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

KING DRUG COMPANY OF FLORENCE, INC., et al., Plaintiffs, v. CEPHALON, INC., et al., Defendants.	:	CIVIL ACTION No. 2:06-cv-1797
VISTA HEALTHPLAN, INC., et al., Plaintiffs, v. CEPHALON, INC., et al., Defendants.	:	CIVIL ACTION No. 2:06-cv-1833
APOTEX, INC., Plaintiff, v. CEPHALON, INC., et al., Defendants.	:	CIVIL ACTION No. 2:06-cv-2768
FEDERAL TRADE COMMISSION, Plaintiff, v. CEPHALON, INC., Defendant.	:	CIVIL ACTION No. 2:08-cv-2141

Goldberg, J. **March 12, 2014**

MEMORANDUM OPINION

The motions currently before me are brought under the consolidated antitrust lawsuits referred to as the In re Modafinil Litigation. This litigation revolves around four Hatch-Waxman "reverse payment" settlements entered into in 2005 and 2006 between Defendants Cephalon, Inc. and four generic drug manufacturers.[1] A number of these motions emanate from the inequitable conduct and invalidity findings in the case of Apotex Inc. v. Cephalon Inc.[2] ("the Apotex patent litigation"). In that case, after a bench trial, I found that Cephalon's RE '516 patent was procured through inequitable conduct and that for various reasons, the patent was invalid.[3]

As the discovery phase in the antitrust case comes to a close and trial approaches, I must now decide how my rulings in the Apotex patent litigation will impact the antitrust trial. This issue is the subject of the pending motions.

To the extent it is possible to synthesize all of the issues raised in these motions into one question, it is this: In analyzing the doctrine of collateral estoppel, what preclusive effect, if any, does the finding of inequitable conduct and invalidity in the Apotex patent litigation have on the antitrust claims? Although admittedly oversimplified, Defendants' position could be characterized as urging that the findings of inequitable conduct and invalidity should have no impact on the antitrust trial and that all questions relating to the procurement of the RE '516 patent should be rehashed before the antitrust jury. At the complete opposite end of the spectrum, Plaintiffs essentially urge that the liability portion of the antitrust trial is not needed because the

[1] The generic defendants are Barr Pharmaceuticals, Mylan Laboratories, Inc., Teva Pharmaceuticals, Ltd., Teva Pharmaceuticals USA, Inc., Ranbaxy Laboratories, Ltd., and Ranbaxy Pharmaceuticals, Inc. ("the Generic Defendants").

[2] 2011 WL 6090696 (E.D. Pa. Nov. 7, 2011), aff'd, 500 Fed. Appx. 959 (Fed. Cir. 2013), cert. denied, 134 S. Ct. 825 (2013).

[3] The Apotex patent litigation has also been consolidated under the In re Modafinil Litigation.

findings of inequitable conduct and invalidity resolve, as a matter of law, most of the antitrust questions in their favor.[4]

A careful examination of the United States Court of Appeals for the Federal Circuit's most recent pronouncement on inequitable conduct in Therasense, Inc. v. Becton, Dickinson & Co., 649 F.3d 1276 (Fed. Cir. 2011), and precedent on collateral estoppel and the Seventh Amendment right to a jury trial leads me to conclude that: (1) Cephalon's Seventh Amendment right precludes application of the doctrine of collateral estoppel to the finding that Cephalon committed inequitable conduct in procuring the '516 patent. This issue may be tried before the antitrust jury; (2) collateral estoppel will, however, apply to the invalidity portion of the Apotex patent litigation opinion and precludes Cephalon from relitigating Walker Process materiality; and (3) the Generic Defendants are not bound by these findings.[5] This opinion explains the bases for these conclusions.

I. Background

A. Events Leading Up to the Filing of the Preclusion Motions

Several important events and decisions have occurred since these lawsuits were originally filed, all of which are important to determining the outcome of the motions at issue. Before delving into the legal analysis, I will take the time here to review these occurrences which include: positions taken by the parties and orders issued pursuant to Rule 42(b), regarding bifurcation of the patent and antitrust claims; pertinent rulings issued by this court and the Federal Circuit regarding Cephalon's inequitable conduct and the validity of the RE '516 patent;

[4] Plaintiffs in the In re Modafinil Litigation are the Direct Purchasers (King Drug case), the End-Payors (Vista case), the Federal Trade Commission (FTC), and Apotex, Inc.

[5] A more precise application of these rulings and how they will practically affect each party's presentation of evidence in the antitrust trial will of course be the subject of future pre-trial discussions.

and the Federal Circuit's opinion in Therasense, which significantly changed the standards regarding inequitable conduct.[6]

1. Bifurcation of the Patent and Antitrust Claims

Apotex's original complaint, filed on June 26, 2006, included antitrust claims and allegations that Cephalon's RE '516 patent was invalid, unenforceable, and not infringed by Apotex's proposed generic drug. In June 2008, while this case was pending before another judge of this court, Apotex moved to sever or bifurcate its patent claims from the antitrust claims, asserting that resolution of the patent case should not be delayed by the antitrust litigation. Cephalon opposed this motion on the grounds that there was "substantial[] overlap" between the patent and antitrust claims, such that bifurcation would result in duplicative discovery and unnecessary extra litigation. Although Cephalon acknowledged that Apotex's invalidity allegations were "essential" to its monopolization claims, it did not object that a separate trial might deprive it of its right to a jury trial in the antitrust case. (Opp. Mem., doc. no. 90, at 2.) In its reply, Apotex recognized that there was some overlap, but contended that this was not only expected, but that separate trials would promote judicial economy:

> The separate proceedings described above recognize that the antitrust claims will turn, at least in part, on resolution of the claims relating to the validity of the patent. If the patent is upheld, the antitrust claims will be substantially weakened—and certain of them, such as the claims under [Walker Process] will likely be rendered unviable. By contrast, the patent challenge involves no antecedent issue that would be decided in adjudicating the antitrust claims.

(Apotex Reply Mem., doc. no. 91, at 3.)

