[PUBLISH]

IN THE UNITED STATES COURT OF APPEALS

FOR THE ELEVENTH CIRCUIT

FILED
U.S. COURT OF APPEALS
ELEVENTH CIRCUIT
AUGUST 29, 2005
THOMAS K. KAHN
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No. 03-13605

D. C. Docket No. 00-03481-CV-AJ

ANDRX PHARMACEUTICALS, INC.,

Plaintiff-Appellant,

versus

ELAN CORPORATION, PLC,

Defendant-Appellee,

SKYEPHARMA, INC.,

Defendant.

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

(August 29, 2005)

Before BIRCH and WILSON, Circuit Judges, and DOWD[*], District Judge.

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[*] Honorable David D. Dowd, Jr., United States District Judge for the Northern District of Ohio, sitting by designation.

BIRCH, Circuit Judge:

In this appeal, we address whether the district court properly granted a patentholder's motion for judgment on the pleadings in a competitor's antitrust suit. The district court granted the motion because it found that the Noerr-Pennington doctrine immunized Defendant-appellee Elan Corporation, PLC ("Elan") from the maintenance of an antitrust suit based on the allegations of Plaintiff-appellant Andrx Pharmaceuticals, Inc. ("Andrx") that Elan engaged in patent infringement proceedings to improperly protect its monopoly on the market for a controlled release naproxen medication. In addition, the district court found that Andrx's allegations regarding a licensing agreement entered into by Elan and another competitor to settle a separate infringement suit were insufficient to support an antitrust action under the Sherman Anti-Trust Act, 15 U.S.C. §§ 1 and 2. Finally, the district court denied Andrx's motion for leave to amend its complaint. For the reasons discussed more fully in this opinion, we conclude the district court properly construed the Noerr-Pennington doctrine to immunize Elan from liability for its infrigement suits, and did not abuse its discretion in denying leave to amend. The district court erred, however, in dismissing Andrx's claims regarding its settlement agreement with one of Andrx's competitors. Accordingly, the district court's order is **AFFIRMED** in part, **REVERSED** in part, and

REMANDED for further proceedings.

I. BACKGROUND[1]

At its core, this litigation concerns the right to manufacture and sell the drug naproxen, an analgesic medication prescribed to treat pain and other disorders. Because the complex statutory regulations which govern the manufacture and sale of drugs in the United States provide context for the facts in this case, we will begin by briefly summarizing the relevant statutory provisions, after which we will recount the relevant facts specific to the parties.

The Food and Drug Administration ("FDA") must give its approval before any new drug can be marketed or sold in the United States. 21 U.S.C. § 355(a). Under § 355, different FDA approval standards apply depending on the drug the applicant is attempting to market. See Valley Drug Co. v. Geneva Pharms., 344 F.3d 1294, 1296 (11th Cir. 2003), cert. denied __ U.S. __, 125 S. Ct. 308 (2004). To gain approval for a drug that has not been introduced previously to the market, an applicant must file a new drug application ("NDA") and must meet the

[1] Because this appeal arises from the district court's grant of Elan's motion for judgment on the pleadings, the facts are derived from the allegations in Andrx's complaint, which we must accept as true, and are presented in the light most favorable to Andrx. See Ortega v. Christian, 85 F.3d 1521, 1524 (11th Cir. 1996). We need not accept as true, however, conclusory legal allegations made in the complaint. See Green Leaf Nursery v. E.I. DuPont de Nemours & Co., 341 F.3d 1292, 1304 n.12 (11th Cir. 2003), cert. denied 541 U.S. 1037, 124 S. Ct. 2094 (2004). Because the district court denied Andrx leave to file a second amended complaint, see R2-73 at 11, our inquiry is limited to the allegations in the first amended complaint.

