IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PFIZER INC, PFIZER PHARMACEUTICALS, LLC, PFIZER LIMITED, C.P. PHARMACEUTICALS INTERNATIONAL C.V., PFIZER IRELAND PHARMACEUTICALS, WARNER-LAMBERT COMPANY, WARNER-LAMBERT COMPANY, LLC and WARNER-LAMBERT EXPORT LTD,	)	
Plaintiffs/Counterdefendants,	)	C.A. No. 07-138-JJF
v.	)	
RANBAXY LABORATORIES LIMITED, and RANBAXY INC.,	)	
Defendants/Counterclaimants.	)	

RANBAXY'S BRIEF IN OPPOSITION TO PFIZER'S MOTION TO DISMISS PURSUANT TO FEDERAL RULE OF CIVIL PROCEDURE 12(b)(1), RANBAXY'S COUNTERCLAIMS WITH RESPECT TO THE '995 PATENT

Of Counsel.
Darrell L. Olson
Joseph M. Reisman
William R. Zimmerman
Payson LeMeilleur
KNOBBE, MARTENS, OLSON & BEAR, LLP
2040 Main Street, 14th Floor
Irvine, California 92614
(949) 760-0404

Frederick L. Cottrell III (#2555)
Cottrell@rlf.com
Jameson A.L. Tweedie (#4927)
Tweedie@rlf.com
RICHARDS, LAYTON & FINGER, P.A.
One Rodney Square
920 N. King Street
Wilmington, DE 19899
(302) 651-7700
Attorneys for Defendants/Counterclaimants

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Defendants/Counterclaimants Ranbaxy Laboratories Limited and Ranbaxy Inc. (collectively "Ranbaxy") hereby oppose Pfizer's Motion To Dismiss Pursuant To Fed. R. Civ. P. 12(b)(1), Ranbaxy's Counterclaims With Respect To The '995 Patent.

I. INTRODUCTION

Ranbaxy filed Abbreviated New Drug Application ("ANDA") No. 78-747, seeking approval to market a generic version of Pfizer's Caduet® product. In this case, Pfizer asserts that Ranbaxy's generic product infringes U.S. Patent Nos. 4,681,893 ("the '893 patent") and 6,455,574 ("the '574 patent"), two of the patents listed in the FDA's *Orange Book* as covering Caduet. Despite asserting these two patents, Pfizer seeks to dismiss Ranbaxy's declaratory judgment Counterclaims relating to Pfizer's U.S. Patent No. 5,273,995 ("the '995 patent"), another *Orange Book*-listed patent for Caduet. Thus, Pfizer is attempting to halt approval of Ranbaxy's generic product by selectively asserting some of its *Orange Book*-listed patents, while simultaneously shielding another *Orange Book*-listed patent from scrutiny and preserving this patent for a future action to further delay Ranbaxy's generic product. This is exactly the type of gamesmanship that the Declaratory Judgment Act and the Hatch-Waxman Act were designed to prevent.

In prior litigation involving Ranbaxy's generic Lipitor® product, the Federal Circuit declared Claim 6 of the '995 patent invalid for failure to satisfy 35 U.S.C. § 112, ¶ 4. Pfizer has sought reissue of the '995 patent to "correct" this defect in Claim 6, as well as defects in other claims. Following the filing of Ranbaxy's Counterclaims in issue here, Pfizer gave Ranbaxy a covenant not to sue on all claims of the '995 patent (other than invalid Claim 6) with respect to Ranbaxy's generic version of Caduet, in an attempt to insulate the '995 patent and any reissue patent from scrutiny in this case. Pfizer now

argues that, in view of the invalidity of Claim 6 and the covenant not to sue, there is no present controversy between the parties regarding the '995 patent and any reissue thereof.

Pfizer's argument ignores the reality of the situation: Pfizer has sought reissue of the '995 patent in order to assert it against Ranbaxy's generic product. Pfizer does not contest this fact, and its intentions are clear in view of its refusal to give Ranbaxy a covenant not to sue covering any reissue of the '995 patent. If the '995 patent were to be removed from this litigation, Ranbaxy faces an untenable dilemma, even if it were to defeat Pfizer's other infringement allegations: (1) launch its generic product in a cloud of uncertainty and face future proceedings regarding '995 patent and any reissue, or (2) delay its product launch still further until future litigation over the '995 patent and its reissue are complete. Ranbaxy should not be forced to make this choice.

Instead, this Court should exercise jurisdiction over Ranbaxy's Sixth and Seventh Counterclaims regarding the enforceability of the '995 patent. Resolution of these Counterclaims does not depend on the scope of the reissue claims. Rather, these Counterclaims relate solely to events that have already occurred, namely Pfizer's conduct before the Patent Office in prosecuting the '995 patent. The reissue proceedings do not affect these Counterclaims because, as a matter of law, Pfizer cannot cure its inequitable conduct through reissue and this inequitable conduct renders the '995 patent and any reissue unenforceable. Thus, the enforceability issue is ripe for adjudication.

Pfizer also seeks dismissal of Ranbaxy's Fourth and Fifth Counterclaims regarding noninfringement and invalidity of the '995 patent. Ranbaxy does not oppose dismissal of these claims **without prejudice**. Assessing noninfringement and invalidity hinges on claim scope. Here, Pfizer's recent covenant not to sue on Ranbaxy's generic

version of Caduet precludes infringement liability on the existing '995 patent, and the scope of any reissue claims is uncertain. Thus, these claims are no longer ripe for adjudication. However, this does not affect the justiciability of Ranbaxy's unenforceability Counterclaims because claim scope is irrelevant to determining whether the '995 patent was procured through inequitable conduct.

To resolve the current dispute regarding the enforceability of the '995 patent and any reissue patent and avoid multiple lawsuits over Ranbaxy's generic product, this Court should exercise jurisdiction over Ranbaxy's unenforceability Counterclaims. Such adjudication will provide certainty prior to the launch of Ranbaxy's generic product.

II. NATURE AND STAGE OF THESE PROCEEDINGS

Pfizer's brief sets forth the nature and stage of these proceedings. (D.I. 15 at 1-2). This is Ranbaxy's brief in opposition to Pfizer's Motion to dismiss Ranbaxy's Counterclaims directed to the '995 patent.

III. SUMMARY OF ARGUMENT

1. This Court has jurisdiction to decide whether the '995 patent and any reissue thereof are unenforceable due to Pfizer's inequitable conduct during prosecution of the '995 patent. There is an actual controversy between the parties regarding the enforceability of the '995 patent and any reissue thereof, the facts necessary to decide the issue are fixed and will not change, and the issue is ripe for adjudication.

IV. STATEMENT OF FACTS

Pfizer's brief sets forth certain facts underlying these proceedings. *Id.* at 2-5. Ranbaxy provides the following additional facts.

Ranbaxy filed ANDA No. 78-747, seeking approval to market a generic version of Pfizer's Caduet product. (D.I. 10, ¶ 93). Pfizer's Caduet product is nothing more than a combination of two well-known, previously marketed drugs, combined for their intended purposes: Lipitor (atorvastatin calcium) to treat high cholesterol and Norvasc (amlodipine besylate) to treat high blood pressure. (D.I. 1, ¶ 16). In an effort to halt Ranbaxy's generic product, Pfizer has asserted two of the patents listed in the FDA's *Orange Book* with respect to Caduet against Ranbaxy in this litigation. (*Id.*, ¶¶ 65-67, 73-75). However, Pfizer did not assert the '995 patent against Ranbaxy in this litigation.

