

IN THE COURT OF APPEALS OF TENNESSEE
AT JACKSON
May 18, 2006 Session

DENNIS COKER, on behalf of himself and all others similarly situated,
v.
THE PURDUE PHARMA COMPANY, ET AL.

An Appeal from the Circuit Court for Shelby County
No. CT-000121-04 Robert L. Childers, Judge

No. W2005-02525-COA-R3-CV - Filed November 30, 2006

This is a class action involving federal preemption. The defendants own a series of patents for the prescription pain medication OxyContin®. In prior separate litigation between the defendants and a generic drug manufacturer, a federal district court in New York found that the defendants committed inequitable conduct before the United States Patent Office in procuring the patents. After this order was entered by the federal court in New York, the plaintiff filed the instant class action in Shelby County, Tennessee, on behalf of all consumers of OxyContin, alleging violations of the Tennessee Trade Practices Act, the Tennessee Consumer Protection Act, and common law monopolization. These state law claims were based on the defendants' conduct before the United States Patent Office. The defendants removed the case to the federal district court for the Western District of Tennessee. The district court remanded the case back to the Tennessee trial court, holding that the finding of inequitable conduct against the defendants by the federal court in New York operated as collateral estoppel on the issue regarding the federal patent laws. On remand, the defendants filed a motion for judgment on the pleadings based on federal preemption. The trial court granted the motion. We affirm, finding that the plaintiff's antitrust and unfair competition claims, based on the defendants' conduct before the Patent Office, are preempted by the federal patent laws.

Tenn. R. App. P. 3 Appeal as of Right; Judgment of the Circuit Court is Affirmed.

HOLLY M. KIRBY, J., delivered the opinion of the Court, in which ALAN E. HIGHERS, J., and DAVID R. FARMER, J., joined.

B.J. Wade, Memphis, Tennessee, and of counsel, William M. Audet, San Francisco, California, Andrew N. Friedman, Phoenix, Arizona, and Robert Shelquist, Minneapolis, Minnesota, for Plaintiff/Appellant Dennis Coker.

W. David Bridgers, Nashville, Tennessee, and Timothy C. Hester, Washington, D.C., for Defendants/Appellees The Purdue Pharma Company, et al.

OPINION

Defendant/Appellees The Purdue Pharma Company, Purdue Pharma L.P., The Purdue Frederick Company, Purdue Pharmaceuticals L.P., and P.F. Laboratories, Inc. (collectively, “Purdue” or “Defendants”) are pharmaceutical companies which own a series of patents for oxycodone hydrochloride controlled release: Patent No. 5,549,912; Patent No. 5,508,042; and Patent No. 5,656,295. This product is manufactured and marketed under the brand-name OxyContin® (“OxyContin”). OxyContin is an opioid analgesic pain medication manufactured with a time-release formulation, which purportedly releases controlled amounts of oxycodone into the patient’s bloodstream over a twelve-hour period of time. Unlike immediate release formulations, OxyContin is designed to provide continuous pain relief.

In order to explain the proceedings in the trial court below regarding the instant class action, we must first outline the proceedings in separate but related litigation between Purdue and generic drug manufacturers Endo Pharmaceuticals, Inc. and Endo Pharmaceuticals Holdings, Inc., (collectively, “Endo”). Prior to the expiration of Purdue’s patents, Endo announced plans to introduce into the market a generic equivalent of OxyContin. Therefore, pursuant to the procedures set forth in the Hatch-Waxman Act, see 21 U.S.C. § 355 *et seq.*, Endo filed an Abbreviated New Drug Application (“ANDA”) with the Food and Drug Administration. Under the Hatch-Waxman Act, the filing of an ANDA affords the first generic drug manufacturer a one hundred eighty (180) day statutory period in which to market its generic product free from competing generic manufacturers. If, however, the generic drug manufacturer seeks to market its product prior to the expiration of the “pioneer” drug owner’s patents, it must notify the owner of the pioneer drug and certify that the relevant patents are either invalid or will not be infringed by the generic version of the drug for which the ANDA was submitted. The owner of the pioneer drug, upon receiving notification, then has forty-five days in which to file suit for patent infringement.

