed in a patent or the use of which is claimed in a patent . . . if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug . . . claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

35 U.S.C. § 271(e)(2)(A). This definition of infringement was added by Hatch-Waxman to allow the invocation of the procedures described in the following paragraph of this opinion.

[5] The patent holder is, of course, free to sue the applicant for infringement under 35 U.S.C. § 271(e)(2)(A) after the 45 day window expires. The 30-month stay of FDA approval, however, will not be triggered.

the expiration of the 30-month stay, the application will be approved on the date on which the court later holds the patent invalid or not infringed. See 21 U.S.C. § 355(j)(5)(B)(iii)(III).

The timing of FDA approval is affected by another provision of Hatch-Waxman in the event that a listed drug is subject to more than one paragraph IV certification. Approval of an ANDA that contains a paragraph IV certification is automatically delayed if another ANDA was previously filed based on the same listed drug and the previous ANDA contains a paragraph IV certification. Approval of the subsequent ANDA is delayed until 180 days after the earlier of (1) the first commercial marketing of the drug under the previous application or (2) the date a court hearing an infringement action brought against the previous filer holds the patent invalid or not infringed.[6] See 21 U.S.C. § 355(j)(5)(B)(iv). This

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[6] When the agreements at issue were entered into, the FDA regulations defined the relevant court decision triggering the end of the 30-month stay or the start of the first filer's 180-day exclusivity period as the decision of the appellate court hearing the infringement action against the first filer. This rule was challenged in court and held invalid by TorPharm Inc., v. Shalala, No. 97-1925, 1997 U.S. Dist. LEXIS 21983 (D.D.C. Sep. 15, 1997), appeal withdrawn and remanded, 1998 U.S. App. LEXIS 4681 (D.C. Cir. Feb. 5, 1998), vacated on other grounds (D.D.C. April 9, 1998) (30-month stay expires upon judgment of the district court holding the patent not infringed), and by Mylan Pharms., Inc., v. Shalala, 81 F. Supp. 2d 30 (D.D.C. 2000) (180-day exclusivity period triggered by judgment of the district court holding the patent invalid). Though the FDA was initially committed to continued adherence to the appellate judgment rule, see 62 Fed. Reg. 63,268 (Nov. 28, 1997), it dropped the rule following the Mylan decision, see 65 Fed. Reg. 43,233, 43,234 (July 13, 2000) (interim rule). The FDA now considers the 180-day exclusivity period to be triggered by any district court judgment holding the patent invalid, not infringed, or unenforceable, whether or not the judgment comes from the district court hearing the infringement suit against the first filer. See Granutec, Inc., v. Shalala,

delaying mechanism gives the first generic manufacturer to file a paragraph IV certification and successfully challenge the scope or validity of a patent on a pioneer drug a 180-day period during which it is the exclusive competitor of the pioneer manufacturer. This exclusivity period is a significant incentive for generic manufacturers to challenge weak or narrow drug patents.

B. Factual History[7]

1. Zenith's and Geneva's ANDAs

Abbott manufactures Hytrin, a brand-name drug with the active ingredient dihydrate terazosin hydrochloride.[8] Hytrin is used to treat hypertension and enlarged prostate, and has been a very successful product for Abbott. Abbott obtained FDA approval of its NDA for Hytrin in 1987 and has held a number of patents related to terazosin hydrochloride over the years. Its first patent, issued in

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Nos. 97-1873 & 97-1874, 1998 WL 153410, *8-9 (4th Cir. April 3, 1998) (unpublished, table decision reported at 139 F.3d 889) (endorsing the FDA's position that, if the successful defense requirement is invalid, the court decision triggering the 180-day exclusivity period is the decision of any district court). See also Teva Pharms., USA, Inc. v. FDA, 182 F.3d 1003 (D.C. Cir. 1999) (reversing district court's denial of an injunction to require the FDA to recognize the dismissal with prejudice of an infringement suit against a subsequent filer as triggering the first filer's 180-day exclusivity period). See post at n.12 for a discussion of the successful defense requirement.

[7] The facts are largely uncontested by the parties.

[8] Terazosin hydrochloride is a crystal. Dihydrate terazosin hydrochloride is a particular crystalline polymorph of terazosin hydrochloride. The opinion will refer to terazosin hydrochloride and its polymorphs simply as terazosin hydrochloride unless greater specificity is appropriate.

1977, covered the basic terazosin hydrochloride compound. See Abbott Labs. v. Novopharm Ltd., Nos. 96-C-611 & 95-C-6657, 1996 WL 131498, *1 (N.D. Ill. March 15, 1996). That patent has since expired, though Abbott has been issued other patents for various crystalline forms of the compound and various methods of using and preparing the compound.

Geneva filed four ANDAs based on Hytrin between 1993 and 1996, each time making paragraph IV certifications with respect to Abbott's listed patents. Abbott brought infringement suits under 35 U.S.C. § 271(e), invoking the 30-month stay of FDA approval of Geneva's ANDAs. On April 29, 1996, Geneva filed two additional ANDAs based on Hytrin, one for a capsule form of terazosin hydrochloride and one for a tablet form[9], making paragraph IV certifications with respect to the relevant patents. Within 45 days of receiving notice of Geneva's paragraph IV certifications, Abbott filed an infringement suit based on the submission of the tablet ANDA, asserting that the Geneva's tablet terazosin hydrochloride product infringed Abbott's patent number 5,504,207 ("the '207 patent").[10] In the suit, Geneva admitted infringement but contested the patent's validity. Apparently through oversight, Abbott failed to file an infringement suit

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[9] The active ingredient in these two drugs is anhydrous terazosin hydrochloride.

[10] The '207 patent, issued on April 2, 1996, claims a method of preparing anhydrous terazosin hydrochloride. The patent is due to expire in October of 2014.

based on the submission of the capsule ANDA. FDA consideration of that ANDA, therefore, proceeded unhindered, and Geneva's capsule ANDA was approved in March of 1998. When Abbott was notified of this approval, it began efforts to amend its complaint to allege that Geneva's terazosin hydrochloride capsule infringed the '207 patent.

