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The New Plague: False Claims Liability Based on Inequitable Conduct During Patent Prosecution

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In January 2009, Amphastar Pharmaceuticals filed a first-of-its-kind qui tam *suit on behalf of the federal government and several states alleging that its competitor, Aventis Pharma, violated the Federal False Claims Act ("FCA") when it fraudulently acquired a patent and then overcharged the government for its patented drug. By utilizing a fraudulently acquired patent to elevate the price of Lovenox, a drug for treating deep-vein thrombosis, Amphastar alleged that Aventis had overcharged the government for every Lovenox pill purchased with government funds, including all prescriptions funded in part by Medicare or other federal insurance programs. The FCA provides a means for litigants to pursue recovery for fraud perpetrated against the federal government. In its complaint, Amphastar alleged that Aventis obtained its patent by engaging in inequitable conduct during prosecution of its patent application before the United States Patent and Trademark Office. Our analysis of FCA claims based on this novel inequitable-conduct theory concludes that a patentee could be liable for violating the False Claims Act if (1) the government purchased the patented product, (2) the prices of that product were in fact elevated because of the exclusivity provided by the fraudulently obtained patent, and (3) the patentee knew, deliberately ignored, or showed reckless disregard in deciding to submit a claim for payment from the government at this elevated price. If the court in* Amphastar *finds Aventis liable under this novel theory, the consequences*

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could be far-reaching. Given the nature of modern patent litigation, with inequitable conduct defenses being nearly ubiquitous, such a ruling could expose nearly every patent holder that does business with the federal government to possible liability under the FCA.

This Article discusses the implications of bringing FCA claims based on an inequitable-conduct theory, explores the rationale behind invoking the FCA in this context, and suggests precautions that practitioners can take in such lawsuits. It proposes a variety of reforms to the False Claims Act to check the problems caused by these types of FCA claims. These proposals may become more relevant after the resolution of the Amphastar *case if the court validates Amphastar's novel theory and others follow suit in bringing FCA claims against pharmaceutical patent holders.*

> I have based the [qui tam provision of the False Claims Act] upon the old-fashioned idea of holding out a temptation, and "setting a rogue to catch a rogue," which is the safest and most expeditious way I have ever discovered of bringing rogues to justice.
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> –U.S. Senator Jacob M. Howard[1]

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[1] CONG. GLOBE, 37TH CONG., 955–56 (1863).

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INTRODUCTION

In January 2009, Amphastar Pharmaceuticals filed a lawsuit under the Federal False Claims Act ("FCA") alleging that its competitor Aventis Pharma fraudulently inflated the price of Lovenox (enoxaparin), a patented drug for treating deep-vein thrombosis, and overcharged the federal government and various state governments by making claims for payment through Medicare and state Medicaid systems.[2] The FCA provides a means for both private litigants and the Department of Justice to pursue recovery for fraud perpetrated against the federal government.[3] Amphastar's FCA suit was based on the novel theory that Aventis defrauded the government when it fraudulently acquired its patent by engaging in inequitable conduct while prosecuting its patent application before the United States Patent and Trademark Office ("USPTO").[4] Aventis's fraudulent acquisition of this patent allowed it to mono-

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[2] Memorandum and Order Re: Amended Complaint at 2, Amphastar Pharmaceuticals Inc., v. Aventis Pharma SA, No. 5:09-cv-00023, (C.D. Cal. Apr. 19, 2013).

[3] *See* False Claims Act, 31 U.S.C. §§ 3729–33 (2012).

[4] Memorandum and Order, *supra* note 2, at 2.

polize Lovenox sales, elevate the price of the drug, and illegally overcharge the government.[5] This lawsuit is currently being litigated and it is unclear whether Amphastar's theory of FCA liability based on inequitable conduct is even valid, let alone whether Amphastar will prevail.[6]

Under the patent law doctrine of inequitable conduct, a patent can be held unenforceable if a court finds that the patentee obtained the patent by engaging in improper conduct before the USPTO.[7] Once referred to as an "absolute plague" on the patent system by the Court of Appeals for the Federal Circuit, inequitable conduct is routinely asserted by defendants in patent cases.[8] Common examples of inequitable conduct include making false statements to the patent office or intentionally withholding material information during prosecution.[9] Where a patentee engages in inequitable conduct and then sells its patented product to the government (or seeks reimbursement through programs such as Medicare), it can be argued that the improperly obtained patent allowed the patentee to sell its product at fraudulently inflated prices, thereby violating the FCA by submitting a false claim for payment.[10] Consequently, if Amphastar's theory prevails, it could expose

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5 *Id*.

6 The parties are currently disputing the sufficiency of Amphastar's allegations that Aventis submitted a fraudulent claim, and whether the allegations are supportable by evidence.

7 *See, e.g.*, Therasense, Inc. v. Becton, Dickinson & Co., 649 F.3d 1276, 1287 (Fed. Cir. 2011).

8 *See* Burlington Indus., Inc. v. Dayco Corp., 849 F.2d 1418, 1422 (Fed. Cir. 1988) (en banc) ("[T]he habit of charging inequitable conduct in almost every major patent case has become an absolute plague."); *Therasense*, 649 F.3d at 1289 ("Left unfettered, the inequitable conduct doctrine has plagued not only the courts but also the entire patent system."). Note, however, that the *en banc* court in *Therasense* heightened the standard for finding inequitable conduct, as discussed in more detail in Part II, *infra*.

9 *See, e.g.*, Purdue Pharma L.P. v. Boehringer Ingelheim GMBH, 237 F.3d 1359, 1366 (Fed. Cir. 2001) ("To prove inequitable conduct in the prosecution of a patent, [the defendant] must have provided evidence of affirmative misrepresentations of a material fact, failure to disclose material information, or submission of false material information, coupled with an intent to deceive." (quoting Baxter Int'l, Inc. v. McGraw, Inc., 149 F.3d 1321, 1327 (Fed. Cir. 1998))).

10 *See, e.g.*, Delia A. Stubbs, *Court Rules in Novel False Claims Act Case Where One Pharmaceutical Company Sues Another*, FDA L. BLOG (Apr. 24, 2013, 6:35 PM), http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2013/04/court-rules-in-novel-false-claims-act-case-where-one-pharmaceutical-company-sues-another.html.

nearly every patent holder that does business with the federal government to possible liability under the FCA and create a new plague on the patent system.

This Article explores the implications of bringing FCA claims based on this novel theory of inequitable conduct. Part I of this Article provides a brief overview of federal and state false claims laws. In addition to claims by competitors like those in the *Amphastar v. Aventis* case, this theory provides an avenue for whistleblowers to profit from their knowledge of fraudulent conduct by serving as a relator in a false claims *qui tam* action.[11] Alternatively, a defendant in a patent infringement suit may gain access to confidential information that could invalidate the patent and be used as the basis for a *qui tam* action. Part II provides an overview of the current state of the doctrine of inequitable conduct, which requires a showing that the patent holder's conduct was both material to patentability and done with the specific intent to deceive the patent office. Part III discusses the *Amphastar v. Aventis* case, and then analyzes the suitability and practicability of the inequitable-conduct-based theory of false-claims liability. Part IV provides strategic considerations for practitioners who are attempting to mitigate this type of false-claims liability. Finally, Part V proposes modifications to the current regulatory regime to resolve problems with FCA claims brought under a theory of inequitable conduct.

I. FEDERAL AND STATE FALSE CLAIMS

The Federal False Claims Act allows for both the Department of Justice and private whistleblowers, referred to as relators, to pursue actions against entities and individuals that have fraudulently claimed government funds.[12] While originally enacted to prevent weapons manufacturers from knowingly selling faulty weaponry to the US Armed Forces, the FCA is now the primary means by which the government combats fraudulent claims for healthcare

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[11] A *qui tam* action is an action brought under a statute that allows a private party, known as a "relator," to sue on behalf of the government. *See* BLACK'S LAW DICTIONARY 1368 (9th ed. 2009). "Qui tam" is an abbreviation of the Latin phrase "qui tam pro domino rege quam pro se ipso in hac parte sequitur," meaning "[he] who sues in this matter for the king as well as for himself." *Id.*

[12] *See* 31 U.S.C. §§ 3729–3733 (2012).

benefits.[13] In addition to the federal government, twenty-nine states and the District of Columbia have adopted false claims acts.[14] In this section, we present background information regarding the Federal False Claims Act and a discussion of various state false claims acts.

A. The Federal False Claims Act

The Government Accountability Office recently estimated that approximately $72 billion in taxpayer funds is lost to fraud, abuse and improper payments each year.[15] The Federal False Claims Act imposes civil liability on individuals and corporations that knowingly make or submit false claims for money or property to the United States.[16] Originally enacted in 1863 by President Abraham Lincoln, the FCA empowered citizens to bring suits on behalf of the government to police the sale of faulty goods to Union forces by wartime profiteers.[17] After several sweeping alterations, however, the FCA has become increasingly utilized to combat healthcare fraud.[18] The most recent of these changes occurred with the passage of the Patient Protection and Affordable Care Act ("ACA") in 2010.[19]

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[13] Joan H. Krause, *Health Care Providers and the Public Fisc: Paradigms of Government Harm Under the Civil False Claims Act*, 36 GA. L. REV. 121, 128 (2001); Robert T. Rhoad & Matthew T. Fornataro, *A Gathering Storm: The New False Claims Act Amendments and Their Impact on Healthcare Fraud Enforcement*, 21 HEALTH LAW. 14, 15 (2009).

[14] U.S. CHAMBER INSTITUTE FOR LEGAL REFORM, THE GREAT MYTHS OF STATE FALSE CLAIMS ACTS 3 (2013), *available at* http://www.instituteforlegalreform.com/uploads/sites/1/State_FCA_Great_Myths_Pages_web.pdf.

[15] U.S. GOV'T ACCOUNTABILITY OFFICE, IMPROPER PAYMENTS: PROGRESS MADE BUT CHALLENGES REMAIN IN ESTIMATING AND REDUCING IMPROPER PAYMENT 3 (2009), *available at* http://www.gao.gov/assets/130/122319.pdf.

[16] 31 U.S.C. § 3729 (2012).

[17] Marc S. Raspanti & David M. Laigaie, *Current Practice and Procedure Under the Whistleblower Provisions of the Federal False Claims Act*, 71 TEMP. L. REV. 23, 24 (1998).

[18] Press Release, U.S. Dep't of Justice, Justice Department Recovers $3.8 Billion from False Claims Act Cases in Fiscal Year 2013 (Dec. 20, 2013), *available at* http://www.justice.gov/opa/pr/2013/December/13-civ-1352.html; *see* False Claims Amendments Act of 1986, Pub. L. No. 99-562, 100 Stat. 3153 (codified as amended at 31 U.S.C. §§ 3729–3733 (2000)); *see also* Fraud Enforcement and Recovery Act of 2009, Pub. L. No. 111-21 Stat. 1617 (2009); Patient Protection and Affordable Care Act, H.R. 3590, 111th Cong. 783-84 (2010) (enacted).

[19] Patient Protection and Affordable Care Act, H.R. 3590, 111th Cong. 783-84 (2010) (enacted) (changes definition of "obligation" to included "retention of overpayments" thereby extending liability to persons receiving Medicare/Medicaid overpayments and knowingly failing to return the amount in excess).

According to the Department of Justice, the federal government recovered nearly $23 billion through use of the FCA between 2009 and 2014.[20]

In addition to providing a means for the government to directly recover funds lost through fraud, the FCA also allows private "relators" to bring *qui tam* actions against defendants that have violated the FCA.[21] Relators pursuing an action under the FCA's whistleblower or *qui tam* provisions can receive fifteen to thirty percent of the proceeds of any successful claim.[22] These false claims actions are discussed in more detail below.

1. Liability

The FCA identifies several types of actions that can give rise to liability.[23] The two most commonly asserted provisions of the FCA establish liability for any person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval," or "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim."[24] For either of these provisions, the plaintiff must prove three essential elements: (1) that the defendant made a *claim* for payment from the government, (2) that the claim was *false or fraudulent* and (3) the defendant made the claim with *knowledge* of the falsity.[25]

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[20] Press Release, U.S. Dep't of Justice, Justice Department Recovers Nearly $6 Billion from False Claims Act Cases in Fiscal Year 2014 (Nov. 20, 2014), *available at* http://www.justice.gov/opa/pr/justice-department-recovers-nearly-6-billion-false-claims-act-cases-fiscal-year-2014 (estimating total recoveries under the FCA between January 2009 and September 2014 at $22.75 billion).

[21] *See* 31 U.S.C. § 3730(b) (2012).

