

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

AMGEN, INC.,

Plaintiff,

v.

F. HOFFMANN-LA ROCHE, LTD,
ROCHE DIAGNOSTICS GMBH, and
HOFFMANN-LA ROCHE INC.

Defendants.

Civil Action No. 05-CV-12237 WGY

U.S. District Judge Young

**ROCHE'S OPPOSITION TO AMGEN'S MOTION REQUESTING THAT
THIS COURT TRY ROCHE'S INEQUITABLE CONDUCT DEFENSES**

Amgen's motion (D.I. 1341) is yet another attempt to have the Court reconsider its ruling recognizing Roche's Constitutional right to a jury trial in this action. As with all of Amgen's previously rejected attempts to reargue, this motion too is baseless and raises nothing but the same rehashed grounds to persuade this Court to trample Roche's Constitutional right to have its inequitable conduct defense tried to the jury. This Court has previously held that Roche's patent claims and defenses are triable to a jury as of right and the Court should reject Amgen's latest efforts to induce this Court to violate the Seventh Amendment for the following reasons:

- Roche's *Walker Process* antitrust counterclaims require jury determination of all facts underlying those claims. This includes inequitable conduct for precisely the reason Amgen admits: a prior judicial determination of *no* inequitable conduct would bind a subsequent jury adjudicating Roche's *Walker Process* claim, which turns on the existence of inequitable conduct. *Beacon Theatres*, *Dairy Queen* and the Federal Circuit's recent holding in *Shum* forbid precisely this end-run around the Seventh Amendment.
- Amgen's contention that adjudicating inequitable conduct may unfairly prejudice the jury or interject unwanted complexity founders on the Seventh Amendment. There is no complexity exception to the Seventh Amendment.

- Amgen's protestations of untoward complexity and unfair prejudice are, in any event, unfounded.

I. THE SEVENTH AMENDMENT REQUIRES A JURY TRIAL ON ROCHE'S INEQUITABLE CONDUCT DEFENSE¹

Amgen does not (and cannot) dispute that Roche's now-bifurcated *Walker Process* counterclaim is triable to a jury as of right. Nor does Amgen contest that inequitable conduct and *Walker Process* fraud "share common facts." On the contrary, Amgen affirmatively argues that if Roche's "inequitable conduct defense fails, its *Walker Process* antitrust counterclaim will be moot." (D.I. 1341 at 5). The reason is straightforward: If Roche cannot demonstrate inequitable conduct, Roche, *a fortiori*, cannot demonstrate *Walker Process* fraud, which is the same inequitable conduct but requires a higher level of demonstrated scienter. *See FMC Corp. v. Manitowoc*, 835 F.2d 114, 1417 (Fed. Cir. 1987). A bench determination of inequitable conduct (or not) will thus unfairly establish, through law of the case or collateral estoppel, facts that a later jury considering Roche's bifurcated *Walker Process* claim must take as binding. In other words, the Court's decision on Roche's inequitable conduct defense could preclude Roche's *Walker Process* claim (notwithstanding that a reasonable jury could find otherwise).

When, as here, adjudication of an otherwise equitable defense (here, inequitable conduct) may affect -- even terminate -- a subsequently adjudicated legal claim that is for a jury (here, *Walker Process*), because the equitable defense and the claim involve common factual issues, the Seventh Amendment requires that a jury decide the factual predicates of the equitable defense. The Federal Circuit recently so held in a case Amgen ignores. *See Shum v. Intel Corp.*, 2007 WL 2404718, at *4-*6 (Fed. Cir. Aug. 24, 2007) (district court violated Seventh Amendment by holding bench trial on equitable claim of prior inventorship because state-law fraud claim shared

¹ Roche incorporates herein by reference its prior submissions in support of its jury trial right on all claims and defenses in this case. (*See, e.g.*, D.I. 184, 739).

with that equitable claim common facts; reversing and requiring a jury trial on prior inventorship). There are additional decisions to the same effect that Amgen cannot distinguish and does not cite. *See Implant Innovations, Inc. v. Nobelpharma AB*, 1996 WL 568791, at *3 (N.D. Ill. Oct. 2, 1996) (“**to have a prior determination of the inequitable conduct aspect of the patent claim would violate the Seventh Amendment jury trial guarantee**” that attached to **Walker Process claims**) (emphasis added); *C.R. Bard, Inc. v. M3 Sys., Inc.*, 1994 WL 258889, at *2 (N.D. Ill. June 9, 1994) (Seventh Amendment required jury determination of inequitable conduct because subsequently-adjudicated legal claims involved “common” “factual issues”); *cf. Therma-Tru Corp. v. Peachtree Doors Inc.*, 44 F.3d 988, 994-95 (Fed. Cir. 1995) (reversing judicial inequitable conduct determination that conflicted with jury findings on validity and infringement).