Zenith, meanwhile, filed an ANDA for a terazosin hydrochloride drug[11] in June of 1994, making a paragraph IV certification with respect to Abbott's Hytrin patents. Abbott was issued a patent claiming forms of terazosin hydrochloride on May 2, 1995, patent no. 5,412,095 ("the '095 patent"), and another on April 2, 1996, the '207 patent. Abbott timely filed this patent information with the FDA, which then required Zenith to amend its ANDA to make a certification with regard to these newly listed patents. Zenith resisted, hoping to avoid the 30-month stay of approval and the 180-day delay of approval based on Geneva's earlier-filed ANDAs.[12] Instead of certifying, Zenith brought suit against Abbott in an attempt to

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[11] The active ingredient of this drug is anhydrous terazosin hydrochloride.

[12] Prior to 1998, the FDA applied the "successful defense" requirement to ANDA filers hoping to take advantage of the 180-day exclusivity period. A subsequently-filed ANDA would only have its approval date delayed by 180 days if the first-filer had successfully defended against an infringement suit. See 59 Fed. Reg. 50,338, 50,367 (Oct. 3, 1994) (adopting successful defense regulation as a final rule, codified at 21 C.F.R. § 314.107). If Zenith's ANDA were ready for approval before Geneva successfully defended Abbott's infringement suit, then the ANDA would be approved without the 180-day delay. If Zenith were forced to make a paragraph IV certification with respect to Abbott's '095 and '207 patents, however, Abbott could invoke the 30-month stay of approval, giving Geneva more time to defend Abbot's infringement action

force Abbott to delist its '095 and '207 patents, relieving Zenith of the obligation to certify with respect to those patents, and seeking a declaration that its terazosin hydrochloride drug did not infringe those patents. Zenith's suit alleged that Abbott listed the '095 and '207 patents knowing that the patents did not claim Hytrin or a method of using Hytrin. Abbott counterclaimed for infringement. Zenith's attempt to obtain a preliminary injunction against the listing of the patents was unsuccessful. See Zenith Labs. v. Abbott Labs., No. 96-1661, 1997 U.S. Dist. LEXIS 23954 (D.N.J. Oct. 1, 1997). Zenith appealed the denial to the Federal Circuit.

2. The Agreements

The agreements challenged by the plaintiffs arose against this backdrop. On March 31, 1998, Abbott and Zenith entered an agreement dismissing Zenith's delisting claims and Abbott's infringement counterclaims ("Zenith Agreement"). In the Zenith Agreement, Zenith acknowledged the validity of each of Abbott's patents claiming terazosin hydrochloride and admitted that any terazosin

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against it.

The successful defense requirement was eventually held to be an unreasonable interpretation of the Hatch-Waxman Act by two courts of appeals. See Mova Pharm. Corp. v. Shalala, 140 F.3d 1060, 1069-70 (D.C. Cir. 1998); Granutec, 1998 WL 153410, at *6-7. The Mova court enjoined the FDA from enforcing the regulation, and the FDA dropped the requirement effective November 10, 1998. See 63 Fed. Reg. 59,710, 59,711 (Nov. 5, 1998) (interim rule).

hydrochloride product Zenith might market would infringe these patents. Zenith agreed not to sell or distribute any pharmaceutical product containing any form of terazosin hydrochloride until someone else introduced a generic terazosin hydrochloride product first or until Abbott's patent no. 4,215,532 (the '532 patent) expired.[13] Zenith agreed not to sell or transfer its rights under any ANDA application relating to a terazosin hydrochloride drug, not to aid any other person in gaining FDA approval of a terazosin hydrochloride drug, and not to aid any other person in opposing or invalidating any of Abbott's patents claiming terazosin. In return, Abbott agreed to a payment schedule according to which Abbott would pay Zenith $3 million up front, $3 million after three months, and $6 million every three months thereafter until March 1, 2000, or until the Agreement terminated by its own terms. If another generic manufacturer introduced a terazosin hydrochloride drug and obtained a 180-day exclusivity period, Abbott's payments would be halved until the period expired. Abbott agreed not to sue Zenith for infringement if it entered the market consistent with the Agreement.

Abbott entered an agreement with Geneva on April 1, 1998 ("Geneva Agreement"). According to the Geneva Agreement, Geneva agreed not to sell or

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[13] The '532 patent claims dihydrate terazosin hydrochloride, the active ingredient in Hytrin. That patent expired on February 17, 2000.

distribute any pharmaceutical product containing any form of terazosin hydrochloride until either Abbott's '532 patent expired, someone else introduced a generic terazosin hydrochloride drug, or Geneva obtained a court judgment that its terazosin tablets and capsules did not infringe the '207 patent or that the patent was invalid. This latter condition required a final judgment from which no further appeal could be taken, including petition for certiorari to the Supreme Court. Geneva agreed not to transfer or sell its rights under its ANDAs, including its right to the 180-day exclusivity period. Geneva also agreed to oppose any subsequent ANDA applicant's attempt to seek approval of its application based on Geneva's failure to satisfy the then-existing successful defense requirement and to join and support any attempt by Abbott to seek an extension of the 30-month stay of FDA approval on Geneva's tablet ANDA. In return, Abbott agreed to pay Geneva $4.5 million each month until either someone else brought a generic terazosin hydrochloride product to market or Abbott won a favorable decision in the district court on its infringement claim. If Geneva won in district court, Abbott's $4.5 million monthly payments would go into escrow pending resolution of the appeal, with the escrowed funds going to the party prevailing on appeal. Abbott reserved the right to terminate its payments after February 8, 2000, if no other generic terazosin hydrochloride product had been marketed as of that date. If Abbott

exercised this right, it would execute a release in Geneva's favor of any claims of infringement based on the '207 patent.

3. Termination of the Agreements

The district court hearing Abbott's infringement suit against Geneva handed down its decision on September 1, 1998. Abbott Labs. v. Geneva Pharms., Inc., Nos. 96-C-3331, 96-C-5868, & 97-C-7587, 1998 WL 566884 (N.D. Ill. Sept. 1, 1998). The court held the '207 patent invalid because the crystalline form of terazosin hydrochloride claimed in the patent was on sale in the United States more than one year before Abbott applied for the patent, see 35 U.S.C. § 102(b). 1998 WL 566884 at *7. Abbott appealed to the Federal Circuit, which affirmed on July 1, 1999. 182 F.3d 1315 (Fed. Cir. 1999). Abbott's petition for certiorari was denied on January 10, 2000. 528 U.S. 1078, 120 S.Ct. 796 (2000).