[22] If the Department of Justice proceeds with the action, the originator of the claim is to receive between fifteen and twenty-five percent. If the government decides not to pursue the claim and the private person proceeds qui tam, that person is entitled to twenty-five to thirty percent. 31 U.S.C. § 3730(d) (2012).

[23] *See* 31 U.S.C. § 3729(a)(1) (2012) (listing seven specific actions that can give rise to liability under the FCA); *see also* United States v. Rivera, 55 F.3d 703, 709 (1st Cir. 1995) ("The paradigmatic example of a false claim under the FCA is a false invoice or bill for goods or services.").

[24] 31 U.S.C. § 3729(a)(1) (2012).

[25] *See id.* § 3729(a) (emphasis added); Burke v. Record Press, Inc., 951 F. Supp. 2d 26, 29 (D.D.C. 2013).

The FCA defines a "claim" in two ways. First, a claim may be "any request or demand . . . for money or property" made to the United States government.[26] In *United States v. Alperstein*, for example, the government brought an action under the FCA alleging that a veteran had submitted false claims for free hospitalization to which he was not entitled.[27] Alternatively, a claim may be made to any recipient of government funds where those funds were intended to be used to advance the government's interest.[28] For example, two subsidiaries of Johnson & Johnson agreed to pay over $81 million to resolve an alleged FCA suit claiming the companies had illegally promoted a drug for uses not approved of by the Food and Drug Administration, which resulted in false claims being submitted to government healthcare programs.[29] Thus, any person receiving funds traceable to the federal government is potentially subject to liability under the FCA.[30]

Such claims only violate the FCA, however, when they are "false or fraudulent."[31] Although the Supreme Court has interpreted the FCA broadly to include "all fraudulent attempts to cause the Government to pay out sums of money," courts have also recognized that not all forms of fraud give rise to liability under the FCA.[32] For example, in *United States* ex rel. *Groxx v. AIDS Re-*

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[26] 31 U.S.C. §3729(b)(2) (2012).

[27] 183 F. Supp. 548 (S.D. Fla. 1960) *aff'd*, 291 F.2d 455 (5th Cir. 1961).

[28] 31 U.S.C. § 3729(b)(2) (2012).

[29] Press Release, U.S. Dep't of Justice, Two Johnson & Johnson Subsidiaries to Pay Over $81 Million (Apr. 29th, 2010), *available at* http://www.justice.gov/opa/pr/2010/April/10-civ-500.html.

[30] By redrafting the definition of "claim" and the intent requirement in the Fraud Enforcement and Recovery Act of 2009, Congress effectively overruled the Supreme Court's decision in *Allison Engine Co., Inc. v. United States* ex rel. *Sanders*, which held that a false claim must be made with the specific intent to defraud the government, rather than merely defrauding a contractor utilizing government funds. *See* 553 U.S. 662, 668–69 (2008).

[31] 31 U.S.C. §3729(a)(1) (2012).

[32] United States v. Neifert-White Co., 390 U.S. 228, 233 (1968) ("This remedial statute reaches . . . to all fraudulent attempts to cause the Government to pay out sums of money."); United States v. McNinch, 356 U.S. 595, 599 (1958) ("[T]he False Claims Act was not designed to reach every kind of fraud practiced on the Government."); *see* United States *ex rel.* Landers v. Baptist Mem'l Health Care Corp., 525 F. Supp. 2d 972, 978–79 (W.D. Tenn. 2007) (precluding liability for violations of "the requirements providers must meet to participate in the Medicare program," because the HCFA/CMS forms do not expressly or impliedly condition payment upon compliance with these conditions).

search Alliance–Chicago, the Seventh Circuit precluded liability for situations in which a certificate of compliance was falsified unless payment was actually conditioned on the receipt of such a certificate.[33] In general, however, claims may be false or fraudulent on their face when the claimant seeks payment for more money than what is due.[34] Other claims meet this requirement, for example, where the party fails to satisfy contractual requirements on which payment is conditioned.[35]

A plaintiff must also prove that the defendant possessed "knowledge" of the falsity.[36] But this knowledge requirement is broadly defined by statute to include: (1) having actual knowledge, (2) acting in deliberate ignorance, or (3) reckless disregard of the truth or falsity of the information.[37] Thus, there is no requirement that an individual specifically intends to defraud the government; instead, a defendant merely needs to act with reckless disregard in committing the falsehood.[38]

2. Qui Tam Provisions

The FCA provides that a private party, known as a "relator," may bring a so-called *qui tam* action on behalf of the United

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[33] 415 F.3d 601, 604 (7th Cir. 2005) ("An FCA claim premised upon an alleged false certification of compliance . . . also requires that the certification of compliance be a condition of or prerequisite to government payment.")

[34] *See, e.g.*, Ry. Logistics Int'l v. United States, 103 Fed. Cl. 252, 260 (Fed. Cl. 2012) (holding that the contractor "outrageously inflated fraudulent claims" pertaining to the rehabilitation of the Iraqi Republic Railway).

[35] *See*, *e.g.*, United States *ex rel.* Wilkins v. United Health Grp., Inc., 659 F.3d 295, 306 (3d Cir. 2011) (holding that impliedly certifying compliance with preconditioned Medicare regulations incurs liability under the FCA).

[36] 31 U.S.C. § 3729(a)(1) (2012).

[37] *Id.* § 3729(b)(1) (2012). Prior to 1986, some courts required that a person have actual knowledge of the fraudulent information used in the claim submitted to the government. *See, e.g.*, United States v. Mead, 426 F.2d 118, 123 (9th Cir. 1970) (requiring the government to "prove that the defendant had the specific intent of deceit"). In 1986, Congress passed the False Claims Act Amendments, which modified 31 U.S.C. § 3729(b)(1) to broaden the knowledge requirement as described above.

[38] *See* Eng'g & Const. Co. v. United States, 58 Fed. Cl. 106 (Fed. Cl. 2003) (contractor acted knowingly, or in deliberate ignorance with reckless disregard of falsehoods when certifying the final bill).

States.[39] The FCA provides specific procedural requirements and guidelines dictating how such actions may be brought.[40]

First, a *qui tam* complaint must be filed under seal and kept as such for no less than sixty days, meaning that all records relevant to the case must be kept secret, even from the defendant, until after the court lifts the seal.[41] The complaint and a written disclosure of all other relevant information known by the whistleblower must also be given to the Department of Justice.[42] There is disagreement among the courts, however, as to the level of specificity required in the complaint. Rule 9(b) of the Federal Rules of Civil Procedure requires that allegations of fraud must be pled with "particularity," yet some circuits additionally require the plaintiff to identify specific false claims that were submitted for payment.[43]

After receiving all the information filed by the relator, the government can then conduct its own investigation.[44] Although the filings are initially kept under seal for sixty days, the government can seek an extension of time to continue its investigation.[45] There are no detailed statistics on the average length of time complaints remain under seal, but the Department of Justice has indicated that it is not unusual for a complaint to remain sealed for two years or

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[39] 31 U.S.C. § 3730(b) (2012).

[40] *See id.*

[41] *Id.* § 3730(b)(2) (2012).

[42] *Id.*

[43] The Fourth, Sixth, Eighth, and Eleventh Circuits have held that Rule 9(b) requires that a complaint identify at least one false claim for payment made to the government in the pleadings while the First, Fifth, Seventh and Ninth Circuits merely require an allegation of a scheme to submit such claims. *See* United States *ex rel.* Nathan v. Takeda Pharm. N.A., Inc., 707 F.3d 451, 457–58 (4th Cir. 2013), *cert. denied*, 134 S. Ct. 1759 (2014); United States *ex rel.* Grubbs v. Kanneganti, 565 F.3d 180, 190 (5th Cir. 2009); United States *ex rel.* Duxbury v. Ortho Biotech Prods., L.P., 579 F.3d 13, 29 (1st Cir. 2009), *cert. denied*, 130 S. Ct. 3454 (2010); United States *ex. rel.* Lusby v. Rolls-Royce Corp., 570 F.3d 849, 854–55 (7th Cir. 2009); Ebeid *ex rel.* United States v. Lungwitz, 616 F.3d 993, 998–99 (9th Cir. 2009) *cert. denied*, 131 S. Ct. 801 (2010).

[44] *See* U.S. DEP'T OF JUSTICE, THE FALSE CLAIMS ACT: A PRIMER 2 (2011), *available at* http://www.justice.gov/civil/docs_forms/C-FRAUDS_FCA_Primer.pdf.

[45] 31 U.S.C. § 3730(b)(3) (2012) provides that "[t]he Government may, for good cause shown, move the court for extensions of the time during which the complaint remains under seal . . . ."

more.[46] At the conclusion of its investigation, the government can either intervene and pursue the action itself or decline to take over the action, allowing the relator to proceed alone.[47] If the Department of Justice declines to intervene, then the government will not be a party to the proceedings, though it can still recover the majority portion of any verdict won by the relator.[48] Fewer than twenty-five percent of *qui tam* actions result in intervention by the government.[49]

However, if the government does intervene, the Department of Justice will assume the primary role of prosecuting the action.[50] The relator may still remain a party to the action, but the court in such cases often imposes limitations on the relator's participation if the government or the defendant shows that unrestrained participation by the relator would be duplicative or cause undue delay.[51] Moreover, the government can dismiss the action even over the objection of the relator provided the relator is given an opportunity for a hearing, or to settle with the defendant provided that the court determines the settlement to be fair.[52] In contrast, the relator may only settle or dismiss the action with the consent of the government.[53]

If the government declines to intervene, the relator may proceed with the action *qui tam*.[54] However, the government retains the right to intervene at a later date, and may request to be served with copies of any filings or deposition transcripts.[55] After the court

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[46] U.S. DEP'T OF JUSTICE, FALSE CLAIMS ACT CASES: GOVERNMENT INTERVENTION IN QUI TAM (WHISTLEBLOWER) SUITS 2 (2012), *available at* http://www.justice.gov/usao/pae/Civil_Division/InternetWhistleblower%20update.pdf.

[47] 31 U.S.C. § 3730(b)(4) (2012).

[48] *See* 31 U.S.C. § 3730(d)(2) (2012) (establishing that the government is entitled to a minimum of seventy percent of recovered funds where the DOJ decides not to pursue any action).

[49] U.S. DEP'T OF JUSTICE, *supra* note 46, at 2.

[50] 31 U.S.C. § 3730(c)(1) (2012).

[51] *Id.* Such limitations may include limiting the number of witnesses the relator may call, the length of those witnesses' testimony, the cross-examination of witnesses or otherwise limiting the relator's participation as the court deems necessary. *Id.*

[52] *Id.* § 3730(c)(2)(A)–(B).

[53] *Id.* § 3730(b)(1).

[54] *Id.* § 3730(b)(3).

[55] *Id.* However, the government must make a showing of good cause to intervene at a later date. *Id.*

unseals the complaint, the relator must serve the complaint upon the defendant within 120 days.[56]

Penalties for violating the FCA can be harsh. If the government or relator is able to prove that the defendant violated the FCA, then the court may award up to triple the amount of actual damages suffered by the government because of the fraud, as well as costs and a civil penalty from $5,500 to $11,000 per claim.[57] In situations where the government intervenes, the relator is entitled to fifteen to twenty-five percent of the government's total recovery, whether through a favorable judgment or settlement.[58] The exact percentage is dependent on the extent to which the information brought forth by the relator "substantially contributed to the prosecution of the action."[59] But if the government declined to intervene and the relator proceeds alone, then the relator is entitled to receive twenty-five to thirty percent of the total recovery, plus an amount for reasonable expenses, attorneys' fees, and costs.[60] However, the FCA also permits the court to lower these awards to whatever the court considers appropriate after taking into consideration the relators role in advancing the case.[61]

The FCA bars *qui tam* actions under certain circumstances.[62] For example, such actions cannot be pursued by a relator with "unclean hands," like someone convicted of criminal conduct aris-

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[56] *See* FED. R. CIV. P. 4(m); U.S. DEP'T OF JUSTICE, *supra* note 46, at 3.

[57] 31 U.S.C. § 3729(a)(1) (2012). However, the court may impose as low as double damages if the defendant fully cooperates with the government in a timely manner prior to the commencement of any criminal, civil or administrative investigation into the alleged violations. *Id.* § 3729(a)(2).

[58] *Id.* § 3730(d)(1). This section also allows for a reduced award of no more than ten percent where the court determines that the information arose primarily from disclosures of specific information related to "allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative or Government Accounting Office report, hearing, audit, or investigation, or from the news media . . . ." *Id.*

[59] *Id.*; *see* United States v. Gen. Elec., 808 F. Supp. 580 (S.D. Ohio 1992) (awarding the relator twenty-two percent of the amount recovered by the United States even though the relator could have disclosed the information earlier).