As this Court is well aware, Pfizer previously asserted the '995 patent against Ranbaxy's generic Lipitor product in a prior case before this Court, *Pfizer, Inc. v. Ranbaxy Labs. Ltd.*, Civ. Action No. 03-209 (JJF) (hereinafter "the Lipitor litigation"). In the Lipitor litigation, Pfizer originally asserted multiple claims of the '995 patent against Ranbaxy's generic version of Lipitor. After discovery, Pfizer granted Ranbaxy a qualified covenant not to sue on all claims of the '995 patent other than Claim 6 with respect to Ranbaxy's generic version of Lipitor, withdrew its allegations with respect to all claims other than Claim 6, and moved to dismiss Ranbaxy's defenses and counterclaims on all claims other than Claim 6 under Fed. R. Civ. P. 12(b)(1) for lack of jurisdiction. (Lipitor litigation D.I. 169). On October 18, 2004, this Court denied Pfizer's Motion to Dismiss. (Lipitor litigation D.I. 235). Thereafter, Pfizer granted Ranbaxy a full covenant not to sue on all claims of the '995 patent with respect to

Ranbaxy's generic version of Lipitor, and the parties dismissed their infringement and validity claims relating to all claims of the patent other than Claim 6. (Lipitor litigation D.I. 255, entered as an Order on Nov. 17, 2004).

Following trial in the Lipitor litigation, this Court issued its opinion addressing the parties' claims regarding infringement and validity of Claim 6 of the '995 patent. *Pfizer Inc. v. Ranbaxy Labs. Ltd*, 405 F. Supp. 2d 495, 507-10, 512-19 (D. Del. 2005). This Court also addressed Ranbaxy's claims that the entire '995 patent, not just Claim 6, was unenforceable due to Pfizer's inequitable conduct during prosecution. *Id.* at 520-25.

On appeal, the Federal Circuit concluded that Claim 6 was invalid for failure to satisfy the requirements of 35 U.S.C. § 112, ¶ 4, reversing this Court's decision to the contrary. *Pfizer, Inc. v Ranbaxy Labs. Ltd*, 457 F.3d 1284, 1291-92 (Fed. Cir. 2006). The Federal Circuit declined to address Ranbaxy's remaining challenges to the '995 patent, stating:

> In light of this holding [that Claim 6 is invalid for failure to satisfy the requirements of 35 U.S.C. § 112, ¶ 4], appellants' remaining arguments concerning the '995 patent are rendered moot. We therefore decline to reach the remaining issues raised.

Id. at 1292. Thus, the Federal Circuit never reached the issue of whether the '995 patent is unenforceable for inequitable conduct, but rather mooted this Court's prior decision on that issue by finding the only asserted claim invalid.

On January 16, 2007, Pfizer filed an application with the Patent Office seeking reissue of the '995 patent to "correct" the invalidity of Claim 6, as well as other errors. (D.I. 10, ¶ 100). On May 17, 2007, Ranbaxy filed a protest of this reissue in the Patent Office, challenging the propriety of the reissue. Ranbaxy's protest also challenged the validity of the reissue claims on various substantive grounds, including anticipation,

obviousness, and double patenting. Ranbaxy's protest did not challenge the enforceability of the '995 patent or the reissue, as those issues cannot properly be raised in a reissue proceeding before the Patent Office.

Now that Ranbaxy is seeking approval to market a generic version of Caduet, Pfizer has again asserted some of its Lipitor-related patents against Ranbaxy. (D.I. 1, ¶¶ 65-67, 73-75). However, Pfizer did not assert the '995 patent against Ranbaxy's generic version of Caduet. To resolve the cloud of uncertainty left over Ranbaxy's generic product by the '995 patent and any reissue thereof, Ranbaxy Counterclaimed with respect to this patent. (D.I. 10, ¶¶ 112-32). Thereafter, Pfizer gave Ranbaxy a covenant not to sue on all claims of the '995 patent, except invalid Claim 6, with respect to Ranbaxy's generic version of Caduet. (D.I. 15, Ex. A). This covenant not to sue does not extend to any reissue of the '995 patent. (*Id*). Thus, Pfizer's refusal to provide a covenant not to sue on any reissue of the '995 patent attests to Pfizer's intention to bring suit against Ranbaxy for infringement of the reissue of the '995 patent in the future.

Just as it did in the prior Lipitor litigation, Pfizer is trying to shield its '995 patent from judicial scrutiny through a covenant not to sue. However, just as the enforceability of the '995 patent was ripe for adjudication in the Lipitor litigation, it is still ripe for adjudication now — indeed, Ranbaxy's enforceability claims are premised solely on activities that have already occurred.

V. ARGUMENT

A. Legal Standards

1. All reasonable inferences should be drawn in Ranbaxy's favor

A motion to dismiss under Fed. R. Civ. P. 12(b)(1) may present either a facial or factual challenge to subject matter jurisdiction. *Mortensen v. First Fed Sav. & Loan*,

549 F.3d 884, 891 (3d Cir. 1977). Pfizer does not state whether its jurisdictional challenge is facial or factual, and Pfizer fails to clearly apply either legal standard. (D.I. 15 at 5-6 (setting forth the legal standards applicable to facial and factual challenges, but failing to consistently apply either standard)).

Pfizer implicitly acknowledges, however, that its challenge is facial by adopting Ranbaxy's jurisdictional allegations as true. (*Id.* at 2 n.1 ("[A]ll facts are taken from uncontested facts in the Complaint or as alleged in Ranbaxy's Amended Answer and Counterclaims.")). Accordingly, in deciding Pfizer's Motion, the allegations in Ranbaxy's Amended Answer and Counterclaims must be accepted as true, and all reasonable inferences must be drawn in Ranbaxy's favor. *Markowitz v. Northeast Land Co.*, 906 F.2d 100, 103 (3d Cir. 1990).

2. The declaratory judgment standard following *MedImmune*

Traditionally, the Federal Circuit and district courts applied the "reasonable apprehension of suit" test to determine whether jurisdiction extended to declaratory judgment claims for patent invalidity, noninfringement, and/or unenforceability. Under this standard, a declaratory judgment plaintiff was required to show: (1) an explicit threat or other action by the patentee, which creates a reasonable apprehension of suit on the part of the declaratory plaintiff that it will face an infringement suit, and (2) present activity which could constitute infringement or concrete steps taken with the intent to conduct such activity. *See, e.g., Super Sack Mfg. Corp. v. Chase Packaging Corp.*, 57 F.3d 1054, 1058-59 (Fed. Cir. 1995).

Recently, however, the Supreme Court rejected this test, concluding that it was overly restrictive and contrary to precedent. *MedImmune, Inc. v. Genentech, Inc.*,

127 S. Ct. 764, 774 n.11 (2007). The Supreme Court articulated the proper test for assessing Article III jurisdiction over claims for declaratory judgment, stating:

> [T]he question in each case is whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

Id. at 771 (internal quotation marks and citations omitted). This test, referred to as the "all the circumstances" test, is now the controlling law, and prior precedent based on the reasonable apprehension of suit test is no longer instructive or controlling. *Teva Pharms. USA, Inc. v. Novartis Pharms. Corp.*, 482 F.3d 1330, 1338-39 (Fed. Cir. 2007) (recognizing that *Medimmune* overruled prior Federal Circuit precedent applying the reasonable apprehension of suit test); *see Merck & Co. v. Apotex, Inc.*, Civ. Action No. 06-230 (GMS), 2007 WL 1470453, at *3-4 (D. Del. May 21, 2007) (confirming abrogation of the reasonable apprehension of suit test).

