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Recalibrating Our Empirical Understanding of Inequitable Conduct

Jason Rantanen*

The belief that allegations of inequitable conduct in patent suits were—and remain—a disease has received widespread publicity and endorsement. Despite the extreme rarity of an ultimate finding of inequitable conduct,[1] the empirical claim recently made by the Court of Appeals for the Federal Circuit sitting en banc in *Therasense v. Becton Dickinson*,[2] by the proponents of the creation of the Supplemental Examination procedure that Congress passed and the President signed in the fall of 2011,[3] and most recently by the Patent Office in its rules on Supplemental Examination,[4] was that inequitable conduct is a plague, "appearing in nearly every patent suit."[5] The rarity of an ultimate finding of inequitable conduct is taken to bolster, rather than diminish, the argument in favor of weakening the doctrine: the inequitable conduct doctrine is a problem precisely because it is always pled though almost never found; it clutters up the administrative and litigation systems despite rarely existing in actuality.[6]

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* Associate Professor of Law, The University of Iowa College of Law. The author would like to thank Lee Petherbridge, David Schwartz, Jonas Anderson, Doru Cojoc, and Dennis Crouch for comments on an earlier draft of this article, as well as Courtney Burks and Zachary Pratt for excellent research assistance.

1. *See* Lee Petherbridge, Jason Rantanen, & Ali Mojibi, *The Federal Circuit and Inequitable Conduct: An Empirical Assessment*, 84 S. Cal. L. Rev. 1293, 1340 (2011) (finding that the Federal Circuit reached an ultimate conclusion that inequitable conduct was committed about 2.5 times a year for the period from 1983-2010).
2. Therasense, Inc. v. Becton, Dickinson and Co., 649 F.3d 1276, 1289 (Fed. Cir. 2011).
3. Joe Matal, *A Guide to the Legislative History of the America Invents Act: Part II of II*, 21 Fed. Cir. B.J. 539, 546 (2012).
4. Changes To Implement the Supplemental Examination Provisions of the Leahy-Smith America Invents Act and To Revise Reexamination Fees, 77 Fed. Reg. 48828 (Aug. 14, 2012) (to be codified at 37 C.F.R. pt. 1).
5. *Therasense*, 649 F.3d at 1289 (quoting Kimberly-Clark Corp. v. Johnson & Johnson, 745 F.2d 1437, 1454 (Fed.Cir.1984)).
6. *See, e.g., id.* ("Left unfettered, the inequitable conduct doctrine has plagued not only the courts but also the entire patent system. Because allegations of inequitable conduct are routinely brought on 'the slenderest grounds,' Burlington Indus., 849 F.2d at 1422, patent prosecutors constantly confront the specter of inequitable conduct charges."). It should be noted that underlying this conclusion is another empirical assumption not addressed in this paper: that inequitable conduct rarely exists because it is rarely found by a court. It is entirely possible, however, that the most egregious cases of inequitable conduct never make their way to a court determination – they are settled between the parties without the facts of the inequitable conduct ever being made public or are made with regard to patents.

Surprisingly, however, the empirical evidence cited to support these claims is slender. While assertions about the rate at which inequitable conduct is pled are common, they are largely unsupported by any actual data.[7] In *Therasense*, for example, the court cited a 1988 "Position Essay" prepared by a committee of the American Intellectual Property Law Association as a study that "estimated that eighty percent of patent infringement cases included allegations of inequitable conduct."[8] The "Position Essay," however, contained no data or other evidence to support its estimate.[9]

More robust was the court's citation of Dr. Christian Mammen's 2009 empirical study of inequitable conduct.[10] This was logical: Mammen's study was a strong work of scholarship that provided a thorough, well-explained empirical analysis of inequitable conduct claims from start to finish, from the pleading stage to their ultimate outcome at the Federal Circuit.[11] It was the first, and to date only, study to address the "plague" claim using such a comprehensive set of empirical data.[12]

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7. While claims of the rate at which inequitable conduct has historically been pled are common, empirical studies are not. *See, e.g.*, Christopher A. Cotropia, *Modernizing Patent Law's Inequitable Conduct Doctrine,* 24 Berkeley Tech. L.J. 723, 739 (2009) ("By recent estimates, the inequitable conduct defense is asserted in around one fourth of all patent cases filed."); Benjamin Brown, Comment, *Inequitable Conduct: A Standard in Motion*, 19 Fordham Intell. Prop. Media & Ent. L.J. 593, 608 (2008) ("[C]ourts addressed, on average, inequitable conduct in less than 20% of all reported patent cases. This figure must be qualified, however, because it is almost impossible to ascertain the number of times inequitable conduct was pled, given that approximately 86% of patent cases settle."); Kevin Mack, Note, *Reforming Inequitable Conduct to Improve Patent Quality: Cleansing Unclean Hands,* 21 Berkeley Tech. L.J. 147, 155–56 & tbl.1 (2006) ("[F]rom 2000 to 2004, an inequitable conduct adjudication appeared in 16% to 35% of all reported patent opinions . . . . [I] t can be inferred that the percent of patent cases in which a litigant ple[d] inequitable conduct is substantially higher than these figures."); *see also* 155 Cong. Rec. S2715 (daily ed. Mar. 3, 2009) (statement of Sen. Hatch) ("The inequitable conduct defense is frequently pled, rarely proven, and always drives up the cost of litigation tremendously.").