[60] 31 U.S.C. § 3730(d)(2) (2012).

[61] *Id.* § 3730(d)(3); *see* United States *ex rel.* Burr v. Blue Cross Blue Shield of Florida, Inc., 882 F. Supp. 166 (M.D.Fla. 1995) (awarding the relator fifteen percent rather than twenty-five percent where the relator's contribution was minimal and vigorously opposed settlement without merit).

[62] 31 U.S.C § 3730(e) (2012).

ing from his role in the FCA violation.[63] The FCA also bars pursuing a *qui tam* action where another individual is already doing so.[64] This is known as the "first-to-file bar." Furthermore, the FCA has a statute of limitations barring actions filed more than the later of six years from the date of violation or three years after the government knows or should have known of the violation, but in no event longer than ten years after the violation of the FCA.[65]

The most litigated affirmative defense, however, is the "public disclosure bar," which bars *qui tam* actions that are based on publicly disclosed information.[66] There is widespread debate among the circuits, however, as to what constitutes "public disclosure." Some circuits, for example, require only a modest amount of disclosure before it rises to the level of public disclosure.[67] Others require that the information be "widespread and notorious" before the bar is triggered.[68] However, the FCA provides an exception to the bar where the relator is an "original source" of the information.[69] An original source is a person who either voluntarily provided the government with the information prior to the public disclosure or who has significant independent knowledge beyond what has already been publically disclosed.[70]

Congress recently narrowed the public disclosure bar and expanded the original source exception in the Patient Protection and Affordable Care Act of 2010.[71] Under these changes, the court

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63 *Id.* § 3730(d)(3).

64 *Id.* § 3730(b)(5).

65 *Id.* § 3731(b).

66 *Id.* § 3730(e)(4). To trigger the public disclosure bar, the information must have been disclosed in a (1) criminal, civil, or administrative hearing in which the government or its agent is a party; (2) congressional, Government Accountability Office, or other Federal report, hearing, or investigation; or (3) media report. *See id.*

67 *See, e.g.*, United States *ex rel.* Fine v. Advanced Sciences, 99 F.3d 1000, 1008 (10th Cir. 1996).

68 *See, e.g.*, United States *ex rel.* Mossey v. Pal-Tech, 231 F. Supp. 2d 94, 97 (D.D.C. 2002).

69 31 U.S.C. § 3730(e)(4)(A) (2012).

70 *Id.* § 3730(b)(4)(B). The FCA previously required that a relator must have "direct and independent knowledge of the information on which the allegations are based" in order to qualify as an original source. This definition was altered in 2010 by the Patient Protection and Affordable Care Act. *See* Pub. L. No. 111-148, 124 Stat. 901.

71 Patient Protection and Affordable Care Act, H.R. 3590, 111th Cong. 783–84 (2010) (enacted); *see also* Fraud Enforcement and Recovery Act of 2009, 11 Stat. 1617, 1623

cannot dismiss an FCA claim based on the public disclosure bar if the government opposes dismissal of the *qui tam* action.[72] Additionally, civil litigation to which the government or its agents are not a party cannot by itself give rise to a public disclosure.[73] The Affordable Care Act also removed the requirement that an original source have "direct and independent knowledge" of the information giving rise to the FCA violation.[74] Now relators without direct knowledge of the violations can bring FCA claims, so long as they have independent knowledge that materially adds to the allegation.[75] In spite of these modifications, the public disclosure bar appears to remain a key issue in FCA *qui tam* actions.[76]

B. State False Claims Actions

Thirty states currently have false claims acts in place.[77] While the state statutes vary to some degree, they generally employ the same procedures as those of the Federal False Claims Act, but with submissions filed with the state attorney general instead of the Department of Justice. Where a relator uncovers fraud under a state-administered Medicaid program, both the state's false claim sta-

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(changes definition of "obligation" to include "retention of overpayments" thereby extending liability to persons receiving Medicare/Medicaid overpayments and knowingly failing to return the amount in excess).

[72] 31 U.S.C § 3730(b)(4)(A) (2012). The alteration effectively overrules the Supreme Court's holding in *Rockwell Int'l Corp. v. United States*, which affirmed the bar as being jurisdictional and therefore non-waivable. 549 U.S. 457, 467–78 (2007).

[73] 31 U.S.C § 3730(b)(4) (2012).

[74] Patient Protection and Affordable Care Act, H.R. 3590, 111th Cong. 783–84 (2010) (enacted).

[75] 31 U.S.C § 3730(b)(4)(B) (2012).

[76] *See* David M. Nadler & Justin A. Chiarodo, *The Public Disclosure Bar: New Answers and Open Questions*, 47 PROCUREMENT LAW. 1, 18 (2011).

[77] *See* JOHN F. CARROLL, CTR. FOR THE ADVANCEMENT OF PUB. INTEGRITY, FALSE CLAIMS ACT: AN INSPECTOR GENERAL'S BEST FRIEND (Nov. 2014), *available at* http://web.law.columbia.edu/sites/default/files/microsites/public-integrity/files/community_contribution_-_john_carrol.pdf. States with false claims acts include California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Virginia, Washington, and Wisconsin, as well as the District of Columbia. Of these, Colorado, Connecticut, Louisiana, Maryland, Michigan, New Hampshire, Texas, Washington, Wisconsin each employ "Medicaid only" False Claims Acts.

tute and the Federal False Claims Act would be implicated. Similarly, in states where no false claims act exists, the federal funding component of a state-administered Medicaid program would likely be sufficient to justify use of the Federal False Claims Act to address Medicaid fraud.

Under the Social Security Act, each state with a false claims act of its own is eligible for a ten percent increase in the percentage of the false claims act recoveries for which a recovery is had.[78] To qualify for the financial incentive, a state's false claims act must: (1) establish liability to the state for false or fraudulent claims, as described in the Federal False Claims Act, with respect to Medicaid spending; (2) contain provisions that are at least as effective in rewarding and facilitating *qui tam* actions for false or fraudulent claims as those described in the FCA; (3) contain a requirement for filing an action under seal for sixty days with review by the State Attorney General; and (4) contain a civil penalty that is not less than the amount of the civil penalty authorized under the FCA.[79] The federal Office of the Inspector General determines whether the state statute meets these criteria, and is thus eligible for the ten percent incentive.[80] Unsurprisingly, the federal incentive has increased the uniformity of the state false claims acts, at least insofar as Medicaid fraud is concerned.

In addition to the state laws, several cities and counties have their own false claims acts. New York City, Chicago, Philadelphia, and Allegheny County, Pennsylvania each have their own version of the False Claim Act with *qui tam* provisions, enabling them to recover money at the municipal or county level.[81]

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[78] Section 1909 of the Social Security Act provides that any state deemed to have qualifying laws may receive a ten-percentage-point increase in its share of any amounts recovered under such laws. *See* 42 U.S.C. § 1396(h) (2012).

[79] OFFICE OF INSPECTOR GENERAL, OIG GUIDELINES FOR EVALUATING STATE FALSE CLAIMS ACTS, *10 (Mar. 13, 2013), *available at* https://oig.hhs.gov/fraud/docs/falseclaimsact/guidelines-sfca.pdf.

[80] Roughly half of the thirty states with false claims acts currently meet these criteria.

[81] *See, e.g.*, N.Y.C. ADMIN. CODE, tit. 7, ch. 8 (West).

II. INEQUITABLE CONDUCT

Inequitable conduct is an affirmative defense in patent litigation, in which the defendant asserts that the patentee has procured its patent through improper conduct before the USPTO.[82] This judicially created doctrine derives from a trio of Supreme Court cases dealing with the equitable doctrine of unclean hands.[83] Prior to the development of the inequitable conduct doctrine, courts often refused to grant an injunction to a patentee that had engaged in egregious misconduct, and thus came to the court with "unclean hands."[84] Under the modern inequitable conduct doctrine, which is tantamount to defrauding the USPTO, the result of a successful showing by a defendant is even more severe. A finding of inequitable conduct may not only jeopardize a company's entire patent portfolio but may spark additional antitrust and unfair competition claims.[85]

As obtaining a patent is an *ex parte* procedure, all persons substantively involved in the prosecution of the patent application owe a duty of candor to the USPTO.[86] This duty requires these persons to disclose all known information material to patentability.[87] Acts typically constituting inequitable conduct include failing to submit material prior art known by the applicant, failing to explain references in a foreign language, misstatements of facts concerning patentability, and mis-description of inventorship.[88] As full disclosure

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[82] *See* Therasense, Inc. v. Becton, Dickinson & Co., 649 F.3d 1276, 1285 (Fed. Cir. 2011).

[83] *See* Keystone Driller Co. v. Gen. Excavator Co., 290 U.S. 240 (1993); Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co., 324 U.S. 806 (1945); Hazel-Atlas Glass Co. v. Hartford-Empire Co., 322 U.S. 238 (1944).

[84] *See Therasense*, 649 F.3d at 1287.

[85] *See* Dow Chemical Co. v. Exxon Corp., 139 F.3d 1470, 1480 (Fed. Cir. 1998) (where inequitable conduct gave rise to an unfair competition claim); Walker Process Equip., Inc. v. Food Mach. & Chem. Corp., 382 U.S. 172, 178 (1965) (where inequitable conduct gave rise to antitrust action).

[86] 37 C.F.R. § 1.56(a) ("Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office . . . .").

[87] 37 C.F.R. § 1.56(a) ("[All persons involved in the patent application owe] a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section.").

[88] *See* McKesson Info. Solutions, Inc. v. Bridge Medical, Inc., 487 F.3d 897, 913–26 (Fed. Cir. 2007) (finding inequitable conduct where attorney failed to disclose material information from related patent application); Critikon, Inc. v. Becton Dickinson Vascular

of information pertaining to an invention may contradict the self-interests of many patent applicants, the doctrine of inequitable conduct imposes severe penalties for violating this duty. If the defense is proved, the entire patent (and possibly all related patents in the same family) will be held unenforceable, even if the claims of the patent are otherwise valid.[89] In fact, the effects of such a finding are so severe that the Court of Appeals for the Federal Circuit in *Therasense, Inc. v. Becton, Dickinson & Co.* recently referred to the doctrine as an "atomic bomb" and elevated the standard of what must be shown to prove inequitable conduct.[90]

To prove inequitable conduct post-*Therasense*, an accused infringer must show by clear and convincing evidence that the patentee either failed to disclose, misrepresented, or submitted false information to the patent office (1) that was material to patentability and (2) with the specific intent to deceive the patent office.[91] The intent and materiality are separate elements and the existence of one cannot provide the basis for inferring the other.[92] Proving that an applicant should have known of the materiality of a reference but did not submit it to the USPTO, for example, does not satisfy the deceptive intent element by itself.[93]

Access, Inc., 120 F.3d 1253, 1256–57 (Fed. Cir. 1997) (inferring intent where applicant "knew or should have known" that information was relevant to the prosecution); Bruno Indep. Living Aids, Inc. v. Acorn Mobility Servs. Ltd., 394 F.3d 1348, 1350–54 (Fed. Cir. 2005) (finding inequitable conduct for failure to cite U.S. Food and Drug Administration proceeding); Cargill, Inc. v. Canbra Foods, Ltd., 476 F.3d 1359, 1366 (Fed. Cir. 2007) (finding inequitable conduct for failing to disclose test data inconsistent with data disclosed in the specification); Ferring B.V. v. Barr Labs., Inc., 437 F.3d 1181, 1194–95 (Fed. Cir. 2006) (finding inequitable conduct where applicant failed to disclose that declarations from outside experts had been previously employed by the applicant); Nilssen v. Osram Sylvania, Inc., 504 F.3d 1223, 1229–30 (Fed. Cir. 2007) (inequitable conduct found where applicant improperly claimed small entity status).

89 Kingsdown Med. Consultants, Ltd. v. Hollister Inc., 863 F.2d 867, 877 (Fed. Cir. 1988); J.P. Stevens & Co. v. Lex Tex. Ltd., 747 F.2d 1553, 1561 (Fed. Cir. 1984); *see also* Consol. Aluminum Corp. v. Foseco Int'l Ltd., 910 F.2d 804, 808–12 (Fed. Cir. 1990).

90 Therasense, Inc. v. Becton, Dickinson & Co., 649 F.3d 1276, 1288 (Fed. Cir. 2011) (en banc) (citations omitted).

91 *See id.* at 1276.

92 *See id.* (rejecting the "sliding scale" approach where a court requires less evidence of intent where a reference is highly material); *see also* Hoffmann-La Roche, Inc. v. Promega Corp., 232 F.3d 1354, 1359 (Fed. Cir. 2003).