In *C.R. Bard*, the court recognized that, under the Seventh Amendment, as elaborated in *Beacon Theatres, Inc. v. Westover*, 359 U.S. 500 (1959), and *Dairy Queen, Inc. v. Wood*, 369 U.S. 469 (1962), a bench “trial on whether Bard engaged in inequitable conduct is *precluded* if it would resolve factual issues common with factual issues” that “will be determined by a jury during the later stages of this case.” 1994 WL 258889, at *2 (emphasis added). Recognizing that the proposed inequitable conduct bench trial would involve resolution of factual questions that would have to be determined by a jury during the validity stage of the trial if the jury found infringement, the court concluded that “the factual issues” raised by the inequitable conduct defense “must be resolved first by the jury.” *Id.* Likewise, here, because determining whether Amgen engaged in inequitable conduct necessarily will decide factual issues that would be integral to a subsequent *Walker Process* claim, the Seventh Amendment requires the jury to determine the factual predicates of Roche’s inequitable conduct defense.

Amgen's arguments for avoiding the Seventh Amendment are baseless. Amgen states that *Beacon Theaters*'s rule is merely "prudential," citing *Parklane Hosiery Co. v. Shore*, 439 U.S. 322 (1979), and not violated by giving this Court's determination of inequitable conduct preclusive effect in a subsequent *Walker Process* jury phase of this action. Amgen clearly misreads *Parklane*. There, the Court upheld employing findings made in an *entirely different* equitable action to create collateral estoppel in a separate, subsequent jury action. *Id.* at 334. Here, in sharp contrast, the inequitable conduct defense and related *Walker Process* counterclaims are part of the "*same action.*" *Id.* (emphasis added). This is precisely the circumstances in which *Beacon Theatre* recognized, and *Parklane* reiterated, that the Constitution does *not* permit a prior judicial determination of factual issues that control legal claims, because such an exercise of judicial discretion would not "preserve the jury trial right." *Id.* at 333-34. Put differently, the Court's bifurcation of the patent claims from the antitrust claims under Rule 42(b) is no license to achieve precisely the result that *Beacon Theatres* and the Seventh Amendment preclude. *See Shum*, 2007 WL 2404718, at *3 ("When deciding whether issues should be separately tried [under Rule 42(b)], trial courts *must* ensure that a litigant's constitutional right to a jury is preserved") (emphasis added). Whatever discretion courts may possess to try equitable issues that bind legal claims in other contexts, that discretion is not properly exercised where, as here, Roche's jury trial right is easily "preserve[d]" by trying inequitable conduct to the jury. *Parklane*, 439 U.S. at 334; *Shum*, 2007 WL 2404718, at *4; *see also Cabinet Vision v. Cabnetware*, 129 F.3d 595, 600-61 (Fed. Cir. 1997) (error to treat jury findings on inequitable conduct defense as advisory because that defense and *Walker Process* claims possess "substantial commonality" and the Seventh Amendment "constrains the court's equitable discretion").

Amgen's other cases are similarly distinguishable. *Gardco Mfg., Inc. v. Herst Lighting Co.*, 820 F.2d 1209 (Fed. Cir. 1987), as a later court observed, "did not include an antitrust claim." *Implant Innovations*, 1996 WL 568791, at *3. Moreover, the court in *Gardco* determined that the issues raised by inequitable conduct and subsequent legal claims were "without commonality either as claims or in relation to the underlying factual issues." *Gardco*, 820 F.2d at 1231; *see also Shum*, 2007 WL 2404718, at *5 (so distinguishing *Gardco*). Here, by contrast, the requisite commonality exists between inequitable conduct and *Walker Process* fraud.