The Agreements did not terminate on their own terms, however. The parties terminated the Agreements on August 13, 1999, apparently in response to an FTC investigation of those Agreements. The FTC action resulted in a consent settlement. See Matter of Abbott Labs., No. C-3945, 2000 WL 681848 (F.T.C. May 22, 2000), also available at http://www.ftc.gov/os/2000/05/c3945.do.htm.

C. Procedural History

All class action and individual antitrust plaintiffs filed a joint motion for

summary judgment that the Agreements were per se illegal under § 1 of the Sherman Act on February 18, 2000. The district court issued an order granting the motion on December 13, 2000. Permission to take an interlocutory appeal from the order under 28 U.S.C. § 1292(b) was granted on April 19, 2002.

D. The Order Granting Summary Judgment

The December 13, 2000, Order granting plaintiffs' motion for partial summary judgment concluded that the Agreements were per se violations of § 1 of the Sherman Act. The Order characterized the Agreements as geographic market allocation Agreements between horizontal competitors, essentially allocating the entire United States market for terazosin drugs to Abbott, who shared its monopoly profits with the other cartel members during the life of the Agreements.

The court found that on the eve of the Agreements,

> both Geneva and Zenith were poised to market generic versions of Hytrin in the United States. Geneva received final FDA approval for its generic capsule in March subject to "validation," and the 30-month stay on its generic tablet proposal was set to expire in October. Zenith declared that it was ready to market a generic tablet upon receipt of a favorable decision from the Federal Circuit and final FDA approval.

In re Terazosin Hydrochloride Antitrust Litig., 164 F. Supp. 2d 1340, 1345-46 (S.D. Fla. 2000). Despite being poised to enter the market, however, "Geneva and Zenith forswore competing with Abbott in the United States market for terazosin

hydrochloride drugs . . . ." Id. at 1348-49.

The court identified four elements of the Agreement with Geneva that were anticompetitive: (1) Geneva's promise not to market its terazosin capsule until the Agreement terminated; (2) Geneva's promise not to market its terazosin tablet until the Agreement terminated; (3) Geneva's promise not to sell its rights in its capsule and tablet ANDAs until the Agreement terminated; and (4) Geneva's promise to aid Abbott in opposing any attempt by other ANDA applicants to enter the market before the Agreement terminated. The court identified three anticompetitive elements of the Agreement with Zenith: (1) Zenith's agreement to dismiss its delisting suit; (2) Zenith's promise not to aid any other entity's challenge to the validity of Abbott's terazosin patents; and (3) Zenith's promise not to market a generic terazosin product until the Agreement terminated. The essence of the Agreements, the court concluded, was to "dissuade[] Geneva and Zenith from marketing the first generic terazosin hydrochloride drugs in the United States for an indefinite period [and] eliminat[e] the risk that either drug maker would sell or purchase the right to introduce such drugs in the interim . . . ." Id. at 1349.

Despite holding the Agreements per se unlawful, the court nonetheless entertained, and rejected, the defendants' arguments that the Agreements were

either pro-competitive or benign.[14] Defendants argued that the Agreements eliminated the "substantial legal and financial risks" that accompany market entry while patent disputes remain unresolved. This justification was rejected for three reasons. First, the Agreement with Geneva was unnecessary to avoid these risks, because Geneva's unilateral decision to forego entry would achieve the same result. Second, the Agreement with Geneva did not resolve the patent litigation; "in fact, it tended to prolong that dispute to Abbott's advantage." Id. at 1350. The litigation was prolonged by the provisions extending the Agreement until the patent dispute was finally resolved, including Supreme Court review, and by Geneva's promise to aid Abbott in any motion seeking to extend the 30-month stay of FDA approval of Geneva's tablet ANDA. Finally, the court rejected the argument that the provision of the Agreement permitting Geneva to enter the market if Abbott elected to suspend its payments was pro-competitive. Although the court may have been willing to "infer that this clause was a catalyst for competition if Geneva paid Abbott for it, [] the suggestion that Abbott handsomely paid Geneva to spur

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[14] Defendants also argued that the Agreements were immune from antitrust liability under the Noerr-Pennington doctrine, see United Mine Workers v. Pennington, 381 U.S. 657, 85 S.Ct. 1585 (1965); Eastern R.R. Presidents Conference v. Noerr Motor Freight, Inc., 365 U.S. 127, 81 S.Ct. 523 (1961); that the Agreements were not subject to per se treatment because of their novelty; and that the Agreements could not have anti-competitive effects because independent regulatory prohibitions prevented market entry by Geneva and Zenith until at least August of 1999. The court rejected these arguments, as well. The defendants do not raise their Noerr-Pennington or ineffective restraints arguments on appeal.

competition in its own lucrative domestic market for terazosin hydrochloride products is patently unreasonable." Id. at 1351. The court did not analyze any potentially efficiency-enhancing effects of the Agreement with Zenith, concluding that the Agreement "would indefinitely postpone Zenith's entry into the United States market and would permit competition only once Abbott lost its exclusive market." Id.

Defendants argued that because the Agreement with Geneva was analogous to an interim patent settlement and the Agreement with Zenith terminated the litigation between Zenith and Abbott, the court should treat the Agreements as patent litigation settlements. The court rejected this argument as well, concluding that the Agreement with Geneva did not resolve Abbott's infringement suit and that the termination of litigation between Zenith and Abbott "was part of a larger scheme to restrain the domestic sale of generic terazosin hydrochloride products." Id. at 1353. Even if the Agreements were patent litigation settlements, the court held, such settlements were not immune from per se analysis. Id.

E. Issues Appealed

On appeal, Abbott and Geneva argue that the district court erred in concluding that the Agreements were per se violations of § 1 of the Sherman Act and that genuine issues of material facts remain in dispute.