requirements outlined in § 355(b). Id. Section 355(b) requires the submission of "exhaustive information about the drug," including reports about the safety and efficacy of the drug. Id. To gain approval for a generic, bioequivalent version of a drug which has already gained approval under § 355(b), however, an applicant may file an abbreviated new drug application ("ANDA"), in which the applicant must satisfy the less exhaustive requirements outlined in § 355(j). See id. While § 355(j) allows an ANDA applicant to satisfy its burden by demonstrating a certain bioequivalency between its drug and a drug approved under § 355(b), § 355(j) does require the ANDA applicant to certify that the manufacture and sale of its drug would not violate any patents held on the drug approved under § 355(b). See § 355(j)(2)(A)(vii). If an ANDA applicant certifies that its generic drug would not violate an existing patent, or would only violate a patent on a § 355(b)-approved drug which is invalid, see § 355(j)(2)(A)(vii)(IV),[2] the ANDA applicant must notify the patentholder, which is then given forty-five days to initiate patent infringement proceedings against the ANDA applicant, see § 355(j)(5)(B)(iii). If the patentholder timely initiates such litigation, FDA approval for the generic drug

[2] As an incentive for drug manufacturers to submit ANDA applications for the production of generic drugs, § 355 grants the first manufacturer to file an ANDA application for a generic drug using the type of certification outlined in § 355(j)(2)(A)(vii)(IV) an exclusive 180-day period to market the generic drug before another ANDA application is approved for a similar generic drug. § 355(j)(5)(B)(iv)(I). This 180-day exclusivity period begins to run "after the date of the first commercial marketing of the drug." Id.

will be stayed for up to thirty months, unless the patent being litigated expires or a final determination on the patent's validity is reached at an earlier date. Id.

Against this background of information on drug approval procedures, we proceed to the facts relevant to the parties on appeal. Elan was the owner of U.S. Patent No. 5,637,320 ("the '320 patent"), which granted it the exclusive right to manufacture and sell in the United States a controlled release naproxen medication. In 1998, SkyePharma Inc. ("SkyePharma")[3] filed an ANDA application pursuant to § 355(j) to manufacture and sell a generic version of Elan's controlled release naproxen medication. In making its application, SkyePharma certified pursuant to § 355(j)(2)(A)(vii)(IV) that its activity would not constitute patent infringement. Consequently, pursuant to § 355(j)(5)(B)(iii), Elan initiated patent infringement proceedings against SkyePharma. According to Andrx's complaint, Elan and SkyePharma settled the litigation by entering into an agreement in which SkyePharma admitted to infringing the '320 patent in exchange for a license from Elan to manufacture a generic controlled release naproxen medication. Because SkyePharma was the first filing ANDA applicant, pursuant to § 355(j)(5)(B)(iv)(I), the license agreement effectively would have given SkyePharma an exclusive 180-day period to market a generic naproxen medication. According to Andrx's

[3] Although SkyePharma was also a named defendant in Andrx's first amended complaint, Andrx settled and voluntarily dismissed its claims against SkyePharma. See R2-73 at 1.

complaint, however, SkyePharma had no intention of marketing its generic drug and therefore would never trigger the running of the 180-day exclusivity period. Accordingly, the settlement agreement had the effect of preventing any generic competition in the controlled release naproxen market and constituted a conspiracy to restrain trade.

In addition to SkyePharma's alleged attempt to seek FDA approval for a generic controlled release naproxen medication, Andrx contends that it also sought to introduce a generic naproxen to the market. After Andrx filed notice of non-infringement as required by § 355(j)(2)(B)(ii), however, Elan filed patent infringement proceedings against Andrx. According to Andrx's complaint, Elan initiated this litigation "despite the absence of any reasonable belief that the claim might fairly be held to be valid upon adjudication." R1-3 ¶ 29, at 5. Andrx alleged that Elan could not maintain its suit because the '320 patent had not been "validly issued because of inter alia, the SCRIP publication of June 22, 1988 which advertised its controlled release naproxen in the United States more than one year prior to the filing of the application which resulted in the '320 patent." Id. ¶ 27.[4]

