IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

FEDERAL TRADE COMMISSION, Plaintiff,	:	CIVIL ACTION
v.	:	No. 2:08-cv-2141
CEPHALON, INC., Defendant.	:	

Goldberg, J. **July 29, 2014**

MEMORANDUM OPINION

In Federal Trade Commission v. Actavis, 133 S. Ct. 2223 (2013), the Supreme Court attempted to provide trial courts with guidance regarding the proper factors to be considered in a "reverse payment"[1] antitrust trial. In doing so, the court stated that it is "normally not necessary to litigate patent validity to answer the antitrust question." Id. at 2236.

In the reverse payment antitrust case before me, such litigation has already occurred wherein the patent in question (RE '516) was found invalid and procured through inequitable conduct. Thus, the issue in this case is not whether the validity of the patent should be litigated in the antitrust trial, but rather, how my previous finding of invalidity and inequitable conduct will shape the antitrust trial.

This question has loomed over this case for some time and was first raised by the private plaintiffs in three related cases, who urged that Cephalon's inequitable conduct and the principles of collateral estoppel mandated that judgment be entered in their favor. The collateral estoppel question was not addressed because I concluded that Cephalon's Seventh Amendment right to a jury trial prevented the private Plaintiffs from using offensive collateral estoppel to preclude re-

[1] A reverse payment settlement refers to a "settlement [that] requires the patentee to pay the alleged infringer, rather than the other way around." Actavis, 133 S. Ct. at 2227.

litigation of the issue of fraud on the Patent and Trademark Office (PTO). King Drug Co. of Florence, Inc. v. Cephalon, Inc., 2014 WL 982848 (E.D. Pa. March 13, 2014). In so ruling, I also put off consideration of the Federal Trade Commission's (FTC) related motion contending that Cephalon be precluded from introducing any evidence related to the strength (or perceived strength) of the RE '516 patent. This is because the FTC may only seek equitable relief, and as such, Seventh Amendment considerations did not apply to their case. See F.T.C. v. Verity Int'l, Ltd., 443 F.3d 48, 67 (2d Cir. 2006) ("The fact that only an equitable remedy is available eviscerates the defendants-appellants' contention that the Seventh Amendment confers a right to a jury trial in this case.").

The effect of Cephalon's inequitable conduct on the antitrust trial where the FTC is the Plaintiff must now be sorted out. After careful consideration, I conclude that principles of collateral estoppel prevent Cephalon from relying on the strength of its patent or litigation "uncertainty" in defending against the FTC's antitrust claims. This Opinion explains the basis of that decision.[2]

[2] In considering the FTC's preclusion motion, I have also considered and rejected Cephalon's argument that the FTC's case became moot upon the entry of generic Provigil competition in 2012. "A case becomes moot only when it is impossible for a court to grant 'any effectual relief whatever' to the prevailing party." Knox v. Serv. Emps. Intl. Union, 132 S. Ct. 2277, 2287 (2012) (quoting Erie v. Pap's A.M., 529 U.S. 277, 287 (2000)). To take just one form of relief the FTC says it may pursue, Cephalon argues that the Court "should deny the FTC's belated request for monetary relief" because: (1) the FTC did not include a specific prayer for disgorgement in its complaint, (2) the FTC has often stated that it did not intend to seek monetary relief, and (3) an FTC policy statement in place for most of this litigation (though now withdrawn) would have counseled against seeking equitable monetary relief. These arguments address only the propriety of certain relief, not the Court's power to grant it. See Arizonans for Official English v. Arizona, 520 U.S. 43, 68-69 (1997) (holding that a claim for nominal damages against the state under 42 U.S.C. § 1983 did not save case from mootness because § 1983 creates no cause of action against a state). Cephalon may or may not be right that the FTC is not entitled to any of the relief it currently seeks. But to try to answer this question on a motion challenging the Court's subject-matter jurisdiction "confuses mootness with the merits." Chafin v. Chafin, 133 S. Ct. 1017, 1024 (2013); see also Powell v. McCormack, 395 U.S. 486, 500

I. Factual & Procedural Background

Cephalon was once the owner of U.S. Reissue Patent No. 37,516 (RE '516), which claimed a specific formulation of modafinil—a molecule with wakefulness-promoting properties. This patent covered Cephalon's flagship drug, Provigil, and when combined with a number of regulatory exclusivity periods Cephalon had obtained, it had the potential to protect Provigil from competition through April 6, 2015.