Appellants argue that courts lack sufficient experience with agreements of the kind at issue to draw the conclusion that "history and analysis have shown that in sufficiently similar circumstances the rule of reason unequivocally results in a finding of liability." Seagood Trading Corp. v. Jerrico, Inc., 924 F.2d 1555, 1567 (11th Cir. 1991) (quotation and citation omitted). Appellants also argue that there are pro-competitive justifications for the Agreements that warrant analysis under the rule of reason. Appellants argue that genuine issues of material fact are in dispute with regard to these potential pro-competitive effects. Finally, Appellants argue that the Agreements are patent litigation settlements that must be analyzed under the rule of reason unless it is shown that the settlements were "sham."[15]

II. STANDARD OF REVIEW

We review a district court's grant of summary judgment de novo, applying the same legal standards applied by the district court. Bailey v. Allgas, Inc., 284 F.3d 1237, 1242 (11th Cir. 2002). Summary judgment is appropriate if "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material

[15] Indeed, all of appellants' arguments rely primarily on the circumstance that the Agreements arose in the context of patent litigation.

fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c). We view the evidence in the light most favorable to the non-movant, resolving all reasonable doubts and drawing all reasonable inferences in that party's favor. Bailey, 284 F.3d at 1243.

III. DISCUSSION

Section 1 of the Sherman Act prohibits "[e]very contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations . . . ." 15 U.S.C. § 1. It is understood that the ban on "contract[s] in restraint of trade" means only unreasonable restraints, State Oil Co. v. Khan, 522 U.S. 3, 10, 118 S.Ct. 275, 279 (1997), that is, restraints that impair competition, Chicago Board of Trade v. United States, 246 U.S. 231, 238, 38 S.Ct. 242, 244 (1918). Some types of agreements are so obviously anticompetitive, or so unlikely to be pro-competitive, that such agreements can be deemed to violate the Sherman Act without much more than an examination of the agreement itself and the relationships of the parties to the agreement. State Oil, 522 U.S. at 10, 118 S.Ct. at 279; Arizona v. Maricopa County Medical Soc., 457 U.S. 332, 344, 102 S.Ct. 2466, 2473 (1982). These agreements are labeled "per se" violations. Regardless of terminology, the ultimate

purpose of the antitrust inquiry is to form a judgment with respect to the competitive significance of the restraint at issue. National Collegiate Athletic Ass'n v. Bd. Regents Okla. Univ., 468 U.S. 85, 103, 104 S.Ct. 2948, 2962 (1984). The analytic focus should be on what conclusions regarding the competitive impact of a challenged restraint can confidently be drawn from the facts demonstrated by the parties. See California Dental Ass'n v. FTC, 526 U.S. 756, 779-81, 119 S.Ct. 1604, 1617-18 (1999), NCAA, 468 U.S. at 103-04, 104 S.Ct. at 2961-62.

The district court focused on the agreements by Geneva and Zenith not to enter the market with FDA-approved (or approval pending) generic terazosin drugs, holding that this exclusionary effect of the Agreements constituted an allocation of the market between horizontal competitors and that the Agreements were therefore per se illegal. We begin our discussion by addressing this exclusionary effect of the Agreements.

A.

An agreement between competitors to allocate markets is, as the district court noted, clearly anticompetitive. Such an agreement has the obvious tendency to diminish output and raise prices. 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. See, e.g., Palmer v. BRG of Georgia, Inc., 498

U.S. 46, 49-50, 111 S.Ct. 401, 403 (1990) (per curiam) (agreements not to compete within certain territorial limits are obviously anticompetitive); United States v. Topco Assocs., 405 U.S. 596, 608, 92 S.Ct. 1126, 1133-34 (1972) (observing that an agreement between competitors to allocate territories is a "classic example" of a per se violation of the Sherman Act, with no purpose other than reducing competition).

If this case merely involved one firm making monthly payments to potential competitors in return for their exiting or refraining from entering the market, we would readily affirm the district court's order. This is not such a case, however, because one of the parties owned a patent. For reasons explained below, and in light of the fact that all parties seem to agree that the ANDAs that were the subjects of the infringement suits infringed Abbott's '207 patent, we reject the district court's characterization of the instant Agreements as illegal per se. We believe any such characterization is premature without further analysis of the kind suggested in this opinion. Because the market allocation characterization was central to the district court's conclusion that the Agreements in their entireties are per se violations of § 1 of the Sherman Act, we will reverse the grant of summary judgment.

A patent grants its owner the lawful right to exclude others. See 35 U.S.C.

§§ 271(a) (defining infringement) & 283 (providing injunctive relief for infringement); Dawson Chem. Co. v. Rohm & Haas Co., 448 U.S. 176, 215, 100 S.Ct. 2601, 2623 (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. Bonito Boats, Inc., v. Thunder Craft Boats, Inc., 489 U.S. 141, 150-51, 109 S.Ct. 971, 977-78 (1989); United States v. Studiengesellschaft Kohle, m.b.H., 670 F.2d 1122, 1127 (D.C. Cir. 1981). The exclusionary right cannot be exploited in every way -- patentees cannot pool their patents and fix the prices at which licensees will sell the patented article, for example, see United States v. New Wrinkle, Inc., 342 U.S. 371, 72 S.Ct. 350 (1952) -- but a patentee can choose to exclude everyone from producing the patented article or can choose to be the sole supplier itself, see, e.g., In re Indep. Serv. Orgs. Antitrust Litig., 203 F.3d 1322, 1328 (Fed. Cir. 2000); SCM Corp. v. Xerox Corp., 645 F.2d 1195, 1209 (2d Cir. 1981); or grant exclusive territorial licenses carving up the United States among its licensees, see 35 U.S.C. § 261. Within reason, patentees can also subdivide markets in ways other than territorial, such as by customer class. Gen. Talking Pictures Corp. v. Western Elec. Co., 304 U.S. 175, 58 S.Ct. 849, aff'd on

reh'g, 305 U.S. 124, 59 S.Ct. 116 (1938) (approving a license restricting the licensee's sales to non-commercial customers). Such arrangements undoubtedly tend to result in lower production and higher prices of the patented article than if competition were unrestrained, but these anticompetitive tendencies do not render them in violation of the Sherman Act.