93 Star Scientific, Inc. v. R.J. Reynolds Tobacco Co., 537 F.3d 1357, 1366 (Fed. Cir. 2008).

Under *Therasense*, the defendant must show but-for materiality with respect to the patentee's omission or misrepresentation to the patent office.[94] Therefore, even when a patentee withholds information, it only warrants a finding of inequitable conduct if, but-for the withholding, the patentee would not have been successful in prosecuting the claim. However, in heightening the standard to but-for materiality, the Federal Circuit carved out an exception in cases of affirmative egregious misconduct.[95] Where a patent applicant has engaged in such conduct, the materiality prong is met regardless of whether the claim would have issued. An affirmative act of egregious misconduct includes actions such as intentionally filing false affidavits.[96] Absent more telling actions, however, merely failing to disclose prior art references does not constitute such misconduct.

The second element of the inequitable conduct analysis requires proving that the patentee deliberately decided to withhold, misrepresent, or falsify a known material reference with the intent to deceive the USPTO.[97] In practice, this element provides a significant hurdle for defendants.[98] Parties are rarely able to show direct evidence of deceptive intent. However, courts may infer such intent from indirect and circumstantial evidence, provided that such an inference is "the single most reasonable inference able to be drawn from the evidence."[99] The evidence presented must therefore be "sufficient to *require* a finding of deceitful intent in the light of all the circumstances."[100] A patentee's deceptive intent, therefore, cannot be inferred where multiple reasonable inferences may

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94 *Therasense*, 649 F.3d at 1291.

95 *See id.* at 1292 (carving out an exception for cases where a patentee "deliberately planned and carefully executed scheme[s]" to defraud the PTO).

96 *See id.* ("When the patentee has engaged in affirmative acts of egregious misconduct, such as the filing of an unmistakably false affidavit, the misconduct is material.").

97 Molins PLC v. Textron, Inc., 48 F.3d 1172, 1181 (Fed. Cir. 1995)

98 Ryan Davis, *Inequitable Conduct A Dying Defense 2 Years Post-Therasense*, LAW360 (May 23, 2013, 9:13 PM), http://www.law360.com/articles/444480/inequitable-conduct-a-dying-defense-2-years-post-therasense.

99 Star Scientific, Inc. v. R.J. Reynolds Tobacco Co., 537 F.3d 1357, 1366 (Fed. Cir. 2008).

100 Kingsdown Med. Consultants, Ltd. v. Hollister Inc., 863 F.2d 867, 873 (Fed. Cir. 1988) (emphasis added).

be drawn from the same evidence.[101] As a result of the elevated standards for both materiality and specific intent, it is significantly more difficult to successfully raise an inequitable conduct defense under *Therasense*.[102]

III. FALSE CLAIMS LIABILITY FOR INEQUITABLE CONDUCT

The Central District of California recently denied Aventis Pharma's motion to dismiss an FCA claim based on an inequitable conduct finding secured by its competitor Amphastar Pharmaceuticals in an underlying patent case.[103] Amphastar alleges that Aventis knowingly charged the government inflated prices for its deep-vein thrombosis drug, Lovenox (enoxaparin), by illegally obtaining a patent through inequitable conduct before the USPTO.[104]

This section provides background information pertaining to the pending FCA action initiated by Amphastar, discusses the parallels between antitrust claims based on inequitable conduct and Amphastar's theory of false claims liability, and analyzes whether inequitable conduct during patent prosecution can serve as a basis for FCA liability. We conclude that given the broadening of the False Claims Act in recent years, it is likely that a court would find inequitable conduct to be a proper basis for a finding of FCA liability, provided certain other elements are proven. Consequently, nearly every patent holder that does business with the federal government, which includes anyone producing pharmaceuticals covered by Medicare or other government programs, may soon be exposed to FCA liability based on *Amphastar v. Aventis*.

A. Amphastar Pharmaceuticals v. Aventis Pharma S.A.

The feud between Aventis and Amphastar began in 2003, when Amphastar filed an Abbreviated New Drug Application ("ANDA") with the FDA seeking the right to manufacture a ge-

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101 *Therasense*, 649 F.3d at 1290–91 (Fed. Cir. 2011).
102 Davis, *supra* note 98.
103 Memorandum and Order, *supra* note 2, at 2.
104 *Id.*

neric version of Aventis's Lovenox.[105] In its ANDA, Amphastar asserted that Aventis's patent covering Lovenox was invalid, unenforceable, and/or not infringed by Amphastar's generic product.[106] Shortly after Amphastar filed its ANDA, Aventis sued Amphastar for patent infringement.[107] Amphastar then successfully raised the defense of inequitable conduct and filed a counterclaim alleging that Aventis violated the antitrust laws by filing a baseless patent infringement suit.[108] The district court granted Amphastar's motion for summary judgment on its inequitable conduct defense, finding that Aventis concealed material information from the USPTO during prosecution and holding the patent unenforceable.[109] On appeal, the Federal Circuit reversed and remanded, holding that the district court applied an incorrect standard and directing the lower court to apply a clear and convincing evidence

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[105] *Id.* ANDAs are a frequently deployed mechanism for the early introduction of generic competition. *See* FED. TRADE COMM'N, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY 10 (2002), *available at* https://www.ftc.gov/sites/default/files/documents/reports/generic-drug-entry-prior-patent-expiration-ftc-study/genericdrugstudy_0.pdf (reporting challenges involving 130 drugs between 1984 and 2000); *Examining the Senate and House Versions of the "Greater Access to Affordable Pharmaceuticals Act": Hearing Before the S. Comm. on the Judiciary*, 108th Cong. 113, 117 (2003) (statement of Timothy Muris, Chairman, Federal Trade Commission) (noting challenges involving more than eighty drugs between January 2001 and June 2003).

[106] Amphastar's ANDA contained a Paragraph IV certification against Aventis's patent on Lovenox. As part of the ANDA, the generic applicant is required to make one of the following certifications regarding *each* patent listed in the *Orange Book* that claims the drug it seeks to copy: (I) that the drug is not patented or that patent information has not been filed; (II) that the patent has expired; (III) that the generic drug will not enter the market until the patent expires; or (IV) that the patent is invalid or will not be infringed by the manufacture, use, or sale of the generic drug for which the application is submitted. 21 U.S.C. § 355(j)(2)(A)(vii)(I)–(IV). These are called Paragraph I, II, III, and IV certifications, respectively. By making a Paragraph IV certification, a generic manufacturer can seek FDA approval to market a generic equivalent of a pioneer's patented drug before the patent term has expired.

[107] Subsection 271(e) of the Patent Act provides that making a Paragraph IV certification alone is an act of patent infringement. 35 U.S.C. § 271(e)(2)(A). Consequently, the mere filing of an ANDA with a Paragraph IV certification allowed Aventis to sue Amphastar for infringing its patent.

[108] Amphastar Pharm. Inc. v. Aventis Pharma SA, No. EDCV-09-0023 MJG, 2012 WL 5512466, at *1 (C.D. Cal. Nov. 14, 2012).

[109] *Id.* (citing Aventis Pharma S.A. v. Amphastar Pharm., Inc., 390 F. Supp. 2d 952 (C.D. Cal. 2005)).

standard.[110] On remand, the district court again found the patent unenforceable on inequitable conduct grounds and the Federal Circuit affirmed.[111]

In the subsequent litigation, the district court dismissed Amphastar's antitrust counterclaims on the grounds that the complaint failed to allege an "antitrust harm," a necessary element of a Sherman Act violation.[112] Even if there had been a harm, the court found that Aventis was shielded from antitrust liability under the *Noerr-Pennington* doctrine, which largely immunizes brand-name manufacturers from liability for petitioning the government, even if anticompetitive in nature.[113] Unbeknownst to Aventis, Amphastar had also filed a *qui tam* complaint under seal with the district court in January 2009.[114] After the government decided not to intervene in the *qui tam* suit, the complaint was unsealed in October 2011. Amphastar's complaint asserted that Aventis made false statements to the USPTO in order to acquire a patent, submitted false claims to the government for Lovenox,[115] and then engaged in baseless patent litigation with Amphastar in an effort to extend its illeg-

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[110] Aventis Pharma S.A. v. Amphastar Pharm., Inc., 525 F.3d 1334, 1337 (Fed. Cir. 2008).

[111] *Id.* at 1349.

[112] Amphastar Pharm. Inc. v. Aventis Pharma SA, No. EDCV-09-0023 MJG, 2012 WL 5512466, at *1 (C.D. Cal. Nov. 14, 2012).

[113] *Id*. A patentee's immunity from antitrust liability derives from the *Noerr-Pennington* doctrine. This immunity may be broken if the defendant can prove that the infringement suit is a "mere sham" and in reality is "an attempt to interfere directly with the business relationships of a competitor." This can occur where the patentee has engaged in illegal vertical agreements in violation of Section 1 of the Sherman Act or if the patentee has engaged in so called *Walker Process* fraud. *See In re* Independent Serv. Orgs. Antitrust Litigation, 203 F.3d 1322, 1326 (Fed. Cir. 2000); California Motor Transp. Co. v. Trucking Unlimited, 404 U.S. 508, 510–11 (1972) ("We said, however, in *Noerr* that there may be instances where the alleged conspiracy 'is a mere sham to cover what is actually nothing more than an attempt to interfere directly with the business relationships of a competitor and the application of the Sherman Act would be justified.'").

[114] Memorandum and Order, *supra* note 2, at 2.

[115] By seeking reimbursement or payment through Medicare or other federal programs, a seller of pharmaceutical products submits a claim for payment to the government within the meaning of the FCA. In this case, the fact that Lovenox was patented permitted Aventis to charge an elevated price for the drug, and submitting claims at that elevated price forms the basis for the "false" or "fraudulent" nature of the claims.

al monopoly.[116] In ruling on motions to dismiss, the district court determined that although the finding of inequitable conduct had been publicly disclosed, Amphastar was the "original source."[117] Nonetheless, the court dismissed the *qui tam* suit, with leave to amend, on the grounds that Amphastar failed to allege with particularity that Aventis's false claims were paid for or approved by the government, as required by Rule 9(b) of the Federal Rules of Civil Procedure.[118]

After amending its complaint, Amphastar asserted that Aventis (1) made false statements to the USPTO in prosecuting two pharmaceutical patents (2) thereby illegally obtained monopoly power over enoxaparin in the US market and (3) leveraged that monopoly power to sell over six million units of Lovenox to the government or its distributors at inflated monopoly prices, totaling at least $470 million in false claims between 1993 and 2002.[119] This amended complaint survived additional motions to dismiss and is currently being litigated.[120]

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[116] Amphastar Pharm. Inc. v. Aventis Pharma SA, No. EDCV-09-0023 MJG, 2012 WL 5512466, at *2 (C.D. Cal. Nov. 14, 2012).

[117] *Id.* at *2.

[118] *Id.* at *13.

[119] Amended Complaint at 12-13, ¶¶ 37, 41, Amphastar Pharmaceuticals Inc., v. Aventis Pharma SA, No. 5:09-cv-00023, (C.D. Cal. Dec. 03, 2012); Memorandum and Order, *supra* note 2, at 7.

[120] Most recently, on March 26, 2015, the Court denied Amphastar's motion for issue preclusion, in which it sought to collaterally estop Aventis from contravening certain facts established during the prior ANDA litigation. Order Re: Issue Preclusion Motion at 1-2, Amphastar Pharmaceuticals Inc., v. Aventis Pharma SA, No. 5:09-cv-00023, (C.D. Cal. March 26, 2015). The Court noted that it was in the process of drafting its order on original source jurisdiction, regarding whether Amphastar was an "original source of the information," on which the suit is based. *Id.* The issue of whether Amphastar is an "original source" is also being litigated in an interlocutory appeal to the Ninth Circuit Court of Appeal. Certification Order 8 U.S.C. § 1292(b) at 1, Amphastar Pharmaceuticals Inc., v. Aventis Pharma SA, No. 5:09-cv-00023, (C.D. Cal. June 6, 2014). In August 2014, the Ninth Circuit granted a petition for permission to appeal the district court's Order denying Aventis' Motion for Summary Judgment for lack of jurisdiction pursuant to 31 U.S.C. § 3730(e)(4)(B), agreeing to examine what exactly a relator's pre-filing disclosure must include if the relator wishes to qualify as an "original source." Amphastar Pharmaceuticals Inc. v. Aventis Pharma S.A., Case No. 14-56382 (9th Cir. 2014). The parties have submitted opening, responsive, and reply briefs, though the Ninth Circuit has yet to issue an opinion.