This motion was never decided by the judge then assigned to the case. Instead, the case was reassigned to me on April 28, 2009, and the bifurcation motion was denied without

[6] I also note that the United States Supreme Court recently articulated the factors to be considered when litigating an antitrust case revolving around a reverse payment settlement agreement. Federal Trade Commission v. Actavis, 133 S. Ct. 2223 (2013).

prejudice along with all other pending motions, as part of the reorganization of these cases. Apotex later filed a First Amended Complaint, followed by a Second Amended Complaint, which again contained both patent and antitrust claims. Apotex also refiled its motion to bifurcate the patent claims (now set forth in Counts 1-5) from the rest of its Complaint.

Cephalon opposed the motion, again on the grounds that there was substantial overlap between the patent and antitrust claims, and also argued that the Court should not rule on bifurcation before deciding Cephalon's motion to dismiss. (Opp. Mem., doc. no. 183, at 5-8.) In its reply, Apotex reiterated that the antitrust trial should not delay the patent case and that a court decision on invalidity was needed to clear the Hatch-Waxman bottleneck so that Apotex could enter the market with its generic drug.[7] (Reply Mem., doc. no. 193, at 1.) Importantly, and especially as far as the Plaintiffs are concerned, Cephalon again failed to raise any concerns that issues decided in the patent trials could have preclusive effect in the antitrust trial and thus compromise its Seventh Amendment rights.

Having been persuaded by Apotex's bifurcation arguments, I granted the bifurcation motion on January 20, 2010.

2. Findings – The Apotex Patent Litigation

I held two separate bench trials on the patent issues in Apotex v. Cephalon in 2011. The first resulted in a ruling that the RE '516 patent is invalid and unenforceable. These decisions were subsequently affirmed by the Federal Circuit. 500 Fed. Appx. 959. In the second trial, I found that Apotex's proposed generic version of Provigil did not infringe the RE '516 patent.

[7] The Generic Defendants took "no position on th[e] motion," except to request that case-management procedures be adopted that minimized duplicative discovery. (Generic Mem., doc. no. 180, at 1.)

In the opinion concluding that the RE '516 patent is invalid and unenforceable—the only opinion relevant to these motions—I made several findings of fact and conclusions of law that form the backdrop of the issues currently before me.

First, the RE '516 patent was found invalid based on the on-sale bar, derivation, obviousness, and lack of an adequate written description. Regarding inequitable conduct, I found that Cephalon "never disclosed to the PTO that: (1) Lafon was the manufacturer of [a batch of modafinil (Batch 003) that fell squarely within the patent claims]; (2) Lafon had measured the particle size of that batch prior to providing it to Cephalon; (3) Lafon had manufactured and tested several modafinil API batches and tablet lots that fell within the claim limitations; [and] **(**4) that the two companies had both supply and license agreements." Apotex, 2011 WL 6090696, at *26. I concluded that Cephalon made affirmative misrepresentations to the PTO by suggesting that the named inventors had physically manipulated the size of the modafinil particles, when in fact it had done nothing to physically change the modafinil it received from Lafon. Id. Based on these conclusions, I found that Cephalon acted with specific intent to deceive the PTO. Id. at *27.

3. The Law in Effect Regarding Inequitable Conduct at the Time of Bifurcation and During the Patent Invalidity Trial

The findings in the Apotex patent litigation were based on a new standard for inequitable conduct articulated in the Therasense decision. Therasense was decided after the patent trial evidence had closed but before I issued my findings regarding inequitable conduct. Importantly, at the time that the parties' positions regarding bifurcation were solidified and during the patent invalidity trial, the standards for inequitable conduct were different, in significant ways, from the standards subsequently set out in Therasense. Compare Therasense, 649 F.3d at 1290-91, with

Nobelpharma AB v. Implant Innovations, Inc., 141 F.3d 1059, 1069-70 (Fed. Cir. 1998), and Dippin' Dots, Inc. v. Mosey, 476 F.3d 1337, 1346-47 (Fed. Cir. 2007).

Specifically, at the time bifurcation was considered, the law on inequitable conduct was that the accused infringer had to prove, by clear and convincing evidence, that the applicant misrepresented or omitted material information with the intent to deceive the PTO. Star Scientific, Inc. v. R.J. Reynolds Tobacco Co., 537 F.3d 1357, 1365 (Fed. Cir. 2008). The intent prong of this standard could be satisfied based on gross negligence. Driscoll v. Cembalo, 731 F. 2d 878, 885 (Fed. Cir. 1984); see also, Kingsdown Medical Consultants, LLC v. Hollister, Inc., 863 F.2d 867, 876 (Fed. Cir. 1988) (finding that gross negligence could be a sufficient level of culpability to satisfy the intent prong where the totality of the circumstances suggested an intent to deceive). The materiality part of this prior standard was analyzed under a "reasonable examiner" test. Am. Hoist & Derrick Co. v. Showa & Sons, Inc., 725 F.2d 1350, 1362 (Fed. Cir. 1984). That is, materiality could be found where "there is a substantial likelihood that a reasonable examiner would have considered the information important in deciding whether to allow the application to issue as a patent." Molins PLC v. Textron, Inc., 48 F.3d 1172, 1179 (Fed. Cir. 1995). If the record contained strong evidence of materiality, the standards for intent could be reduced and materiality and intent could be considered together, applying a "sliding scale" analysis. Am. Hoist & Derrick, 725 F.2d at 1363.

In contrast, at the time of bifurcation, Walker Process fraud entailed distinctly more serious deception than inequitable conduct. Two cases relied upon by Cephalon firmly support this position.

In Nobelpharma, 141 F.3d 1059, the court noted the differences between a Walker Process claim and inequitable conduct, stating:

> Consistent with the Supreme Court's analysis in Walker Process, as well as Justice Harlan's concurring opinion, we have distinguished "inequitable conduct" from Walker Process fraud, noting that inequitable conduct is a broader, more inclusive concept than the common law fraud needed to support a Walker Process counterclaim.