8. *Therasense*, 649 F.3d at 1289.

9. Committee Position Paper, *The Doctrine of Inequitable Conduct and the Duty of Candor in Patent Prosecution: Its Current Adverse Impact on the Operation of the United States Patent System*, 16 AIPLA Q.J. 74 (1988); Thomas F. Cotter, *An Economic Analysis of Patent Law's Inequitable Conduct Doctrine,* 53 Ariz. L. Rev. 735, 737 n.2 (2011). In any event, the relevance of the rate at which inequitable conduct was pled in 1988 is of dubious relevance to the rate at which it was being pled contemporaneously with the *Therasense* decision.

10. *Therasense*, 649 F.3d at 1289.

11. Christian E. Mammen, *Controlling the "Plague": Reforming the Doctrine of Inequitable Conduct*, 24 Berkeley Tech. L.J. 1329, 1358 (2009) (concluding that a defense of inequitable conduct was raised in about 40% of all patent cases filed in 2007 and 2008).

12. Besides the Mammen study, the sole other empirical study of the rate at which inequitable conduct is pled of which I am aware is a 2011 report by five researchers at LexMachina that found that inequitable conduct was pled in 3,033, out of 13,786 total patent infringement cases (about 22% of cases) for the period between January 1, 2005 and May 31, 2010. That study does not provide any more refined data on pleadings than these numbers, and does not appear to have been subsequently cited. Lex Machina, Inequitable Conduct Defense in Patent Litigation (2005–2010) (Jan. 15, 2011) https://lexmachina.com/2011/01/15/inequitable-conduct-defense-in-patent-litigation-2005-2010/ (select "Download" to access the report).

While the Mammen study provides a number of results regarding inequitable conduct (the majority of which are undisturbed by this analysis), the primary evidence supporting the "plague" claim was a reported *ten-fold* increase in the rate at which inequitable conduct was pled between the years 2000 and 2008, increasing from a rate of 4% of patent cases in 2000 to 40% of patent cases by 2008,[13] a figure that has been cited by commentators[14] and the Patent Office in its Rules on Supplemental Examination.[15] It also represents the primary (and perhaps sole) actual empirical data supporting the claim of a dramatic increase in pleadings of inequitable conduct.

In contrast, substantially more empirical data is available about the other end of the lifecycle of an inequitable conduct claim, that is, its final fate before the United States Court of Appeals for the Federal Circuit.[16] In addition to the Mammen study, which also looked at the outcome of appeals involving inequitable conduct before the Federal Circuit, there are multiple studies providing data on outcomes at the Federal Circuit level.[17] These studies have found that the Federal Circuit rarely reaches an ultimate conclusion of inequitable conduct: historically, the frequency averaged about two-and-a-half times a year for the period from 1983-2010.[18]

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13. *See* Mammen, *supra* note 11 at 1358.
14. *See e.g.*, Cotter, *supra* note 9, at 737 n.2 (citing Mammen for the 40% figure); Sona De, *The Inequitable Conduct Defense: Before and After* Therasense, 24 Intell. Prop. & Tech. L.J. 15, 15 (2012) (citing Mammen for the 10-fold increase); Jeffrey M. Kuhn, *Information Overload at the U.S. Patent and Trademark Office: Reframing the Duty of Disclosure in Patent Law As a Search and Filter Problem*, 13 Yale J.L & Tech. 90, 92 (2010); Christian Mammen, *Revisiting the Doctrine of Inequitable Conduct Before the Patent and Trademark Office*, 21 Fordham Intell. Prop. Media & Ent. L.J. 1007, n.11 (2011) (citing the 2009 study for its chart showing the steady increase in assertions of the defense); Zhe (Amy) Peng et al., *A Panacea for Inequitable Conduct Problems or Kingsdown Version 2.0? The* Therasense *Decision and a Look into the Future of U.S. Patent Law Reform*, 16 Va. J.L. & Tech. 373, 388 (2011) (reprinting the Mammen data); Nicole H. Kattah & Rebecca M. McNeil, *Patent Legislation—Meeting the Challenges of Reform?*, Finnegan (Jan. 28, 2011) *available at* http://www.finnegan.com/resources/articles/articlesdetail.aspx?news=55afa121-df47-4a71-9f49-028499843331 (citing Mammen for the 40% figure).
15. Changes To Implement the Supplemental Examination Provisions of the Leahy-Smith America Invents Act and To Revise Reexamination Fees, 77 Fed. Reg. 48828 (Aug. 14, 2012) (to be codified at 37 C.F.R. pt. 1) ("Note that inequitable conduct is pled in approximately 40 percent of the patent cases filed annually in the U.S. District Courts" and also citing Mammen for the chart "estimating the steady increase in assertions of the inequitable conduct defense.").
16. In theory, the Supreme Court could grant certiorari on a question involving the doctrine of inequitable conduct. Although the doctrine is itself rooted in a trio of Supreme Court decisions from the 1930's and 40's, see *Therasense* 649 F.3d at 1306, the Court has never granted certiorari on a petition involving inequitable conduct in its modern form.
17. *See* Petherbridge, Rantanen, & Mojibi, *supra* note 1; Donald R. Dunner, et al., *A Statistical Look at the Federal Circuit's Patent Decisions: 1982–1994*, 5 Fed. Cir. B.J. 151, 173 tbl. 4 (1995). For a comprehensive summary of empirical literature on inequitable conduct, *see* Petherbridge, Rantanen, & Mojibi, *supra* note 1, at fn. 30.
18. *See, e.g.,* Mammen, *supra* note 11, at 1354 (finding an average of 2.5 Federal Circuit rulings of inequitable conduct per year from 1983-2008); Petherbridge, Rantanen, & Mojibi, *supra* note 1, at 1340 (same for the period 1983-2010). *See also,* Dunner, et al., *supra* note 17, at 173 tbl. 4 (1995) (finding inequitable conduct in 19% of the appeals addressed between October 1, 1982–March 15, 1994).