The above discussion illustrates the point that a patentee's allocation of territories is not always the kind of territorial market allocation that triggers antitrust liability, and this is so because the patent gives its owner a lawful exclusionary right. In characterizing the Agreements as territorial market allocations agreements, the district court did not consider that the '207 patent 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.[16] To the extent that Zenith and Geneva agreed not to market admittedly infringing products before the '207 patent expired or was held invalid, the market allocation characterization is inappropriate.

Zenith's agreement not to market an infringing generic terazosin hydrochloride drug terminated, by its own terms, when either another generic

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[16] The '207 patent was, of course, declared invalid on September 1, 1998, a judgment affirmed on January 10, 2000. The antitrust consequences of this subsequent invalidation will be addressed below.

manufacturer marketed a terazosin product and any exclusivity period expired or Abbott's '532 patent expired in February of 2000. The effect of the Zenith Agreement on the production of Zenith's infringing terazosin product appears to be no broader than the potential exclusionary effect of the '207 patent, and was actually narrower to the extent it permitted Zenith to market its drug before the '207 patent expired. Geneva's agreement not to market an infringing terazosin product terminated at the earliest of (1) a final, unappealable judgment holding the '207 patent invalid; (2) the marketing of a terazosin product by another generic manufacturer; or (3) the expiration of the '532 patent. The 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 '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.[17]

With respect to the foregoing aspects of the two Agreements' exclusionary effects, which were the foundation of the district court's characterization of the

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[17] We say "may" because we do not hold that the '207 patent would have allowed Abbott to obtain a preliminary injunction or a stay of an adverse judgment pending appeal. We mean only that these are among the considerations that the district court should address on remand. We do note that appellees have not at this stage argued that Abbott would have been unable to obtain such relief.

Agreements as market allocation agreements, these are at the heart of the patent right and cannot trigger the per se label.[18] Unlike some kinds of agreements that are per se illegal whether engaged in by patentees or anyone else, such as tying or price-fixing, the exclusion of infringing competition is the essence of the patent grant. As one court has concluded, "when patents are involved . . . the exclusionary effect of the patent must be considered before making any determination as to whether the alleged restraint is per se illegal." In re Ciprofloxacin Hydrochloride Antitrust Litig., 261 F. Supp. 2d 188, 249 (E.D.N.Y. 2003). Because the district court failed to consider the exclusionary power of Abbott's patent in its antitrust analysis, its rationale was flawed and its conclusion that these Agreements constitute per se violations of the antitrust laws must be reversed.

While our holding at this early stage of the litigation is appropriately narrow,

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[18] Appellees argue that the Agreements have broader exclusionary tendencies in that they also prohibited the marketing of non-infringing terazosin products, prohibited Geneva from marketing infringing products beyond the date a district court held the '207 patent invalid, and prohibited Geneva from waiving its 180-day exclusivity period. As we explain below, these prohibitions may be beyond the scope of Abbott's lawful right to exclude and, if so, would expose appellants to antitrust liability for any actual exclusionary effects resulting from these provisions that appellees can prove at the causation and damages stages of litigation. Our point thus far is that appellees have failed to prove that appellants should face per se antitrust liability for treble damages for the failure of Zenith and Geneva to market admittedly infringing products when no court had declared Abbott's patent invalid or unenforceable at the time of the Agreements.

the decision below and the arguments of the parties invite our discussion of several matters that promise to be relevant on remand. We first discuss appellees' argument that the antitrust analysis need not consider Abbott's patent rights because the '207 patent was declared invalid. We then discuss appellees' argument that the lawful right of exclusion does not include the right to pay competitors not to produce infringing products. Finally, we offer several observations with respect to the framework to be developed on remand for deciding the appropriate antitrust analysis.

B.

The individual Sherman Act plaintiffs-appellees argue that because the '207 patent was declared invalid after the Agreements were entered into, Abbott never had any patent rights and our antitrust analysis need not consider the '207 patent. We reject the appellees' argument that the agreements by Geneva and Zenith not to produce infringing products are subject to per se condemnation and treble-damages liability merely because the '207 patent was subsequently declared invalid. 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. Polk Bros. v. Forest City Enters., 776 F.2d 185, 189 (7th Cir. 1985); SCM Corp., 645 F.2d at 1207. At the time the Agreements were entered into, no court had declared

Abbott's '207 patent invalid, and the appellees have advanced no argument other than mere invalidity.[19] We hold that the mere subsequent invalidity of the patent does not render the patent irrelevant to the appropriate antitrust analysis.

The right of exclusion conferred by a patent has been characterized as a defense to an antitrust claim, see Walker Process Equip., Inc., v. Food Mach. & Chem. Corp., 382 U.S. 172, 179, 86 S.Ct. 347, 351 (1965) (Harlan, J., concurring), or as a limited exception to the general rule that markets should be free from barriers to competition, see id., 382 U.S. at 176, 86 S.Ct. at 350; United States v. Line Material Co., 333 U.S. 287, 309, 68 S.Ct. 550, 561 (1948); id., 333 U.S. at 310, 68 S.Ct. at 562. Appellees' argument implies that this defense is unavailable with respect to the Agreements because the '207 patent was subsequently held invalid.

The only time the Supreme Court has addressed the circumstances under which the patent immunity from antitrust liability can be pierced, it held that the antitrust claimant must prove that the patentee enforced a patent with the knowledge that the patent was procured by fraud on the Patent Office. Walker

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[19] That is, appellees have neither alleged nor asserted that the patent was procured by fraud, that appellants knew the patent was invalid, that there was no objective basis to believe that the patent was valid, or any such similar allegations. We therefore are not called upon to decide what the antitrust consequences of such circumstances might be.