Id. at 1069. In so ruling, the Federal Circuit emphasized that Walker Process fraud "is a more serious offense than inequitable conduct." Id. at 1070. This is because a finding of inequitable conduct "may be based on evidence of a lesser misrepresentation or an omission, such as omission of a reference that would merely have been considered important to the patentability of a claim by a reasonable examiner," while "[a] finding of Walker Process fraud requires higher threshold showings of both intent and materiality." Id.

Dippin' Dots, Inc. v. Mosey, 476 F.3d 1337, 1346 (Fed. Cir. 2007) also supports Cephalon's position that, pre-Therasense, a finding of inequitable conduct could not be applied preclusively to establish Walker Process fraud. The Federal Circuit emphasized that "[a] finding of inequitable conduct does not, by itself, suffice to support a finding of Walker Process fraud." Id. The Court explained that "inequitable conduct [was] a broader, more inclusive concept than the common law fraud needed to support a Walker Process counterclaim." Id. (quoting Nobelpharma, 141 F.3d at 1069). Comparing the two doctrines, the Dippin' Dots court stated that "the difference in breadth between inequitable conduct and Walker Process fraud admits the possibility of a close case whose facts reach the level of inequitable conduct, but not of fraud before the PTO." Id. at 1347.

Thus, had Therasense not raised the standards for inequitable conduct, Plaintiffs could not credibly argue that my finding of Cephalon's inequitable conduct had any preclusive effect on the pending Walker Process antitrust claims. Plaintiffs concede this point, as they must, (Tr. 1/23/14 at 143:4-5) but strenuously assert that Therasense now mandates that my finding of

inequitable conduct should be applied to the antitrust trial through the doctrine of collateral estoppel.

4. The Therasense Decision

In Therasense, noting the consequences, expense, and overuse of the inequitable conduct doctrine, the Federal Circuit undertook a careful re-examination of the inequitable conduct standards.649 F.3d at 1290-91. In doing so, the Federal Circuit's intention was to "tighten[] the standards for finding both intent and the materiality in order to redirect a doctrine that has been overused to the detriment of the public." Id. at 1290.

In heightening the inequitable conduct standards, the Federal Circuit articulated the following principles:

- Regarding the information supplied (or omitted) to the PTO, a finding of negligence or even gross negligence no longer satisfied the fraudulent intent requirement;

- In order to establish inequitable conduct, it must be proven, by clear and convincing evidence that "the patentee acted with the specific intent to deceive the PTO." The court stressed that the alleged infringer must show that, "the applicant knew of the reference, knew that it was material, and made a deliberate decision to withhold it";

- Regarding intent and materiality, the court held that the use of a sliding scale is prohibited, and that intent may not be inferred based solely on materiality; and

- Materiality is established in assessing "whether the PTO would have allowed the claim if it had been aware of the undisclosed reference," and must be proven by a preponderance of the evidence.

Id. at 1290-91.

B. The Specific Motions at Issue

Plaintiffs have filed five motions that seek to establish all or part of Cephalon and the Generic Defendants' liability for antitrust violations. Four of these motions rely upon the preclusive effect of my rulings in the Apotex patent litigation. The majority of Plaintiffs' motions will be resolved through this opinion.[8]

Of the consolidated cases, the FTC's is the most straightforward, because it includes only Cephalon as a defendant and challenges only the legality of the reverse payment settlement agreements. Because the FTC's case seeks only equitable relief, Cephalon has no Seventh Amendment right to a jury trial. Because this makes much of the reasoning that follows inapplicable to the FTC's case, its motion will be addressed in a separate, pending opinion. Consequently, a decision on the FTC's motion will be addressed in a separate, pending opinion.

The Direct Purchasers' preclusion motion seeks to collaterally estop Cephalon from challenging the facts and conclusions underlying my invalidity and inequitable conduct finding, and also asserts that the facts found at the Apotex patent litigation establish, as a matter of law, Cephalon's liability for Walker Process fraud. The Direct Purchasers alternatively request that if I decline to apply collateral estoppel, I find that the elements of their claim are nonetheless

[8] The only exceptions are the Direct Purchasers' motion seeking partial summary judgment on its Sherman Act § 1 claim that Cephalon and the Generic Defendants were all part of a "hub-and-spoke" conspiracy to restrain trade; the portion of the End-Payors' motion addressing the application of specific state antitrust, consumer protection, and unjust enrichment laws; the portion of Apotex's motion requesting summary judgment as to Cephalon's monopoly power; and, as discussed above, the FTC's motion.

Cephalon and the Generic Defendants have also filed two summary judgment motions across the three private-plaintiff cases (six motions total), seeking summary judgment on Plaintiffs' claims of an overall conspiracy among all Defendants. Cephalon has also filed a motion to dismiss for lack of subject matter jurisdiction in the FTC's case, arguing that this case is now moot given that generic entry into the modafinil market occurred in 2012. These motions will also be resolved separately, and are also not addressed in this opinion.

established by the undisputed facts. The Direct Purchasers also contend that knowledge of the fraud in the patent procurement should be imputed to Cephalon during the time the infringement litigation with the Generic Defendants was filed and the settlement agreements were signed. In other words, they seek a ruling that, at all times relevant to this case, Cephalon knew that its patent was unenforceable. The End Payors join in the Direct Purchasers' collateral estoppel arguments. Because I do not address the End Payors' state law claims in this opinion, there is no need to refer to their arguments separately.

Apotex seeks both preclusion (based on the law of the case doctrine) and a ruling that the facts and findings in the Apotex patent litigation opinion establish Cephalon's antitrust liability on both Walker Process and sham litigation theories. Apotex also seeks summary judgment on its Sherman Act section 1 claim that the reverse payment agreements between Cephalon and the Generic Defendants were illegal conspiracies in restraint of trade.