B. Distinguishing Walker Process *Claims*

Although Amphastar's theory of false claims liability is novel, the use of the defense of inequitable conduct as the basis for a counterclaim is not unprecedented. In fact, inequitable conduct is frequently used as the basis for certain antitrust counterclaims, which are known as *Walker Process* claims. Such claims are typically brought under Section 2 of the Sherman Act, which prohibits the use of anticompetitive conduct to acquire or maintain a monopoly.[121] A patent can give its owner market exclusivity, thereby thwarting competition in a given field for a limited period of time. However, when patent holders sue their competitors for infringement, they generally enjoy immunity from antitrust liability under the *Noerr-Pennington* doctrine, which immunizes petitioning the government for redress, even when such conduct is anticompetitive.[122] This immunity can be defeated, however, if the accused infringer establishes that the patent was obtained from the USPTO through knowing and willful fraud, commonly referred to as *Walker Process* fraud.[123] As discussed in Part II, *supra*, in order to prove in-

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[121] *See* 15 U.S.C. § 2 (2012) (providing that "[e]very person who shall monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States, or with foreign nations, shall be deemed guilty of a felony . . . .").

[122] *See* Nobelpharma AB v. Implant Innovation, Inc., 141 F.3d 1059, 1068 (Fed. Cir. 1998); Eastern R.R. Presidents Conference v. Noerr Motor Freight, Inc., 365 U.S. 127, 136–37 (1961) (clarifying that "the Sherman Act does not prohibit two or more persons from associating together in an attempt to persuade the legislature or the executive to take particular action with respect to a law that would produce a restraint or a monopoly" and that the "concept of representation depends upon the ability of the people to make their wishes known to their representatives"); United Mine Workers v. Pennington, 381 U.S. 657, 670 (1965) ("Noerr shields from the Sherman Act a concerted effort to influence public officials regardless of intent of purpose . . . . Joint efforts to influence public officials do not violate the antitrust laws even though intended to eliminate competition."); California Motor Transp. Co. v. Trucking Unlimited, 404 U.S. 508, 510 (1972) ("Certainly the right to petition extends to all departments of the Government.").

[123] *See* Walker Process Equip., Inc., v. Food Machinery & Chem. Corp., 382 U.S. 172, 177 (1965) (holding that a party who uses a patent procured through intentional fraud on the USPTO to obtain or preserve a monopoly may be subject to antitrust liability). Note that *Walker Process* claims differ from *Handgards* claims, which are antitrust counterclaims that attempt to establish that the patent holder knowingly asserted a patent that was invalid or did not infringe the defendant's technology merely to disrupt a competitors business practices. *See* Handgards, Inc. v. Ethicon, Inc., 601 F.2d 986 (9th Cir. 1979).

equitable conduct under the new *Therasense* standard, an accused infringer must demonstrate that a patentee made a material misrepresentation to the patent office with the specific intent to deceive the patent office.[124] This elevated standard for proving inequitable conduct is essentially the same as what is needed to prove *Walker Process* fraud.[125]

In the same way inequitable conduct serves as the basis for *Walker Process* antitrust claims, inequitable conduct may also serve as the basis for FCA claims. Prior to *Therasense*, establishing *Walker Process* fraud required significantly more than proving inequitable conduct.[126] However, with the heightened standards adopted under *Therasense*, there is now a significant overlap between the elements of an inequitable conduct defense and a *Walker Process* counterclaim.[127] Similarly, a showing of fraud on the patent office may serve as the basis for establishing that the patent holder made a fraudulent claim for payment from the government in violation of the False Claims Act. However, there remain several key differences between *Walker Process* claims and FCA claims, which renders the analogy of using inequitable conduct as the basis for the latter problematic.

1. Overview of *Walker Process* Antitrust Claims

An antitrust claim relying on *Walker Process* fraud requires an accused infringer to show (1) the patent holder engaged in knowing and willful fraud before the USPTO in order to obtain the patent; (2) clear and convincing evidence of deceptive intent which must be independent of the evidence of fraud; (3) that the patent would

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[124] Therasense, Inc. v. Becton, Dickinson & Co., 649 F.3d 1276, 1296 (Fed. Cir. 2011) (en banc).

[125] Asim M. Bhansali & William S. Hicks, *Trial Management After Therasense: Inequitable Conduct,* Walker Process *Fraud, and the Seventh Amendment*, 21 COMPETITION: J. ANTI. & UNFAIR COMP. L. SEC. ST. B. CAL. 1 (2012).

[126] *See* Nobelpharma AB v. Implant Innovations, Inc., 141 F.3d 1059, 1069 (Fed. Cir. 1998) ("[I]nequitable conduct is a broader, more inclusive concept than the common law fraud needed to support a *Walker Process* counterclaim.").

[127] *See, e.g.*, Gideon Mark & T. Leigh Anenson, *Inequitable Conduct and* Walker Process *Claims After* Therasense *and the America Invents Act*, 16 U. PA. J. BUS. L. 361, 403 (2014) (noting the "virtual alignment of inequitable conduct and Walker Process fraud that was accomplished by Therasense"); *see also* Metris U.S.A., Inc. v. Faro Tech., Inc., 882 F. Supp. 2d 160, 174 (D. Mass 2011).

not have issued but-for the misrepresentation or omission of material facts; and (4) that the patent holder was aware of this fraud while attempting to enforce the patent.[128] These four elements form the crux of both *Walker Process* fraud and inequitable conduct, and provide grounds for breaking the antitrust immunity granted under *Noerr-Pennington*.[129] To establish liability and damages under an antitrust theory, however, it is also necessary to prove the elements of a Sherman Act violation, including a showing that the patentee had monopoly power in a relevant and definable market, and willfully acquired or maintained that power through anticompetitive behavior.[130]

Both *Walker Process* claims and the defense of inequitable conduct are focused on misconduct before the USPTO and require that the patent applicant intentionally misled the examiner. Not surprisingly, both claims typically arise out of the same conduct and are supported by the same evidence.[131] Prior to *Therasense*, inequitable conduct was considered a "broader, more inclusive concept than the common law fraud needed to support a *Walker Process* counterclaim."[132] However, *Therasense* raised the standard for inequitable conduct to essentially the same level as *Walker Process* fraud.[133]

In spite of their similarities, there exist important distinctions between the two doctrines.[134] Most significantly, *Walker Process* claims require proving the additional elements of an antitrust viola-

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[128] *See Nobelpharma*, 141 F.3d at 1068–71.

[129] The decision to strip a plaintiff of the *Noerr-Pennington* immunity is controlled by Federal Circuit law when the claim is brought in its jurisdiction, however the remainder of the antitrust analysis proceeds under the law of the circuit in which the claim arose. *See Nobelpharma*, 141 F.3d at 1068; Unitherm Food Sys., Inc. v. Swift-Eckrich, Inc., 375 F.3d 1341, 1357 (Fed. Cir. 2004).

[130] *See* Walker Process Equip., Inc. v. Food Mach. & Chem. Corp., 382 U.S. 172, 174 (1965).

[131] *See* Dippin' Dots, Inc. v. Mosey, 476 F.3d 1337, 1346 (Fed. Cir. 2007).

[132] *Nobelpharma*, 141 F.3d at 1069.

[133] *See* Therasense, Inc. v. Becton, Dickinson & Co., 649 F.3d 1276 (Fed. Cir. 2011); *see also* Metris U.S.A., Inc. v. Faro Tech., Inc., 882 F. Supp. 2d 160, 174 (D. Mass 2011).

[134] Obviously there is a difference in result—inequitable conduct is a defense to infringement that renders a patent unenforceable, while *Walker Process* fraud subjects the patentee to antitrust liability including treble damages.

tion beyond what is necessary to establish inequitable conduct.[135] For example, prosecution of bad-faith patent litigation, where the patentee knows that its patent is invalid or that the defendant's product does not infringe, can form the basis of a monopolization claim, but more is needed.[136] While fraudulently procuring a patent constitutes inequitable conduct, that fraudulent action by itself has no competitive impact and thus cannot constitute a violation of the Sherman Act without more.[137] *Walker Process* claims must rely on the *enforcement* of a fraudulently obtained patent that causes anti-competitive injury; simply obtaining the patent, whether by fraud or not, is insufficient to establish the antitrust claim.

2. Federal False Claims v. *Walker Process* Antitrust Claims

A *Walker Process* claim and an FCA claim based on an inequitable conduct theory are therefore closely related. In essence, a *Walker Process* claim relies on the theory that a fraudulently obtained (or misused) patent permits the patentee to obtain monopoly power and reap monopoly profits. Where inequitable conduct is the alleged fraud, a suit under the FCA based on this theory would essentially mirror a *Walker Process* claim. Rather than allege anti-competitive effects under the Sherman Act, the government or relator would assert that the fraudulently obtained patent (regardless of whether it was enforced) permitted the patentee to fraudulently overcharge the government for patented items. In other words, but-for the inequitable conduct before the USPTO, the product at issue would have been unpatented, subject to rigorous marketplace competition, and therefore significantly cheaper. A *Walker Process* claim requires a showing that a fraudulently obtained patent

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[135] Violation of § 2 of the Sherman Act requires showing (1) the possession of monopoly power in the relevant market and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident. United States v. Grinnell Corp., 384 U.S. 563, 570–71 (1966).

[136] *See* Bio-Technology Gen. Corp. v. Genentech, Inc., 267 F.3d 1325, 1333 (Fed. Cir. 2001); Loctite Corp. v. Ultraseal, Ltd., 781 F.2d 861 (Fed. Cir. 1985), *overruled by* Nobelpharma AB v. Implant Innovations, Inc., 141 F.3d 1059 (Fed. Cir. 1998).

[137] FMC Corp. v. Manitowoc Co., Inc., 835 F.2d 1411, 1418 n.16 (Fed. Cir. 1987) ("Mere procurement of a patent, whatever the conduct of the applicant in the procurement, cannot without more affect the welfare of the consumer and cannot in itself violate the antitrust laws.").

granted the patent holder actual monopoly power in a definable market, and that the patentee then used the unlawfully obtained monopoly power to stave off competition and reap excessive profits, thus causing antitrust injury to consumers. Similarly, an FCA claim requires a showing that a fraudulently obtained patent permitted the patent holder to charge an elevated price and stave off competition, thus causing the government harm by overcharging. In both cases, the measure of damages from the consumer/government perspective is what the price of the product would have been absent the fraudulently obtained patent (or, in *Walker Process* claims, patent misuse). Where a *Walker Process* claim is supported, an FCA claim will be as well, though the reverse is not necessarily true.

One way of proving an FCA violation would then be to prove monopolization, as under a *Walker Process* counterclaim. But a patentee need not monopolize a definable market in order to raise prices. Excluding others from making a patented improvement to a product can justify charging a higher price without capturing or monopolizing an entire market. Because a *Walker Process* claim relies on antitrust laws, it is subject to a more stringent set of rules than is needed to prove an FCA claim. A violation of Section 2 of the Sherman Act, for example, requires that the accused infringer show that the patentee has market power and engaged in anticompetitive conduct, thereby causing an antitrust injury.[138]

In practice, proving market power presents a significant hurdle to *Walker Process* claimants. Although market power can be proven by either direct or circumstantial evidence, patents by themselves do not necessarily confer monopoly power.[139] The fact that a company holds a patent on a particular product does not demonstrate a lack of alternative devices in the marketplace. As such, identifying the relevant market is itself a challenging and often determinative

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[138] *See* United States v. Grinnell Corp., 384 U.S. 563, 570–571 (1966).

[139] Rebel Oil Co., Inc. v. Atlantic Richfield Co., 51 F.3d 1421, 1434 (9th Cir.1995); Northern Pacific R.R. Co. v. United States, 356 U.S. 1, 10, n.8 (1958); *see* Robert Merges, *Reflections on Current Legislation Affecting Patent Misuse*, 70 J. PAT. & TRADEMARK OFF. SOC'Y 793, 793 (1988).

analysis.[140] In *Unitherm Food System v. Swift-Eckrich*, the Federal Circuit explained that a relevant product market is composed of "products that have reasonable interchangeability for the purposes for which they are produced."[141] There, the Federal Circuit overturned the lower court's finding of market power, which was predicated on expert testimony that the patented products were technologically unique. The Federal Circuit stressed that the proper inquiry is not technological substitutability of a product, but economic substitutability.[142] Therefore, where a patented product is economically substitutable with another product, market power cannot be established even when a patentee is nonetheless able to raise prices.[143] This significant challenge must be overcome in a claim asserting *Walker Process* fraud, but would not necessarily hinder an FCA claim based on inequitable conduct.