Process, 382 U.S. at 177, 86 S.Ct. at 350 (considering a monopolization claim against a patentee for suing to enforce a patent allegedly procured by fraud). Good faith procurement furnishes a complete defense to the antitrust claim. Id. Justice Harlan's concurrence explained that the effect of antitrust liability on the incentives for innovation and disclosure created by the patent regime must be taken into account when a court considers whether a patentee is stripped of its immunity from the antitrust laws:

> It is well also to recognize the rationale underlying this decision, aimed of course at achieving a suitable accommodation in this area between the differing policies of the patent and antitrust laws. To hold, as we do, that private suits may be instituted under § 4 of the Clayton Act to recover damages for Sherman Act monopolization knowingly practiced under the guise of a patent procured by deliberate fraud, cannot well be thought to impinge upon the policy of the patent laws to encourage inventions and their disclosure. Hence, as to this class of improper patent monopolies, antitrust remedies should be allowed room for full play. On the other hand, to hold, as we do not, that private antitrust suits might also reach monopolies practiced under patents that for one reason or another may turn out to be voidable under one or more of the numerous technicalities attending the issuance of a patent, might well chill the disclosure of inventions through the obtaining of a patent because of fear of the vexations or punitive consequences of treble-damage suits. Hence, this private antitrust remedy should not be deemed to reach § 2 monopolies carried on under a nonfraudulently procured patent.

382 U.S. at 179-80, 86 S.Ct. at 351-52. This approach is commonly used by courts considering the intersection of patent law and antitrust law. See, e.g., SCM Corp.,

645 F.2d at 1203-06 (considering antitrust claims against a patentee for acquiring and refusing to license various patents); Handgards, Inc., v. Ethicon, Inc., 601 F.2d 986, 992-93 (9th Cir. 1979) (considering a monopolization claim against a patentee for asserting a patent it allegedly knew to be invalid). A suitable accommodation between antitrust law's free competition requirement and the patent regime's incentive system is required by the complementary objectives of the two:

> It is commonly said . . . that the patent and antitrust laws necessarily clash . . . At the same time, the two regimes seek the same object: the welfare of the public . . . [A]ntitrust law forbids certain agreements tending to restrict output and elevate prices and profits above the competitive level. Patent law also serves the interests of consumers by protecting invention against prompt imitation in order to encourage more innovation than would otherwise occur.

H. Hovenkamp, Antitrust Law: An Analysis of Antitrust Principles and Their Application, ¶ 1780a (1999) ("Hovenkamp") (citations and quotations omitted). See also D. Crane, "Exit Payments in Settlement of Patent Infringement Lawsuits: Antitrust Rules and Economic Implications," 54 Fla. L. Rev. 747, 748 n.1 (2002) ("It is generally recognized that antitrust and patent law, although polar opposites in their treatment of monopolies, share common objectives."); Zenith Elecs. Corp. v. Exzec, Inc., 182 F.3d 1340, 1352 (Fed. Cir. 1999) ("The patent and antitrust laws are complementary in purpose in that they each promote innovation and competition . . . .") (citation omitted).

Employing this approach, we conclude that exposing 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.[20] This uncertainty, coupled with a treble damages penalty, would tend to discourage settlement of any validity challenges except those that the patentee is certain to win at trial and the infringer is certain to lose. By restricting settlement options, which would effectively increase the cost of patent enforcement, the proposed rule would impair the incentives for disclosure and innovation. See Ciprofloxacin, 261 F. Supp. 2d at 256 (expressing concern for the effect of settlement-restricting antitrust liability rules on the incentives for research and development); cf. Walker Process,

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[20] The cost and complexity of most patent litigation is a familiar problem to the court system. See, e.g., Blonder-Tongue, 402 U.S. at 331-32 & 334-38, 91 S.Ct. at 1444 & 1445-48; Cyber Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1475-76 (Fed. Cir. 1998) (Rader, J., dissenting) (discussing claim construction); Matter of Schering-Plough Corp., No. 9297, 2002 WL 1488085, *166-67 & *239-40 (F.T.C. June 27, 2002), also available at http://www.ftc.gov/os/caselist/d9297.htm. See also Crane, 54 Fla. L. Rev. at 757. The cost savings of settlement, both to the parties and to the public, are equally widely-recognized. See Aro Corp. v. Allied Witan Co., 531 F.2d 1368, 1372 (6th Cir. 1976) ("Public policy favors settlement of disputes without litigation. Settlement is of particular value in patent litigation, the nature of which is often inordinately complex and time consuming.").

382 U.S. at 180, 86 S.Ct. at 352 (Harlan, J., concurring) (permitting antitrust liability based on a showing mere invalidity "might well chill the disclosure of inventions through the obtaining of a patent because of fear of the vexations or punitive consequences of treble-damages suits").

There may be circumstances under which the unreasonableness of a settlement agreement regarding a subsequently-invalidated or unenforceable patent would be sufficiently apparent that antitrust liability would not undermine the encouragement of genuine invention and disclosure. Cf. Walker Process, 382 U.S. at 179-180, 86 S.Ct. at 351 (Harlan, J., concurring) (noting that exposing patentees to antitrust liability for the assertion of a patent known to have been procured by fraud "cannot well be thought to impinge upon the policy of the patent laws to encourage inventions and their disclosure"). In this regard we note that some lower courts have extended Walker Process to permit antitrust claims against patentees for the anticompetitive effects of infringement lawsuits when the antitrust claimant proves that the patentee knew that the patent was invalid, Handgards, 601 F.2d at 994-96, or knew that the patent was not infringed, Loctite Corp. v. Ultraseal Ltd., 781 F.2d 861, 876-77 (Fed. Cir. 1985), overruled on other grounds by

Nobelpharma AB v. Implant Innovations, Inc., 141 F.3d 1059 (Fed. Cir. 1998).[21] To the extent that the appellees have demonstrated nothing more than subsequent invalidity, we hold that this alone is insufficient to render the patent's potential exclusionary effects irrelevant to the antitrust analysis.

C.

The class action plaintiffs-appellees argue that the patent right does not include the right to pay infringers, with the implication that any exclusion resulting from payment rather than judicial enforcement is not protected from per se antitrust liability by the patent laws. Our discussion with regard to the important role played by settlement in the enforcement of patent rights leads us to reject this argument as well. Appellees have not explained why a monetary payment as part of a patent litigation settlement should be flatly prohibited as a per se violation, particularly where the alleged infringer has not yet caused the patentee any harm and the patentee does not have a damages claim to bargain with. See Ciprofloxacin, 261 F. Supp.2d at 251-52 (discussing the asymmetries of litigation risk created by Hatch-Waxman and rejecting the argument that payments from the patentee to the

[21] Similarly, it has been suggested that the "sham" exception to the antitrust immunity afforded by the Noerr-Pennington doctrine is or may be available also to antitrust plaintiffs seeking to pierce the patent immunity. See Independent Services Organizations, 203 F.3d at 1326-27. Because the parties have not briefed such potential exceptions to the patent immunity from antitrust liability, we do not address them at this time.

infringer are subject to per se antitrust analysis); Crane, 54 Fla. L. Rev. at 774 (discussing the dynamics of settlement before the alleged infringer has entered the market).