B. Ranbaxy's Inequitable Conduct Counterclaims Present A Justiciable Controversy

Under the "all the circumstances" test, the allegations in Ranbaxy's inequitable conduct Counterclaims, viewed in a light most favorable to Ranbaxy, demonstrate that there is a current, justiciable controversy between the parties regarding the enforceability of the '995 patent and any reissue of this patent. The parties clearly hold adverse legal interests by virtue of Pfizer's current attempt to block Ranbaxy's generic version of Caduet in this action. Indeed, the parties' adverse legal interests are part of a broader controversy, including Pfizer's prior enforcement of the '995 patent in the prior Lipitor litigation and Pfizer's efforts to reissue the '995 patent so as to assert it against Ranbaxy's generic versions of both Lipitor and Caduet. The parties' dispute is

sufficiently immediate and real for declaratory judgment relief to be proper. Thus, Ranbaxy requests that this Court deny Pfizer's Motion.

1. The controversy regarding the '995 patent and the reissue application is ripe for adjudication

a. The reissue proceedings will not impact Ranbaxy's unenforceability Counterclaims

Pfizer asserts that any challenge to a reissue of the '995 patent is hypothetical and not ripe. (D.I. 15 at 12-13). To the contrary, Ranbaxy's unenforceability Counterclaims are fully justiciable at the present time.

The question of "sufficient immediacy and reality" under *Medimmune* is really a question of ripeness. "The doctrine of ripeness focuses on the conduct of the [declaratory judgment defendants] to determine whether the defendants actions have harmed, are harming, or are about to harm the [declaratory judgment] plaintiff." *Teva*, 482 F.3d at 1337.

Ranbaxy's Counterclaims are ripe for adjudication. Pfizer is harming Ranbaxy by initiating the instant lawsuit in which Pfizer seeks to block Ranbaxy's ability to obtain approval for and market a generic version of Caduet. Moreover, Pfizer's past conduct in asserting the '995 patent against Ranbaxy shows that there is a real dispute regarding the '995 patent and the reissue thereof. Indeed, the harm to Ranbaxy is exacerbated by Pfizer's efforts to insulate the '995 patent and any reissue from scrutiny in litigation. By doing so, Pfizer is intentionally creating a cloud of uncertainty that effectively precludes Ranbaxy from launching its generic product, even after receiving FDA approval to do so. This harm is real and ongoing. The relief requested by Ranbaxy is not speculative, and, if granted, would remove the harm being caused by Pfizer's actions. As such, Ranbaxy's unenforceability Counterclaims are ripe for review.

Importantly, Ranbaxy's unenforceability Counterclaims are premised on Pfizer's conduct before the Patent Office during prosecution of the '995 patent. (D.I. 10, ¶¶ 116-32). These Counterclaims do not require that the scope of any reissue claims be fixed. Indeed, because Ranbaxy's unenforceability Counterclaims are based solely on events that have already occurred, **the scope of the reissue claims is wholly irrelevant to adjudicating Ranbaxy's Counterclaims**. Contrary to Pfizer's assertion, there is no future event necessary to address Ranbaxy's Counterclaims, nor do these Counterclaims depend on future reissue proceedings in the Patent Office. Rather, the relevant events have all occurred, and the only remaining issue is the legal consequence of Pfizer's inequitable conduct. Indeed, this issue was sufficiently ripe long ago as this Court addressed it at trial in the prior Lipitor litigation.

If, as Ranbaxy alleges, Pfizer procured the '995 patent through inequitable conduct, then that entire patent and any reissue thereof are unenforceable, regardless of any events that may occur during prosecution of the reissue in the Patent Office. *Hewlett-Packard Co. v. Bausch & Lomb, Inc.*, 882 F.2d 1556, 1563 (Fed. Cir. 1989) ("[W]hen inequitable conduct is found, all claims of the patent are rendered unenforceable, not merely those claims directly affected by the misconduct."). Moreover, the inequitable conduct that occurred during prosecution of the '995 patent cannot be cured during reissue. *Id.* at 1563 n.7 ("It is well-settled that, [where] inequitable conduct [occurs] during prosecution of the original application, reissue is not available to obtain new claims and thereby rehabilitate the patent."); *Manual of Patent Examining Procedure* ("MPEP") § 2012 ("It is clear that 'fraud' cannot be purged

through the reissue process.") (relevant portions attached as Attachment A).[1] "The reissue application and the patent are inseparable as far as the questions of 'fraud,' 'inequitable conduct,' or 'violation of the duty of disclosure' are concerned." MPEP § 2012.

The reissue proceedings will also not address the inequitable conduct allegations raised by Ranbaxy. The Patent Office does not assess allegations of inequitable conduct during reissue proceedings. *Id.* § 1448. Rather, in a reissue proceeding, the Examiner presumes that the original patent is enforceable, absent a prior judicial determination or party admission that the patent was procured through inequitable conduct. *Id.* § 2012. Because the Patent Office will not examine whether the '995 patent is unenforceable due to Pfizer's inequitable conduct, there is no risk of inconsistent decisions if the Court decides this issue while the reissue is pending.

A decision by this Court that the '995 patent is unenforceable would moot the pending reissue proceeding because reissue is not available for patents procured through inequitable conduct. *Hewlett-Packard*, 882 F.2d at 1563 n.7. The Patent Office would honor this Court's judgment that the original '995 patent is unenforceable and reject the pending claims. MPEP § 2012. However, without this Court's intervention, the question of whether the '995 patent and any reissue are enforceable will remain unresolved, even though all of the facts underlying this dispute have already occurred.

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[1] "[A]lthough [the MPEP] does not have the force of law, [it] is well known to those registered to practice in the PTO and reflects the presumptions under which the PTO operates." *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253, 1257 (Fed. Cir. 1997).

b. The precedent regarding reissue upon which Pfizer relies is no longer good law and is inapplicable to the present case

In asserting that this Court lacks jurisdiction over Ranbaxy's Counterclaims, Pfizer purports to apply the "all the circumstances" test from *Medimmune*. However, the cases that Pfizer actually relies upon to support its arguments are premised on the now-rejected "reasonable apprehension of suit" test. (D.I. 15 at 12 (citing *Spectronics Corp. v. H.B. Fuller Co.*, 940 F.2d 631, 634 (Fed. Cir. 1991) (requiring "an objectively **reasonable apprehension** on the part of the accused infringer that the patent holder will initiate suit") (emphasis added); *Amana Refrigeration, Inc. v. Quadlux, Inc.*, 172 F.3d 852, 855 (Fed. Cir. 1999) (requiring "reasonable apprehension" of suit on the part of the declaratory judgment plaintiff); *Super Sack*, 57 F.3d at 1058 (same); *GAF Bldg. Materials Corp. v. Elk Corp.*, 90 F.3d 479, 481 (Fed. Cir. 1996) (same); *Czarnik v. Illumina, Inc.*, 437 F. Supp. 2d 252, 258 (D. Del. 2006) (same))). Pfizer even goes so far as to call these cases "**current precedent**." (D.I. 15 at 12 (emphasis added).) To the contrary, these cases are not current precedent and their precedential value, if any, is greatly diminished in view of the Supreme Court's rejection of the reasonable apprehension of suit test underlying these cases.

None of the cases cited by Pfizer warrant dismissal of Ranbaxy's declaratory judgment Counterclaims of inequitable conduct. Rather, these cases are easily distinguishable from the present factual situation.