In October 2000, Purdue timely filed a patent infringement suit against Endo in the United States District Court for the Southern District of New York. *See Purdue Pharma L.P. v. Endo Pharm., Inc.*, Nos. 00 CIV. 8029(SHS), 01 CIV. 2109(SHS), 01 CIV. 8177(SHS), 2004 WL 26523 (S.D.N.Y. Jan. 5, 2004). Purdue alleged that Endo’s generic product infringed its patents for OxyContin. *Id.* at *1. In response, Endo Pharmaceuticals, Inc., counterclaimed against Purdue, seeking a declaration that the OxyContin patents were invalid and unenforceable because of Purdue’s conduct in obtaining those patents. *Id.* Specifically, Endo asserted that Purdue committed “inequitable conduct” before the United States Patent and Trademark Office (“PTO”) by allegedly misrepresenting the proof in support of its claim that OxyContin “reduced the dosage range and eased titration in comparison to other opioid formulations.”¹ *Id.* at *21. Following an eleven-day bench trial, Judge Sidney H. Stein agreed with Purdue that Endo’s generic product infringed

¹A patent applicant has a duty to disclose to the PTO information it knows to be material to patentability. *Purdue Pharma L.P.*, 2004 WL 26523, at *20. A breach of this duty can rise to the level of “inequitable conduct,” which renders the patent unenforceable. *Id.* To establish that a patent is unenforceable due to inequitable conduct, a party must show by clear and convincing evidence that the patent applicant failed to disclose material information with an intent to deceive the PTO. *Id.*

Purdue's OxyContin patents. Judge Stein found, however, that Purdue's patents were unenforceable because Purdue had made material and intentional misrepresentations before the PTO when it obtained the patents. *Id.* at *27. Based on the latter finding, Judge Stein dismissed Purdue's patent claims and entered an injunction barring enforcement of the OxyContin patents.² *Id.*

On January 12, 2004, Plaintiff/Appellee Dennis Coker ("Coker" or "Plaintiff") filed a class action lawsuit against Purdue on behalf of himself and "all natural persons in the State of Tennessee who indirectly purchased OxyContin® manufactured by [Purdue] at any time during the period [of] December 1, 1995 to the present." According to Purdue, Coker's lawsuit is one of approximately seventy antitrust and unfair competition lawsuits filed against Purdue based on Judge Stein's January 2004 decision. In his complaint, Coker sets forth three separate causes of action: violations of the Tennessee Trade Practices Act, Tenn. Code Ann. § 47-25-101 *et seq.*; violations of the Tennessee Consumer Protection Act, Tenn. Code Ann. § 47-18-101 *et seq.*; and common law monopolization. In particular, Coker alleges that Purdue established and maintained monopolies, contracts, agreements, combinations, and conspiracies in restraint of trade and commerce in the market of oxycodone hydrochloride controlled release products. As a result, Coker avers, consumers of OxyContin have paid and continue to pay artificially inflated and non-competitive prices for the pain medication. These allegations were based on two factual theories: (1) Purdue made material misrepresentations to the PTO in obtaining the OxyContin patents, and (2) Purdue engaged in "sham litigation" against potential producers of generic equivalents of OxyContin.

On February 27, 2004, Purdue removed Coker's case to the United States District Court for the Western District of Tennessee. As a basis for removal, Purdue argued that, although Coker's allegations were couched in terms of state law claims, their disposition depended entirely on the resolution of substantial questions of federal patent law. Purdue contended that the allegations involving conduct before the PTO in obtaining the OxyContin patents and its enforcement of the OxyContin patents in federal court could not be resolved absent a construction of federal patent law. Therefore, Purdue maintained, the allegations in Coker's complaint established federal question jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).³ In response, Coker filed a motion to remand.

²Purdue appealed Judge Stein's inequitable conduct judgment to the United States Court of Appeals for the Federal Circuit. *See Purdue Pharma L.P. v. Endo Pharm., Inc.*, 410 F.3d 690 (Fed. Cir. 2005). The Federal Circuit initially affirmed Judge Stein's ruling, *id.* at 701, but subsequently granted a rehearing. *See Purdue Pharma L.P. v. Endo Pharm., Inc.*, 438 F.3d 1123 (Fed. Cir. 2006). On petition for rehearing, the appellate court affirmed Judge Stein's finding that Purdue made material misrepresentations to the PTO, but vacated his finding that Purdue intended to deceive the PTO. *Id.* at 1131, 1134. Consequently, the Federal Circuit has remanded the case back to the district court with instructions to "reconsider its intent finding," "rethink the relevance of the evidence," and "reweigh its materiality and intent findings to determine whether the sanction of unenforceability due to inequitable conduct is warranted." *Id.* at 1135.

³As an alternative basis for federal jurisdiction, Purdue also asserted the doctrine of "complete preemption" under the Employment Retirement Income Security Act of 1974 (ERISA), 29 U.S.C. § 1001 *et seq.* This was rejected by the federal district court, and is not an issue in this appeal.