[4] Patent law provides that a patent shall not be granted if the invention was "described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States." 35 U.S.C. § 102. This statutory provision is termed the "on-sale bar" to patent validity. See Ferag AG v. Quipp Inc., 45 F.3d 1562, 1566 (Fed. Cir. 1995). Because Elan purportedly advertised its controlled release naproxen for sale in the publication SCRIP World Pharmaceutical News, Andrx argued that the on-sale bar was triggered, thereby invalidating the '320 patent. Andrx's

Moreover, Andrx alleged that "Elan's goal and intention in bringing [the infringement proceedings] was solely to . . . cause Andrx damage from the automatic administrative delay in the approval process" pursuant to § 355(j)(5)(B)(iii). Id. ¶ 29, at 5-6. In addition to these allegations, Andrx alleged that "Elan has engaged in a pattern and practice of baseless and sham litigation" against companies seeking to complete ANDAs for generic controlled release naproxen medications. Id. ¶ 26, at 5. According to Andrx, Elan sought through this behavior to preserve its monopoly over the controlled release naproxen market in the United States. Id. ¶ 39, at 7.

Based on these allegations, Andrx filed suit against Elan and SkyePharma and alleged violations of the Sherman Anti-Trust Act, 15 U.S.C. §§ 1 and 2, and the Florida antitrust laws, FLA. STAT. ch. 542.18 and ch. 542.19. Citing the Noerr-Pennington doctrine and precedent which allowed for the licensing settlement reached by Elan and SkyePharma, the district court granted Elan's motion for judgment on the pleadings. In addition, the district court denied Andrx's motion to amend its complaint on account of Andrx's undue delay. On appeal, Andrx argues

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arguments notwithstanding, the district court found that the SCRIP publication did not trigger the on-sale bar. See Elan Corp., PLC v. Andrx Pharms., Inc., 272 F. Supp. 2d 1325, 1340 (S.D. Fla. 2002). The district court did find, however, that a letter written by Elan to Lederle Laboratories in 1987 triggered the on-sale bar and invalidated the '320 patent. Id. at 1349. This latter finding was reversed by the Federal Circuit, which remanded Elan's patent infringement suit for further proceedings. See Elan Corp., PLC v. Andrx Pharms., Inc., 366 F.3d 1336, 1342 (Fed. Cir. 2004).

that the district court erred in dismissing with prejudice its suit against Elan because the district court misconstrued the Noerr-Pennington doctrine and its sham litigation exception. In addition, Andrx argues that the district court erred by denying its motion for leave to amend its complaint.

II. DISCUSSION

A. Judgment on the Pleadings

"We review de novo the district court's ruling on a motion for judgment on the pleadings pursuant to Federal Rule of Civil Procedure 12(c)." Horsley v. Rivera, 292 F.3d 695, 700 (11th Cir. 2002). The application of the Noerr-Pennington doctrine is a question of law, and therefore also reviewed de novo. See Tec Cogeneration Inc. v. Fla. Power & Light Co., 76 F.3d 1560, 1567 (11th Cir. 1996), modified in part on other grounds, 86 F.3d 1028 (11th Cir. 1996) (per curiam). Judgment on the pleadings is proper when no issues of material fact exist, and the moving party is entitled to judgment as a matter of law based on the substance of the pleadings and any judicially noticed facts. See Horsley, 292 F.3d at 700.

The Sherman Anti-Trust Act provides that "[e]very contract . . . in restraint of trade or commerce among the several States, or with foreign nations, is . . . illegal." 15 U.S.C. § 1. The Act also proscribes acts which seek "to monopolize

any part of the trade or commerce among the several States, or with foreign nations." 15 U.S.C. § 2.[5] Citing the Sherman Act and the Florida antitrust statutes, Andrx alleges that Elan improperly sought to monopolize the controlled release naproxen market and prevent competition by: (1) initiating sham patent infringement litigation against Andrx; and (2) entering into a settlement agreement with SkyePharma which granted SkyePharma exclusive licensing rights to manufacture and sell a generic controlled release naproxen medication. We will examine each set of allegations in turn.