Under a *Walker Process* theory, an accused infringer must also show that the patent holder has engaged in anticompetitive conduct. This amounts to not only showing that the patent was obtained through fraud, but that the patent holder was aware that the patent was acquired through fraud at the time of the lawsuit.[144] In circumstances where a patent holder prosecuted the patent in question, such a showing is straightforward. However, when the patent holder was not involved in the prosecution of the patent application (for example, because the patent was licensed or purchased from another party), this element proves more difficult. Under an FCA claim based on inequitable conduct, by contrast, a relator need only show that the patentee billed the government while deliberately ignoring or recklessly disregarding the fraudulent

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[140] *See* Unitherm Food Sys., Inc. v. Swift-Eckrich, Inc., 375 F.3d 1341 (Fed. Cir. 2004) (overturning a jury verdict where the court determined the relevant market to be essentially the patented invention and failed to consider products that were economically substitutable).

[141] *See id.* at 1363 (quoting United States v. AMR Corp, 335 F.3d 1109, 1113 (10th Cit. 2003)).

[142] *Unitherm*, 375 F.3d at 1363–64.

[143] *See id.*

[144] *See* Nobelpharma AB v. Implant Innovations, Inc., 141 F.3d 1059, 1069–70 (Fed. Cir. 1988); *see also* David Hovenkamp, *Antitrust and Patent Exclusions After Therasense* 26 (U. Iowa Legal Studies Research Paper No. 11-39, Dec. 12, 2011), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1916074.

circumstances under which the patent was obtained.[145] Thus, the bar is again lower for FCA claims than similar *Walker Process* claims.

Hence, while *Walker Process* claims and FCA claims for inequitable conduct overlap significantly, there are material differences between the two theories. Unlike FCA claims, *Walker Process* claims require proof of monopolization conduct, market definition, and market power. While *Walker Process* claims focus on the patentee's conduct while in possession of a patent, FCA claims based on inequitable conduct focus on the fraudulent actions of the patentee before the USPTO and the subsequent ability to charge higher prices. Defenses regarding market power (i.e. one's ability to charge a fraudulently higher price) could arise in FCA litigation, but showing market power is not a necessary element as it would be in a *Walker Process* claim.

Overall, *Walker Process* claims are significantly more difficult to prove than FCA claims. This suggests that if inequitable conduct can serve as the basis for an antitrust claim, it should clearly be sufficient to serve as the basis for the more easily proved FCA claims. The only area where FCA claims face a higher burden than *Walker Process* claims is at the pleading stage of litigation. While both theories implicate Rule 9(b) in that fraud on the PTO must be pled with particularity, only the FCA claim (and only in certain circuits) would also require a plaintiff to include representative examples of false claims made to the government.[146] However, this difference in pleading standards between the two theories does not alter the conclusion that the factual underpinnings necessary to support a *Walker Process* antitrust counterclaim should be more than sufficient to support an FCA claim based on inequitable conduct.

C. Suitability of Inequitable Conduct as a Basis in FCA Actions

While the analogy to *Walker Process* counterclaims suggests similarities with Amphastar's FCA claim, it is not yet clear how liability under the FCA can arise due to inequitable conduct and

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[145] 31 U.S.C. § 3729(b)(1) defines knowledge as (1) having actual knowledge, (2) acting in deliberate ignorance, or (3) reckless disregard of the truth or falsity of the information.

[146] *See supra* note 43.

whether such liability is proper. Here, we discuss the difficulty of proving Amphastar's novel theory of FCA liability, and the problems associated with allowing inequitable conduct to serve as the basis for an FCA violation.

1. Challenges of Establishing Liability

The path to establishing FCA liability based on inequitable conduct is fraught with obstacles. Any plaintiff alleging an FCA violation must prove three essential elements: (1) the defendant made a claim for payment from the government, (2) the claim was false or fraudulent, and (3) the defendant made the claim with knowledge of the falsity.[147] An FCA suit based on an inequitable-conduct theory draws upon two discrete instances of fraud. First, the patentee must have committed fraudulent acts while prosecuting the patent application as discussed in Part II. Second, the patentee must have known of the fraudulent acquisition of the patent and nevertheless made claims for payment to the government at prices above what it could have charged absent its fraudulently obtained patent and/or enforcement of that patent. Presumably, an accused infringer would only raise a false claims allegation after a court had made a finding of inequitable conduct, though it is possible for a competitor to file suit before the court issues a final ruling of inequitable conduct, based solely on evidence uncovered by the accused infringer in discovery. However, because some circuits require that FCA claims be pled with representative examples of false claims made to the government, an alleged infringer who plans to bring a false claims allegation claim may need to conduct additional investigations beyond what is discovered in the patent infringement case in order to adequately plead the FCA claim. This could include Freedom of Information Act-type requests for information regarding payments made by the government.

Because two separate instances of fraud need to be proven, an FCA claim will likely be heavily fact-dependent. The first element—that the patentee made a claim for payment from the government—could likely be proven merely by pointing to the defendant's promotion and sale of products that were paid for through

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[147] *See* 31 U.S.C. § 3729(a)(1) (2012); Burke v. Record Press, Inc., 951 F. Supp. 2d 26, 29 (D.D.C. 2013).

government programs, such as Medicare, as seen in Amphastar's allegations against Aventis.[148] The second element—that the claim was false or fraudulent—would be established by showing that a patent was acquired through inequitable conduct, allowing the patentee to sell its product at elevated prices.[149] The third element—proving that the patent holder made the claim with knowledge of the falsity—would further require that the defendant, at the very least, had reckless disregard in charging those elevated prices for products purchased (or reimbursed) with government funds.

Recasting these elements to more directly address an FCA claim based on inequitable conduct, a plaintiff much show (1) that the government purchased a product incorporating the patented subject matter; (2) that the patent was obtained due to inequitable conduct before the patent office, allowing the patent holder to charge inflated prices; and (3) the patentee knew or showed reckless disregard in charging the government at these inflated prices.[150]

Showing that a patent holder in fact sold a patented product at elevated prices may be straightforward in some instances, but it could be the subject of extensive expert testimony. If a plaintiff can obtain documentation from either the government or the patent holder establishing that a claim for payment for the patented product was made, then the first element of the FCA claim is met. But even if this can be shown, there remains the formidable hurdle of

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148 *See* Memorandum and Order, *supra* note 2.

149 This element can then be broken into two distinct parts, subject to different types of proof: (1) the patent was fraudulently acquired, provable with reference to communications with the patent office and internal communications demonstrating knowledge of omitted materials; and (2) that the patent actually allowed the patentee to charge elevated prices, which likely requires economic expert testimony and evidence that either the patentee was able to exclude competitors from the market or was able to use its patent to tout a unique feature or characteristic of its product that justified elevated prices. If the patent was not obtained by fraud, there is no fraudulent claim submitted to the government. Likewise, if the patent had no effect on the price charged to the government, there would be no false or fraudulent claim submitted to the government.

150 Mirroring the elements of an FCA violation: (1) that the defendant made a *claim* for payment from the government, (2) that the claim was *false or fraudulent* and (3) the defendant made the claim with *knowledge* of the falsity. *See* 31 U.S.C. § 3729(a) (2012); Burke v. Record Press, Inc., 951 F. Supp. 2d 26, 29 (D.D.C. 2013).

overcoming a Rule 9(b) objection at the pleading stage. Rule 9(b) requires that allegations of fraud, such as violations under the FCA, must be pled with particularity to ensure that frivolous and unsupported claims do not make their way into court.[151] The district court in *Aventis v. Amphastar*, for example, ruled in favor of Aventis on its motion to dismiss Amphastar's *qui tam* suit because of Amphastar's failure to plead with particularity that a false claim was made.[152] However, the court granted Amphastar leave to amend its complaint, and Amphastar was able to add additional details to its amended complaint that satisfied the pleading requirement. Absent such specificity in the allegations, a court is likely to dismiss any such FCA claim. Potential plaintiffs must therefore rely on documentation or other evidence uncovered in the underlying patent litigation (or otherwise available to them) rather than mere unsupported allegations. This may have practical implications for parties facing inequitable conduct allegations as well as the courts moderating these disputes.[153]

To meet the second element of an FCA claim, the plaintiff must first prove that a patent was obtained due to inequitable conduct. In some cases, the plaintiff could simply rely on a court's finding of inequitable conduct in an underlying patent infringement action. But if, for example, the underlying litigation is stayed or as-yet unresolved, one may need to affirmatively plead the elements of an inequitable conduct defense. Next, the plaintiff must prove that the price the government paid—or for which the FCA defendant submitted claims—was higher than it would have been absent the enforcement of the now-unenforceable patent. This essentially requires a showing of actual harm to the government and a causal link between the inequitable conduct and the fraudulent overcharging.

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[151] FED. R. CIV. P. 9(b). Note, however, that not all circuits require that examples of an actual claim be pled in an FCA complaint. In the Fourth, Sixth, Eighth, and Eleventh Circuits, FCA claims must be pled with representative samples of the alleged fraudulent conduct. Foglia v. Renal Ventures Mgmt., LLC, 754 F.3d 153, 155 (3d Cir. 2014). However, in the First, Third, Fifth, and Ninth Circuits, FCA claims only need to be pled with particular details of a scheme to submit false claims and reliable indicia that lead to a strong inference that claims were actually submitted. *Id.* at 156–57.

[152] Amphastar Pharm. Inc. v. Aventis Pharma SA, No. EDCV-09-0023 MJG, 2012 WL 5512466, at *13 (C.D. Cal. Nov. 14, 2012).

[153] *See infra* Part IV.

Thus, the court must distinguish between instances where the patented device or component caused an actual increase in the price of the product with instances where having a patent on the technology may have had no such effects. In practice, it is likely that this type of analysis would closely mirror the analysis conducted under the Sherman Act in establishing monopoly power. For example, although a showing of monopoly power is not necessary to prove that prices were in fact elevated, such a showing can create an inference of unlawfully elevated prices where actual direct evidence is lacking. In contrast, if the patentee's competitors used alternative components not covered by the patent, then the presence of the patent may not have actually enabled the patent holder to charge a supra-competitive price. Economically substitutable alternatives may negate one's ability to charge elevated prices, just as they negate a finding of monopoly power. That said, a showing of monopoly power is not necessarily needed to show that prices were elevated; an FCA claim may be therefore be sustained without the patentee having monopoly power. For example, if a pioneering smart phone manufacturer developed a new, faster processor, patented the technology, and subsequently used that processor in a particular brand of smart phones, the price of that brand of smart phone may increase simply because it is the only phone in the market with the faster processor. That does not, however, indicate that the company has the ability to fix prices in the entire mobile-phone industry, nor would it be necessary to show such market power to prove an FCA claim.

This analysis may be slightly different in the context of the pharmaceutical industry. In order to market a new prescription drug, a pioneering pharmaceutical company must first obtain regulatory approval from the Food and Drug Administration.[154] As part of the approval process, the pharmaceutical company must list all patents that claim its brand-name drug in the FDA's so-called *Orange Book*.[155] Listing these patents in the *Orange Book* essentially

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[154] *See* 21 U.S.C. § 355(a) ("No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application . . . is effective with respect to such drug.").

[155] The "Orange Book" is the common name for the FDA publication "Approved Drug Products with Therapeutic Equivalence Evaluations." This publication is updated monthly. FDA, CTR. FOR DRUG EVALUATION & RESEARCH, APPROVED DRUG PRODUCTS

prevents the FDA from granting a competitor the right to market and sell a generic version of the patented drug unless the generic challenger (i.e., ANDA applicant) can show that the patent is invalid or not infringed by the proposed generic.[156] It is almost axiomatic that products without a generic competitor, even if they face economic competition from drugs that target similar symptoms, are priced significantly higher than generics. And because the mere filing of an application to manufacture a patented drug is considered an action of patent infringement,[157] the mere listing of these patents in the *Orange Book* is a *de facto* act of patent assertion that alone can lead to significantly elevated prices. If the drug patent was acquired by fraud on the patent office, then the second element of an FCA claim is likely proven. Whereas a *Walker Process* claim on that basis might depend on an actual showing of monopolization, an FCA claim against a brand-name drug manufacturer could likely rely solely on the fact that the exclusivity provided by the FDA itself permits the patent holder to charge significantly elevated prices (in part because it serves as a bar to competition).

Under the third element of an FCA claim, a plaintiff must also prove that the patent holder knowingly, or at least recklessly, over-

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WITH THERAPEUTIC EQUIVALENCE EVALUATIONS (2008) [hereinafter *Orange Book*], *available at* http://www.fda.gov/cder/ob/docs/preface/ecpreface.htm. The FDCA requires a patent holder to include in its NDA "the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1) (2012). The patent numbers and expiration dates are then published in the *Orange Book*. Process patents and certain composition of matter patents are precluded from being listed in the *Orange Book*, though generic manufacturers may still be sued for infringing these unlisted patents.