We cannot conclude that the exclusionary effects of the Agreements not to enter the market were necessarily greater than the exclusionary effects of the '207 patent merely because Abbott paid Geneva and Zenith in return for their respective agreements. If Abbott had a lawful right to exclude competitors, it is not obvious that competition was limited more than that lawful degree by paying potential competitors for their exit. The failure to produce the competing terazosin drug, rather than the payment of money, is the exclusionary effect, and litigation is a much more costly mechanism to achieve exclusion, both to the parties and to the public, than is settlement. See Aro Corp., 531 F.2d at 1372. To hold that an ostensibly reasonable settlement of patent litigation gives rise to per se antitrust liability if it involves any payment by the patentee would obviously chill such settlements, thereby increasing the cost of patent enforcement and decreasing the value of patent protection generally. We are not persuaded that such a per se rule would be an appropriate accommodation of the competing policies of the patent and antitrust laws.

It may be that the size of the payment to refrain from competing, sometimes

called a "reverse payment" or an "exit payment," raises the suspicion that the parties lacked faith in the validity of the patent[22], particularly when those payments are non-refundable in the event that the patentee prevails on the infringement claim (as a bond posted as part of a preliminary injunction would be). However, in the instant case and given the state of the current record, it is difficult to infer from the size of the payments alone that the infringement suits lacked merit. We do not know, for example, what lost profits Abbott expected from generic competition or what profits Geneva and Zenith expected to gain from entry, the risk of the defendants' inability to satisfy a judgment, or the litigation costs each side expected to save from settlement. We do not know how much of the payment might have been in exchange for provisions of the Agreements other than Zenith's and Geneva's acknowledgment of validity.[23] Without these facts we cannot confidently draw the conclusion, merely from the size of the payments, that there were no genuine disputes over the validity of the patent. Given the asymmetries of risk and large profits at stake, even a patentee confident in the validity of its patent might

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[22] For example, the size of the payments might be evidence supporting a claim that the patentee knew that the patent was procured by fraud, or knew that the patent was invalid, or that there was no objective basis to believe the patent was valid. See discussion in Part B, supra.

[23] For example, it seems reasonable to assume that part of the payments to Geneva were in return for Geneva's agreement not to waive its 180-day exclusivity period. Payments for provisions other than the acknowledgment of validity would not shed light on the parties' evaluations of the merits of the validity issue.

pay a potential infringer a substantial sum in settlement. See, e.g., Ciprofloxacin Hydrochloride, 261 F. Supp. 2d at 196, 234 (settlement agreements under which a patentee paid an infringer $49.1 million to acknowledge the validity of a patent, and at least $398 million for the infringer to remain off the market, though the patent was subsequently approved by the PTO on reexamination and unsuccessfully challenged in court three times).

Another possibly suspicious characteristic of the payments to Geneva is their structure (i.e., tying their duration to the length of the litigation), which, as the district court noted, may have given Geneva an incentive to delay resolution of the infringement suit.[24] But if the payments were in furtherance of the seemingly reasonable purpose of compensating Geneva for any lost profits during the course of litigation (much like a bond posted as part of a preliminary injunction), it is difficult to imagine how else to structure the payments but by tying them to the length of the litigation.

We recognize that the Sixth Circuit appeared to take the opposite view in In re Cardizem CD Antitrust Litig., 332 F.3d 896, 908 (6th Cir. 2003) ("[I]t is one thing to take advantage of a monopoly that naturally arises from a patent, but

[24] Neither appellees nor the district court have offered any similar suspicions with regard to the structure of payments under the Zenith Agreement.

another thing altogether to bolster the patent's effectiveness in inhibiting competition by paying the only potential competitor $40 million per year to stay out of the market.").[25] When the exclusionary power of a patent is implicated, however, the antitrust analysis cannot ignore the scope of the patent exclusion. "[T]he protection of the patent laws and the coverage of the antitrust laws are not separate issues." Studiengesellschaft, 670 F.2d at 1128. As the above discussion indicates, we do not think that a payment from the patentee to the alleged infringer should be automatically condemned under the antitrust laws[26], nor do we think that the evidence regarding the exit payments in this case allows a confident conclusion to be drawn at this stage of the litigation that the exclusionary effect of the

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[25] The terms of the agreements at issue in the Cardizem CD case were similar to the terms of the Agreements in this case.

[26] The Sixth Circuit seems to have placed considerable reliance upon the generic's agreement to delay entering the market in exchange for exit payments, although it may also have been influenced by other provisions of the agreement which might more readily seem to exceed the potential exclusionary power of the patent. For example, the Sixth Circuit mentioned the effect of the agreements regarding the 180-day exclusivity period as well, and its reference to the district court opinion in that case might reflect some reliance on the restriction on non-infringing products. See Cardizem CD, 332 F.3d at 907-08; In re Cardizem CD Antitrust Litig., 105 F. Supp. 2d 682, 705 (E.D.Mich. 2000). However, the Sixth Circuit opinion did not purport to measure the several provisions against the exclusionary power of the patent, or differentiate between provisions that fell within the scope of the patent's protection and those which did not. Cf. Cardizem CD, 105 F. Supp. 2d at 701 ("The anticompetitive effects of [the] patent are likewise not at issue."). To the extent that the Sixth Circuit suggests that a settlement of patent litigation was a per se violation of the antitrust laws merely because it involves a generic's agreement to delay marketing until resolution of the patent infringement case in exchange for exit payments, we respectfully disagree. We believe that the potential exclusionary power of the patent must first be considered.

Agreements were bolstered by the exit payments to a degree that exceeds the potential exclusionary power of the patent.

Because these matters were given scant attention in the district court, considering the court's primary conclusion that the Agreements were market division agreements like those in Palmer and Topco, these questions have not been explored. We simply note them here to explain our conclusion that the presence of an exit payment as part of the settlement does not alone demonstrate that the Agreements had obvious anticompetitive tendencies above and beyond Abbott's potential exclusionary rights under the '207 patent.