For example, in *Spectronics*, the declaratory judgment plaintiff alleged noninfringement and invalidity, but did not allege that the original patent was procured through inequitable conduct. *Spectronics*, 940 F.2d at 632. The Court concluded that the infringement and validity of the reissued patent were wholly dependent on the scope of

the claims involved in the reissue proceedings. Because the scope of those claims was unclear pending reissue, the Court concluded that it was premature to decide the issues of noninfringement and invalidity prior to issuance of the reissue patent. *Id.* at 636-37.

Here, in contrast, the scope of the reissue claims is irrelevant to whether inequitable conduct occurred during prosecution of the original patent. Either the '995 patent was procured through inequitable conduct or it was not. If it was, then the '995 patent and any reissue thereof necessarily would be unenforceable, **regardless of the scope of the reissue claims**. The other cases cited by Pfizer are distinguishable on this same basis. *See Amana Refrig.*, 172 F.3d at 855 (stating that the declaratory judgment plaintiff pleaded patent invalidity and noninfringement, but not inequitable conduct of the original patent); *GAF Bldg. Materials*, 90 F.3d at 483 (affirming dismissal for lack of jurisdiction because "[a] declaratory judgment of 'invalidity' or 'noninfringement' with respect to [the] pending patent application would have had no legal meaning or effect"; inequitable conduct was not asserted).[2]

The decision in *Black & Decker, Inc. v. Robert Bosch Tool Corp.*, 371 F. Supp. 2d 965 (N.D. Ill. 2005), cited by this Court in its *Czarnik* decision, also does not support Pfizer's argument. In *Black & Decker*, the alleged infringer brought declaratory

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[2] Pfizer's also cites *Super Sack* and this Court's decision in *Czarnik* to support its argument that a pending reissue application deprives the Court of declaratory judgment jurisdiction. (D.I. 15 at 12.) However, neither of these cases stands for such a proposition. *Super Sack*, 57 F.3d at 1058 (noting, in dictum, that *Spectronics* previously held that the courts lack jurisdiction over **invalidity** claims, where a covenant not to sue is provided covering past, present and future conduct, even if a reissue is pending); *Czarnik v. Illumina, Inc.*, 437 F. Supp. 2d 252, 259 (D. Del. 2006) (dismissing a putative inventor's claim of patent unenforceability, because there was never a threat that the patent would be asserted against him, and because he was not engaging in any activity that could infringe the patent).

judgment counterclaims seeking, *inter alia*, a declaration that a pending patent application was unenforceable based on inequitable conduct. *Black & Decker*, 371 F. Supp. 2d at 967-68. The Court dismissed this unenforceability counterclaim because "it is possible for an applicant to cure inequitable conduct during the prosecution of the application." *Id* at 971. The Court also explained that because no patent had issued from this application, there was no property right to declare unenforceable. *Id*

The facts of *Black & Decker* are easily distinguishable from those of the present case. In *Black & Decker*, the patentee could cure inequitable conduct during prosecution of the application. *Id.* Thus, the controversy was not ripe because the patentee's future actions during prosecution could effect the unenforceability claim. Here, in stark contrast, Pfizer cannot cure the inequitable conduct that occurred during prosecution of the original '995 patent during the reissue proceedings. Not only is this inequitable conduct not curable, it taints the reissue, as well. *Hewlett-Packard*, 882 F.2d at 1563 n.7; *Hoffman-La Roche, Inc. v. Lemmon Co.*, 906 F.2d 684, 688-89 (Fed. Cir. 1990) ("Thus, if the district court finds that there was inequitable conduct in the prosecution of the original patent then the reissue patent is invalid and an appropriate judgment should be entered."); *In re Clark*, 522 F.2d 623, 627 (C.C.P.A. 1975) (stating that reissue cannot rescue a patentee who committed inequitable conduct during original prosecution). Thus, Ranbaxy's Counterclaims do not depend on any future event. Additionally, unlike in *Black & Decker* in which there was no property right to declare unenforceable, Pfizer clearly has an existing property right (the '995 patent) that this Court can declare unenforceable. Such a ruling would also render any reissue of the '995 patent

unenforceable. Thus, the reasoning of *Black & Decker* is clearly inapposite to the facts of the present case.

2. The covenant not to sue does not moot the controversy

Although Pfizer has covenanted not to assert the '995 patent against Ranbaxy, Pfizer has refused to make any similar guarantees regarding any reissue of the '995 patent. Thus, there remains a continuing controversy over Ranbaxy's right to lawfully market its generic product. Indeed, Pfizer's failure to grant a covenant not to sue for any such reissue, coupled with the ongoing reissue proceeding and Pfizer's listing of the '995 patent in the *Orange Book* as covering Caduet, places Ranbaxy in the precise predicament that the Declaratory Judgment Act and Hatch-Waxman Act were designed to avoid. Ranbaxy is left with the choice of launching its generic product amid the uncertainty created by the reissue of the '995 patent, or staying off the market (even after resolution of the other asserted patent claims) until future litigation over the '995 patent and its reissue are complete. As the Supreme Court recognized in *Medimmune*, Article III does not impose this dilemma on litigants before allowing their disputes to be heard in the federal courts:

> The rule that a [declaratory judgment] plaintiff must destroy a large building, bet the farm, or . . . risk treble damages and the loss of 80 percent of its business, before seeking a declaration of its actively contested legal rights finds no support in Article III.

Medimmune, 127 S. Ct. at 775

The Federal Circuit's recent decision in *SanDisk Corp. v. STMicroelectronics, Inc.*, 480 F.3d 1372 (Fed. Cir. 2007), is instructive. In *SanDisk*, the Federal Circuit held that a justiciable case or controversy existed, even though the patent owner affirmatively represented that it would not sue the declaratory judgment plaintiff. *Id.* at 1382-83. In

view of the surrounding circumstances, the Federal Circuit concluded that the patentee's "course of conduct" showed a preparedness and willingness to enforce its patent rights despite its statement that it would not bring suit. The Federal Circuit explained that "[the patentee's] statement that it does not intend to sue does not moot the actual controversy created by its acts." *Id.* at 1383 (citing *Md. Cas. Co. v. Pac. Coal & Oil Co.*, 312 U.S. 270, 273 (1941), for the proposition that jurisdiction could be obtained even where the defendant could not have sued the declaratory judgment plaintiff).

Under the Federal Circuit's decision in *SanDisk*, the dispute between Ranbaxy and Pfizer is justiciable under the Declaratory Judgment Act. In both cases, the parties were engaged in substantial disagreements regarding the patents at issue, after which the declaratory judgment defendants promised not to bring suit. As explained in *SanDisk*, a promise not to sue does not moot the otherwise threatening behavior of a patentee. *Id.* To hold otherwise would encourage the "kinds of extra-judicial patent enforcement with scare-the-customer-and-run tactics" that the Declaratory Judgment Act was designed to prevent. *Id.* at 1383 (quoting *Arrowhead Indus. Water, Inc. v. Ecolochem, Inc.*, 846 F.2d 731, 735 (Fed. Cir. 1988)).

The allegations supporting Ranbaxy's Counterclaims also mirror those found to create a substantial controversy in *Teva Pharmaceuticals USA, Inc. v. Novartis Pharmaceutical Corp* , 482 F.3d 1330 (Fed. Cir. 2007). The Federal Circuit's decision in *Teva* followed the Supreme Court's ruling in *Medimmune*, and, therefore, the *Teva* decision represents the Federal Circuit's current approach to assessing jurisdiction over declaratory judgment claims.