But the life of the RE '516 patent was challenged long before that date. On December 24, 2002, the first day allowed by law, four generic drug manufacturers sought permission from the FDA to market generic versions of Provigil. In doing so, the generics were required by the Hatch-Waxman Act to make a certification regarding the RE '516 patent. All four certified that the RE '516 patent was either invalid or not infringed by the proposed generic drugs.[3]

These certifications—technical acts of infringement under Hatch-Waxman—prompted Cephalon to file a lawsuit for patent infringement against the four generic companies. Between late 2005 and early 2006, all four of these cases settled, with Cephalon paying the generics millions of dollars in return for various business arrangements and, most importantly for purposes of this case, promises from each of the generics to drop their respective invalidity contentions and not market a generic version of Provigil until April 6, 2012. These settlements, which potentially delayed the entry into the market of generic Provigil, immediately drew antitrust scrutiny from private plaintiffs and, as relevant here, the FTC.

(1969) (holding that claim for backpay saved case from mootness, despite argument that the claim was brought in the wrong court and thus the requested relief could not be ordered).

[3] A more detailed discussion of the regulatory landscape that forms the backdrop for this case can be found in the Actavis decision, 133 S. Ct. 2223, 2227-29 (2013), and in my earlier opinion denying Cephalon's motions to dismiss the complaints, King Drug Co. of Florence, Inc. v. Cephalon, Inc., 702 F. Supp. 2d 514, 519-21 (E.D. Pa. 2010).

The settlements also left other companies who wished to market a generic version of Provigil in a bind. Under another feature of Hatch-Waxman, no other company could sell generic Provigil until six months after the four settling generics began to market their versions. Thus, in order to be allowed to enter the market sooner, a generic would need to receive a court determination that the RE '516 patent was invalid or not infringed. Here, along with its antitrust claims, Apotex, Inc. sought a declaratory judgment invalidating the patent. See King Drug Co. of Florence, Inc. v. Cephalon, Inc., 2014 WL 2813312, at *1-3 (E.D. Pa. June 23, 2014) (recounting these and other facts surrounding the reverse payment settlement agreements and the pending antitrust cases).

After an extensive bench trial, I found merit in Apotex's contentions, and held that Cephalon's patent was invalid on several grounds, and unenforceable as a result of Cephalon's inequitable conduct during the procurement process. Apotex, Inc. v. Cephalon, Inc., 2011 WL 6090696 (E.D. Pa. Nov. 7, 2011). In short, I concluded that Cephalon knew, but failed to disclose to the Patent Office, that another company had invented the drug formulation for which it sought a patent. Id. at *26. I further found that Cephalon omitted this information from its presentation to the Patent Office with the specific intent to deceive the Office into granting an invalid patent. Id. at *27. This ruling was subsequently affirmed by the United States Court of Appeals for the Federal Circuit, Apotex, Inc. v. Cephalon, Inc., 500 Fed. Appx. 959 (Fed. Cir. 2013), and further review was denied, 134 S. Ct. 825 (2013).

II. The Parties' Positions

While the Actavis decision held that reverse payment settlements should be analyzed under antitrust law's rule of reason, the "analysis left it unclear how the lower courts should deal

with the patent's merits." Note, Reverse Payment Settlements: The Ongoing Dilemma After FTC v. Actavis, 8 Brook. J. Corp. Fin. & Com. L. 516, 533 (2014).