1. Patent Infringement Proceedings

While the Sherman Anti-Trust Act does proscribe activity in restraint of trade, its reach has been tempered when its invocation would impair the exercise of constitutional rights. Recognizing that the First Amendment guarantees the right to "petition the Government for a redress of grievances," U.S. CONST. amend I, and that this guarantee overrides the effect of a contrary federal statute, see Marbury v. Madison, 5 U.S. 137, 177-78 (1803), and not wanting to "impute to Congress an intent to invade the First Amendment right to petition," Prof'l Real Estate Investors

[5] As the district court noted, the Florida antitrust statutes, FLA. STAT. ch. 542.18 and ch. 542.19, closely track the language of the Sherman Act and are analyzed under the same rules and case law. See All Care Nursing Serv. v. High Tech Staffing Servs., Inc., 135 F.3d 740, 745 n.11 (11th Cir. 1998). Accordingly, our discussion of federal antitrust law applies with equal force to the Florida statutory provisions.

v. Columbia Pictures Indus., Inc., 508 U.S. 49, 56, 113 S. Ct. 1920, 1926 (1993) (internal quotations omitted), the Supreme Court has held that a defendant is immune from Sherman Act liability for concerted efforts to petition government to pass legislation which has the effect of restraining or monopolizing trade in favor of the defendant. See E. R.R. Presidents Conf. v. Noerr Motor Freight, Inc., 365 U.S. 127, 136, 81 S. Ct. 523, 529 (1961) (granting antitrust immunity for publicity campaign designed to spur the adoption of monopoly-facilitating legislation); United Mine Workers v. Pennington, 381 U.S. 657, 670, 85 S. Ct. 1585, 1593 (1965) (noting that Noerr shielded a defendant from antitrust liability for "efforts to influence public officials . . . even though intended to eliminate competition"). Subsequent precedent has extended Noerr-Pennington immunity to defendants who exercise their right to petition government by resorting to administrative and/or judicial proceedings. See Cal. Motor Transp. Co. v. Trucking Unlimited, 404 U.S. 508, 510, 92 S. Ct. 609, 611-12 (1972). Noerr-Pennington immunity thus shields a defendant from antitrust liability for resorting to litigation to obtain from a court an anticompetitive outcome.

An exception to the Noerr-Pennington doctrine exists, however, where the defendant engages in "sham litigation." Prof'l Real Estate Investors, 508 U.S. at 56, 113 S. Ct. at 1926; see Noerr, 365 U.S. at 144, 81 S. Ct. at 533 (finding

Sherman Act immunity inappropriate where the exercise of the right to petition was "a mere sham to cover what is actually nothing more than an attempt to interfere directly with the business relationships of a competitor"). To prevail on the argument that Noerr-Pennington immunity should be abrogated based on the sham litigation exception, a litigant must establish that: (1) "the lawsuit [is] objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits"; and (2) the party bringing the allegedly baseless suit did so with a "subjective motivation . . . to interfere directly with the business relationships of a competitor." Prof'l Real Estate Investors, 508 U.S. at 60-61, 113 S. Ct. at 1928. Construing the first prong of the sham litigation exception test, the Court noted that the existence of probable cause to bring a lawsuit is sufficient to thwart a claim that litigation was objectively baseless. See Prof'l Real Estate Investors, 508 U.S. at 62, 113 S. Ct. at 1929. Moreover, the Court noted that "[a] winning lawsuit is by definition a reasonable effort at petitioning for redress and therefore not a sham." Prof'l Real Estate Investors, 508 U.S. at 60 n.5, 113 S. Ct. at 1928 n.5.