This Essay focuses primarily on the first quantitative issue: the rate at which inequitable conduct is pled. Despite routinely being the subject of empirical claims, there is surprisingly little data to draw upon. This Essay examines the only prior study to address this issue and builds on that study's approach to provide a clearer picture of the pleading rate for inequitable conduct. The purpose of this Essay is thus not to develop a refined theory of inequitable conduct based on a detailed empirical examination of the Federal Circuit's inequitable conduct jurisprudence; that has been done elsewhere.[19] Rather, its goal is to apply relatively simple and straightforward techniques that can be easily replicated in order to better understand the rate at which inequitable conduct claims are asserted.

The results of this approach reveal that while pleadings involving inequitable conduct did – probably – experience a modest increase from 2000 to 2008, the "strong upward trend" of 4% to 40%[20] is implausible, as is the Federal Circuit's assertion of an 80% pleading rate in *Therasense*.[21] More significantly, to the extent one accepts that meaningful patterns can be established by a few years' worth of data, as courts, the patent office, and commentators seem willing to do, since 2008, allegations of inequitable conduct have fallen precipitously, at least to the extent they can be measured by Answers and Counterclaims. In 2008, 41% of patent cases in which Answers were filed contained the term "inequitable conduct" in an Answer; for 2012, that rate fell to 21%. Federal Circuit determinations of inequitable conduct remain rare, of course; one would expect nothing else - particularly in light of *Exergen* and *Therasense*.

Beyond the immediate issue of inequitable conduct, however, the analysis presented by this Essay raises a greater issue about the use of empirical studies. Empirical legal studies present a dilemma: they are an extremely valuable tool, but at the same time carry a risk of misuse and error. As illustrated by the example addressed in this Essay, such studies can be misused even when the scholar creating the study does everything necessary to make the study as transparent as possible. The final section of this Essay addresses this issue, arguing for greater scholarly engagement with (as opposed to passive citation of) empirical legal studies.

I. The Rate at Which Inequitable Conduct is Pled

Inequitable conduct is a doctrine whose oft-described purpose is to ensure that patent applicants act with candor in their dealings with the patent office during the ex parte process

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19. Petherbridge, Rantanen, & Mojibi, *supra* note 1; *see also* Lee Petherbridge, Jason Rantanen, & R. Polk Wagner, *Unenforceability* (2012), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2167417 (empirically examining the differences between patents found unenforceable and several other types of patents and concluding that the doctrine is likely to be operating better than the conventional wisdom would suggest).
20. Mammen, *supra* note 11, at 1357, tbl.2.
21. Therasense, Inc. v. Becton, Dickinson & Co., 649 F.3d 1276, 1289 (Fed. Cir. 2011) (citing a study that "estimated that eighty percent of patent infringement cases included allegations of inequitable conduct").

of patent examination.[22] Unlike most other mechanisms that police a party's behavior in interacting with the government through government-imposed consequences,[23] inequitable conduct is a defense and counterclaim that may be raised by another private party, namely, the accused infringer in a patent suit.[24] A successful inequitable conduct claim is potent: it may render the entire patent unenforceable.[25] Inequitable conduct is thus both an affirmative defense that may be raised by an accused infringer and a counterclaim that may be asserted; in either case it must be pled with particularity.[26]