The FTC's motion, styled "Motion For Preclusion Of Patent Issues or, In the Alternative, Partial Summary Judgment," asks that I enter an order "preventing Cephalon from introducing evidence at trial related to the potential validity, enforceability, or infringement of its RE '516 patent." (Br. of FTC 3.) The FTC offers three grounds in support of its position. First, the FTC posits that Actavis clearly directs that the merits or perceived merits of the underlying patent dispute are irrelevant to the antitrust analysis. Second, the FTC, relying on principles of collateral estoppel, urges that my ruling that the RE '516 patent is invalid and was procured by inequitable conduct precludes Cephalon from now claiming that its infringement case had merit. And third, under ordinary summary judgment principles, the FTC asserts that undisputed facts conclusively establish the invalidity of the RE '516 patent under the on-sale bar and derivation.

Cephalon counters that what matters in the antitrust analysis is not whether the RE '516 patent was ultimately declared invalid—a judgment made over five years after the reverse payment settlements were signed. Rather, Cephalon stresses that the appropriate inquiry is whether there was legitimate "uncertainty and risk on both sides of the patent litigation" when the settlements at issue were negotiated. (Br. of Ceph. 30.) Cephalon points out that my findings of invalidity and inequitable conduct were "unknown to and unpredictable by the parties" at the time of the negotiations and thus, are not relevant to the antitrust analysis. (Br. of Ceph. 31.) Cephalon also stresses that binding it to the finding of inequitable conduct would violate its right to due process of law, because at the time of the inequitable conduct patent trial, it was unaware of the possibility that any of the findings might have conclusive effects in the antitrust case.

III. Discussion

The FTC's motion first invites me to read Actavis as mandating that a patent's strength or weakness is irrelevant to the antitrust analysis of a reverse payment settlement. In the FTC's view, "the likelihood of a reverse payment bringing about anticompetitive effects does not depend on the likelihood of the patent being found invalid or not infringed." (Br. of FTC 2.) And further, because the Supreme Court identified a "payment [that] . . . seeks to prevent the risk of competition," as the "relevant anticompetitive harm," the FTC asserts that there is simply no room for a defense based on the strength of the patent. Actavis, 133 S. Ct. at 2236. Indeed, in the FTC's view, a defendant that sought to show that it paid to avoid the possibility of an invalidity ruling in uncertain patent litigation would not be defending itself at all, but proving the plaintiff's case. (Br. of FTC 5 ("Thus, even if a patent holder could demonstrate at trial that it faced only a 'small risk of invalidity' . . . such proof would not justify a payment for reduced competition.").)

I need not decide this issue here, but doubt that the FTC's position reflects the most accurate reading of Actavis. It is true that the Court noted that it "is normally not necessary to litigate patent validity to answer the antitrust question." Actavis, 133 S. Ct. at 2236. But in my view, the use of the word "normally" reflects the Court's expression that under certain discrete circumstances there could be situations where the validity of the patent should be litigated within a reverse payment antitrust trial. Moreover, in the same paragraph the Court specifically mentions the patent and observes that "the size of the unexplained reverse payment can provide a workable surrogate for a patent's weakness, all without forcing a court to conduct a detailed exploration of the validity of the patent itself." Id. at 2236-37. I do not read this language as precluding consideration of the patent, but rather, as offering an alternative to full blown exploration of the patent's validity within an antitrust trial.

Thus, I decline to grant the FTC's motion based upon the language in Actavis, which according to the FTC, precludes consideration of the RE '516 patent. I am however, persuaded by the FTC's collateral estoppel arguments.

Under the doctrine of collateral estoppel, known as issue preclusion, "once an issue is actually and necessarily determined by a court of competent jurisdiction, that determination is conclusive in subsequent suits based on a different cause of action involving a party to the prior litigation." Montana v. United States, 440 U.S. 147, 153 (1979). This rule serves the "dual purpose of protecting litigants from the burden of re-litigating an identical issue with the same party or his privy and of promoting judicial economy by preventing needless litigation." Parklane Hosiery Co. v. Shore, 439 U.S. 322, 326 (1979). Preclusion is appropriate when: (1) the issue sought to be precluded is the same as that involved in the prior action; (2) the issue was actually litigated; (3) the issue was actually determined in a valid and final judgment; and (4) the determination was essential to the prior judgment. Burlington Northern R.R. Co. v. Hyundai Merchant Marine Co., 63 F.3d 1227, 1231-32 (3d Cir. 1995).