Implant Innovations rejected precisely the argument Amgen now makes based on *Gardco*. In *Implant Innovations*, the alleged infringer advanced *Walker Process* counterclaims and an inequitable conduct defense. The court granted the patentee's motion to bifurcate the antitrust claims, but recognized that, in contrast to *Gardco*, "the inequitable conduct issue overlaps with the antitrust claims" because rejection of inequitable conduct would terminate the *Walker Process* claims. 1996 WL 568791, at *3. Accordingly, the court ruled that "to have a prior determination by the Court of the inequitable conduct aspect of the patent claim would violate the Seventh Amendment jury trial right." 1996 WL 568791, at *3. "Rather, in order to preserve [the putative infringer's] Seventh Amendment jury trial guarantee [on its *Walker Process*] claims, ... *inequitable conduct issue must be tried by a jury.*" *Id.* (emphasis added).²

Implant Innovations, which Amgen does not cite, also defeats Amgen's further argument

² Amgen's other cases are also distinguishable, either because they did not involve *Walker Process* counterclaims (and thus did not raise the Seventh Amendment issues presented here), *see, e.g., Hebert v. Lisle Corp.*, 99 F.3d 1109 (Fed. Cir. 1996); *Trading Techs. Int'l, Inc. v. eSpeed, Inc.*, 2007 U.S. Dist. LEXIS 61620 (D. Ill. Aug. 20, 2007), or involved inapposite circumstances, *see, e.g., Johns Hopkins Univ. v. CellPro*, 1997 U.S. Dist. LEXIS 24161, at *18-1 (D. Del. 1997) (parties consented to bench trial on inequitable conduct and only following adverse decision raised Seventh Amendment objection); *Applera Corp. v. Micromass UK Ltd.*, 204 F. Supp. 2d 781, 82 (D. Del. 2002) (no apparent objection to judicial determination of no inequitable conduct and subsequent termination of *Walker Process* claims).

that the Seventh Amendment is somehow inapplicable because *Walker Process* requires elements beyond inequitable conduct. (D.I. 1341 at 4-5). The Seventh Amendment precludes a prior bench trial on “factual issues” “common” to a subsequently-tried jury claim. *Shum*, 2007 WL 2404718, at *3-*4; *C.R. Bard*, 1994 WL 258889, at *2. Because, as Amgen concedes, a judicial determination of inequitable conduct would *control* and possibly preclude Roche’s *Walker Process* counterclaim, the required “common factual issues” are plainly present. *See Implant Innovations*, 1996 WL 568971, at *3 (requisite commonality between inequitable conduct and *Walker Process* present because “should the patents be found valid and enforceable in the patent trial, a motion for directed verdict on Defendant’s *Walker Process* [claims] may be in order” (internal quotations omitted)).

That *Walker Process* requires proof of additional elements thus does not negate the existence of the overlap that triggers the Seventh Amendment. *See Cabinet Vision*, 129 F.3d at 600-61. The Federal Circuit recently made this plain in *Shum*, 2007 WL 2404718 at *5-*6:

Moreover, appellees admit in their brief, “[o]nce the district court decided that Verdiell, and not Shum, had truly invented the technology, th[e] fraud claims were eviscerated.” Appellees also contend that “[i]f this Court affirms the district court’s inventorship ruling, Shum’s arguments that Verdiell misrepresented or concealed the true inventor of the technology must fail.” *Thus, the record underscores that Shum’s inventorship claim is “inextricably intertwined” with at least one of his state law claims.*”

(emphasis added). Just as the *Shum* court recognized that an adverse bench ruling on inventorship would terminate legal state-law fraud claims, so too here an adverse adjudication by this Court on Roche’s inequitable conduct defense would (as Amgen concedes) terminate Roche’s *Walker Process* counterclaims. Consequently, as in *Shum*, where the Seventh Amendment required a jury trial on the equitable claim of prior inventorship, here the Seventh Amendment requires a jury trial on Roche’s inequitable conduct defense.

Amgen's further argument that if Roche cannot persuade the Court of its inequitable conduct defense it ought not present the issue to the jury (D.I. 1341 at 5) is misplaced. The question of whether a reasonable fact finder could find in Roche's favor on inequitable conduct is separate and distinct from the question of whether Roche is entitled to a jury as of right. In other words, "the purpose of [judgment as a matter of law] is not to cut litigants off from their right of a trial by jury if they have real issues to try." *Poller v. Columbia Broadcasting Sys., Inc.*, 368 U.S. 464, 467 (1962). Here, because the Court denied Amgen's motion for summary judgment on Roche's inequitable conduct defense (D.I. 762), the Court has determined that there are "real issues to try" and a reasonable finder of fact could conclude that Amgen engaged in inequitable conduct.

Accordingly, Amgen's latest attempt to take inequitable conduct away from the jury runs contrary to well-established principles of law and should be denied.