Based on this precedent, we agree with the district court that the Noerr-Pennington doctrine shields Elan from antitrust liability for filing two patent infringement suits against Andrx in relation to the manufacture and sale of

controlled release naproxen. The United States Constitution expressly permits the government to grant exclusive monopolies in the form of patents, see U.S. CONST. art. I, § 8, cl. 8, and therefore the Sherman Act cannot be read to impede a litigant from seeking to defend constitutionally-permitted patent rights. See Prof'l Real Estate Investors, 508 U.S. at 56, 113 S. Ct. at 1926 (declining to impute an unconstitutional purpose to Sherman Anti-Trust Act). Moreover, as the Supreme Court has noted, engaging in litigation to seek an anticompetitive outcome from a court is First Amendment activity that is immune from antitrust liability. See Cal. Motor Transp. Co., 404 U.S. at 510, 92 S. Ct. at 611-12. Thus, we conclude Noerr-Pennington immunity was triggered by Elan's filing suit against Andrx. In addition, we conclude that the sham litigation exception is inapplicable. Andrx's main contention in its complaint that the patent litigation was a sham hinged on its claim that the on-sale bar found in 35 U.S.C. § 102 was triggered by Elan's naproxen advertisement in the publication SCRIP World Pharmaceutical News. Two courts have subsequently rejected that argument. See Elan Corp., PLC, 272 F. Supp. 2d at 1340 (rejecting argument that the SCRIP advertisement triggered on-sale bar); Elan Corp., PLC, 366 F.3d at 1342 (rejecting the argument that the on-sale bar was triggered). Thus, while Elan may not have won its infringement lawsuit at this point, it certainly has made a winning argument against Andrx's

contentions of patent invalidity. Cf. Prof'l Real Estate Investors, 508 U.S. at 60 n.5, 113 S. Ct. at 1928 n.5. Thus, it is manifest that Elan's patent infringement proceedings were not objectively baseless, and therefore not a sham. Accordingly, because the Noerr-Pennington doctrine applies, and the sham litigation exception is inapplicable, the district court properly found that Elan was immunized from antitrust liability for filing infringement proceedings against Andrx.

2. Elan-SkyePharma Settlement Agreement

In contrast, we conclude that the district court erred in finding that Andrx had not sufficiently pled an antitrust violation in relation to the licensing agreement which Elan signed with SkyePharma to terminate patent infringement litigation. Under the Federal Rules of Civil Procedure, the plaintiff is required in the complaint to make "a short and plain statement of the claim showing that the [plaintiff] is entitled to relief." FED. R. CIV. P. 8(a)(2). While courts had previously applied a heightened pleading requirement in antitrust cases, this view has subsequently been rejected in favor of applying Rule 8(a)'s notice pleading standard. Quality Foods de Centro America, S.A. v. Latin American Agribusiness Dev. Corp., S.A., 711 F.2d 989, 995 (11th Cir. 1983); see Spanish Broad. Sys. of Fla., Inc. v. Clear Channel Communications, Inc., 376 F.3d 1065, 1077 (11th Cir. 2004) (concluding that the "liberal pleading regime" outlined by Fed. R. Civ. P.

8(a)(2) applies to allegations of antitrust violations); Covad Communications Co. v. BellSouth Corp., 299 F.3d 1272, 1279 (11th Cir. 2002) (describing the threshold requirements for properly pleading an antitrust violation as "exceedingly low"), vacated on other grounds by 540 U.S. 1147, 124 S. Ct. 1143 (2004). Accordingly, absent some doctrine which immunizes the conduct alleged, such as the Noerr-Pennington doctrine, "dismissals [on the pleadings] are particularly disfavored in fact-intensive antitrust cases." Covad Communications Co., 299 F.3d at 1279. Against this background, we examine whether Andrx's allegations sufficiently state a claim under § 1 and/or § 2 of the Sherman Anti-Trust Act.