II. Discussion

As noted above, Plaintiffs all contend that my finding of inequitable conduct, coupled with my findings of invalidity, establish all the elements of Walker Process fraud as a matter of law. Named for the Supreme Court case in which it was recognized as an antitrust theory, Walker Process fraud occurs when a patentee "obtained [a] patent by knowingly and willfully misrepresenting facts to the Patent Office." Walker Process Equip., Inc. v. Food Mach. & Chem. Corp., 382 U.S. 172, 177 (1965). Proof of the fraud is "sufficient to strip [the patentee] of its exemption from the antitrust laws," leaving only proof of the other elements of a violation of § 2 of the Sherman Act, such as market definition, market power, and damages. Id. Walker Process fraud is a variant of common law fraud, and has been broken down into similar elements. See Unitherm Food Sys., Inc. v. Swift-Eckrich, Inc., 375 F.3d 1341, 1358 (Fed. Cir. 2004) (listing

the five elements). These elements fit into two categories: materiality and intent to deceive. Dippin' Dots, 476 F.3d at 1346-47.

A. Collateral Estoppel / Law of the Case

Collateral estoppel "has the dual purpose of protecting litigants from the burden of relitigating 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). The party invoking the doctrine must show four elements: (1) that the issue sought to be precluded is the same as the one involved in the prior action; (2) that the issue was actually litigated in the prior action; (3) that the issue was actually determined in a valid, final judgment; and (4) that the determination of the issue was essential to the prior judgment. E.g., Burlington Northern R.R. Co. v. Hyundai Merchant Marine Co., 63 F.3d 1227, 1231-32 (3d Cir. 1995). Where, as here, a plaintiff who was not involved in the prior action[9] seeks to prevent the defendant from relitigating an issue determined against the defendant in that action (referred to as offensive, non-mutual collateral estoppel), the court has "broad discretion" to determine whether fairness concerns make application of the doctrine inappropriate. Parklane, 439 U.S. at 329-331.[10]

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,

[9] As noted supra, none of the Plaintiffs, except Apotex, were involved in the patent bench trials.

[10] The law of the case doctrine operates in much the same manner as collateral estoppel. The primary distinction is that collateral estoppel applies in a separate proceeding (hence the name), while the law of the case doctrine applies within a single proceeding (and as such is occasionally referred to as "direct estoppel"). Wright & Miller, Federal Practice & Procedure § 4418; Public Interest Research Grp. of N.J., Inc. v. Magnesium Elektron, Inc., 123 F.3d 111, 116-17 (3d Cir. 1997). But like collateral estoppel, the law of the case doctrine can only be applied where an issue was actually decided and, naturally, only forecloses relitigation of an identical issue later in the case. Public Interest Research Grp., 123 F.3d at 116-17. Because these doctrines essentially establish the same principles in the context of this case, I need not distinguish them further.

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 mark omitted)).

Thus, to determine whether collateral estoppel applies, I need only grapple with the first collateral estoppel element—whether the issues sought to be precluded in the antitrust trial are the same as the ones decided in the Apotex patent litigation. This is a somewhat complicated question, because it requires that I compare the conclusions reached in a protracted invalidity/inequitable conduct patent trial, and decided under new inequitable conduct standards (Therasense), with the elements of a Walker Process claim.

Cephalon makes several arguments as to why the invalidity and inequitable conduct issues litigated in the patent trial are not identical. These arguments focus on the time the fraud on the PTO was committed as compared with the subsequent enforcement of the patent through the generic litigation, and the separate and distinct persons from Cephalon who were involved in each situation. Cephalon also stresses that the fraud standards required for inequitable conduct, even under Therasense, are different than the fraud standards for Walker Process, and thus proof of the former does not equal proof of the latter. (See generally Ceph. Opp. 30-34.) Plaintiffs, for their part, simply urge that now, after the Federal Circuit's revision of the inequitable conduct

standard, the elements of inequitable conduct and Walker Process align, warranting application of collateral estoppel.

However, even if Plaintiffs are correct, and the elements of inequitable conduct are now identical to Walker Process fraud, I must still consider whether the issue of preclusion is permissible in light of Cephalon's Seventh Amendment rights.[11]

B. Cephalon's Seventh Amendment Rights

Cephalon has pressed several reasons for not applying collateral estoppel, but its most compelling argument, and one that I agree with, is that application of estoppel would deprive it of its Seventh Amendment right to a jury trial in the antitrust case. The Seventh Amendment to the United States Constitution provides:

> In Suits at common law, where the value in controversy shall exceed twenty dollars, the right of trial by jury shall be preserved, and no fact tried by a jury, shall be otherwise re-examined in any Court of the United States, than according to the rules of the common law.

U.S. Const. amend. VII. "[T]he right to trial by jury applies to treble damage suits under the antitrust laws, and is, in fact, an essential part of the congressional plan for making competition

[11] I disagree with Cephalon that Direct Purchasers have failed to plead a Walker Process claim. Cephalon points out several words that the Direct Purchasers did not use in their Complaint, like "fraud" or "Walker Process," while the Direct Purchasers reply that they included numerous allegations regarding the infringement action against the Generic Defendants, as well as allegations that "material information was intentionally withheld from the PTO" in connection with the prosecution of the patent. Further, the Complaint contains a Count alleging violation of section 2 of the Sherman Act, and directed only against Cephalon. A Walker Process theory fits comfortably under this Count, and Cephalon does not suggest that allegations that the inventors at Cephalon "failed to inform," "misrepresented," and "intentionally concealed" material information from the PTO were inadequate to put it on notice that fraud in obtaining the patent was an issue in the case. See Elec. Constr. & Maintenance Co., Inc. v. Maeda Pac. Corp., 764 F.2d 619, 622 (9th Cir. 1985) ("A party does not need to plead specific legal theories in the complaint, as long as the opposing part receives notice as to what is at issue in the lawsuit."). The same reasoning applies to the End Payors' Complaint, which contains similar allegations, including a Count alleging that Cephalon violated section 2 of the Sherman Act.

rather than monopoly the rule of trade . . . ." Beacon Theatres, Inc. v. Westover, 359 U.S. 500, 504 (1959).

Plaintiffs generally do not contest that Cephalon has a right to a jury determination of fact issues in the antitrust case. Instead, they assert that Cephalon waived this right when it failed to object on Seventh Amendment grounds to bifurcation of the patent claims.