II. AMGEN'S ALLEGATIONS OF JURY CONFUSION AND PREJUDICE ARE BASELESS AND UNFOUNDED IN LAW

In an attempt to persuade the Court to ignore the law and focus instead on Amgen's idea of "fairness," Amgen argues that potential jury confusion, complexity and prejudice warrant taking the inequitable conduct defense away from the jury. (D.I. 1341 at 6-11). There is, however, no "complexity", "confusion" or "prejudice" exception to the Seventh Amendment, *see, e.g., In re U.S. Fin. Sec. Litig.*, 609 F.2d 411, 432 (1979) ("We hold that there is no complexity exception to the Seventh Amendment right to jury trial in civil cases."); *SRI Int'l v. Matsushita Elec. Corp. of Am.*, 775 F.2d 1107, 1127-30 (Fed. Cir. 1985) (Markey, C.J., additional views). As one court has stated:

Those who would seek an "elitest" approach to the use of the jury trial would undermine one of our most fundamental rights. There is no complexity exception to a jury trial that would authorize the denial of a jury when it is otherwise

available under the Seventh Amendment.

Kian v. Mirro Aluminum Co., 88 F.R.D. 351, 355, 209 U.S.P.Q. 272, 275 (E.D. Mich. 1980).

It is, therefore, no surprise that not one of the cases cited by Amgen in support of its “complexity” and “prejudice” arguments involve the situation presented here -- where a party is entitled to a jury as a matter of right under the Seventh Amendment. Indeed, *Trading Techs. Int’l v. eSpeed, Inc.*, cited by Amgen (D.I. 1341 at p. 7 n.21), specifically states that the bench trial Amgen proposes is appropriate *only* where it “does not violate the Seventh Amendment.” 2007 U.S. Dist. LEXIS 61620, at *3 (N.D. Ill. Aug. 20, 2007).

Even if there was a “complexity exception” to the Seventh Amendment, the fact remains that Roche’s inequitable conduct case is scientifically less technical and certainly no more complex than the other phases of this case in which the jury has already heard considerable evidence.

Moreover, Amgen mischaracterizes Roche’s inequitable conduct defenses. For one, as the Court recognized in denying Amgen’s motion for summary judgment of no inequitable conduct, (D.I. 762), Amgen errs in arguing that “Roche cannot offer any evidentiary support” for its inequitable conduct defense. (D.I. 1341 at 7). Furthermore, the dynamic of the evidence adduced at trial, which was not even available at the pleading or the summary judgment phases, provides the jury with additional evidence and factual bases upon which the jury may determine that inequitable conduct occurred. In that regard, under controlling First Circuit authority, the Court should conform the pleadings to the trial proof on this issue as well. Fed. R. Civ. P. 15(b); *see also Law v. Ernst & Young*, 956 F.2d 364, 375 (1st Cir. 1992).

Roche’s inequitable conduct defenses were a part of this case long before this Court made its ruling to bifurcate ODP. Hence, Roche’s “first allegation” of inequitable conduct (*see* D.I.

1341 at 9) is plainly not the pretext that Amgen claims. In addition, it is black letter law that inequitable conduct may be found even if the patent-at-issue would have been valid and enforceable but for the applicant's misconduct. *See, e.g., Digital Control Inc. v. Charles Machine Works*, 437 F.3d 1309, 1318 (Fed. Cir. 2006) ("Under the 'reasonable examiner' standard, a misstatement or omission may be material even if disclosure of that misstatement or omission would not have rendered the invention unpatentable"). Therefore, the merits of Roche's inequitable conduct defense do not depend on the merits of Roche's obviousness-type double patenting defenses. The fact that the Court is deciding Roche's ODP defenses does not change the facts surrounding Amgen's material misrepresentations and omissions to the patent examiner(s), evidence of Amgen's intent to deceive and other related issues, such as witness credibility, which presently are factual questions for the jury to decide. *See, e.g., General Electro Music Corp. v. Samick Music Corp.*, 19 F.3d 1405, 1411 (Fed. Cir. 1994) (even when prosecuting attorney testifies to lack of intent, "the jury's assessment of [his] character is entitled to great deference"). Simply put, inequitable conduct and ODP are separate issues and the fact that one of Roche's inequitable conduct allegations relates to Amgen's fraudulent attempt to overcome an ODP rejection during patent prosecution does not diminish Roche's right to a jury trial.