On April 23, 2004, U.S. District Judge Bernice Donald granted Coker's motion to remand. *See Coker v. Purdue Pharma Co.*, 314 F.Supp.2d 777 (W.D. Tenn. 2004). In remanding the case, Judge Donald found that Coker's state law claims against Purdue were based on two types of misconduct, namely, material misrepresentations before the PTO during prosecution of the OxyContin patents and sham litigation against Endo in an effort to enforce the OxyContin patents, and that both types of misconduct necessarily involved questions of federal patent law. *Id.* at 782. Judge Donald went on to find, however, that, under an alternative theory, Coker's state law claims could be resolved without determining questions of federal law. Judge Donald noted that Coker's complaint refers to Judge Stein's January 2004 decision when it states:

After a non-jury trial, a federal court found that, *inter alia*, the Defendants had made numerous misrepresentations to the U.S. PTO and to the Federal Court regarding the product. In addition, the Court found that the Defendants had no evidence to support their claim that the drug was "effective" in low dosages for 90% of its patients.

Id. at 783. Judge Donald concluded that Judge Stein's January 2004 decision operated as collateral estoppel and effectively replaced any patent law questions on the issue of whether Purdue made material misrepresentations before the PTO in prosecution of the OxyContin patents.⁴ *Id.* Consequently, because at least one theory in support of Coker's state law claims did not require the resolution of any substantial questions of federal patent law, Judge Donald remanded the case to the state trial court below.⁵ *Id.* at 783-84, 787.

On remand, on June 8, 2004, Purdue filed a motion for judgment on the pleadings. Purdue asserted that Coker's complaint should be dismissed because: (1) the claims based on material misrepresentations before the PTO were preempted by federal patent law; and (2) the remaining claims based on "sham litigation" were subject to exclusive federal jurisdiction pursuant to 28 U.S.C. § 1338.⁶ In short, Purdue averred that federal patent laws bar the imposition of state tort

⁴Judge Donald commented that the appeal of Judge Stein's ruling did not bar the preclusive effects of the judgment unless and until it was reversed. *Purdue Pharma Co.*, 314 F.Supp.2d at 783 (citing *Huron Holding Corp. v. Lincoln Mine Operating Co.*, 312 U.S. 183, 189 (1941)). As noted above, the Federal Circuit has since vacated Judge Stein's finding of intent, and the case is now pending in the United States District Court for the Southern District of New York.

⁵In addition to removing Coker's case to federal court, Purdue also filed a motion to transfer the proceedings to the Southern District of New York on March 4, 2004. At the time of the motion, Purdue reported that thirty other antitrust lawsuits had been filed against Purdue, which were similarly based on Judge Stein's January 2004 decision. Of these thirty cases, Purdue stated that nineteen had already been filed in the United States District Court for the Southern District of New York, making it the most sensible forum. The motion to transfer was never heard, however, because Judge Donald remanded Coker's case back to the trial court for lack of federal jurisdiction. *See Purdue Pharma Co.*, 314 F.Supp.2d at 780 & n.3.

⁶We note that Judge Donald did not consider the separate question of whether federal patent law preempted the state law claims at issue; she addressed only the issue of whether Coker's complaint established federal question jurisdiction to support removal to the federal district court, which is governed by the "well-pleaded complaint rule."

(continued...)

liability based on conduct before the PTO unless the complaint alleges that the patents were procured through fraud. Purdue, argued that, while the complaint alleged “material misrepresentations,” it did not allege fraud. Furthermore, if the misrepresentation claims were preempted, then only the “sham litigation” allegation remained at issue. Referencing Judge Donald’s prior decision on the motion to remand, Purdue asserted that these claims were the subject of exclusive federal jurisdiction because the issue of whether Purdue engaged in “sham litigation” to enforce its patent rights necessarily involved questions of federal patent law.

On April 6, 2004, Coker filed his response to Purdue’s motion for judgment on the pleadings. First, Coker asserted that Judge Donald’s finding of collateral estoppel definitely resolved the issue of federal preemption. According to Coker, any federal questions on the issue of material misrepresentations were replaced by collateral estoppel, and the state law issues that remained were not preempted by the federal patent laws. Coker next averred that Judge Stein’s finding of inequitable conduct effectively stripped Purdue of any patentholder immunity from prosecution on state law claims. Coker argued that Judge Stein’s finding of inequitable conduct not only established that Purdue made material misrepresentations before the PTO, but also that Purdue did so willfully and with knowledge. Finally, Coker maintained that his complaint did, in fact, allege fraud. Pointing to specific phrases in the complaint—e.g., “concerted action” and “with the purpose”—Coker argued that the complaint alleged intentional, fraudulent conduct, rather than mere negligence or recklessness.