It is true that Cephalon, while objecting to bifurcation on several grounds, did not invoke the Seventh Amendment. (See Ceph. Opp. to Bifurcation, Doc. No. 183.) Nor did Cephalon, at any point during the patent invalidity bench trial, mention that resolution of the inequitable conduct claims might deprive it of its jury rights in the antitrust portion of the case. In fact, Cephalon specifically suggested that Apotex's inequitable conduct claim remain part of the patent trial, rather than being tried during the antitrust portion of the case. (Apotex Ex. GG ("We believe that the inequitable conduct claim should continue to be a part of the March patent trial and that it should not be moved to the antitrust portion of the case.").) Indeed, Cephalon made no mention of its Seventh Amendment rights until a status conference was held on December 6, 2011, and after it had already participated in a bench trial on the issues of invalidity and unenforceability. (Dec. 6, 2011 Tr. 46:5-9.)

Cephalon responds to all of this by stressing that it had no basis to raise a Seventh Amendment objection at the bifurcation stage because it was clear at that point—prior to Therasense—that Walker Process fraud involved higher standards for both materiality and intent than were required to show inequitable conduct, and therefore it had no reason to anticipate any type of preclusive significance from the Apotex patent litigation. Cephalon points out that it was only after Therasense issued—on May 25, 2011—that it could have been aware of the fact that

collateral estoppel might be applied to its detriment, and thus a waiver of its jury rights should not occur.

Waiver need not be intentional; it can also occur through "inaction or acquiescence." In re City of Phila. Litig., 158 F.3d 723, 726 (3d Cir. 1998). Thus, participation in a bench trial without objection could waive a jury right, even if the party made a timely demand for a jury trial in a pleading. Wilcher v. City of Wilmington, 139 F.3d 366, 379 (3d Cir. 1998). The rationale for this rule is straightforward—a party should not be permitted to silently take part in a bench trial and then demand a do-over on Seventh Amendment grounds after losing. In re City of Phila. Litig., 158 F.3d at 727. "Promotion of such tactics would not only lead to an unnecessary squandering of judicial resources but would also reduce a trial court's bench proceeding to a meaningless exercise in futility." Id. However, because the "right of jury trial is fundamental, courts indulge every reasonable presumption against waiver." Tracinda Corp. v. DaimlerChrysler AG, 502 F.3d 212, 222 (3d Cir. 2007) (quoting Aetna Ins. Co. v. Kennedy, 301 U.S. 389, 393 (1937)) (internal quotation marks omitted).

For the reasons expressed below, and under the particular and unique circumstances of this case, I conclude that a finding that Cephalon waived its Seventh Amendment rights is not appropriate.

First, Rule 42(b) weighs heavily against waiver. While this rule permits a district court to order that certain issues or claims be tried separately, it clearly instructs that the "court must preserve any federal right to a jury trial" when doing so. F.R.C.P. 42(b) (emphasis added). Thus, although judicial discretion is allowed, under Rule 42(b), that discretion must "wherever possible, be exercised to preserve a jury trial." Beacon Theatres, 359 U.S. at 510.

Second, Supreme Court precedent on Rule 42(b) counsels against a finding of waiver. In Beacon Theatres, the Court held that although the trial judge does have discretion to try equitable matters first, when legal and equitable claims are brought in the same action, that discretion must carefully take into consideration the parties' Seventh Amendment rights. Id. at 510. The Court went on the stress:

> In the Federal courts this (jury) right cannot be dispensed with, except by the assent of the parties entitled to it; nor can it be impaired by any blending with a claim, properly cognizable at law, of a demand for equitable relief in aid of the legal action, or during its pendency. This long-standing principle of equity dictates that only under the most imperative circumstances, circumstances which in view of the flexible procedures of the Federal Rules we cannot now anticipate, can the right to a jury trial of legal issues be lost through prior determination of equitable claims.

Id. at 510-11 (quotation marks and footnotes omitted).

The Supreme Court reiterated the importance of preserving a litigant's Seventh Amendment right in Lytle v. Household Manufacturing, Inc., 494 U.S. 545 (1990). In Lytle, claims were brought in the same suit involving race discrimination and retaliation under Title VII and 42 U.S.C. § 1981. Id. at 548. The district court dismissed the § 1981 claim ruling that Title VII was the plaintiff's only remedy, and then at the close of the plaintiff's case, dismissed the race discrimination portion of the Title VII claim. Id. The court then entered judgment for the defendant on the retaliation claim at the conclusion of trial. Id. On appeal, the circuit court found that the trial court had erred in dismissing the § 1981 claim, but nonetheless found that collateral estoppel precluded the relitigation of the § 1981 claims because the elements of the two claims were the same. Id. at 549. The circuit court also found that judicial economy weighed in favor of not relitigating issues before a jury that had already been determined by the court. Id. at 550.

The Supreme Court reversed and found that collateral estoppel should not apply to issues common to equitable and legal claims, stating: "[i]t would be anomalous to hold that a district

court may not deprive a litigant of his right to jury trial by resolving an equitable claim before a jury hears a legal claim raising common issues, but that a court may accomplish the same result by erroneously dismissing the legal claims." Id. at 552. In so holding, the Court stressed that concerns about judicial economy are an "insufficient basis for departing from our long-standing commitment to preserving a litigant's right to a jury trial." Id. at 554.

Numerous cases decided since Beacon have reiterated that where bifurcation of the legal and equitable portions of a case are being considered pursuant to Rule 42(b), a litigant's constitutional right to a jury trial must be preserved. See Shum v. Intel Corp., 499 F.3d 1272, 1276 (Fed. Cir. 2007) (quoting Dimick v. Schiedt, 293 U.S. 474, 486 (1935)) (finding that a court's discretion to bifurcate under Rule 42 is not without limits because "[m]aintenance of the jury as a fact-finding body is of such importance and occupies so firm a place in our history and jurisprudence that seeing any curtailment of the right to a jury trial should be scrutinized with the utmost care"); Roebuck v. Drexel University, 852 F.2d 715, 737 (3d Cir. 1988) (citing Tull v. United States, 481 U.S. 412 (1987)) (where legal and equitable claims are joined, right to a jury trial on the legal claim remains intact); Bowers v. City of Philadelphia, 2007 WL 219651 (E.D. Pa. 2007) (noting that the fact that a judge has decided equitable issues first does not foreclose a party's Seventh Amendment right); Celgene v. Barr Labs., Inc., 2008 WL 2447354, at *1 (D.N.J. 2008) (holding that in a Hatch-Waxman antitrust/patent dispute, decision to bifurcate under Rule 42(b) "must not" infringe on right to jury trial).