[156] *See generally* Matthew Avery, Note, *Continuing Abuse of the Hatch–Waxman Act by Pharmaceutical Patent Holders and the Failure of the 2003 Amendments*, 60 HASTINGS L.J. 171 (2008); Matthew Avery & Mary Nguyen, *The Roadblock for Generic Drugs: Declaratory Judgment Jurisdiction for Later Generic Challengers*, 15 N.C. J.L. & TECH. 1 (2013), *available at* http://ncjolt.org/wp-content/uploads/2013/11/Avery-+-Nguyen-Final.pdf.

[157] The Hatch–Waxman Act provides that filing an Abbreviated New Drug Application ("ANDA") with a so-called Paragraph IV certification that the patent is invalid or will not be infringed by the manufacture, use, or sale of the generic drug for which the application is submitted is itself an act of patent infringement. 35 U.S.C. § 271(e)(2)(A) ("It shall be an act of infringement to submit . . . an [ANDA] for a drug claimed in a patent or the use of which is claimed in a patent . . . .").

charged the government. This means that the plaintiff must convince a judge or jury that the patent holder knew, should have known, or recklessly disregarded (1) that the patent would be unenforceable for reasons of inequitable conduct and (2) that in the absence of this enforcement, the price of the product would have been lower than what was charged to the government. Because a plaintiff relying on Amphastar's theory of FCA liability would likely only file suit after a finding of inequitable conduct in the underlying patent infringement case, proving that the patentee knew or should have known that the patent was unenforceable may be a simple matter of *res judicata*. Inequitable conduct already requires proving but-for materiality and specific intent to deceive the patent office. Thus, a finding of inequitable conduct will necessarily include a finding that the patentee had specific intent to withhold material information from the patent office. As such, a showing of inequitable conduct in the underlying patent infringement case alone should be sufficient to demonstrate in an FCA case that the patentee knew or should have known that its patent would not have otherwise been granted and would be unenforceable under the law. However, this is not the case if the patent holder was not the party that engaged in the inequitable conduct, but merely acquired the patent after the fact. In that case, it may be more difficult for the FCA plaintiff to establish that the patent holder had knowledge that the patent would be unenforceable. Without a showing of this knowledge, establishing the second portion of this element would not be possible.

Lastly, showing that, in the absence of the patent holder's fraudulently obtained patent, the price of the relevant product would have been lower than what was charged to the government will likely be more difficult for an FCA plaintiff to prove. Knowing that a particular patent is unenforceable does not necessarily indicate that a patent holder knows that its pricing of a product is elevated, especially on products covered by multiple patents. Further, the product might incorporate other unique features or rely on branding to justify a higher price than other alternatives in the market. Absent a clear causal relationship between the fraudulently obtained patent and the elevated price, or a showing of monopolization based on that patent, it may be difficult to prove elevated pric-

ing, and even more difficult to prove that a defendant knew of such elevated pricing. While the FCA only requires the plaintiff to show the patent holder recklessly disregarded the risk that the government was being overcharged, there remains a heavy burden of proof that the plaintiff must overcome. Again, however, in the pharmaceutical context, the burden of proof is likely lowered by the industry-wide price disparity between generic and patent-protected drugs, and the fact that most brand-name drugs are only covered by a few patents.[158]

2. Is Such Liability Proper?

Antitrust claims, such as *Walker Process* claims, do not extend liability to all improper conduct of patent holders in the marketplace, as the Sherman Act requires proof of additional elements.[159] Where the Sherman Act requires proving both that the defendant had market power in a relevant market and inflicted an antitrust harm, an FCA suit based on inequitable conduct would merely require proof that prices were in fact higher such that the government was actually overcharged. Unlike a *Walker Process* claim, engaging in the often-difficult task of defining a relevant market and showing whether a party has acquired or is likely to acquire monopoly power would be unnecessary to prove an FCA claim.

In contrast to the Sherman Act, which is only intended to stop specific antitrust harms, the scope of the FCA is broad and is "intended to reach all types of fraud, without qualification, that might result in financial loss to the Government."[160] The FCA incentivizes whistleblowers with knowledge of fraud on the government to come forward with that information. As a result of this incentive

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[158] *See* Lisa Larrimore Ouellette, *How Many Patents Does It Take To Make a Drug? Follow-On Pharmaceutical Patents and University Licensing*, 17 MICH. TELECOMM. TECH. L. REV. 299, 300 (2010) ("The average was nearly 3.5 patents per drug in 2005, with over five patents per drug for the best-selling pharmaceuticals; these numbers have increased over time.").

[159] The Sherman Act requires a showing that the defendant has monopoly power or is likely to acquire monopoly power. *See* United States v. Grinnell Corp., 384 U.S. 563, 570–71 (1966) ("The offense of monopoly under § 2 of the Sherman Act has two elements: (1) the possession of monopoly power in the relevant market and (2) the willful acquisition or maintenance of that power . . . .").

[160] United States *ex rel.* Hendow v. Univ. of Phoenix, 461 F.3d 1166, 1170 (9th Cir. 2006).

system, nearly $35 billion has been recovered in the past thirty years, with over seventy percent of FCA suits being filed by private relators.[161] Consequently, holding liable those patentees who acquired their patents through fraud for selling their patented products to the government at elevated prices seems to align with the purpose of the FCA. Moreover, extending FCA liability to situations where patent holders are knowingly overcharging the government, and by extension taxpayers, is consistent with recent modifications to both the FCA and the doctrine of inequitable conduct.

The FCA was recently modified under the Affordable Care Act to cover more fraudulent acts than ever before. Congress significantly diminished the public disclosure bar, which was the most credible objection a party might raise in defending against a false claims allegation.[162] In principle, once a finding of inequitable conduct has been publicly released, relators should be prevented from raising *qui tam* claims. Prior to the Affordable Care Act, the FCA explicitly stated that information publicly disclosed through civil litigation would raise the public disclosure bar.[163] Under the Affordable Care Act amendments, however, public disclosure during litigation only triggers the bar when the government is also a party to the suit.[164] Even if the public disclosure bar is properly invoked, a relator would have two possible remedies. First, if the government objects to the court dismissing the case, then the relator may proceed with the claim.[165] Second, the Affordable Care Act lo-

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[161] U.S. DEP'T OF JUSTICE, FRAUD STATISTICS – OVERVIEW, OCT. 1, 1987 – SEPT. 30, 2013, (Dec. 23, 2013), *available at* http://www.justice.gov/civil/docs_forms/C-FRAUDS_FCA_Statistics.pdf; Joel D. Hesch, *Breaking the Siege: Restoring Equity and Statutory Intent to the Process of Determining Qui Tam Relator Awards Under the False Claims Act*, 29 T.M. COOLEY L. REV. 217, 229 (2012) ("Whistleblower qui tam suits have become the Government's chief anti-fraud tool and account for about 70% of all funds the DOJ recovers from defrauders.").

[162] Patient Protection and Affordable Care Act, H.R. 3590, 111th Cong. 783–84 (2010) (enacted).

[163] 31 U.S.C. § 3730(e)(4)(A) (2009).

[164] 31 U.S.C. § 3730(e)(4)(A)(i) (2012) ("The court shall dismiss an action or claim under this section, unless opposed by the Government, if substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed … in a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party . . . .").

[165] 31 U.S.C. § 3730(e)(4)(A) (2009).

wered the threshold for acquiring the "original source" status that provides an exception to the public disclosure bar. The FCA previously required that a relator must have "direct and independent knowledge of the information on which the allegations are based" in order to qualify as an original source.[166] This definition was altered by the Affordable Care Act to include relators who merely have "knowledge that is independent of and materially adds" to the allegations raised.[167]

Shortly after Congress enacted these changes to the FCA, the Federal Circuit coincidentally raised the standards for proving inequitable conduct in *Therasense* to include only the most egregious of frauds.[168] While inequitable conduct previously only required a showing that an omitted reference or misrepresentation was material, the *Therasense* standard requires "but-for" materiality.[169] Thus, the reference must have been so material that the examiner would not have issued the patent absent the patentee applicant's deception. Additionally, *Therasense* requires a finding that the patent applicant had specific intent to deceive the examiner.[170] Such intent must be affirmatively established and cannot simply be inferred from the materiality of the omitted source or misrepresentation.[171] These heightened requirements mean that only the most egregious frauds committed against the USPTO will rise to the level of inequitable conduct.

The broadening of the FCA over several decades, combined with the recent narrowing of the inequitable conduct doctrine, has made claims like Amphastar's feasible. The FCA was created to stop fraudulent appropriation of taxpayer funds. Using inequitable conduct as the basis for an FCA claim aligns with this policy, especially under the heightened *Therasense* standard which punishes only the most egregious forms of fraud before the patent office. These instances of fraud, coupled with the patent holder's knowledge that its own fraud affects the prices paid by the government,

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166 31 U.S.C. § 3730(e)(4)(B) (2009).
167 31 U.S.C. § 3730(e)(4)(B) (2012).
168 Therasense, Inc. v. Becton, Dickinson & Co., 649 F.3d 1276, 1288 (Fed. Cir. 2011).
169 *Id.* at 1291.
170 *See id.* at 1290.
171 *See id.*

are precisely what the FCA was designed to punish. The broadening of the FCA and the parallel heightening of the inequitable conduct standard have therefore created a substantial overlap where liability can be found in the most egregious cases of fraudulent conduct.

IV. AVOIDING FALSE CLAIMS LIABILITY

In light of the attention Amphastar's suit is receiving in the false claims bar, it is important that attorneys involved in patent prosecution or false claims litigation consider steps to limit or avoid liability under the FCA. The FCA bears the extreme penalty of treble damages, a large portion of which, when based on a theory of inequitable conduct, will likely go directly to a competitor. In this section we highlight several measures attorneys and their clients may consider taking to limit exposure to FCA liability.

A. Contractual Additions When Purchasing Patents

In situations where clients are purchasing or licensing patents from another party, attorneys should consider the possibility of FCA liability that could arise as a result of the seller or licensor's inequitable conduct. Several simple steps taken at the outset of one's manufacture or sale of patented products, including particular considerations included in any licensing contracts, could avoid significant liability and minimize legal expenses in defending against a suit brought under the FCA. For example, a licensee or purchaser of a patent may wish to insert into any license or purchase agreement provisions making clear that the license or purchase is not limited to the patent itself, and will survive invalidity, or guaranteeing partial reimbursement if the patent is invalidated as well as indemnification against potential actions relating to government overcharges stemming from inequitable conduct. It may also be beneficial to include in such contracts representations that seller or licensor of the patent believes in good faith that each patent involved is valid and enforceable. Having such clear representations from the original patentee will provide additional evidence that the current patent owner had no knowledge that the patent

was unenforceable under the law and therefore could not have *knowingly* overcharged the government.

Likewise, a party selling patented goods to the government should consider inserting provisions in its contracts providing for single reimbursement upon a showing that its patent is invalid or unenforceable.[172] Alternatively, arbitration clauses, or clauses that otherwise avoid payment of treble damages where inequitable conduct is found could prove to be an effective tool to limit exposure to FCA liability.

B. Court Orders to Seal Evidence of Inequitable Conduct

When inequitable conduct has been discovered in an underlying patent litigation, the patentee should attempt to seal evidence of the inequitable conduct to prevent it from being used in a subsequent FCA suit. Because FCA claims must be pled with particularity, sealing evidence of the basis for the alleged fraud (i.e., evidence of the fraudulent obtained patent) may allow the FCA defendant to get the claim dismissed at the pleading stage. However, sealing such evidence may be challenging. The presumption of public access to court records is rooted in the First Amendment. The Supreme Court of California has noted that "every lower court opinion of which we are aware that has addressed the issue of First Amendment access to civil trials and proceedings has reached the conclusion that the constitutional right of access applies to civil as well as to criminal trials."[173] Several circuits also have recognized a constitutional right of access to court records, with the Ninth Circuit noting that "the public and press have a first amendment right of access to pretrial documents in general."[174] This extends to discovery documents, where "[g]enerally, the public can gain access to litigation documents and information produced during discovery unless the party opposing disclosure shows 'good cause' why a protective order is necessary."[175] However, the Federal Rules of Civil Procedure provide several exceptions to the general rule of

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[172] That is, a provision limiting potential damages to restitution or reimbursement, and waiving any right to seek treble damages.

[173] NBC Subsidiary (KNBC-TV), Inc. v. Superior Court, 980 P.2d 337, 358 (Cal. 1999).

[174] Associated Press v. United States District Court, 705 F.2d 1143, 1145 (9th Cir. 1983).