Here, there is no significant dispute as to the last three collateral estoppel elements. As I observed in an earlier opinion:

> Regarding the second estoppel element, there can be little doubt that the issues decided in the Apotex patent trial were vigorously litigated between teams of capable attorneys. Indeed, Cephalon was represented by at least five attorneys at the invalidity trial. As to the third estoppel element, the issues were determined in a valid, final judgment, which was subsequently affirmed on appeal. Further, all of the issues resolved in the Apotex patent litigation—including the alternative justifications for holding the patent invalid—were essential to the judgment entered against Cephalon. See Henglein v. Colt Indus. Operating Corp., 260 F.3d 201, 212 (3d Cir. 2001) (holding that in a declaratory judgment action, "[e]very issue that the parties have litigated and that the court has undertaken to resolve is necessary to the judgment, and should be precluded" (quoting 18 Charles A. Wright, Arthur R. Miller & Edward H. Cooper, Federal Practice & Procedure § 4421 (1981) (internal quotation marks omitted)).

King Drug Co. of Florence, Inc. v. Cephalon, Inc., 2014 WL 982848, at *6 (E.D. Pa. March 13, 2014). These conclusions apply equally to the FTC's motion.

That leaves the question of whether the issues determined in the patent case (invalidity and unenforceability) are identical to any issues yet to be decided in the FTC's antitrust case. The FTC urges that my prior rulings would bar Cephalon from attempting to establish that the RE '516 patent is actually valid or enforceable. Cephalon seems to appreciate this reality, and states that it "does not seek to litigate patent validity at the antitrust trial." (Br. of Ceph. 30.)

Rather, Cephalon wishes to "introduce evidence showing that there was uncertainty and risk on both sides of the patent litigation when it negotiated the settlements with the Generic Defendants." (Br. of Ceph. 30.) Litigation uncertainty, Cephalon argues, is relevant to the analysis of the reverse payment agreements, and was not at issue in the patent case. Cephalon urges that a judicial finding of invalidity in 2011 has no bearing on the anticompetitiveness of the parties' settlements in 2005 and 2006. See Valley Drug Co. v. Geneva Pharma., Inc., 344 F.3d 1294, 1306 (11th Cir. 2003) ("[T]he reasonableness of agreements under the antitrust laws [is] to be judged at the time the agreements are entered into."). In Cephalon's view, the issue in the antitrust trial—whether the settlement reflected a good faith resolution of uncertain litigation—is worlds apart from the issues considered at the Apotex patent trial. (Br. of Ceph. 31.)

Cephalon's argument does have some merit with respect to subsequent determinations of invalidity. An invalidity claim litigated to verdict can have only two outcomes: the patent is valid or it is not. Prior to verdict, the parties are likely to disagree in good faith about the merits of the claim: "No one can be certain that he will prevail in a patent suit." Asahi Glass Co., Ltd. v. Pentech Pharma., Inc., 289 F. Supp. 2d 986, 993 (N.D. Ill. 2003). The fact that a patent's strength is a spectrum does not change simply because a judge later determines that the patent was, in

fact, invalid all along. Cf. 35 U.S.C. § 282(a) ("A patent shall be presumed valid."). Thus, if the question before me is whether a later determination of invalidity by itself forecloses proof of litigation uncertainty, the answer is conceivably no.