Despite Rule 42(b)'s clear directive that when ordering separate trials a court shall "always" preserve a party's Seventh Amendment right to a jury trial, Plaintiffs, particularly the Direct Purchasers, insist that under Parklane Hosiery Company v. Shore, 439 U.S. 322 (1979), collateral estoppel does not offend the Seventh Amendment. Parklane involved a stockholder's

class action suit alleging fraud regarding a false and misleading proxy statement in connection with a merger. Id. at 324. Prior to the jury trial on the class action claims, the SEC brought a separate action regarding the falsity of the proxy statement, seeking injunctive relief. Id. A bench trial was first held on the equitable SEC claims. Id. at 324-25. Importantly, this bench trial did not, like the case before me, take place after Rule 42(b) bifurcation issues were considered.

After the district court found that the proxy statement was materially false and misleading, the plaintiffs moved for partial summary judgment in the class action, asserting that the defendants were collaterally estopped from relitigating the fraud issue. Id. at 325. The Supreme Court agreed, finding that the defendants were given a "full and fair opportunity" to litigate the fraud issue, and consequently re-trying the same facts was precluded by collateral estoppel. Id. at 333-34.

Although the Parklane Court found that collateral estoppel applied, there are significant differences between the procedural posture of Parklane and the case before me. The primary and most obvious difference is that Parklane did not implicate Rule 42(b), which as previously noted, mandates that a party's Seventh Amendment rights must be preserved.[12] Rather, a bench trial on the equitable issues occurred first based upon a separate SEC suit seeking injunctive relief. Here, because Apotex brought its patent and antitrust suits in the same lawsuit, Rule 42(b) is clearly implicated. See Roebuck, 852 F.2d at 739 n.42 (Parklane distinguished as involving separate lawsuits).

[12] Far from involving a situation in which a conscious decision was made to try equitable claims before legal claims, the Supreme Court in Parklane made clear that the petitioners had no opportunity to request that the cases be structured differently, whether by expediting trial of the private action of staying the SEC's case. Parklane, 439 U.S. at 337 n.24. Under those circumstances, the Court concluded that collateral estoppel did not conflict with the jury right.

Lytle, where the two causes of action were brought in the same case, recognized this important distinction, and even after considering Parklane, held that "[w]hen legal and equitable claims are joined in the same action, the right to jury trial on the legal claim, including all issues common to both claims, remains intact." Lytle, 494 U.S. at 550 (quoting Curtis v. Loehner, 415 U.S. 189, 196 n.11 (1974)).

It is worth repeating that prior to Therasense, it was perfectly logical for Cephalon to not consider Seventh Amendment waiver issues. After all, while "a Walker Process [claim] and an affirmative defense of inequitable conduct share common factual elements," before Therasense inequitable conduct required lesser showings of both intent and materiality. Cabinet Vision v. Cabnetware, 129 F.3d 595, 600 (Fed. Cir. 1997). Thus, collateral estoppel—which requires identity of the issues—would generally not apply to the court's equitable findings.[13] To find waiver when the standard for inequitable conduct had changed so drastically between bifurcation and the inequitable conduct verdict would not accord with our duty to "indulge every reasonable presumption against waiver." Tracinda, 502 F.3d at 222.

Thus, I decline to give collateral estoppel effect to the findings underlying our inequitable conduct determination. Cephalon will have the opportunity to relitigate the issue of fraudulent intent in the antitrust trial.[14]

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[13] Still, at least one pre-Therasense decision denied a motion to bifurcate based on a Seventh Amendment objection. Celgene Corp. v. Barr Labs., 2008 WL 2447354, at *2-3 (D.N.J. June 13, 2008).

[14] My decision not to give collateral estoppel effect to my inequitable conduct finding necessarily requires the denial of Apotex's motion for summary judgment on its sham litigation, monopolization, and attempted monopolization theories under section 2, all of which depend in one way or another on a finding that Cephalon committed fraud. (See Apotex Liability Mem. 13-18.) The same is true for Apotex's section 1 claim. (See Apotex Liability Mem. 21-23.) Apotex's motion for summary judgment on the monopoly power aspects of its claims will be taken up in a separate opinion.

C. Materiality

My conclusions regarding Cephalon's inequitable conduct do not, however, end the collateral estoppel inquiry. This is because the Apotex patent litigation also resulted in findings that the RE '516 patent was invalid on the grounds of an on-sale bar, obviousness, and derivation. Plaintiffs argue that when I determined that the RE '516 patent was invalid on these grounds, I decided an issue identical to the materiality elements of the Walker Process inquiry. Put more simply, they contend that invalidity is an element of Walker Process fraud. On this point, I agree with Plaintiffs.

The standard of "materiality in a Walker Process case requires that the patent would not have issued but for the patent examiner's justifiable reliance on the patentee's misrepresentation or omission." Dippin' Dots, 476 F.3d at 1347. In order to prove their Walker Process claims, Plaintiffs must show that, in prosecuting the RE '516 patent, Cephalon misrepresented or omitted "facts indicating invalidity." Areeda & Hovenkamp ¶705e; see also In re Ciproflaxin Hydrochloride Antitrust Litig., 363 F. Supp. 2d 514, 546 n.28 (E.D.N.Y. 2005) ("[A] patent must be invalid before it can be a candidate for Walker Process fraud."). The reason that invalidity is necessary for a Walker Process claim is that a valid patent, even if procured by outright lies or thievery, does not harm consumers, because they face the same circumstances that they would have even if the misconduct had not occurred. See Brunswick Corp. v. Riegel Textile Corp., 752 F.2d 261, 265 (7th Cir. 1984) (noting that "stealing a valid patent" is not an antitrust violation because it does harm competition, while "obtaining an invalid patent" may be); cf. Therasense,

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Similarly, I deny the End Payors' motion for summary judgment as to several state law claims, which is based on the "[a]ssum[ption] [that] this Court grants the [Direct Purchasers' motion] and finds that Cephalon's conduct establishes the necessary acts of monopolization and Walker Process fraud under the Sherman Act." (E.P. Mem. at 4.) Because I have decided not to apply the inequitable conduct findings in the antitrust portion of the case, this prerequisite to the End Payors' motion is missing.