In *Teva*, the patentee (Novartis) listed five patents in the *Orange Book* for its drug Famvir®. *Id.* at 1334. The generic manufacturer (Teva) sought FDA approval to market a generic version of Famvir. *Id.* at 1334-35. Novartis brought suit against Teva, but only with respect to one of the listed patents. *Id.* Teva then brought declaratory judgment claims against the remaining four *Orange Book*-listed patents, and Novartis moved to dismiss these claims for lack of subject matter jurisdiction. *Id.* at 1335.

Applying the *Medimmune* standard, the Federal Circuit reversed the District Court's judgment that it lacked jurisdiction over Teva's counterclaims. *Id.* at 1334, 1346. The Federal Circuit concluded that Teva's declaratory judgment claims presented an Article III controversy because: (1) the patents at issue in Teva's counterclaims were listed in the *Orange Book* for Famvir, which implies that a claim for infringement of these patents could reasonably be asserted against anyone making a generic Famvir product; (2) Teva filed its ANDA with a Paragraph IV certification covering the patents in Teva's counterclaims, which qualifies as an act of infringement under 35 U.S.C. § 271(e)(2); (3) the policies underlying applicable federal legislation[3] would be promoted by exercising jurisdiction over Teva's counterclaims; (4) Novartis had already sued Teva over other patents listed in the *Orange Book* for Famvir; and (5) the possibility of future

---

[3] Specifically, the Federal Circuit noted that the "civil action to obtain patent certainty" provision of 21 U.S.C. § 355(j)(5)(C), the ANDA declaratory judgment provision of 35 U.S.C. § 271(e)(5), and the Hatch-Waxman Act were designed to prevent patentees from insulating their drugs from generic competition by "gaming" the system through piecemeal litigation. Such gamesmanship frustrates the central purpose of the Hatch-Waxman Act and the subsequent ANDA declaratory judgment amendment to the Act, which is "to enable competitors to bring cheaper, generic . . . drugs to market as quickly as possible." *Teva*, 482 F.3d at 1344 (quoting 149 Cong. Rec. S15885 (Nov. 25, 2003) (remarks of Sen. Kennedy, ranking member of Senate HELP committee)).

litigation over the remaining, non-asserted patents existed between the parties. *Id.* at 1342-45.

Here, those same five factors support a finding that Ranbaxy's Counterclaims present an Article III controversy. First, the '995 patent is listed in the *Orange Book* for Caduet, which allows Pfizer to assert a claim for infringement of the '995 patent against Ranbaxy's generic Caduet product.

Second, like the generic company in *Teva*, Ranbaxy submitted an ANDA with a Paragraph IV certification for the patents listed in the *Orange Book* for Caduet, including the '995 patent, an act which qualifies as an act of infringement under § 271(e)(2). (D.I. 1, Ex. D). The filing of Ranbaxy's ANDA with a Paragraph IV certification constitutes a single act of "infringement," regardless of the number of patents that Ranbaxy actually certified against in its Paragraph IV letter. *Teva*, 482 F.3d at 1340 ("[S]ubmitting an ANDA, regardless of how many paragraph IV certifications it may contain, is a single act of infringement . . . .").

Third, the same policies relied upon by the Federal Circuit in *Teva* are promoted by adjudicating Ranbaxy's unenforceability Counterclaims now, instead of at Pfizer's discretion in a future action with the same underlying facts. One of the purposes underlying the enactment of federal legislation authorizing civil actions to obtain patent certainty, ANDA declaratory judgment actions, and the Hatch-Waxman Act was to allow for early adjudication (*i.e.*, prior to launching of a generic product) of patent disputes between patentees and generic manufacturers. *Id.* at 1342-44. Likewise, these same statutes were enacted to stop patentees from "gaming" the system by dragging out

piecemeal litigation, which improperly delays consumer access to cheaper, generic drugs. *Id.* at 1342-43.

Fourth, just as in *Teva*, Pfizer is already asserting other patents allegedly covering Caduet against Ranbaxy. Thus, there is already an Article III controversy between the parties regarding Ranbaxy's ANDA and its Paragraph IV certification, which included a certification against the '995 patent. *Id.* at 1344; (D.I. 1, Ex. D).

Fifth, Ranbaxy faces future litigation over the '995 patent because Pfizer has refused to give Ranbaxy a covenant not to sue with respect to any reissue of the '995 patent and because the '995 patent is still listed in the *Orange Book* for Caduet. Like the patentee in *Teva*, Pfizer is trying to subject Ranbaxy to multiple lawsuits over the same single act of infringement, namely, the filing of Ranbaxy's ANDA with a Paragraph IV certification. Pfizer's present suit "leaves open the possibility of future litigation regardless of whether [Ranbaxy] wins or loses" the instant case. *Teva*, 482 F.3d at 1345. "This threat of protracted litigation creates a present and real harm that is a relevant circumstance in finding whether a justiciable controversy exists." *Id.*

Viewing the five foregoing factors together, as required by the Supreme Court's "all the circumstances" test, the parties' dispute over the enforceability of the '995 patent and any reissue presents a justiciable controversy sufficient to invoke this Court's Article III jurisdiction. *Id.* at 1341.

This Court's recent decision in *Merck & Co. v. Apotex*, 2007 WL 1470453, is not to the contrary. In *Merck*, this Court dismissed the generic manufacturer's noninfringement and invalidity counterclaims because the patentee had granted "a comprehensive covenant not to sue." *See id.* at *1-2. Unlike in *Merck* where the

comprehensive covenant mooted all counterclaims, here the covenant provided is not comprehensive, and, thus, there is still an ongoing controversy regarding the enforceability of the '995 patent and any reissue of that patent. Thus, the *Merck* case is distinguishable. However, the *Merck* case is instructive for its recognition of the abusive practices of pioneer drug companies holding generic manufacturers at bay through the use of covenants not to sue and challenges to subject matter jurisdiction, *see id.* at *5-6, which are the very abuses Pfizer is employing here to shield the '995 patent and its reissue from judicial scrutiny.

C. Ranbaxy Has Standing To Challenge The '995 Patent And The Reissue

Article III standing requires "[a] plaintiff [to] allege personal injury fairly traceable to the defendant's allegedly unlawful conduct and likely to be redressed by the requested relief." *Allen v. Wright*, 468 U.S. 737, 751 (1984). When determining standing under Article III, "injury-in-fact is the most determinative." *Teva*, 482 F.3d at 1337 (citing *Schlesinger v. Reservists Comm. to Stop the War*, 418 U.S. 208, 218 (1974)). "An injury-in-fact must be 'personal,' 'concrete and particularized,' and 'actual or imminent.' " *Id.* (quoting *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992)).

Under controlling precedent, Ranbaxy has standing to assert its unenforceability Counterclaims. Like the accused infringer in *Teva*, Ranbaxy is suffering a "direct legal injury from the actions that [Pfizer] has already taken," namely its listing of the '995 patent and the already asserted patents in the *Orange Book* for Caduet. *Id.* at 1345. Further, Ranbaxy is suffering a direct legal injury as a result of Pfizer's instant suit against Ranbaxy that challenges Ranbaxy's ANDA. *See id.* As explained by the Federal Circuit in *Teva*, "[i]t is this exact type of uncertainty of legal rights that the ANDA declaratory judgment action was enacted to prevent." *Id.* (citing 35 U.S.C.

§ 355(j)(5)(C)). "The legislative history of the ANDA declaratory judgment amendment explicitly states that the 'uncertainty' caused by a brand-name company when it chooses to sue on only selective patents submitted in a single ANDA is an injury sufficient to support a justiciable controversy." *Id* Accordingly, under controlling precedent, Ranbaxy has standing to litigate its Counterclaims. This harm to Ranbaxy is only exacerbated by the existence of the pending reissue, while creates a continuing cloud of uncertainty over Ranbaxy's ability to legally market its generic product.