The fundamental elements of an inequitable conduct claim have long been constant: the requirement of materiality, which involves an inquiry into the severity of the patent applicant's wrongful conduct, and the requirement of intent, which involves a parallel inquiry into whether the material act or omission was committed with the "intent to deceive" the patent office.[27] This is not to say that there has been unwavering and consistent application of these elements; *Therasense* itself illustrates that both materiality and intent have each been subject to wide disagreement over the relevant standards, and *Therasense* itself altered the way they are analyzed.[28]

A. Limitations of the Prior Study

As a starting point, it is important to recognize that the Mammen study was a substantial and important contribution to the literature on inequitable conduct. It was the first to thoroughly investigate inequitable conduct over the entire lifespan of the Federal Circuit using empirical data, and it approached the issue from a variety of perspectives. In addition

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22. Petherbridge, Rantanen, & Mojibi, *supra* note 1, at 1296. This is the primary justification given for the doctrine; other theories have been articulated as well. *See, e.g.* Jason Rantanen & Lee Petherbridge, Commentary, *Toward a System of Invention Registration: The Leahy-Smith America Invents Act*, 110 Mich. L. Rev. First Impressions 24 (2011).
23. Ryan Vacca, *Patent Reform and Best Mode: A Signal to the Patent Office or a Step Toward Elimination?*, 75 Alb. L. Rev. 279 (2012).
24. *Therasense*, 649 F.3d at 1285.
25. *See* Kingsdown Med. Consultants, Ltd. v. Hollister, Inc., 863 F.2d 867, 877 (Fed. Cir. 1988) (relevant part en banc) ("When a court has finally determined that inequitable conduct occurred in relation to one or more claims during prosecution of the patent application, the entire patent is rendered unenforceable.").
26. 6 Donald S. Chisum, Chisum on Patents § 19.03 [6][b][ii] (2007). An inequitable conduct claim might also be raised by an alleged infringer in an initial Declaratory Judgment Complaint; however, this is unlikely to substantially impact the results of this study given that a patent holder will almost inevitably respond to the Declaratory Judgment Complaint with a counter-assertion of patent infringement, thus causing the accused infringer to re-assert its inequitable conduct claim as a defense and leading, for purposes of this study, to a "hit."
27. *See, e.g.*, *Therasense*, 649 F.3d 1276; Molins PLC v. Textron, Inc., 48 F.3d 1172, 1178, 1181 (Fed. Cir.1995); Petherbridge, Rantanen & Mojibi, *supra* note 1, at 1297–98. A third doctrinal step, the "balancing of the equities" has also long been considered part of the inequitable conduct inquiry, but in practice it rarely affects the outcome. *See* Petherbridge, Rantanen & Mojibi, *supra* note 1, at 1321.
28. *Therasense*, 649 F.3d at 1287–90.

to its groundbreaking nature, it was also an extremely transparent study: Mammen carefully reported each step of the methodology he employed in great detail so that it could be replicated by future scholars; far more detail, in fact, than many empirical legal studies provide. Indeed, this Essay would have involved a substantially greater undertaking if Mammen had not been so transparent with his methodology. In addition, many of the observations of the study remain completely undisturbed by the limitations discussed below; indeed, some were subsequently confirmed.[29] The purpose of the following discussion is simply to subject a narrow slice of the study to scholarly critique; it is in no way intended to challenge the study as a whole.

That narrow slice involves Mammen's observation of a dramatic rise in the rate at which inequitable conduct was being pled, which led him to conclude that "the prevalence of inequitable conduct cases is expanding, especially at the pleading stage."[30] For reference, the relevant portion the key table from the 2009 study is below.[31]

Figure 1: Table 2 from Mammen, "Controlling the Plague"

	A	B	C	D	E	F	G	H
	District Courts			Federal Circuit			IC @ CAFC ÷ IC Pled	IC @ CAFC ÷ Patent Cases Filed
Year	Patent Cases Filed	IC Pled	IC Pled ÷ Cases Filed	IC	No IC	DCT Vacated		
2000	2484	110	4%	3	11	1	2.73%	0.12%
2001	2520	200	8%	2	16	0	1.00%	0.08%
2002	2700	362	13%	2	8	2	0.55%	0.07%
2003	2814	565	20%	2	13	2	0.35%	0.07%
2004	3075	759	25%	0	4	2	0.00%	0.00%
2005	2720	827	30%	5	6	3	0.60%	0.18%
2006	2830	926	33%	3	16	3	0.32%	0.11%
2007	2896	1148	40%	5	6	1	0.44%	0.17%
2008	2909	1157	40%	4	14	1	0.35%	0.14%

On its face, Mammen's Table 2 appears to support the concept of a growing plague of inequitable conduct claims. It indicates that between 2000 and 2008, the number of pleadings containing "inequitable conduct" went from 110 to 1157, resulting in an increase

29. *See* Petherbridge, Rantanen, & Mojibi, *supra* note 1, at 1300, 1311, 1313, 1341 (confirming Mammen's findings on issues relating to Federal Circuit appeals of inequitable conduct).
30. Mammen, *supra* note 11, at 1361.
31. Data from 1991 to 1999 is omitted from Mammen Table 2. Although Mammen's searches of pleadings extended back to 1991, he himself expressed skepticism about the reliability of the period prior to 2000. *Id*. at 1349 n. 87.

of the rate at which inequitable conduct was being pled from 4% of patent cases to 40% of patent cases. A plague indeed.