649 F.3d at 1292 ("[E]nforcement of an otherwise valid patent does not injure the public merely because of misconduct, lurking somewhere in the patent prosecution, that was immaterial to the patent's issuance."). It is only when a patentee's dishonest conduct allows him to obtain "exclusionary rights to which he was not legally entitled under the patent laws" that the Sherman Act comes into play. E.I. du Pont de Nemours & Co. v. Berkley & Co., Inc., 620 F.2d 1247, 1274 (8th Cir. 1980). Thus, invalidity is a prerequisite to a successful Walker Process fraud claim.

Precedent supports the conclusion that a prior finding of invalidity can establish materiality for Walker Process purposes. In Dippin' Dots, Inc. v. Mosey, the Federal Circuit affirmed the jury's verdict that undisclosed sales of the product were prior art and rendered the patent invalid, and later remarked that the same sales satisfied the "strict threshold" of Walker Process materiality. 476 F.3d 1337, 1344-45, 1347 (Fed. Cir. 2007); see also 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."); C.R. Bard, Inc. v. M3 Sys., Inc., 157 F.3d 1340, 1365 (Fed. Cir. 1998) ("[S]ince the inventorship issue was not grounds of invalidity, it cannot satisfy the 'but for' test of fraud.").[15]

Unitherm Food Systems is also instructive. In Unitherm, the district court held ConAgra's patent invalid on summary judgment for having been in prior use and on sale before the critical date. 375 F.3d at 1354. The court then instructed the antitrust jury:

> I have previously determined that Defendant failed to disclose certain information to the PTO. I have also determined that the PTO relied on that omission and had

[15] See also C.R. Bard, 157 F.3d at 1365 (noting that to be material, an omission must "mislead the examiner into taking favorable action that would not otherwise have been taken").

> Defendant disclosed that information to the PTO the patent would not have issued.

Unitherm, Brief for Appellant,[16] 2003 WL 24305437, at 39. The Court of Appeals, while not specifically addressing the propriety of the jury instruction, affirmed the jury's finding of Walker Process fraud. Unitherm, 375 F.3d at 1354. Thus, invalidity findings by the court were translated into binding jury instructions on Walker Process materiality.

Of course to be relevant to the Walker Process inquiry, the invalidity findings must have been based on the same omitted information that forms the basis of Plaintiffs' Walker Process fraud claims. That is true here for all the grounds of invalidity except the lack of a proper written description.

In the Apotex patent litigation, I concluded that Cephalon's supply agreement with Lafon, which was not disclosed to the PTO, established an on-sale bar to patentability. I further concluded that the undisclosed information that (1) Lafon had manufactured and shipped to Cephalon a batch of modafinil (Batch 003) that fell squarely within the patent claims; (2) Lafon was aware of the particle size of the batch; and (3) Lafon had manufactured and tested several other batches and tablet lots that fell within the claim limitations, rendered the patent invalid on grounds of derivation and obviousness. Apotex, 2011 WL 6090696, at *13-23; see id. at *26 ("Had the PTO been aware of this information, it would not have allowed the patent to issue."). These material omissions also underlie Plaintiffs' Walker Process claims. I therefore conclude that collateral estoppel applies to bar Cephalon from relitigating the issue of Walker Process materiality.[17]

[16] The quoted jury instruction does not appear in the Federal Circuit's opinion.

[17] There is no doubt that the invalidity issues were actually litigated and determined in a valid final judgment, and were essential to that judgment. Cephalon argues that it lacked an incentive

The waiver analysis is also distinct for the invalidity findings. Unlike the relationship between inequitable conduct and Walker Process, the connection between invalidity and materiality was settled and clear at the time of bifurcation. Thus, while I have carefully considered Cephalon's Seventh Amendment rights, Plaintiffs' waiver arguments regarding materiality are persuasive. If Cephalon wished to protect its right to a jury trial on the issue of materiality, it was imperative that it object on that ground at the time of bifurcation. Because Cephalon did not do so, it will be bound by those findings, and the jury will be instructed accordingly.

D. The Generic Defendants

Having resolved the collateral estoppel issue, I am well aware that many questions remain as to how these rulings will be implemented before the antitrust jury. One question that can be answered now, albeit only in part, is the effect that my collateral estoppel rulings have on the Generic Defendants.

The Generic Defendants urge that any attempts to apply preclusion risks "fundamental prejudice and unfairness" to them, by limiting their ability to raise "certain patent-related issues at the trial of the antitrust case." My decision not to instruct the jury that Cephalon obtained its patent by fraud should eliminate most of the Generic Defendants' concerns that they will be prejudiced at trial. At most, the jury will only be instructed that Cephalon's patent—which the

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to vigorously litigate defenses to enforcement of "a patent with a very short remaining life . . . versus an [antitrust] case that has some very sizable damages claims." (Tr. 1/23/14 102:17-18); see also Croskey v. U.S. Office of Special Counsel, 1997 WL 702364, at *4 (D.C. Cir. Oct. 17 1997) ("An example of such unfairness [as would justify not applying collateral estoppel] would be when the losing party clearly lacked any incentive to litigate the point in the first trial, but the stakes of the second trial are of a vastly greater magnitude."). I reject this notion. The patent trial took place when all parties knew the antitrust case was on the horizon. More fundamentally, I cannot credit the argument that Cephalon "lacked any incentive" to defend the integrity of the primary patent covering its flagship drug, especially in light of the team of five highly capable attorneys that tried the Apotex patent case.

Generic Defendants were accused of infringing—was later found to be invalid, and that certain omissions were "material." This is quite different than advising the jury that Cephalon committed fraud on the PTO.