D. The Court Should Exercise Jurisdiction Over Ranbaxy's Counterclaims

This Court has discretion to exercise subject matter jurisdiction over claims for declaratory relief. *Glaxo Inc. v. Novopharm* Ltd. 110 F.3d 1562, 1570 (Fed. Cir. 1997). "Although the district court is given the discretion, in declaratory judgment actions, to dismiss the case, there are boundaries to that discretion." *SanDisk*, 480 F.3d at 1383. "When there is an actual controversy and a declaratory judgment would settle the legal relations in dispute and afford relief from uncertainty or insecurity, in the usual circumstance the declaratory judgment is not subject to dismissal." *Id.* (internal quotation marks and citation omitted).

The current posture of the parties' dispute leaves no doubt that the Court should exercise its discretion to resolve Ranbaxy's Counterclaims now, instead of in a piecemeal fashion at some later juncture. Resolution of the enforceability of the '995 patent would settle the dispute regarding the enforceability of the '995 patent, and, consequently, any reissue resulting from it.

VI. CONCLUSION

For the foregoing reasons, this Court should exercise jurisdiction over Ranbaxy's Sixth and Seventh Counterclaims regarding the unenforceability of the '995 patent, and deny Pfizer's Motion To Dismiss.

Frederick L. Cottrell III (#2555)
Cottrell@rlf.com
Jameson A.L. Tweedie (#4927)
Tweedie@rlf.com
RICHARDS, LAYTON & FINGER, P.A.
One Rodney Square
920 N. King Street
Wilmington, DE 19899
(302) 651-7700
Attorneys for Defendants/Counterclaimants
Ranbaxy Laboratories Limited and
Ranbaxy Inc

Of Counsel:
Darrell L. Olson
Joseph M. Reisman
William R. Zimmerman
Payson LeMeilleur
KNOBBE, MARTENS, OLSON & BEAR
2040 Main Street, 14th Floor
Irvine, California 92614

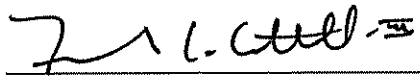
Dated: May 31, 2007

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CERTIFICATE OF SERVICE

I hereby certify that on May 31, 2007, I caused to be served by hand delivery the foregoing document and electronically filed the same with the Clerk of Court using CM/ECF which will send notification of such filing(s) to the following:

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Jeffrey B. Bove
Mary W. Bourke
Connolly, Bove, Lodge & Hutz
The Nemours Building
1007 North Orange Street
P. O. Box 2207
Wilmington, DE 19899



Frederick L. Cottrell, III (#2555)
Cottrell@rlf.com
Richards, Layton & Finger, P.A.
One Rodney Square
P.O. Box 551
Wilmington, Delaware 19899
(302) 651-7700

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PFIZER INC, PFIZER PHARMACEUTICALS, LLC, PFIZER LIMITED, C.P. PHARMACEUTICALS INTERNATIONAL C.V., PFIZER IRELAND PHARMACEUTICALS, WARNER-LAMBERT COMPANY, WARNER-LAMBERT COMPANY, LLC and WARNER-LAMBERT EXPORT LTD,	)	
Plaintiffs/Counterdefendants,	)	C.A. No. 07-138-JJF
v.	)	
RANBAXY LABORATORIES LIMITED, and RANBAXY INC.,	)	
Defendants/Counterclaimants.	)	

[PROPOSED] ORDER DENYING PFIZER'S MOTION TO DISMISS PURSUANT TO FEDERAL RULE OF CIVIL PROCEDURE 12(b)(1), RANBAXY'S COUNTERCLAIMS WITH RESPECT TO THE '995 PATENT

This matter, having come before the Court upon Pfizer's Motion to Dismiss Pursuant to Federal Rule of Civil Procedure 12(b)(1), Ranbaxy's Counterclaims With Respect To The '995 Patent, and the Court having considered the submissions of the parties, IT IS HEREBY ORDERED that:

Pfizer's Motion to Dismiss Pursuant to Federal Rule of Civil Procedure 12(b)(1), Ranbaxy's Counterclaims With Respect To The '995 Patent is DENIED.

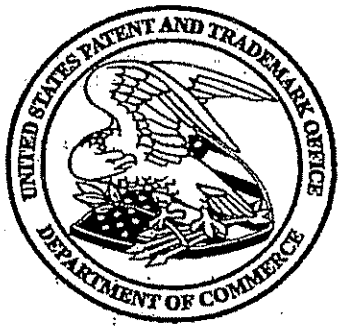
Dated: _____

_____
Honorable Joseph J. Farnan, Jr.

EXHIBIT A

Manual of PATENT EXAMINING PROCEDURE

Original Eighth Edition, August 2001
Latest Revision August 2006



U.S. DEPARTMENT OF COMMERCE
United States Patent and Trademark Office

Rev. 5, Aug. 2006

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Additions to the text of the Manual are indicated by arrows (>\<) inserted in the text. Deletions are indicated by a single asterisk (*) where a single word was deleted and by two asterisks (**) where more than one word was deleted. The use of three or five asterisks in the body of the laws, rules, treaties, and administrative instructions indicates a portion of the law, rule, treaty, or administrative instruction which was not reproduced.

First Edition, November 1949
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Revision 1, February 2003
Revision 2, May 2004
Revision 3, August 2005
Revision 4, October 2005
Revision 5, August 2006

Foreword

This Manual is published to provide U.S. Patent and Trademark Office (USPTO) patent examiners, applicants, attorneys, agents, and representatives of applicants with a reference work on the practices and procedures relative to the prosecution of patent applications before the USPTO. It contains instructions to examiners, as well as other material in the nature of information and interpretation, and outlines the current procedures which the examiners are required or authorized to follow in appropriate cases in the normal examination of a patent application. The Manual does not have the force of law or the force of the rules in Title 37 of the Code of Federal Regulations.

A separate manual entitled "Trademark Manual of Examining Procedure" is published by the USPTO as a reference work for trademark cases.

Examiners will be governed by the applicable statutes, rules, decisions, and orders and instructions issued by the Director of the USPTO and other officials authorized by the Director of the USPTO. Orders and Notices still in force which relate to the subject matter included in this Manual are incorporated in the text. Orders and Notices, or portions thereof, relating to the examiners' duties and functions which have been omitted or not incorporated in the text may be considered obsolete. Interference procedure not directly involving the Primary Examiner are not included in this Manual and, therefore, Orders and Notices relating thereto remain in force.

Subsequent changes in practice and other revisions will be incorporated in the form of substitute or additional pages for the Manual.

Suggestions for improving the form and content of the Manual are always welcome. They should be addressed to:

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patent, even though no amendment is physically entered into the case. Thus, for a reissue oath/declaration submitted after allowance to correct an additional error (or errors), the reissue applicant must comply with 37 CFR 1.312 in the manner discussed above.

1445 Reissue Application Examined in Same Manner as Original Application

As stated in 37 CFR 1.176, a reissue application, including all the claims therein, is subject to "be examined in the same manner as a non-reissue, non-provisional application." Accordingly, the claims in a reissue application are subject to any and all rejections which the examiner deems appropriate. It does not matter whether the claims are identical to those of the patent or changed from those in the patent. It also does not matter that a rejection was not made in the prosecution of the patent, or could have been made, or was in fact made and dropped during prosecution of the patent; the prior action in the prosecution of the patent does not prevent that rejection from being made in the reissue application. Claims in a reissue application enjoy no "presumption of validity." *In re Doyle*, 482 F.2d 1385, 1392, 179 USPQ 227, 232-233 (CCPA 1973); *In re Sneed*, 710 F.2d 1544, 1550 n.4, 218 USPQ 385, 389 n.4 (Fed. Cir. 1983). Likewise, the fact that during prosecution of the patent the examiner considered, may have considered, or should have considered information such as, for example, a specific prior art document, does not have any bearing on, or prevent, its use as prior art during prosecution of the reissue application.