Amgen's arguments regarding this Court's prior exclusion of rulings from past litigations is a strawman that is easily disposed with. The Court's exclusion was aimed at avoiding the prejudice that would undoubtedly result from Amgen's suggestion that those prior proceedings were dispositive in this case. As the Court made clear, the prior decisions were irrelevant as far as they touched on similar issues in this case. (Trial Tr. 458:12-24). However, where, as here, those prior rulings are highly pertinent to Roche's inequitable conduct defense because it

evidences Amgen's knowledge of information that would have been material to a reasonable examiner, any "confusion" is substantially outweighed by the prejudice to Roche if the evidence is not presented.

Amgen's argument with respect to Roche's inequitable conduct contentions relating to misrepresentations and omissions as to purported differences between urinary EPO and recombinant EPO is similarly without merit. (*See* D.I. 1341 at 10).¹ As an initial matter, any overlap between these issues and those presented during the invalidity phase undermines Amgen's argument that inequitable conduct is too "complex" for a jury to understand. As Amgen admits, the parties have already presented the jury with substantive evidence on this issue. The only asserted bases for Amgen's purported concerns of prejudice are that (1) the withheld material was cumulative and (2) the Court has already rejected the same claim in the *TKT* litigation. As to the argument that the withheld evidence is cumulative, although untrue, Amgen is surely free to make that argument to the jury. Indeed, in defending against a charge of inequitable conduct, patentees often argue to the jury that the allegedly withheld information is merely cumulative. *See, e.g., Dippin' Dots, Inc. v. Mosey*, 476 F.3d 1337, 1347-48 (Fed. Cir. 2007) (jury presented with issue of whether information was cumulative). In any event, Amgen does not explain how the issue of cumulativeness amounts to prejudice.

As to the latter point, this Court did not consider the entirety of Roche's argument, nor the entirety of Roche's evidence in *TKT*. In any event, it is wholly unclear how this "fact" could ever amount to prejudice or confusion in the current case, where the ultimate holding in *TKT* is irrelevant and, as this Court has properly recognized, not binding on Roche. (Summary Judgment Hearing Tr. (7/17/07) 26:11-19).

¹ For each theory of inequitable conduct, Amgen's misconduct is also evidenced by the fact that Amgen and its attorneys buried material information.

Finally, there is no substance to Amgen's challenge to Roche's allegation that Amgen committed inequitable conduct by failing to disclose rejections in co-pending applications. First, Amgen does not even contend that presentation of this defense would cause prejudice, instead treating this as a renewed motion for summary judgment. (D.I. 1341 at 10-11). Furthermore, the Federal Circuit has acknowledged that the basis for Roche's inequitable conduct argument is proper under the patent laws. *McKesson Info. Solutions, Inc. v. Bridge Med., Inc.*, 487 F.3d 897 (Fed. Cir. 2007) (inequitable conduct where applicant failed to disclose rejections in co-pending applications).

Amgen's argument that the co-pending applications had already been deemed to be patentably distinct (D.I. 1341 at 10) is wholly unsupported by any evidence and is, in fact, untrue. For example, Amgen's '422 patent, which issued from the '179 application, is by Amgen's own admission patentably *indistinct* from the '933 patent, which issued from the '178 application, because Amgen terminally disclaimed the '422 patent over the '933 patent. (TRX 2009.766). Each of these patents is central to Roche's defense. Moreover, Amgen's argument that Examiner Martinell "necessarily reviewed the prosecution histories" (D.I. 1341 at 10-11) is belied by its own citation to MPEP § 704.01 (8th ed. Rev. 5 Aug. 2006) which instructs the examiner to give full faith and credit and not "attempt to reorient the examination of a prior examiner, or make a new search in the mere hope of finding something." More importantly, as Roche pointed out in opposing summary judgment on its inequitable conduct defense, *McKesson* disposes of Amgen's argument that Examiner Martinell "necessarily" knew the detailed history of all pending applications. *See McKesson*, 487 F.3d at 925-26 (noting that an attorney should not "assume that [a PTO examiner] retains details of every pending file in his mind when he is reviewing a particular application"). In any event, none of Amgen's arguments have any

relevance to its pending motion and should therefore be ignored.

III. CONCLUSION

Based on the foregoing this Court should preserve Seventh Amendment right to a jury trial and again deny Amgen's motion.

Dated: October 14, 2007
Boston, Massachusetts

Respectfully submitted,

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