There are two significant limitations of this data, however, that subsequent users of the data have failed to consider, leading to overreliance on the results from the 2009 study. Fortunately, Mammen provided complete details of his process for collecting the above data. Thus, Mammen's study can be replicated, a key element of validity for any empirical study of this type, and those limitations identified and addressed.

First, to collect his data, Mammen searched Westlaw's Answers and Counterclaims database for documents containing both of the terms "inequitable conduct" and "patents," and reported the number of hits.[32] This approach, while an appealing methodology, is subject to artifacts that result from the composition of the Westlaw database. Particularly significant to this study that there is strong reason to suspect that the completeness of Westlaw's electronic database of court filings is not consistent over all time periods studied; to the contrary, the size of Westlaw's database has a direct, positive correlation with the year, at least for the period 2000 to approximately 2007.[33] Put another way, Westlaw contains a substantially greater number of patent-related pleadings *in general* for the year 2008 than for the year 2000, likely because during the early part of the decade most courts did not utilize electronic dockets that Westlaw can easily draw from. The result is that there is strong reason to suspect that Table 2 from the Mammen study may be providing data about an increase in the contents of the Westlaw database from 2000 to 2008, rather than on an increasing number of inequitable conduct pleadings.

A second crucial limitation of the data reported in Table 2 of the 2009 study is that it compares *pleadings filed* to *cases filed* to arrive at a percentage of cases that involved a claim of inequitable conduct.[34] Absent prior knowledge of a one-to-one ratio of Answers and Counterclaims to cases, this comparison is an apples-to-oranges calculation. Indeed, rather than assuming a one-to-one ratio, the opposite assumption is more plausible, given that patent cases often involve multiple accused infringers and multiple iterations of Complaints, Answers and Counterclaims.[35] These First Amended Complaints, Second Amended Complaints, etc. typically restate the same

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32. Mammen, *supra* note 11, at 1349–50 n. 82–88.
33. The empirical support for this assertion is provided in Table 1. It reflects a 620% increase in Answers and Counterclaims that contain the term "patent" that are searchable in Westlaw from the 2000 to the 2008. Indeed, searching for almost any term in this database will likely lead to a similar increase. For example, searching for the term "chicken" in this database produces 285 results for 2000 and 1610 for 2008, an increase of 635%. ("chicken" search conducted on December 6, 2012).
34. Mammen's procedure describes drawing data on numbers of pleadings from Westlaw and the Stanford IP Clearinghouse (now known as LexMachina) and data on numbers of patent cases filed in a given year from the U.S. Courts annual reports. *See* Mammen, *supra* note 11, at 1349–50 n. 82–88.
35. For example, in *Abbott Laboratories v. Sandoz, Inc*., Case No. 05c5373 (N.D. Ill.), Abbott filed at least a Complaint, First Amended Complaint, Second Amended Complaint, and Third Amended Complaint; various accused infringers filed Answers and Counterclaims in response each.

allegations and should not be counted multiple times. In addition, where there are multiple accused infringers in a single patent suit, the accused infringers will typically piggy-back on the allegations made by each other. Consequently, even if one assumes that Westlaw's database was reasonably complete by 2008, the process of comparing pleadings to cases will *overstate* the number of cases in which inequitable conduct was actually alleged. For example, if one hypothesizes that four Answers and Counterclaims, on average, were filed in each patent case, then a direct comparison of pleadings to cases (without taking this factor into account) would cause the rate at which inequitable conduct was being pled to appear to be four times what it actually is. In actuality, this assumption is probably fairly close, or perhaps even a bit low.[36]

The net result of these two limitations is that they raise a serious question as to whether the 2009 study simply reports on the growing completeness of the databases that were searched, and whether the ratios calculated in the study are indicative of the rates at which inequitable conduct was actually being pled in patent cases.

B. Recalibrating the Measure of Pleadings

Due to Mammen's careful recordation of his procedures, however, the limitations described above may be overcome by recalibrating the approach described in the 2009 study to yield a more accurate picture. To obtain the data presented in this section, I conducted the same search performed by Mammen on the same database, that is, I searched Westlaw's "Pleadings" database for "Answers and Counterclaims" containing the search terms "'inequitable conduct' & patent on a yearly basis.[37] To properly calibrate this data, I also conducted a search in which I used only the term "patent," thus establishing a baseline of the size of the Westlaw population of those pleadings.[38] The results are presented in Table I below.[39]

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36. To get a sense of how many Answers are typically filed in a patent case, I conducted an advanced search on LexMachina, limited to "patent" cases filed between 1/1/2005 and 1/10/2005, and limited the results to "answers." This resulted in 538 documents across 93 cases with a mean of 5.8, a median of 4, and a range of 1-58. The search was conducted on September 28, 2012.