As we noted previously, Section 1 of the Sherman Act provides that "[e]very contract . . . in restraint of trade or commerce among the several States, or with foreign nations, is . . . illegal." 15 U.S.C. § 1. To prevail on a claim that a patent infringement settlement agreement violates § 1 of the Sherman Act, a plaintiff must prove "(1) the scope of the exclusionary potential of the patent; (2) the extent to which the agreements exceed that scope; and (3) the resulting anticompetitive effects" in the relevant market. Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1066 (11th Cir. 2005) (citing Valley Drug Co., 344 F.3d at 1312). With regard to the first element, the allegations in Andrx's complaint demonstrated that the '320 patent was necessary to the manufacture and sale of a controlled release naproxen

medication, and that its owner could effectively exclude competitors from making other controlled release naproxen medications. See R1-3 ¶¶ 22-23, 33-35. With regard to the second element, Andrx alleged that the Elan-SkyePharma licensing agreement, coupled with SkyePharma's putative agreement to refrain from ever marketing a generic controlled release naproxen medication, "effectively barr[ed] any generic competitors from entering the market. Id. ¶¶ 22-23. If true, this dynamic would exceed the scope of exclusion intended by the '320 patent. See 21 U.S.C. § 355(j) (outlining criteria for drug manufacturers to enter the market with a generic version of previously-approved patented products). With regard to the third element, Andrx described the relevant market as the "[c]ontrolled release naproxen" market. See R1-3 ¶ 17. Andrx alleged that Elan had sufficient market power to affect the controlled release naproxen market because it was the only supplier of naproxen in the United States. See id. ¶ 16. Finally, demonstrating the anticompetitive effects, Andrx alleged that Elan's licensing agreement with SkyePharma, and SkyePharma's putative agreement to refrain from marketing its generic drug, would "prevent competition in the market for controlled release naproxen." Id. ¶¶ 22-23; see also id. ¶ 44 (stating that the conduct of Elan and SkyePharma "foreclosed" entry by competitors into the relevant market and "precluded" competition). Additionally, Andrx alleged that the agreement had the

result of depriving the general public of a less expensive generic product. See id. ¶ 43. Thus, Andrx sufficiently pled facts for a § 1 claim that the Elan-SkyePharma settlement agreement constituted an antitrust violation.

Section 2 of the Sherman Act outlaws conduct which seeks "to monopolize any part of the trade or commerce among the several States, or with foreign nations." 15 U.S.C. § 2. "To state a claim for attempted monopolization, plaintiff must show specific intent on the part of the defendant to bring about a monopoly and a dangerous probability of success." Quality Foods de Centro America, S.A., 711 F.2d at 996. In its complaint, Andrx alleged that Elan had the "specific intent to monopolize and preserve a monopoly in the controlled release naproxen market." R1-3 ¶ 49. In addition, as we already noted, Andrx alleged that Elan was the only supplier of naproxen in the United States, see id. ¶ 16, and therefore had "achieved a probability of success," id. ¶ 56. Accordingly, we conclude that Andrx sufficiently pled a violation of § 2 of the Sherman Act.

In sum, then, while the allegations regarding Elan's infringement suits against Andrx were immunized under the Noerr-Pennington doctrine, Andrx did sufficiently state a claim under both §1 and §2 of the Sherman Anti-Trust Act that Elan's settlement agreement with SkyePharma, coupled with SkyePharma's putative agreement not to market, violated antitrust law. Accordingly, we remand

this case for further proceedings as to those allegations. Our conclusion as to the sufficiency of the complaint does not preclude, however, Andrx's claims from being challenged at the summary judgment stage. See Quality Foods de Centro America, S.A., 711 F.2d at 999 (reversing a district court's dismissal of antitrust claims on the pleadings, but noting that the claims "may very well wash out on summary judgment"). Our determination recognizes that antitrust cases are "fact-intensive," Covad Communications Co., 299 F.3d at 1279, and require appropriate market analysis, see Schering-Plough Corp., 402 F.3d at 1065-66, and therefore are typically inappropriate for a Rule 12 dismissal in the absence of an applicable immunity doctrine. Accordingly, with regard to Andrx's allegations that the Elan-SkyePharma settlement agreement and SkyePharma's alleged agreement to refrain from marketing a generic controlled release naproxen medication violated §§ 1 and 2 of the Sherman Anti-Trust Act, the case is remanded for further proceedings.