1448 Fraud, Inequitable Conduct, or Duty of Disclosure Issues [R-2]

The Office no longer investigates and rejects reissue applications under 37 CFR 1.56. The Office will not comment upon duty of disclosure issues which are brought to the attention of the Office in reissue applications except to note in the application, in appropriate circumstances, that such issues are no longer considered by the Office during its examination of patent applications. Examination as to the lack of deceptive intent requirement in reissue applications will continue but without any investigation of fraud, inequitable conduct, or duty of disclosure issues. Applicant's statement in the reissue oath or declaration of lack of deceptive intent will be accepted as dispositive except in special circumstances such as an admission or judicial determination of fraud, inequitable conduct, or violation of the duty of disclosure.

ADMISSION OR JUDICIAL DETERMINATION

An admission or judicial determination of fraud, inequitable conduct, or violation of the duty of disclosure is a special circumstance, because no investigation need be made. Accordingly, after consulting with the Technology Center (TC) Special Program Examiner (SPRE), a rejection should be made using the appropriate one of form paragraphs 14.21.09 or 14.22 as reproduced below.

Any admission of fraud, inequitable conduct or violation of the duty of disclosure must be explicit, unequivocal, and not subject to other interpretation. Where a rejection is made based upon such an admission (see form paragraph 14.22 below) and applicant responds with any reasonable interpretation of the facts that would not lead to a conclusion of fraud, inequitable conduct or violation of the duty of disclosure, the rejection should be withdrawn. Alternatively, if applicant argues that the admission noted by the examiner was not in fact an admission, the rejection should also be withdrawn.

Form paragraph 14.21.09 should be used where the examiner becomes aware of a judicial determination of fraud, inequitable conduct or violation of the duty of disclosure on the part of the applicant **independently of the record of the case,** i.e., the examiner has external knowledge of the judicial determination.

Form paragraph 14.22 should be used where, **in the application record,** there is (a) an explicit, unequivocal admission by applicant of fraud, inequitable conduct or violation of the duty of disclosure which is not subject to other interpretation, or (b) information as to a judicial determination of fraud, inequitable conduct or violation of the duty of disclosure on the part of the applicant. External information which the examiner believes to be an *admission* by applicant should never be used by the examiner, and such external information should never be made of record in the reissue application.

¶ *14.21.09 Rejection, 35 U.S.C. 251, No Error Without Deceptive Intention - External Knowledge*

Claims [1] rejected under 35 U.S.C. 251 since error "without any deceptive intention" has not been established. In view of the judicial determination in [2] of [3] on the part of applicant, a conclusion that any error was "without deceptive intention" cannot be supported. [4]

Examiner Note:

1. In bracket 1, list all claims in the reissue application.
2. In bracket 2, list the Court or administrative body which made the determination of fraud or inequitable conduct on the part of applicant.
3. In bracket 3, insert --fraud--, --inequitable conduct-- and/or --violation of duty of disclosure--.
4. In bracket 4, point out where in the opinion (or holding) of the Court or administrative body the determination of fraud, inequitable conduct or violation of duty of disclosure is set forth. Page number, column number, and paragraph information should be given as to the opinion (or holding) of the Court or administrative body. The examiner may add explanatory comments.

**>

¶ *14.22 Rejection, 35 U.S.C. 251, No Error Without Deceptive Intention-Evidence in the Application*

Claims [1] rejected under 35 U.S.C. 251 since error "without any deceptive intention" has not been established. In view of the reply filed on [2], a conclusion that any error was "without deceptive intention" cannot be supported.

[3]

Examiner Note:

1. In bracket 1, list all claims in the reissue application.
2. In bracket 2, insert the filing date of the reply which provides an admission of fraud, inequitable conduct or violation of duty of disclosure, or that there was a judicial determination of same.
3. In bracket 3, insert a statement that there has been an admission or a judicial determination of fraud, inequitable conduct or violation of duty of disclosure which provide circumstances why applicant's statement in the oath or declaration of lack of deceptive intent should not be taken as dispositive. Any admission of fraud, inequitable conduct or violation of duty of disclosure must be explicit, unequivocal, and not subject to other interpretation.

<

See MPEP § 2012 for additional discussion as to fraud, inequitable conduct or violation of duty of disclosure in a reissue application.

1449 Protest Filed in Reissue Where Patent Is in Interference [R-3]

If a protest (see MPEP Chapter 1900) is filed in a reissue application related to a patent involved in a pending interference proceeding, the reissue application should be referred to the Office of Patent Legal Administration (OPLA) before considering the protest and acting on the reissue application.

The OPLA will check to see that:

(A) all parties to the interference are aware of the filing of the reissue; and

(B) the Office does not allow claims in the reissue which are unpatentable over the pending interference count(s), or found unpatentable in the interference proceeding. After the reissue application has been reviewed by the OPLA, the reissue application with the protest will be returned to the examiner. See MPEP § 1441.01 for a discussion as to protests under 37 CFR 1.291* in reissue applications.

1449.01 Concurrent Office Proceedings [R-5]

I. CONCURRENT REEXAMINATION PROCEEDINGS:

37 CFR 1.565(d) provides that if "a reissue application and an *ex parte* reexamination proceeding on which an order pursuant to 37 CFR 1.525 has been mailed are pending concurrently on a patent, a decision will normally be made to merge the two proceedings or to suspend one of the two proceedings." 37 CFR 1.991 provides that if "a reissue application and an *inter partes* reexamination proceeding on which an order pursuant to 37 CFR 1.931 has been mailed are pending concurrently on a patent, a decision may be made to merge the two proceedings or to suspend one of the two proceedings". If an examiner becomes aware that a reissue application and an *ex parte* or *inter partes* reexamination proceeding are both pending for the same patent, he or she should >immediately< inform the Technology Center (TC) >or Central Reexamination Unit (CRU)< Special Program Examiner (SPRE)*.

Pursuant to 37 CFR 1.177, a patent owner may file more than one reissue application for the same patent. If an examiner becomes aware that multiple reissue applications are pending for the same patent, and an *ex parte* or *inter partes* reexamination proceeding is pending for the same patent, he or she should >immediately< inform the TC SPRE*.

Where a reissue application and a reexamination proceeding are pending concurrently on a patent, *and an order granting reexamination has been issued* for the reexamination proceeding, the Office of Patent

cause (37 CFR 1.655(b)) must be shown as to why the issues of fraud and/or inequitable conduct were not timely raised during the preliminary motion period. Issues of fraud and/or inequitable conduct will not be considered in any interference in which the times for taking testimony or the times for filing briefs for final hearing have already been set, unless 'good cause' is shown under 37 CFR 1.655(b). An example of good cause would be where fraud or inequitable conduct is first discovered during taking of testimony. See notice published in the *Official Gazette* at 1133 O.G. 21 (December 10, 1991).<

2012 Reissue Applications Involving Issues of Fraud, Inequitable Conduct, and/or Violation of Duty of Disclosure [R-2]

Questions of "fraud," "inequitable conduct," or violation of "duty of disclosure" or "candor and good faith" can arise in reissue applications.