On November 5, 2004, the trial court heard oral arguments on Purdue’s motion for judgment on the pleadings. Subsequently, the trial court issued the following opinion and order:

FEDERAL PREEMPTION DEFENSE

Plaintiff bases his state law claims in the present case on Defendant Purdue’s conduct in obtaining its federal patent rights. More specifically, Plaintiff alleges that Purdue made material misrepresentations to the United States Patent and Trademark Office in procuring its patents. Federal law pertaining to such actions is well established. The case of *Hunter Douglas, Inc. v. Harmonic Design, Inc.* . . . specifically preempts state law claims based on conduct in obtaining a federal patent unless the plaintiff alleges that the patent was procured through fraud. In the present case, Plaintiff alleges only misrepresentation to the PTO and not fraud. The

⁶(...continued)

Coker v. Purdue Pharma Co., 314 F.Supp.2d 777, 781 (W.D. Tenn. 2004). The well-pleaded complaint rule “provides that federal jurisdiction exists only when a federal question is presented on the face of the plaintiff’s properly pleaded complaint,” *Caterpillar Inc. v. Williams*, 482 U.S. 386, 392 (1987), and the district court’s review of the complaint proceeds without consideration of potential federal defenses, including the defense of federal preemption. *See Franchise Tax Bd. v. Constr. Laborers Vacation Trust*, 463 U.S. 1, 10 (1983); *see also Metro. Life Ins. Co. v. Taylor*, 481 U.S. 58, 63 (1987) (“Federal preemption is ordinarily a federal defense to the plaintiff’s suit. As a defense, it does not appear on the face of a well pleaded complaint, and, therefore, does not authorize removal to federal court.”). Consequently, when Judge Donald remanded the case for lack of jurisdiction, the substantive defense of preemption remained for the state court to decide.

complaint includes no reference to the term “fraud,” and no effort is made by the Plaintiff to meet the heightened pleading requirement of Tenn. R. Civ. P. 9.02, applicable to allegations of fraud. Because Plaintiff in the present action alleges only misrepresentation and not fraud, his claim relating to Purdue’s procurement of its patents is preempted by federal patent law.

SHAM LITIGATION ALLEGATIONS

Having established the defense of federal preemption, the only remaining allegation in Plaintiff’s complaint is that Defendants engaged in sham litigation against potential producers of a generic equivalent of OxyContin. Judge Donald determined in her remand order that the Plaintiff’s sham litigation allegation necessarily involved the resolution of questions of federal patent law. She merely remanded the entire case to this Court once she determined that allegations of misrepresentation could be proven without resorting to any question of federal law. However, having applied Purdue’s federal preemption defense to the Plaintiff’s claims of material misrepresentation before the PTO, this Court lacks subject matter jurisdiction over the sham litigation claim because, as Judge Donald ruled, it necessarily involves the resolution of questions of federal law and is therefore subject to the exclusive jurisdiction of the federal courts.

(citation omitted). Thus, the trial court first found that the “material misrepresentation” claims were preempted by federal law, and consequently that the trial court lacked subject matter jurisdiction over the remaining “sham litigation” allegation. Accordingly, the trial court granted Purdue’s motion for judgment on the pleadings and dismissed Coker’s complaint. The trial court entered its opinion and order on September 27, 2005. Coker, on behalf of himself and all other persons similarly situated, filed a notice of appeal on October 24, 2005.

On appeal, Coker argues that the trial court erred in granting judgment on the pleadings to Purdue. We focus our review on the trial court’s finding that the state law claims, which are based on Purdue’s conduct before the United States Patent and Trademark Office, are preempted by federal patent law.⁷

A motion for judgment on the pleadings made by the defendant is essentially a motion to dismiss for failure to state a claim upon which relief can be granted. *Waldron v. Delffs*, 988 S.W.2d 182, 184 (Tenn. Ct. App. 1998) (citing 3 Nancy F. MacLean & Bradley A. MacLean, *Tennessee Practice* 190 (2nd ed. 1989)). Such a motion to dismiss under Tenn. R. Civ. P. 12.02(6) tests only the sufficiency of the complaint, and not the strength of the plaintiff’s proof. *Cook v. Spinnaker’s of Rivergate, Inc.*, 878 S.W.2d 934, 938 (Tenn. 1994). The motion “admits the truth of all relevant

⁷At oral argument, counsel for Coker conceded that the trial court’s finding on the issue of “sham litigation” is not before this Court. Therefore, as reflected above, our review examines only the trial court’s finding on the issue of Purdue’s federal preemption defense. For purposes of this appeal, the “sham litigation” allegation is considered waived.

and material averments contained in the complaint, but asserts that such facts do not constitute a cause of action.” *Stein v. Davidson Hotel Co.*, 945 S.W.2d 714, 716 (Tenn. 1997). In ruling on such a motion, courts should construe the complaint liberally in favor of the plaintiff, taking all allegations of fact in the complaint as true. *Stein*, 945 S.W.2d at 716; *Cook*, 878 S.W.2d at 938. “The motion should be denied unless it appears that the plaintiff can prove no set of facts in support of her claim that would entitle her to relief.” *Cook*, 878 S.W.2d at 938; *see also Waldron*, 988 S.W.2d at 184. Therefore, in reviewing on appeal the trial court’s grant of judgment on the pleadings, we take the factual allegations in the complaint as true and review the trial court’s legal conclusions *de novo* with no presumption of correctness. Tenn. R. App. P. 13(d); *Doe v. Sundquist*, 2 S.W.3d 919, 922 (Tenn. 1999); *Stein*, 945 S.W.2d at 716.