However, in addition to concluding that the RE '516 patent was invalid, I also found the patent unenforceable as a result of inequitable conduct. After Therasense v. Becton, Dickinson & Co., 649 F.3d 1276 (Fed. Cir. 2011) (the standard that guided my analysis in the Apotex litigation), inequitable conduct became equivalent to common law fraud, committed on the PTO. In Therasense, the court concluded that, to establish inequitable conduct, the "accused infringer must prove that the patentee acted with the specific intent to deceive the PTO," and that the patent would not have issued "but-for" the deception, id. at 1290-91. No amount of wordsmithing can avoid the inescapable conclusion that the language of Therasense describing inequitable conduct amounts to fraud.[4] See Unitherm Food Sys., Inc. v. Swift-Eckrich, Inc., 375

[4] Cephalon advances two arguments for the proposition that, even after Therasense, inequitable conduct is a lesser offense than fraud. These arguments are unpersuasive. First, Cephalon contends that fraud can only be proven with a showing of intent that is completely separate from materiality, while intent for inequitable conduct purposes may be inferred from materiality. (Br. of Ceph. 43.) Therasense rejected this position. Therasense, 649 F.3d at 1290 ("[A] court must weigh the evidence of intent to deceive independent of its analysis of materiality.") Second, Cephalon argues that materiality for inequitable conduct purposes is evaluated with a preponderance-of-the-evidence standard, while such proof in fraud cases must be clear and convincing. (Br. of Ceph. 45.) This is true but irrelevant here. Apotex, 2011 WL 6090696, at *25. In addition to finding that Cephalon omitted key information with the intent to deceive, I also concluded that the same information invalidated the patent on several grounds. Because invalidity must be proven by clear and convincing evidence, where undisclosed information invalidates the patent in district court, that information is necessarily material for the purposes of a fraud analysis. See Dippin Dots, Inc. v. Mosey, 476 F.3d 1337, 1344-45, 1347 (Fed. Cir. 2007) (concluding that undisclosed sales rendered patent invalid for obviousness, and that same sales proved materiality for Walker Process purposes); Cornucopia Prods., LLC v. Dyson, Inc., 881 F. Supp. 2d 1086, 1100 (D. Ariz. 2012) ("Materiality [for Walker Process purposes] is generally established by showing that omitted or misrepresented prior art (or other relevant information) would have required the examiner to reject the application."). In sum, my findings in the Apotex litigation, made consistent with the Therasense standards for inequitable conduct, supply the necessary determinations, to establish fraud on the PTO by clear and convincing evidence.

F.3d 1341, 1358 (Fed. Cir. 2004) ("[T]he elements of common law fraud include: (1) a representation of a material fact, (2) the falsity of that representation, (3) the intent to deceive or, at least, a state of mind so reckless as to the consequences that it is held to be the equivalent of intent (scienter), (4) a justifiable reliance upon the misrepresentation by the party deceived which induces him to act thereon, and (5) injury to the party deceived as a result of reliance on the misrepresentation."), rev'd on other grounds, 546 U.S. 394 (2005).

The conclusion that Cephalon committed fraud on the Patent Office is significant because patents procured by fraud do not, as a general rule, provide a defense under the antitrust laws. Walker Process Equip., Inc. v. Food Mach. & Chem. Corp., 382 U.S. 172, 177 (1965); see also Cheminor Drugs, Ltd. v. Ethyl Corp., 168 F.3d 119, 124 (3d Cir. 1999) ("[A] material misrepresentation that affects the very core of a litigant's . . . case will preclude Noerr-Pennington immunity."); Handgards, Inc. v. Ethicon, Inc., 601 F.2d 986, 994 (9th Cir. 1979) (patent lawfully procured but later enforced with knowledge of invalidity). Even under the more accommodating scope-of-the-patent test for judging the legality of reverse payment settlements, courts were inclined to make an exception to antitrust immunity for cases of fraud. E.g., In re Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323, 1337 (Fed. Cir. 2008); see also Actavis, 133 S. Ct. at 2236 ("[I]t is not normally necessary to litigate patent validity to answer the antitrust question (*unless, perhaps, to determine whether the patent litigation is a sham*)" (emphasis added and citation omitted)). Justice Harlan's concurring opinion in Walker Process explained the reason for the differing antitrust treatment of fraudulently-obtained patents and patents that are merely invalid:

> 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.

Walker Process, 382 U.S. at 179 (Harlan, J., concurring).