REQUIREMENT FOR "ERROR WITHOUT ANY DECEPTIVE INTENTION"

Both 35 U.S.C. 251 and 37 CFR 1.175 promulgated pursuant thereto require that the error must have arisen "without any deceptive intention." *In re Heany*, 1911 C.D. 138, 180 (1911), unequivocally states:

> Where such a condition [fraudulent or deceptive intention] is shown to exist the right to reissue the patent is forfeited.

Similarly, the court in *In re Clark*, 522 F.2d 623, 627, 187 USPQ 209, 213 (CCPA 1975) indicated:

> Reissue is not available to rescue a patentee who had presented claims limited to avoid particular prior art and then had failed to disclose that prior art . . . after that failure to disclose has resulted in invalidating of the claims.

It is clear that "fraud" cannot be purged through the reissue process. See conclusions of Law 89 and 91 in *Intermountain Research and Eng'g Co. v. Hercules Inc.*, 171 USPQ 577, 631-32 (C.D. Cal. 1971).

Clearly, where several patents or applications stem from an original application which contained fraudulent claims ultimately allowed, the doctrine of unclean hands bars allowance or enforcement of any of the claims of any of the applications or patents. See *Keystone Driller Co. v. General Excavator Co.*, 290 U.S. 240, 245, 19 USPQ 228, 230 (1933); *East Chicago Machine Tool Corp. v. Stone Container Corp.*, 181 USPQ 744, 748 (N.D. Ill.), *modified*, 185 USPQ 210 (N.D. Ill. 1974). See also *Chromalloy American Corp. v. Alloy Surfaces Co.*, 339 F. Supp. 859, 173 USPQ 295 (D.Del. 1972) and *Strong v. General Electric Co.*, 305 F. Supp. 1084, 162 USPQ 141 (N.D. Ga. 1969), *aff'd*, 434 F.2d 1042, 168 USPQ 8 (5th Cir. 1970), *cert. denied*, 403 U.S. 906 (1971) where fraud or inequitable conduct affecting only certain claims or only one of related patents was held to affect the other claims or patent. Clearly, "fraud" practiced or attempted in an application which issues as a patent is "fraud" practiced or attempted in connection with any subsequent application to reissue that patent. The reissue application and the patent are inseparable as far as questions of "fraud," "inequitable conduct," or "violation of the duty of disclosure" are concerned. See *In re Heany, supra;* and *Norton v. Curtiss*, 433 F.2d 779, 792, 167 USPQ 532, 543 (CCPA 1970), wherein the court stated:

> We take this to indicate that any conduct which will prevent the enforcement of a patent after the patent issues should, if discovered earlier, prevent the issuance of the patent.

Clearly, if a reissue patent would not be enforceable after its issue because of "fraud," "inequitable conduct" or "violation of the duty of disclosure" during the prosecution of the patent sought to be reissued, the reissue patent application should not issue. *>Where no investigation is needed to establish< such circumstances, an appropriate remedy would be to reject the claims in the application in accordance with 35 U.S.C. 251. See MPEP § 1448.

The examiner is **not to make any investigation** as to the lack of deceptive intent requirement in reissue applications. Applicant's statement (in the oath or declaration) of lack of deceptive intent will be accepted as dispositive except in special circumstances such as **an admission or judicial determination** of fraud, inequitable conduct or violation of the duty of disclosure, where no investigation need be made and the fact of the admission or judicial determination exists *per se*. Also, any admission of fraud, inequitable conduct or violation of the duty of disclosure must be explicit, unequivocal, and not subject to other interpretation. Where a rejection is made based upon such an admission (see MPEP § 1448) and applicant

responds with any reasonable interpretation of the facts that would not lead to a conclusion of fraud, inequitable conduct or violation of the duty of disclosure, the rejection should be withdrawn. Alternatively, if applicant shows that the admission noted by the examiner was not in fact an admission, the rejection should also be withdrawn.

2012.01 Collateral Estoppel [R-2]

The Supreme Court in *Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found.*, 402 U.S. 313, 169 USPQ 513 (1971) set forth the rule that once a patent has been declared invalid via judicial inquiry, a collateral estoppel barrier is created against further litigation involving the patent, unless the patentee-plaintiff can demonstrate "that he did not have" a full and fair chance to litigate the validity of his patent in "the earlier case." See also *Ex parte Varga*, 189 USPQ 209 (Bd. App. 1973). As stated in *Kaiser Industries Corp. v. Jones & Laughlin Steel Corp.*, 515 F.2d 964, 987, 185 USPQ 343, 362 (3rd Cir. 1975):

> In fashioning the rule of *Blonder-Tongue*, Justice White for a unanimous Court made it clear that a determination of patent invalidity, after a thorough and equitable judicial inquiry, creates a collateral estoppel barrier to further litigation to enforce that patent.

Under 35 U.S.C. 251, the *>Director< can reissue a patent only if there is "error without any deceptive intention." The *>Director< is without authority to reissue a patent when "deceptive intention" was present during prosecution of the parent application. See *In re Clark*, 522 F.2d 62, 187 USPQ 209 (CCPA 1975) and *In re Heany*, 1911 C.D. 138, 180 (1911). Thus, the collateral estoppel barrier applies where reissue is sought of a patent which has been held invalid or unenforceable for "fraud" or "violation of duty of disclosure" in procuring of said patent. It was held in *In re Kahn*, 202 USPQ 772, 773 (Comm'r Pat. 1979):

> Therefore, since the Kahn patent was held invalid, inter alia, for "failure to disclose material facts of which * * * [Kahn] was aware" this application may be stricken under 37 CFR 1.56 via the doctrine of collateral estoppel as set forth in Blonder-Tongue, supra.
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> *****
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> The Patent and Trademark Office . . . has found no clear justification for not adhering to the doctrine of collateral estoppel under Blonder-Tongue in this case. Applicant has had his day in court. He appears to have had a full and fair chance to litigate the validity of his patent.

See MPEP § 2259 for collateral estoppel in reexamination proceedings.

2013 Protests Involving Issues of Fraud, Inequitable Conduct, and/or Violation of Duty of Disclosure [R-2]

37 CFR 1.291 permits protests by the public against pending applications.

Submissions under 37 CFR 1.291 are not limited to prior art documents such as patents and publications, but are intended to include any information, which in the protestor's opinion, would make or have made the grant of the patent improper (see MPEP § 1901.02). This includes, of course, information indicating the presence of "fraud" or "inequitable conduct" or "violation of the duty of disclosure," which will be entered in the application file, generally without comment >other than to state that such information will not be considered (see MPEP § 2010).< See MPEP § 1901.06.

Protests should be in conformance with 37 CFR 1.291(a) and (b), and include a statement of the alleged facts involved, the point or points to be reviewed, and the action requested. Any briefs or memoranda in support of the petition, and any affidavits, declarations, depositions, exhibits, or other material in support of the alleged facts, should accompany the protest.

2014 Duty of Disclosure in Reexamination Proceedings [R-2]

As provided in 37 CFR 1.555, the duty of disclosure in >both *ex parte* and *inter partes*< reexamination proceedings applies to the patent owner. That duty is a continuing obligation on the part of the patent owner throughout the proceedings. However, issues of "fraud," " inequitable conduct," or "violation of duty of disclosure" are not considered in reexamination. See MPEP § 2280 >for *ex parte* reexamination proceedings and MPEP § 2684 for *inter partes* reexamination proceedings<. If questions of "fraud" or "inequitable conduct" or "violation of the duty of disclosure" are discovered during reexamination proceedings, the existence of such questions will be noted by the examiner in an Office action