Furthermore, we look at the record as it stood at the time of the trial court’s ruling. Therefore, to the extent that we refer to Purdue’s separate but related patent infringement litigation against Endo, we look only to Judge Stein’s ruling as it stood when the trial court granted Purdue’s motion for judgment on the pleadings. *See* Tenn. R. App. P. 14(a).

We begin our analysis of the federal preemption issue presented on this appeal with the Supremacy Clause of the United States Constitution. Article VI, Clause 2, of the Constitution mandates that the “Laws of the United States . . . shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.” Under this provision, the United States Supreme Court has long held that “state law that conflicts with federal law is ‘without effect.’” *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992) (quoting *Maryland v. Louisiana*, 451 U.S. 725, 746. (1981)). Accordingly, state law is preempted if it “stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.” *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941).⁸

The federal laws at issue in this case are the federal patent laws, which derive from Congress’ power under Article I, Section 8, Clause 8, of the Constitution. This provision grants Congress the power “[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.” Pursuant to this authority, Congress enacted the federal Patent Act, granting an inventor with a valid patent in effect a lawful monopoly on the patented item, within the parameters of the federal statutes. *See*

⁸State law may be preempted in one of three ways: explicit preemption, field preemption, and conflict preemption. *See generally English v. General Elec. Co.*, 496 U.S. 72, 78-79 (1990). Explicit preemption arises, of course, when the federal statute at issue explicitly provides for such preemption. In contrast, for both field and conflict preemption, congressional intent to preempt is implied. *See Hunter Douglas, Inc. v. Harmonic Design, Inc.*, 153 F.3d 1318, 1332 (Fed. Cir. 1998). Field preemption occurs when a state attempts to regulate conduct “in a field that Congress intends the federal government to occupy exclusively.” *Id.* In an area in which federal law does not preclude the enforcement of state laws on the same subject, a state law may nevertheless be preempted “to the extent that it actually conflicts with federal law” so that it is impossible to comply with both the state and federal laws, i.e. conflict preemption. *Id.* Conflict preemption may also be found where the state law in question “stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.” *Id.* (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)). It is undisputed that the only type of preemption at issue in this case is the latter type of conflict preemption.

35 U.S.C. §§ 1-376 (2000). Congress has also provided federal means to invalidate a patent. *See* 28 U.S.C. § 2201-02 (2000); 35 U.S.C. §§ 282, 302-07 (2002). There are three objectives underlying the federal patent laws: to “provid[e] an incentive to invent;” to “promot[e] the full disclosure of inventions;” and to “ensur[e] that ‘that which is in the public domain cannot be removed therefrom by action of the States.’” *Dow Chem. Co. v. Exxon Corp.*, 139 F.3d 1470, 1474 (Fed. Cir. 1998) (quoting *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 480-81 (1974)). Under the Supremacy Clause, therefore, a state cause of action that stands as an “obstacle” to the accomplishment of these objectives is preempted and must be dismissed.

In this case, Coker’s antitrust and unfair competition claims against Purdue hinge on Purdue’s conduct before the PTO in obtaining its patents. Consequently, we must determine the extent to which these state law claims may be pursued. The United States Supreme Court, in *Walker Process Equipment, Inc. v. Food Machinery and Chemical Corp.*, 382 U.S. 172 (1965), addressed a similar issue in the context of federal antitrust law. Specifically, the Court considered “whether the maintenance and enforcement of a patent obtained by fraud on the Patent Office” may be the basis of a federal antitrust claim brought under Section 2 of the Sherman Act. *Id.* at 173. There, the Court held that proof that the patentholder procured its patent by “knowingly and willfully misrepresenting facts to the Patent Office” would be sufficient to subject a patentholder to liability under the federal antitrust laws. *Id.* at 177.

In a concurring opinion, Justice Harlan elaborated on the Court’s reasoning, explaining that the Court’s decision sought to achieve a balance between the differing objectives and policies underlying the federal patent and antitrust laws. *Id.* at 179. According to Justice Harlan, the imposition of liability on a patentholder for “knowingly” practicing a monopolization under the authority of a patent obtained by “deliberate fraud” does not “impinge upon the policy of the patent laws to encourage inventions and their disclosure.” *Id.* at 179-80. He defined the reach of the Court’s holding, however, stating:

[T]o 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 available to reach [Section] 2 monopolies carried on under a nonfraudulently procured patent.