Indeed, the Generic Defendants, like Cephalon, insist that they have no interest in relitigating the validity of the patent, for the simple reason that validity is not identical to any of the claims brought against them. Moreover, the Generic Defendants are not parties to the Walker Process claims, because they neither procured nor enforced the patent. Accordingly, the fact that the patent was found invalid in the 2011 Apotex patent litigation should have no bearing on the proofs necessary to hold the Generic Defendants liable for antitrust violations. The Generic Defendants will still be able to argue, should they so choose, that settlement was pro-competitive, and that they were unaware of Cephalon's alleged fraud or the invalidity of the patent. In short, nothing in this opinion should be interpreted to limit the ability of the Generic Defendants to put on their defense. Whether that defense will occur with Cephalon at the same trial will be decided at a future date.

E. Disputed Issues of Material Fact

Aside from asserting that the findings in the Apotex patent litigation should have preclusive effect, the Direct Purchasers also assert that the undisputed facts establish that Cephalon acted with the intent to deceive the PTO. They offer three arguments in support of this contention: First, the "sheer number and extreme materiality" of Cephalon's omissions and misrepresentations leaves no room for any other conclusion. Second, in response to an interrogatory seeking "all good faith justifications on which you rely" for not disclosing the invalidating information to the PTO, Cephalon responded only that the references (specifically the Supply and License Agreements) were not material, and that it was "unaware of any

information known to the applicants and material to patentability that was not disclosed to the PTO." (DP MSJ, Ex. 67, at 10-11.) Because it has now been determined that the information was material to patentability, Direct Purchasers assert that Cephalon has no justification left to invoke at trial, and that the only alternative is that Cephalon acted with intent to deceive. Third, the Direct Purchasers argue that, under Therasense, I was permitted to find intent to deceive on Cephalon's part only if the evidence was "sufficient to require a finding of deceitful intent in the light of all the circumstances." Therasense, 649 F.3d at 1290; see also id. at 1290-91 ("Hence, when there are multiple reasonable inferences that may be drawn, intent to deceive cannot be found."). Accordingly, the Direct Purchasers argue that any reasonable jury would be required to find that Cephalon acted with intent to deceive when considering their Walker Process claim.

It is important to first note that "issues of knowledge and intent are particularly inappropriate for resolution by summary judgment, since such issues must often be resolved on the basis of inferences drawn from the conduct of the parties." Riehl v. Travelers Ins. Co., 772 F.2d 19, 24 (3d Cir. 1985) (citing Ness v. Marshall, 660 F.2d 517, 519 (3d Cir. 1981)); see also Coolspring Stone Supply, Inc. v. Am. States Life Ins. Co., 10 F.3d 144, 148 (3d Cir. 1993) ("Summary judgment is inappropriate when a case will turn on credibility determinations and, as we have previously noted, on state of mind." (citation omitted)). Based on these considerations, I reject the Direct Purchasers' first argument. It is not my place to remove from the antitrust jury the function of assessing credibility, assigning weight to the evidence and drawing the inferences about Cephalon's intent. This process, after all, is the core of the jury's role. Tennant v. Peoria & P.U. R.R. Co., 321 U.S. 29, 35 (1944) ("The very essence of [the jury's] function is to select from among conflicting inferences and conclusions that which it considers most reasonable."). This is especially true when the inferences concern intent.

The Direct Purchasers' second argument is similarly unpersuasive. Cephalon's response stated that if it did not present particular information to the PTO, it is because that information was not material. I have concluded that Cephalon's position on materiality was wrong. But the question of fraud concerns Cephalon's knowledge and intent at the time of the patent prosecution. And my conclusion that a jury may not reconsider whether the information Cephalon failed to disclose to the PTO was actually material does not foreclose Cephalon from arguing (and introducing evidence) that it did not believe the information to be material at the time it obtained the patent.

I reject the Direct Purchasers' third argument for the same reasons. Therasense did say that the evidence must be sufficient to "require" a finding of intent to deceive, but by this the court meant only that "specific intent to deceive must be 'the single most reasonable inference able to be drawn from the evidence.'" 649 F.3d at 1290 (quoting Star Scientific, Inc. v. R.J. Reynolds Tobacco Co., 537 F.3d 1357, 1366 (Fed. Cir. 2008)). I concluded that intent to deceive was the single most reasonable inference after an eight-day bench trial. That conclusion does not mean that a jury could not take a different view of witnesses' credibility, factual disputes, or the range of reasonable inferences and ultimately conclude that Cephalon did not act with the intent to deceive required for Walker Process fraud. This portion of the Direct Purchasers' motion will thus be denied.

IV. Conclusion

Plaintiffs' most aggressive motions seek to eliminate the need for a trial on most of the antitrust issues by imposing liability on Cephalon as a matter of law based on my prior findings that Cephalon procured an invalid patent through inequitable conduct in front of the PTO. Plaintiffs' motions were made possible only by the recent change in inequitable conduct law as

articulated in Therasense. If Therasense had existed at the time Apotex moved to bifurcate the patent issues (a bench trial) from the antitrust issues (a jury trial), an order granting bifurcation would have violated Cephalon's Seventh Amendment rights. Accordingly, it was only by an intervening change in the law that Plaintiffs were able to obtain the two prerequisites to filing these motions: (1) a bench trial on the patent issues separate from the jury trial on the antitrust issues, and (2) inequitable conduct findings rendered based upon a standard high enough to make a colorable argument that they also meet the threshold for Walker Process fraud. Under these circumstances the Seventh Amendment precludes the application of collateral estoppel to the bench findings of inequitable conduct.

On the other hand, the invalidity findings in the earlier patent trial were made under standards that pre-existed this case. Given that common issues existed between the invalidity defenses and the Walker Process claims, and that this was apparent at the time of bifurcation, Cephalon should have preserved its right to a jury trial on those issues. It did not do so, and I therefore conclude that Cephalon waived any Seventh Amendment defense to the application of the invalidity findings to the antitrust case. I further find that, under principles of collateral estoppel, my invalidity findings establish the materiality elements of Walker Process fraud.

An appropriate order follows.