I thus find that obtaining its patent by fraud precludes Cephalon from defending the antitrust claim brought by the FTC on the grounds of litigation uncertainty. "[O]ne who acted fraudulently in obtaining a patent necessarily knows its patent is unenforceable." Phillip E. Areeda and Herbert Hovenkamp, Antitrust Law ¶ 706a2.

Not only is this ruling consistent with collateral estoppel principles and fraud and inequitable conduct precedent, it also comports with common sense and basic fairness. Cephalon should not be allowed to justify a reverse payment on the grounds that it resolved "uncertainty and risk" that existed because of its own affirmative misconduct. Without its misrepresentations and omissions—made with specific intent to deceive the PTO—Cephalon would never have been in the position to institute infringement litigation in the first place. That misconduct must now serve to preclude Cephalon from arguing that any portion of its payment went to resolve "uncertainty" about the boundaries of its patent rights. In short, I conclude that in this instance, the issue of fraud on the PTO conclusively resolved a key issue that Cephalon wishes to raise at trial—that is, litigation uncertainty.

In reaching this conclusion, I have carefully considered Cephalon's submission of two statements from persons of high rank within the company that state that at the time of the settlements they believed Cephalon to have a strong patent. The first is a statement from Cephalon's then-CEO Frank Baldino, who testified that "I was very confident that we had a very

solid patent here." (Ceph. Ex. 36.) The second is a statement from Cephalon's then-General Counsel, John Osborn, stating that "we had a patent that we believed was strong." (Ceph. Ex. 57.) (Osborn invoked the attorney-client privilege and refused to answer when asked the basis for this opinion.) These opinions, even if admissible, do not change the outcome of the FTC's motion.[5]

These statements attempt to escape the effect of Cephalon's fraud by proffering the opinions of persons who were allegedly ignorant of it. However, even assuming that Dr. Baldino and Mr. Osborn were being sincere, permitting this evidence would ignore basic principles of agency law, which holds that a corporation is charged with knowledge of acts done by its agents acting within the scope of their employment. Restatement (Third) of Agency § 5.03 & cmt. c (2006). This is true in the case of fraud on the PTO, even where the patent is not enforced until years later. Unitherm, 375 F.3d at 1359 ("The undisputed facts surrounding Singh's patent application demonstrate that he filed it as an employee of ConAgra, to whom he assigned it. These same facts therefore establish ConAgra's liability for any damages arising from Singh's misstatements."); Acme Precision Prods., Inc. v. Am. Alloys Corp., 422 F.2d 1395, 1398 (8th Cir. 1970) ("[K]nowledge by a corporation, obtained by and through its officers and key employees, of facts of continuing importance to the business of the corporation, even after the termination of services of that officer or employees, is conclusive upon the corporation.").

Here, there can be no dispute that the individuals who committed inequitable conduct during the patent prosecution were acting within the scope of their employment with Cephalon.

[5] The FTC, as well as the Direct Purchaser Class Plaintiffs, have moved to strike these statements from Cephalon's opposition, or to compel the attorney-client privileged advice on which they are based. Given that they do not change my analysis here, and that consideration of these specific statements was unnecessary to my decision on the Direct Purchasers' preclusion motion, I will deny both motions as moot.

See Apotex, 500 Fed. Appx. at 959 ("We [affirm] with the understanding that the court's inequitable conduct finding was based on the conduct of Dr. Peter Grebow and Mr. Richard Burgoon, while acting within the course and scope of their employment or as officers and/or employees of Cephalon."). Therefore, Cephalon—the signatory to the settlement agreements and the entity accused of antitrust violations—must be held to have had knowledge of its own misconduct, notwithstanding the alleged lack of specific knowledge on the part of Dr. Baldino and Mr. Osborn.[6]

Cephalon's final argument is that applying collateral estoppel in this instance would violate its due process rights, because prior to Actavis there was "well-established precedent making clear that a finding of invalidity or unenforceability in Apotex's patent case would not be relevant to the antitrust analysis of the early-entry settlement agreements Cephalon reached with the Generic Defendants." Further, Cephalon observes that Apotex, in seeking to bifurcate its patent claims from the antitrust case, relied on the "clear differences" between inequitable conduct and any issue to be tried in the antitrust case. Therefore, Cephalon argues, it lacked notice of the import of the rulings in the Apotex patent case, and collateral estoppel should not apply.