Id. at 180. Thus, under *Walker Process* and in particular Justice Harlan’s concurring opinion, a federal antitrust claim based on a patentholder’s conduct before the PTO could be pursued if the plaintiff alleged and proved that the patent was obtained through knowing and deliberate fraud. *Walker Process* did not, however, sanction the pursuit of such a claim if it involved a “nonfraudulently procured patent.” *Id.*; *see also Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1068 (Fed Cir. 1998) (following *Walker Process* and holding that a patentholder may

be subject to federal antitrust liability if the plaintiff proves that the patentholder obtained its patent through “knowing and willful fraud”).

Since *Walker Process*, the Federal Circuit⁹ has squarely addressed the extent to which a plaintiff may pursue state antitrust claims based on a patentholder’s conduct before the PTO. In doing so, the Federal Circuit discussed the preemptive effects of the federal patent laws and set forth a clear rule of law, which essentially extends the reasoning of *Walker Process* to state law antitrust claims. In *Hunter Douglas, Inc. v. Harmonic Design, Inc.*, the court considered “to what extent federal patent law preempts state law causes of action prohibiting tortious activities in the marketplace, when to prevail on them, the plaintiff must prove that a United States Patent is either invalid or unenforceable.” 153 F.3d 1318, 1321 (Fed. Cir. 1998), *overruled on other grounds*, *Midwest Indus., Inc. v. Karavan Trailers, Inc.*, 175 F.3d 1356 (Fed. Cir. 1999). In *Hunter Douglas*, defendant Harmonic owned several patents on technology surrounding motorized window blinds. *Hunter Douglas*, 153 F.3d at 1321. Plaintiff Hunter Douglas, a competing manufacturer of motorized window blinds, sued Harmonic, alleging that the Harmonic patents were unenforceable because the patents had been obtained by virtue of inequitable conduct before the PTO. *Id.* Hunter Douglas asserted state law claims against Harmonic which depended in part on resolving the issue of whether the Harmonic patents were valid and enforceable., i.e. “federal patent law issues housed in state law causes of action.” *Id.* at 1322, 1334. In response, Harmonic argued that the state law claims asserted by Hunter Douglas were preempted by federal patent law. *Id.* at 1331.

In addressing Harmonic’s defense of preemption, the *Hunter Douglas* court first determined that the type of preemption at issue was conflict preemption, framing the issue as “whether the state law actions frustrate ‘the accomplishment and execution of the full purposes and objectives of Congress.’ ” *Id.* at 1335 (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)). To address this issue, the Federal Circuit formulated a conduct-based approach:

To determine whether . . . state law torts are in conflict with federal patent law and accordingly preempted, we assess [the] defendant's allegedly tortious conduct. If a plaintiff bases its tort action on conduct that is protected or governed by federal patent law, then the plaintiff may not invoke the state law remedy, which must be preempted for conflict with federal patent law. Conversely, if the conduct is not so protected or governed, then the remedy is not preempted.

Hunter Douglas, 153 F.3d at 1335. The *Hunter Douglas* court explained that this approach considers whether the tort “as-applied” conflicts with federal patent law, and thus focuses the analysis on the conduct that forms the basis of the state law cause of action. *See id.*

⁹The Federal Circuit has exclusive jurisdiction over appeals from the United States District Courts arising under the federal patent laws, see 28 U.S.C. § 1295(a)(1) (2000). The Federal Circuit recently held that its law, not the law of the regional circuit from which the case originated, governs the issue of whether federal patent law preempts certain state law causes of action. *Midwest Indus., Inc. v. Karavan Trailers, Inc.*, 175 F.3d 1356, 1358-59 (Fed. Cir.1999).

The *Hunter Douglas* court went on to identify specific types of conduct that may not be the subject of state tort liability, because to do so would conflict with the objectives underlying the federal patent laws. *Id.* at 1335-36. Regarding the patent application proceedings, the Federal Circuit found that federal patent law bars the imposition of liability for state law torts based on conduct before the PTO, unless the plaintiff shows that “the conduct amounted to fraud or rendered the application process a sham.” *Id.* at 1336 (citing *Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059 (Fed. Cir. 1998); *Abbott Laboratories v. Brennan*, 952 F.2d 1346 (Fed. Cir. 1991)). To escape preemption, the *Hunter Douglas* court stated, a plaintiff would need to allege, and ultimately prove, that the defendant engaged in fraud before the PTO, because to require less than a showing of fraud “would impermissibly alter the balance between the competing purposes of federal patent law that Congress has prescribed.” *Id.* at 1337. Thus, where a case involves a “patentholder’s conduct in obtaining its . . . patent, if the plaintiff . . . fail[s] to allege that the defendant patentholder was guilty of fraudulent conduct before the PTO . . . , then the complaint would be dismissed for failure to state a claim upon which relief can be granted because of federal preemption.” *Id.* at 1336.