D.

Our discussion so far has been limited to the exclusionary effects of the instant Agreements to delay entrance into the market, the subsequent invalidation of the patent, and the mere fact of exit payments. To the extent that these or other effects of the Agreements are within the scope of the exclusionary potential of the patent, such effects are not subject to per se antitrust condemnation.[27] From the preceding discussion, we conclude that deciding the antitrust implications of these

[27] Application of rule of reason analysis is similarly inappropriate, as the anticompetitive effects of exclusion cannot be seriously debated. Rule of reason and per se analysis are both aimed at assessing the anticompetitive effects of particular conduct; what is required here is an analysis of the extent to which antitrust liability might undermine the encouragement of innovation and disclosure, or the extent to which the patent laws prevent antitrust liability for such exclusionary effects.

exclusionary effects requires an analysis of the effects of antitrust liability on the innovation and disclosure incentives created by the patent regime, with the aim of "achieving a suitable accommodation between the differing policies." Walker Process, 382 U.S. at 179, 86 S.Ct. at 351 (Harlan, J., concurring).

As alluded to earlier, however, see supra at ___ n.18 (M/S at 26, n.18), the instant Agreements are not confined to matters involving restrictions on infringing products, exit payments, and a subsequent court decision declaring the patent invalid. Appellees also challenge other provisions of the Agreements, such as those prohibiting the marketing of "any" generic terazosin product; Geneva's agreement not to waive its 180-day exclusivity period; and Geneva's agreement not to come to market until a final, unappealable judgment of invalidity rather than on a district court judgment. These arguments require consideration of the scope of the exclusionary potential of the patent, the extent to which these provisions of the Agreements exceed that scope, and the anticompetitive effects thereof. Because these considerations require a different analytic framework than that applied by the district court and advocated by the parties on appeal, it is appropriate to remand to the district court to apply an appropriate framework derived from this decision, and the arguments of the parties and the facts developed on remand. To aid in the development of an appropriate framework, we offer the following observations.

We recognize the patent exception to antitrust liability, but also recognize that the exception is limited by the terms of the patent and the statutory rights granted the patentee. "[T]he 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." Line Material, 333 U.S. at 300, 68 S.Ct. at 557. See also New Wrinkle, 342 U.S. at 378, 72 S.Ct. at 353 ("Patents give no protection from the prohibitions of the Sherman Act to [price fixing] when the licenses are used, as here, in the scheme to restrain."); United States v. Masonite Corp., 316 U.S. 265, 277, 62 S.Ct. 1070, 1077 (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.").

The appropriate analysis on remand will likely require an identification of the protection afforded by the patents and the relevant law[28] and consideration of the extent to which the Agreements reflect a reasonable implementation of these. Appellants, for example, contend that certain provisions of the Geneva Agreement are analogous to a consensual preliminary injunction and stay of judgment pending appeal. To evaluate this claim, the provisions of this Agreement should be

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[28] We express no view at this time on what role the FDA's regulation of market entry might play in the appropriate antitrust analysis.

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. Cf. Hovenkamp at ¶ 2046 ("some care must be taken to ensure that . . . the settlement . . . is not more anticompetitive than a likely outcome of the litigation").

Any provisions of the Agreements 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.[29] Standard Oil Co., Ind., v. United States, 283 U.S. 163, 175, 51 S.Ct. 421, 425-26 (1931) (recognizing that cross-licensing agreements and a division of royalties could be used to monopolize or fix prices and examining the evidence to assess the potential for anticompetitive effects as a result of the agreements at issue). The appropriate analysis of the market effects of such provisions may depend on the nature of the provision challenged. It may be that some challenged provisions are so obviously anticompetitive that they can be condemned as illegal on the evidence so far

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[29] Courts have not hesitated to apply traditional antitrust principles to agreements not within the scope of the patent protection. See Line Material, 333 U.S. at 307, 68 S.Ct. at 560 (holding a patent pooling agreement that fixed the prices at which licensees would sell the patented product per se illegal); Masonite, 316 U.S. at 274, 62 S.Ct. at 1076 (holding a price-fixing agreement among patentees and their licensees per se illegal).

adduced, or it may be that the tendencies of some challenged provisions cannot be confidently predicted without further inquiry.

> [T]here 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. What is required, rather, in an enquiry meet for the case, looking to the circumstances, details, and logic of a restraint.

Cal. Dental, 526 U.S. at 780-81, 119 S.Ct. at 1618.[30] If on remand the court should conclude that part, but not all, of the provisions of the Agreements violate the Sherman Act, it may also be helpful to identify with specificity which provisions or combination of provisions are illegal[31] and the nature of the anticompetitive effects of those provisions or combinations in order to aid subsequent determinations on causation and antitrust injury. Finally, the particular circumstances of this case and the arguments of the parties on remand may demonstrate other relevant

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[30] Because the appellants' arguments supporting the application of the rule of reason rely primarily on the circumstance that the Agreements arise out of patent litigation, and because the determination of the appropriate analysis should await the inquiries to be made on remand, we decline at this time to address the issue further. We note, however, that the application of the rule of reason is not synonymous with exhaustive factual inquiry. "[S]ome rule-of-reason cases can be disposed of merely on the basis of the parties' arguments and, more often, on the basis of a limited summary judgment record." Hovenkamp, ¶ 1508.

[31] This is not to suggest that the provisions should be considered in isolation; agreements that are anticompetitive when considered in isolation (such as covenants not to compete) can still be lawful if they are ancillary to another agreement and, when viewed in combination, will have the overall effect of enhancing competition. See Business Elecs. Corp. v. Sharp Elecs. Corp., 485 U.S. 717, 729, 108 S.Ct. 1515, 1523 & n.3 (1988), Polk Bros., 776 F.2d at 189. We simply suggest that careful consideration of individual provisions may be helpful should it appear that the Agreements are unlawful only in part.

considerations.

IV. CONCLUSION

The district court's order granting partial summary judgment is REVERSED and this case is REMANDED for further proceedings consistent with this opinion.[32]

[32] All pending motions are DENIED.