37. For the Westlaw data, the specific procedure involved searching the "Westlaw Classic" FED-FILING-ALL database, limited in the document template drop down menu to "Search Pleadings" and in the checkbox to "Answers and Counterclaims," and using the search phrase '"inequitable conduct" & patent & da(=yyyy).' The number of "hits" (i.e.: documents meeting those search criteria) are reported in Table 1. The search was conducted on February 18, 2013.

38. The procedure was identical to the procedure used to obtain the first set of data except that the search phrase used was 'patent & da(=yyyy).'

39. Due to their nature, online databases are constantly subject to improvement, and thus may become more complete over time even with respect to past periods. This is particularly true with documents such as court filings, as the material available at any given point in time on Westlaw represents only a subset of the entire population. Thus, a search conducted at a different point in time will likely exhibit at least minor variations in totals as Westlaw backfills with past documents. However, as a comparison between Table 2 of Mammen and Table 1 above reveals, these variations appear to be relatively minor (ex.: an increase in the database completeness of about 4% for the year 2008), and there is no reason to conclude that they would be more likely to have a greater effect on the number of pleadings containing "inequitable conduct" & patent than pleadings containing only "patent" (and vice versa).

Table 1: Answers and Counterclaims Filed Per Year (Westlaw)

Year	"Patent"	"Patent" & "Inequitable Conduct"	% of patent Answers & Counterclaims
2000	641	112	17%
2001	1212	211	17%
2002	1943	367	19%
2003	3279	573	17%
2004	4776	771	16%
2005	3548	838	24%
2006	3952	945	24%
2007	4508	1185	26%
2008	3990	1203	30%
2009	3937	1023	26%
2010	3645	911	25%
2011	2282	452	20%
2012	2511	402	16%

The data in Table 1 present a strikingly different picture of inequitable conduct allegations in pleadings than provided by Table 2 of the 2009 study. As a percentage of *Answers and Counterclaims in Westlaw containing the term "patent,"* the term "inequitable conduct" appeared in about 17% in 2000; rose to a high of 30% in 2008, and has fallen since.[40] While this data supports the claim of an upward trend from 2000 to 2008, it is much less supportive of a claim that allegations "skyrocketed."[41] More importantly, since 2008 the trend of alleging inequitable conduct is downward, with inequitable conduct being pled less and less often.

This data, while informative, nevertheless tells us little about the rate at which inequitable conduct is being alleged in cases. Perhaps, one might argue, the above results are largely

40. To assess whether or not these results actually involved Answers or Counterclaims alleging inequitable conduct, a randomly selected sample of ten of the documents returned for the search involving "inequitable conduct" were selected and examined for the years 2000, 2005 and 2010. Of the ten results for 2000, all involved Answers, with inequitable conduct pled in eight; two were Answers to Counterclaims alleging inequitable conduct. Of the ten results for 2005, nine were Answers pleading inequitable conduct. All ten results for 2010 were Answers; six pled inequitable conduct, two were reservations of a right to amend, and two were responses to Counterclaims of inequitable conduct. Although these samples are small, they indicate that, if anything, the numbers in Table 1 may overstate the rate at which inequitable conduct is pled.

41. As discussed further below, these results do not in any way indicate the quality of the inequitable conduct claims. This is an important limitation on the methodology used by both this study and the 2009 study, as the presence of "token" inequitable conduct claims in the data reported in Tables 1 and 2 may lead to the erroneous conclusion that substantive allegations of inequitable conduct are more common than they actually are. Of course, one might be concerned about these "token" inequitable conduct claims; absent meaningful information about their prevalence and effects, however, it is difficult to draw any significant conclusions about their impact.

driven by a small number of infringement suits in which there were many Answers filed.[42] Thus, to obtain this information, I conducted a similar search using an alternate data repository, LexMachina.[43] Table 2 reports on the results of a search of LexMachina in which the units of analysis are cases, rather than documents.[44]

Table 2: Patent Cases with Pleadings of Inequitable Conduct (LexMachina)

Year	Patent Cases with an Answer	Patent Cases with an Answer Containing "Inequitable Conduct"	Percentage
2000	233	60	26%
2001	420	136	32%
2002	726	220	30%
2003	1,026	328	32%
2004	1,421	455	32%
2005	1,565	549	35%
2006	1,750	603	34%
2007	1,914	773	40%
2008	2,093	863	41%
2009	2,000	742	37%
2010	2,094	741	35%
2011	2,453	706	29%
2012	3,277	698	21%