Thus, consistent with the Supreme Court’s holding in *Walker Process*, the *Hunter Douglas* court established a “clear line” between conduct which may expose a patentholder to state tort liability and conduct which is protected under the federal patents laws. *See id.* at 1336. Applying the reasoning in *Hunter Douglas* to the case at bar, then, our task becomes to determine whether Coker’s complaint alleges that Purdue engaged in fraudulent conduct before the PTO in procurement of the OxyContin patents.

Coker, however, insists that we need not determine whether the complaint alleges such fraudulent conduct, because the combined rulings of Judge Donald and Judge Stein determine the preemption issue raised on this appeal. Coker first asserts that Judge Donald’s finding of collateral estoppel on the issue of inequitable conduct resolves all federal questions regarding Purdue’s conduct before the PTO, leaving only state law issues to be decided. Coker maintains that if the federal questions concerning Purdue’s conduct before the PTO are judicially established, this removes any potential for conflict between the federal patent laws and the remaining state law issues. Second, Coker contends that Judge Stein’s finding of inequitable conduct is sufficient, as the subject of collateral estoppel in state court, to strip Purdue of any limited patentholder immunity from state tort liability.

We disagree with Coker’s assertion that these rulings resolve the preemption issue. As previously discussed, Judge Stein found that Purdue made material misrepresentations before the PTO during prosecution of the OxyContin patents. *Purdue Pharma L.P. v. Endo Pharm., Inc.*, Nos. 00 CIV. 8029(SHS), 01 CIV. 2109(SHS), 01 CIV. 8177(SHS), 2004 WL 26523, at *20-27 (S.D.N.Y. Jan. 5, 2004). Judge Stein concluded that Purdue engaged in inequitable conduct before the PTO, which rendered Purdue’s patents unenforceable. *Id.* at *27. Judge Stein’s decision was initially affirmed on appeal to the Federal Circuit. *Purdue Pharma L.P. v. Endo Pharm., Inc.*, 410 F.3d 690, 701 (Fed. Cir. 2005). There is a difference, however, between a finding of “inequitable” conduct and “fraudulent” conduct. In *Nobelpharma AB v. Implant Innovations, Inc.*, the Federal

Circuit explained the difference between the two: “[i]nequitable conduct in fact is a lesser offense than common law fraud, and includes types of conduct less serious than ‘knowing and willful’ fraud.” 141 F.3d 1059, 1069 (Fed. Cir. 1998). The *Nobelpharma* court stated specifically: “[i]nequitable conduct is . . . an equitable defense in a patent infringement action and serves as a shield, while a more serious finding of fraud potentially exposes a patentee to antitrust liability and serves as a sword.” *Id.* at 1070.

Therefore, Judge Stein’s January 2004 decision does not resolve the question of whether Purdue committed knowing and willful fraud before the PTO in obtaining the OxyContin patents. Moreover, the issues of knowledge and willfulness were not judicially established by the finding of inequitable conduct. Consequently, while Judge Donald’s finding of collateral estoppel may have resolved any federal questions on the issue of material misrepresentations before the PTO, it left undecided the issue of whether Purdue acted with the knowledge and willfulness necessary to strip it of immunity from state tort liability. Accordingly, the rulings by Judge Stein and Judge Donald do not determine whether Purdue committed the requisite fraud before the PTO. As noted in *Hunter Douglas*, Coker must allege and ultimately prove such fraud in order to escape federal preemption.

We turn, then, to the complaint to ascertain whether it alleges that Purdue engaged in fraudulent conduct before the PTO. Coker’s complaint sets forth three causes of action: violations of the Tennessee Trade Practices Act; violations of the Tennessee Consumer Protection Act; and common law monopolization. These claims are clearly based on Purdue’s conduct before the PTO during prosecution of the OxyContin patents. Specifically, the complaint reads: “Defendants’ OxyContin® has not faced competition from generic bioequivalent[s] because of Defendants’ unlawful efforts to obtain and enforce a monopoly for the product through material misrepresentations to the United States Patent and Trademark Office.” (Compl. ¶ 22). Thus, although Coker alleges “material misrepresentations” by Purdue to the PTO, he does not explicitly allege fraud.

Despite this, Coker maintains that the complaint, in fact, pleads the requisite fraud. In support of this assertion, Coker quotes four paragraphs of the complaint in his brief to this Court. These paragraphs read as follows:

Defendants’ contract, combination, or conspiracy has included *concerted* action and undertakings among these Defendants *with the purpose* and effect to preclude Plaintiff and the Class from the opportunity to purchase less expensive, generic bioequivalents to OxyContin®.