[175] Phillips v. Gen. Motors Corp., 289 F.3d 1117, 1121 (9th Cir. 2002).

public access. Rule 26(c) provides that "[u]pon motion by a party or by a person from whom discovery is sought . . . and for good cause shown, the court in which the action is pending . . . may make any order which justice requires to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense."[176] Rule 26(c) specifically contemplates issuance of a protective order to ensure that "trade secret or other confidential research, development, or commercial information not be revealed or be revealed only in a designated way."[177] This exception is often used to prevent or severely restrict the disclosure of source code, trade secrets, and other highly sensitive corporate information, particularly information that could provide a competitive advantage to competitors if disclosed.[178]

Because much of the discovery oriented toward uncovering inequitable conduct delves into what the inventors of patented technologies or processes knew at the time they filed their patent application, including lab notes, internal reports and the like, the trade secret exception to public disclosure could be used to restrict the release of that information. As seen in the Northern District of California's model protective order for patent and trade secret cases, such discovery can be restricted to attorneys' eyes only, and the standard order requires the destruction or return of any such information or documentation discovered within a short period after the end of the litigation.[179] Such a protective order could completely preclude third parties from uncovering documents supporting an FCA claim, and could also present a strong bar to the opposing party's use of such documents in subsequent FCA litigation.

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176 FED. R. CIV. P. 26(c).

177 FED. R. CIV. P. 26(c)(7).

178 *See, e.g.*, Model Protective Order for Litigation Involving Patents, Highly Sensitive Confidential Information and/or Trade Secrets, *available at* http://www.cand.uscourts.gov/model-protective-orders.

179 *See id.* ¶ 7.1 ("Basic Principles. A Receiving Party may use Protected Material that is disclosed or produced by another Party or by a Non-Party in connection with this case only for prosecuting, defending, or attempting to settle this litigation. Such Protected Material may be disclosed only to the categories of persons and under the conditions described in this Order. When the litigation has been terminated, a Receiving Party must comply with the provisions of section 15 below (FINAL DISPOSITION)."); *see also id.* ¶ 15 ("Within 60 days after the final disposition of this action . . . each Receiving Party must return all Protected Material to the Producing Party or destroy such material.")

Accordingly, parties accused of inequitable conduct during patent infringement suits would be well served by insistence on strong protective orders in the underlying patent litigation. Under an order such as the Northern District of California's model, anything acquired by the defendant in discovery that is covered by the terms of the protective order would be protected from use in a subsequent suit.[180] While *Walker Process* claims are often brought as counterclaims in the underlying patent litigation, and thus can rely on the documents produced in that same case, a *qui tam* action must be filed as a separate case and delivered to the attorney general for their approval. Thus, a protective order could prevent a FCA plaintiff from successfully pleading its claims, and it would likely be difficult for the plaintiff to unseal the evidence of inequitable conduct. In the words of the Second Circuit, "[i]t is 'presumptively unfair for courts to modify protective orders which assure confidentiality and upon which the parties have reasonably relied.'" [181]

C. Public Disclosure of the Fraud

The public disclosure bar prevents a *qui tam* plaintiff from bringing suit if the fraud has been publicly disclosed. Theoretically, a patent holder could avoid liability by publicly disclosing its own fraud. For example, if a patent holder learns that its patent is unenforceable due to prior fraudulent activity of the patent applicant,

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[180] *See id.* ¶ 1.

[181] AT&T Corp. v. Sprint Corp., 407 F.3d 560, 562 (2d Cir. 2005) (quoting SEC v. TheStreet.com, 273 F.3d 222, 230 (2d Cir. 2001)). Note, however, that several other circuits have permitted modifications of protective orders in "collateral litigation." *See In re* Linerboard Antitrust Litig., 333 F. Supp. 2d 333, 340 (E.D. Pa. 2004) (permitting a modification because the reliance interest of objecting parties "can be preserved by subjecting the intervenor to the provisions of a protective order" where such protection are necessary); *see also* Foltz v. State Farm Mut. Auto. Ins. Co., 331 F.3d 1122, 1132 (9th Cir. 2003) ("Where reasonable restrictions on collateral disclosure will continue to protect an affected party's legitimate interests in privacy, a collateral litigant's request to the issuing court to modify an otherwise proper protective order so that collateral litigants are not precluded from obtaining relevant material should generally be granted."). Interestingly, the First Circuit found that permitting modification of a protective order to grant a third party access to documents would be especially inappropriate in the event that the Federal Government was the proposed intervenor. *See* Public Citizen v. Liggett Group, Inc., 858 F.2d 775, 791 (1st Cir. 1988) (citing Martindell v. International Telephone & Telegraph Corp., 594 F.2d 291 (2d Cir. 1979). In an FCA case, of course, the federal government is the party involved, even if represented by a *qui tam* relator.

publicly disclosing this information might raise a public disclosure bar. Likewise, publicly disclosing one's fraud via a press release as soon as the question of inequitable conduct has been decided, preferably couched in terms that disclose the facts but avoid terms like "fraud," could avoid liability. Attorneys should be cautious with this approach, however, as the recent amendments to the FCA essentially allow for the government to have the final word as to whether public disclosure will ultimately prevent the relator from pursuing a *qui tam* suit. Approaching the government directly with such information may be a far better approach and may avoid potentially embarrassing public disclosures. This proactive approach could also lead to the possibility of amicable settlements with minimal public disclosure (and thus minimal embarrassment for the patentee).

V. PREVENTING THE PLAGUE: SUGGESTIONS FOR LEGISLATIVE ACTION

If the courts validate Amphastar's novel theory, nearly every patent holder that sells patent products to the federal government could be at risk for liability under the FCA. In this section we discuss amendments to the FCA that may help to ensure fair treatment to patent holders while maintaining effective disincentives for fraudulently overcharging the government.

A. Limiting Damages in False Claims Suits

Fraudulent conduct during prosecution of a patent application can lead to harsh consequences. But at some point those consequences become so cumbersome as to both hinder the effectiveness and efficiency of patent prosecution as well as punish wrongdoers to an extent that is incommensurate with their behavior. Currently, the most egregious of such fraud may incur the harsh penalties of an inequitable conduct finding (the patent and related patents are rendered unenforceable) and treble damages under the Sherman Act (i.e. *Walker Process* fraud). Now, under Amphastar's theory, inequitable conduct may also lead to false claims liability and possibly treble damages for suits filed by either the government or a relator. However, the omissions or misrepresentations forming the ba-

sis of an inequitable conduct defense would likely occur long before the sale of any goods to the government and would only be tenuously connected to such a sale. As such, punishing this type of fraud via the False Claims Act seems to be far beyond what was envisioned by President Lincoln when he enacted this law in 1863.

To bring the scope of the FCA back in line with its original intent, we urge the enactment of legislation to provide for and alleviate some of these harsh realities. First, providing a specific remedy for products covered by fraudulently obtained patents may provide one avenue for such reform. Alternatively, limiting damages under Amphastar's theory to actual damages could soften the potentially overbearing FCA liability. While making false claims to the United States government should obviously be punished, the punishment should be proportional to the wrongful conduct. Furthermore, treble damages are arguably unnecessary under the Amphastar theory since treble damages are already available to claimants under a *Walker Process* theory.

B. Negating Liability by Granting Amnesty or Curing Inequitable Conduct

Another option is to grant amnesty to patent holders who come forward regarding fraud on the government, along the lines of the amnesty granted under the US Government's Antitrust Criminal Penalty Enhancement and Reform Act ("ACPERA").[182] This would provide a way to avoid the threat of treble damages, or even to reduce overall liability for companies that voluntarily come clean. Nor, as discussed above, would the fact of the inequitable conduct itself automatically lead to damages. The patent owner would still preserve potentially strong arguments regarding causation and damages, and could likely escape with a settlement significantly lower than the possible liability in a treble-damages scenario. The ACPERA program has been very effective in limiting liability in antitrust cases and incentivizing private parties to come forward, but its use has been limited essentially to cartel cases where parties are faced with a "prisoner's dilemma" of either cooperating with the government and admitting to a conspiracy, thereby limiting

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[182] Pub. L. No. 108-237, tit. II, 118 Stat. 661, 665.

their own liability, or continuing to operate under the conspiracy and risking heightened liability.[183] In the FCA context, as under ACPERA, competitors are strongly incentivized to turn in their competitors. Patent holders, by contrast, are strongly disincentivized from admitting inequitable conduct because it could invalidate a valuable patent. In the pharmaceutical context, the removal of patent protection can result in immediate generic competition and a ninety percent reduction in drug prices and, as a consequence, in profits.[184] But the fact that ACPERA relies on a prisoner's-dilemma incentive does not preclude an amnesty program involving monopolists from succeeding. Rather, the likely effect of such a program would be a race to disclosure in cases where the proverbial tea leaves make it clear that a finding of inequitable conduct is likely.

Alternatively, the new supplemental examination procedures created as part of the America Invents Act of 2011 could be used to rehabilitate patents tainted by inequitable conduct. Prior to the passage of the America Invents Act, inequitable conduct was considered an unfixable injury that was fatal to patent protection. While other deficiencies in a patent could be cured by reissue or reexamination,[185] inequitable conduct could not. Supplemental examination is a new procedure introduced by the America Invents Act. It is available for all patents and can be instituted if a substantial new question of patentability is raised by any information relevant to the patents. Supplemental examination is specifically designed to allow the USPTO to consider prior art that should have been disclosed by the patentee during the normal application procedure, removing

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[183] *See* Michael W. Scarborough & Dylan I. Ballard, *The Case for Eliminating ACPERA's Supplemental Cooperation Requirement for Amnesty Applicants*, 20 COMPETITION: J. ANTI. & UNFAIR COMP. L. SEC. ST. B. CAL. 34, 35, 43 (2011) ("It has been suggested by some observers that the amnesty applicant's ACPERA dilemma–either fail to cooperate and risk being subjected to heightened civil liability, or attempt to cooperate and risk fatally undermining one's case on the merits (and still fail to secure any guarantee of reduced liability)–does not often obtain in practice because amnesty applicants typically lack strong defenses on the merits.").

[184] *See* Benjamin G. Druss et al., *Listening To Generic Prozac: Winners, Losers, And Sideliners*, 23 HEALTH AFF. 210, 213–14 (2004).

[185] *See, e.g.*, Aventis Pharma S.A. v. Amphastar Pharm., Inc., 525 F.3d 1334, 1341 n.6 (Fed. Cir. 2008) (curing deficiencies by reissue); Molins PLC v. Textron, Inc., 48 F.3d 1172, 1182 (Fed. Cir. 1995) (curing deficiencies by reexamination).

the possibility of inequitable conduct based upon failure to disclose the prior art. A request for supplemental examination may only be filed by the patent owner. If the request is granted, the USPTO may order an *ex parte* reexamination to address the issues raised. After supplemental examination, a patent cannot be held unenforceable due to conduct relating to inadequate disclosure during the prior examination of the patent if that conduct is corrected during supplemental examination, effectively creating an opportunity for safe harbor against inequitable conduct that would otherwise render the patent unenforceable.[186] However, if the Director of the USPTO becomes aware that material fraud on the patent office may have been committed in connection with the patent, the Director must refer the matter to the Attorney General.[187] Consequently, supplemental examination may be used to prevent possible liability under the FCA by negating possible claims of inequitable conduct.

CONCLUSION

Amphastar's novel theory of False Claims Act liability based on a finding that Aventis engaged in inequitable conduct during the prosecution of its patent has already made waves among attorneys in the false-claims bar. The broadening of the FCA over the past several decades, combined with the recent narrowing of the inequitable conduct doctrine in *Therasense*, has made Amphastar's claim feasible. Furthermore, the legislative and judicial history surrounding the FCA and the doctrine of inequitable conduct suggest that such liability is proper under the FCA. But the *Amphastar* litigation is currently stalled in discovery disputes, and whether it will lead to a new plague of FCA liability for patent holders will not be known unless and until the suit is resolved in court. If Amphastar prevails, it will be responsible for dramatically expanding the scope of FCA liability, affecting both the false-claims attorneys who will have a new weapon in their arsenal and the patent attorneys who

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[186] *See* 35 U.S.C. § 257(c)(1) (2012); *see also* Jason Rantanen & Lee Petherbridge, *Toward a System of Invention Registration: The Leahy–Smith America Invents Act*, 110 MICH. L. REV. FIRST IMPRESSIONS 24, 25 (2011) (calling supplemental examination an "amnesty program").

[187] 35 U.S.C. § 257(e) (2012).

may never have encountered the FCA before. In light of the extreme penalty of treble damages for violating the FCA, a large portion of which will likely go directly to a competitor, patentees and their attorneys would be wise to take proactive steps to limit or avoid liability under the FCA.