42. For example, in the sample discussed in footnote 36, one case had 58 Answers filed.
43. LexMachina, https://lexmachina.com/ (last visited Feb. 18, 2013) (previously known as the Stanford IP Litigation Clearinghouse). This search involved conducting an "advanced search," restricted to patent cases and answers, using the search term "inequitable conduct," with a date restriction of pleadings docketed between 1/1/yyyy and 12/31/yyyy. The searches were then repeated without the term "inequitable conduct." Results were then limited to those that involved "documents" (as opposed to docket entries) and organized by "Cases"; hits were counted on that basis. Because of a technical limitation imposed by LexMachina, viz. a limit of 2000 cases per search when organized by case, both search series were further broken up into two groups: The 1st through 5th Circuits and the 6th through 12th and D.C. Circuits, with the totals combined for a given year. All searches were conducted on February 18, 2013. *Compare with* Mammen, *supra* note 11 at 1349, fns. 85-86. Note that Mammen's search of LexMachina imposed a date restriction on the year cases were filed, rather than on the filing date of the pleadings. However, responsive pleadings involving inequitable conduct need not be filed in the same year as the case was filed. As a consequence, the results of answer the question "How many answers containing "inequitable conduct" were filed *at any time* for cases filed in a given year?" as opposed to the question "How many answers containing "inequitable conduct" were filed in a given year?"
44. As with the Westlaw data, to assess the quality of the results, a randomly selected sample of ten cases that LexMachina identified as containing an Answer with "inequitable conduct" were selected for the years 2000, 2005 and 2010, and the documents for those cases examined. Of the ten results for 2000, all involved Answers, with inequitable conduct pled in eight; one was an answer to a Counterclaim alleging inequitable conduct (the counterclaim was not in LexMachina) and one was a preservation of a right to amend the pleading to add a claim of inequitable conduct. Of the ten results for 2005, all involved Answers, with inequitable conduct pled in eight; one was a preservation of a right to amend and the last did not involve a claim of inequitable conduct claim. All ten results for 2010 were Answers that pled inequitable conduct. Note that these results say nothing about the *quality* of the inequitable conduct claims; some were merely token claims.

The results presented in Table 2 are consistent with the results of Table 1, in that both show a moderate increase in inequitable conduct pleadings through 2008, followed by a substantial decline. For example, of the 233 patent cases in which Answers were filed in 2000 that are collected in LexMachina, 60, or 26%, have an Answer that also contains the term "inequitable conduct." By 2008, that percentage had risen to 41%.[45] Furthermore, as with the percentages of Answers filed per year alleging inequitable conduct, the percentage of *cases* involving new pleadings containing an inequitable conduct claim has fallen—to about 21% of cases in 2012.[46]

An instinctive reaction to this data might be to speculate on causation. On the surface, they seem to be consistent with the hypothesis that the Federal Circuit's attempts to limit the inequitable conduct doctrine have had a significant impact on patent challengers' willingness to assert inequitable conduct claims. As previously noted, an inequitable conduct claim is both an affirmative defense that may be raised by an accused infringer and a counterclaim that may be pled.[47] As a claim that inherently involves fraud or mistake, its elements must be stated with particularity under Federal Rule of Civil Procedure 9(b).[48] While this has long been a requirement, in its 2009 *Exergen* opinion the Federal Circuit provided new guidance on the requirements of pleading inequitable conduct, holding that the pleading must identify "the specific who, what, when, where, and how of the material misrepresentation or omission committed before the PTO."[49] The court further held that pleadings must "allege sufficient underlying facts from which a court may reasonably infer that a party acted with the requisite state of mind."[50] *Exergen* has been widely viewed as substantially tightening the standards for pleading inequitable conduct.[51] The Federal Circuit's opinion in *Therasense*, which heightened the standards for establishing both

45. In other words, the above evidence suggests that the 40% figure reported in the Mammen study was accurate for the year 2008, despite the methodological issues discussed above. This may be due to the under-inclusiveness of the Westlaw court filings database and the erroneous assumption of a one-to-one ratio of pleadings-to-cases canceling each other out for that specific year.
46. Again, note that these results indicate nothing about the quality of those inequitable conduct pleadings, in that they include both substantive claims and "token" claims.
47. Chisum, *supra* note 26, at § 19.03 [6][b][ii]. An inequitable conduct claim might also be raised in a Declaratory Judgment Complaint, although for some of the practical reasons discussed below, this may be difficult.
48. "In all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity." Fed. R. Civ. P. 9(b); *Ferguson Beauregard/Logic Controls, Div. of Dover Resources, Inc. v. Mega Sys., LLC,* 350 F.3d 1327, 1344 (Fed.Cir.2003) ("[I]nequitable conduct, while a broader concept than fraud, must be pled with particularity.").
49. Exergen Corp. v. Wal-Mart Stores, Inc., 575 F.3d 1312, 1327 (Fed. Cir. 2009).
50. *Id.*
51. Lisa A. Dolak, *Beware the Inequitable Conduct Charge! (Why Practitioners Submit What They Submit)*, 91 J. Pat. & Trademark Off. Soc'y 558, 569 (2009); Thomas L. Irving et al., *The Evolution of Intent: A Review of Patent Law Cases Invoking the Doctrine of Inequitable Conduct from* Precision *to* Exergen, 35 U. Dayton L. Rev. 303, 321 (2010); David O. Taylor, *Patent Fraud*, 83 Temp. L. Rev. 49, 72–73 (2010); Priscilla G. Taylor, Note, *Bringing Equity Back to the Inequitable Conduct Doctrine?*, 27 Berkeley Tech. L.J. 349, 367 (2012).

the materiality and intent elements,[52] likely accelerated this trend by both diminishing the incentive to plead inequitable conduct (because defendants are less likely to succeed on it) and making it harder to actually plead (because the elements of materiality and intent are more difficult to allege).