For the purpose of formulating and effectuating their contract, combination, or conspiracy, Defendants performed the various acts, as alleged herein, including depriving consumers of the ability to purchase the product at a competitive price.

The acts done by each of the Defendants as part of, and in furtherance of, their contract, combination, or conspiracy were authorized, ordered, or done by their

officers, agents, employees, or representatives while actively engaged in the management of Defendants' affairs.

* * *

Defendants [have] exerted [their] monopoly power to demand and obtain combinations of capital, skill, and acts with numerous others with the *intent, purpose, and effect* of creating and carrying out restrictions in trade and commerce.

(Compl. ¶¶ 39, 40, 41, 48) (bold and emphasis in original). Coker also cites to paragraphs 52, 57, 59, 60, 61, 66, and 68, which contain similar phraseology: “for the purpose of” appears in paragraph 52 and “with the intent, purpose, and effect of” appears in paragraph 57. Paragraphs 60 and 61 even use the term “fraudulent,” albeit to describe Purdue’s business acts and practices, allegedly in violation of the Tennessee Consumer Protections Act and the common law. Based on the above provisions, Coker insists that the complaint pleads fraud, rather than mere negligence or recklessness.

Regardless, none of the allegations in the complaint cited by Coker address Purdue’s conduct before the PTO in procurement of the OxyContin patents. Instead, these generalized allegations characterize Purdue’s business acts and practices towards consumers of OxyContin—the class on whose behalf Coker brought the state law claims. Under the rule of law established in *Hunter Douglas*, however, before a patent-holder can be exposed to state tort liability based on conduct before the PTO, the plaintiff must allege and ultimately prove that the patent-holder “was guilty of fraudulent conduct *before the PTO.*” *Hunter Douglas*, 153 F.3d at 1336 (emphasis added). Therefore, we must focus on the allegations in the complaint that specifically address Purdue’s conduct in procurement of the OxyContin Patents.

Only two allegations in Coker’s complaint explicitly address Purdue’s conduct before the PTO. First, the complaint alleges that Purdue unlawfully sought to “obtain and enforce a monopoly for the product through material misrepresentations to the United States Patent and Trademark Office.” (Compl. ¶ 22). Second, the complaint refers to Judge Stein’s January 2004 decision, stating:

After a non-jury trial, a federal court found that, *inter alia*, [Purdue] had made numerous misrepresentations to the U.S. PTO . . . regarding the product. In addition, the Court found that [Purdue] had no evidence to support their claim that the drug was “effective” in low dosages for 90% of its patients.

(Compl. ¶ 33). No other allegations or claims in the complaint refer to Purdue’s conduct before the PTO.

In examining these allegations, we are guided by the Federal Circuit’s definition of the “knowing and willful” fraud sufficient to strip a patentholder of its immunity from federal antitrust liability. In *Nobelpharma*, the Federal Circuit discussed “ ‘fraud,’ as that term was used by the Supreme Court in *Walker Process.*” *Nobelpharma*, 141 F.3d at 1069. The *Nobelpharma* court

noted that *Walker Process* fraud “may not be based upon [the] equitable balancing of lesser degrees of materiality and intent” required for inequitable conduct, but, instead, must be “based on independent and clear evidence of deceptive intent together with a clear showing of reliance, *i.e.*, that the patent would not have issued but for the misrepresentation.” *Id.* at 1071.

In addition, we note that allegations of fraud in Tennessee are subject to heightened pleading requirements under Rule 9.02 of the Tennessee Rules of Civil Procedure. Rule 9.02 states that “[i]n *all* averments of fraud . . . , the circumstances constituting fraud . . . shall be stated with particularity” in the complaint. Tenn. R. Civ. P. 9.02 (emphasis added).

Under all of these circumstances, we must conclude that Coker’s complaint does not plead that Purdue engaged in fraudulent conduct before the PTO. It alleges only that Purdue made numerous material misrepresentations to the PTO regarding OxyContin, but does not allege that Purdue intended to deceive the PTO and likewise does not allege that the OxyContin patents would not have issued but for the PTO’s reliance on Purdue’s misrepresentations. Moreover, as noted by the trial court, Coker made no effort to conform the pleadings to the heightened requirements of Tenn. R. Civ. P. 9.02. Consequently, we agree with the finding of the trial court that Coker’s complaint pleads only misrepresentations, not fraud. Accordingly, we must hold that Coker’s complaint seeks to impose state tort liability on Purdue based on conduct that is protected by the federal patent laws. Under *Hunter Douglas*, Coker’s claims are preempted by the federal patent laws. Therefore, Coker’s complaint must be dismissed for failure to state a claim upon which relief can be granted.

The decision of the trial court is affirmed, and the costs of this appeal are assessed against Plaintiff/Appellant Coker, for which execution may issue, if necessary.

HOLLY M. KIRBY, JUDGE