B. Motion to Amend

We review the district court's denial of a motion for leave to amend for clear abuse of discretion. See Lowe's Home Ctrs., Inc. v. Olin Corp., 313 F.3d 1307, 1315 (11th Cir. 2002). Under the Federal Rules of Civil Procedure, after a responsive pleading has been filed, a litigant must obtain leave to amend the

complaint, which "shall be freely given when justice so requires." FED. R. CIV. P. 15(a). Leave may be denied because of "undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of allowance of the amendment, [or] futility of amendment." Foman v. Davis, 371 U.S. 178, 182, 83 S. Ct. 227, 230 (1962).

Based on the foregoing precedent and the facts of this case, we discern no abuse of discretion in the district court's denial of Andrx's motion for leave to amend. As the district court noted, Andrx filed its first amended complaint in March 2001, and was put on notice that its "sham litigation exception" theory was insufficient at least by March 2002. However, Andrx did not move to amend until it appeared in the district court in April 2003 to argue Elan's motion for judgment on the pleadings. See Smith v. Duff & Phelps, Inc., 5 F.3d 488, 493 (11th Cir. 1993) (finding no abuse of discretion where litigant waited more than a year to seek leave to amend after it was put on notice that its claim was defective). Moreover, we note that in its second amended complaint, Andrx purported to advance a "sham litigation exception" theory based on Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp., 382 U.S. 172, 86 S. Ct. 347 (1965), a theory not pled in the first amended complaint. See Burger King Corp. v. Weaver,

169 F.3d 1310, 1319 (11th Cir. 1999) (finding no abuse of discretion where plaintiff attempted to introduce new theory of recovery in amended complaint). Finally, we agree with the district court that Andrx's explanations for its delay in filing for leave to amend do not demonstrate that justice required the grant of the motion to amend. See Carruthers v. BSA Adver., Inc., 357 F.3d 1213, 1218 (11th Cir. 2004) (per curiam). Accordingly, even though Andrx was motivated to amend its complaint to avoid the court's grant of Elan's motion for judgment on the pleadings, Andrx's undue delay in moving for leave to amend, its attempt to inject a new theory of recovery, and its failure to show that justice required the grant of its motion demonstrate that the district court did not clearly abuse its discretion in denying Andrx's motion for leave to amend. See Lowe's Home Ctrs., Inc., 313 F.3d at 1315.

III. CONCLUSION

In this appeal, we were called upon to determine whether Andrx, a drug manufacturer seeking to introduce to the market a generic controlled release naproxen medication, could maintain suit against Elan, the owner of the patent for controlled release naproxen, for its initiation of patent infringement proceedings against Andrx and for its settlement agreement with SkyePharma which purportedly shielded Elan from generic competition in the naproxen market.

Because the Noerr-Pennington doctrine immunized Elan from antitrust liability as to the former allegations, the district court properly found that the allegations could not state a claim for relief under antitrust law. But, because the latter allegations sufficiently pled antitrust violations, the district court erred by granting Elan's motion for judgment on the pleadings, and therefore the case must be remanded for further proceedings in relation to the alleged antitrust violations stemming from the Elan-SkyePharma settlement agreement. On remand, because the district court did not clearly abuse its discretion in denying Andrx's motion for leave to amend, the district court's inquiry should be limited to the allegations of antitrust violations contained in Andrx's first amended complaint. Accordingly, the district court's grant of Elan's motion for judgement on the pleadings is **AFFIRMED** in part and **REVERSED** in part, and **REMANDED** for further proceedings.