It is simply incorrect that Cephalon had no notice of the potential impact of an inequitable conduct ruling. As noted above, the scope-of-the-patent cases were quite uniform in recognizing an exception to immunity for fraudulently-obtained patents. The antitrust complaints also plainly accused Cephalon of fraudulently procuring its patent. (E.g., DPCP Second Am. Compl. ¶74.) I further recognized at the motion to dismiss stage that "fraud and

[6] The FTC does not discuss the imputation of knowledge issue in its separate brief, but does incorporate the arguments made by the Direct Purchasers in their preclusion motion. (Br. of FTC 7 n.4.) Cephalon responded to both of those motions in a consolidated opposition.

misrepresentations to the PTO" could be sufficient to "establish that the agreements in question grant greater rights than those conferred under the patent." King Drug, 702 F. Supp. 2d at 533. After Therasense, a finding of inequitable conduct satisfies the stringent fraud-on-the-PTO threshold (at least where the omitted or misrepresented information also grounds a ruling of invalidity).

Cephalon nonetheless complains that the Therasense decision, which made Apotex's case harder to prove, was not announced until after the evidence had closed in the patent trial. Cephalon does not and could not argue that my ruling in the Apotex case—made and affirmed on the Therasense standards—violated its due process rights. In short, Cephalon knew all along that its conduct in front of the PTO was an issue in this case, and had a full and fair opportunity to litigate that issue in the Apotex patent trial. There is nothing unfair about holding Cephalon to that result now.[7]

IV. Conclusion

In sum, in the antitrust case brought by the FTC, I hold that collateral estoppel binds Cephalon to the finding of inequitable conduct made in the Apotex patent trial. Inequitable

[7] It is important to stress the distinction between my earlier ruling and this one. In concluding that Cephalon's Seventh Amendment right to a jury trial precluded the application of collateral estoppel to my earlier inequitable conduct finding, I did not rely on the fact that Therasense had changed the standards for inequitable conduct after Cephalon had tried its patent case. Instead, beginning from the largely undisputed premise that Cephalon had a right to have a jury determine fraud in the antitrust trial, I analyzed whether Cephalon had waived that right by failing to object on Seventh Amendment grounds at the time Apotex sought bifurcation and an earlier bench trial on inequitable conduct. King Drug Co. of Florence, Inc. v. Cephalon, Inc., 2014 WL 982848, at *7 (E.D. Pa. March 13, 2014). I held that it had not, because case law at the time of bifurcation made clear that inequitable conduct (not in itself relevant to the antitrust cases) was a lesser offense than fraud on the PTO (potentially relevant to the antitrust cases). Because a finding of inequitable conduct at the time of bifurcation would not have been binding in the subsequent antitrust trials, I concluded that Cephalon's failure to raise the issue did not amount to waiver. Id. at *10.

conduct, under the Therasense standard as applied to this case, is congruent with a finding of fraud on the patent office. Cephalon's conduct forecloses any attempt to use the strength of its patent, or litigation uncertainty and business risk, as a defense to the FTC's claim that the reverse payment settlements were unlawful restraints of trade. Accordingly, I will grant the FTC's motion to preclude Cephalon from presenting any evidence at trial "related to the potential validity, enforceability, or infringement of its RE '516 patent."[8]

This, of course, does not eliminate the need for a trial. It may still be that the payments made to the generic companies "reflect[] traditional settlement considerations," such that they are not anticompetitive under the rule of reason. Actavis, 133 S. Ct. at 2236. Issues relating to the form the proofs will take are the subject of other pending motions for summary judgment.

An appropriate order follows.

[8] Given my determination that collateral estoppel applies, I need not consider here the FTC's alternative argument that the undisputed facts are sufficient to hold the RE '516 patent invalid.