A second possible explanation is that despite the substantial benefits associated with a successful inequitable conduct claim,[53] at least a set of accused infringers may have independently arrived at the conclusion that inequitable conduct is perhaps not the most efficacious or efficient weapon to use except in a limited set of cases where the pacts are particularly favorable to the patent challenger. While the benefits of a successful inequitable conduct claim are indeed great, sometimes those benefits may be outweighed by the cost of advancing the claim, particularly in cases where it is relatively weak compared to other more routine defenses such as obviousness. Perhaps, in other words, inequitable conduct was something of a fad, and when parties and lawyers realized that it was not a panacea for patent infringement, they stopped alleging it in every situation.

Or perhaps the decline beginning in 2009 was caused by the economy; perhaps a combination of factors; perhaps something else entirely.

Or perhaps that initial instinct of explaining the variation is just mistaken. Perhaps the data reflected in the above charts is simply random variation in pleadings over time. Regressed over the entire time period, there is no statistically significant relationship.[54] Perhaps next year we will see an uptick in pleadings of inequitable conduct. The bottom line is that we should be cautious about extending out trend lines based on the existence of the line alone; we should instead make sure that expectations for the future are based on reasons, not extrapolations.

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Even with the recalibration undertaken in this study, there are substantial questions left unanswered about inequitable conduct allegations. Two are particularly salient to questions of causality and interpretation. First, the above data simply reports on quantity of pleadings; they provide no information on their *quality*, a significant issue given that at least some of the inequitable conduct assertions contained in these pleadings are nothing more than bald assertions of inequitable conduct.[55] During a quality-control

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52. Therasense, Inc. v. Becton, Dickinson and Co., 649 F.3d 1276, 1290 (Fed. Cir. 2011).
53. Jason Rantanen, *Slaying the Troll: Litigation As an Effective Strategy Against Patent Threats*, 23 Santa Clara Computer & High Tech. L.J. 159, 187–89 (2006).
54. A linear regression of time [2000-2012] versus the percentage data from table 2 produced a slope variable with a p-value of 0.87; in contrast, a linear regression of time [2000-2008] versus the percentage data produced a slope variable with a p-value < 0.001 and an adjusted R-squared of 0.83 indicating a high degree of correlation.
55. I acknowledge that "bald" or "token" assertions of inequitable conduct are only one way to measure quality. It is conceivable that a party could plead inequitable conduct in great detail and the claim could still be completely meritless.

review of the study, I noticed a number of pleadings along the lines of "The applicable doctrines of anticipation, inequitable conduct and public domain bar any recovery by Plaintiff in this case."[56] I came to think of these claims as "token" inequitable conduct claims. Further empirical work is necessary to ascertain the degree to which the above data represent non-token allegations of inequitable conduct. In particular, it is conceivable that the downward trend in pleadings since 2008 is a result of the elimination of these token inequitable conduct claims, rather than a meaningful shift in non-token claims.

Second, to better understand the landscape of inequitable conduct claims, and the burden they impose on patent litigation generally, further empirical work on the rate at which pleadings of inequitable conduct proceed to an actual determination by a district court is necessary. The data that is available suggests that substantive district court determinations of inequitable conduct are, while not rare, at least uncommon, and factual evaluations of the issue are even rarer.[57] If a substantial proportion of inequitable conduct allegations are of the token type, however, the ratio between inequitable conduct pleadings and determinations may perhaps not have been as great as believed.

Despite these limitations, the data reported in this study provides an important update to our understanding of inequitable conduct pleadings. First, the data are inconsistent with the claim that inequitable conduct claims were raised "in nearly every patent suit,"[58] even at the high point of the range in 2008. Second, they suggest that the claim of a ten-fold skyrocketing of inequitable conduct pleadings from 2000 to 2008 is unfounded. Third, while they are consistent with a claim of a modest upward trend in inequitable conduct allegations from 2000-2008, the data suggest that assertions of inequitable conduct have fallen substantially over the last few years and are trending downwards.

II. The Rate at Which Inequitable Conduct Claims Succeed at the Federal Circuit

At the other end of the cycle of an inequitable conduct claim is the claim's ultimate fate before the Federal Circuit. Prior to *Therasense,* these determinations were uncommon: the Federal Circuit addressed the issue of inequitable conduct in its written opinions only about

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56. *See, e.g.,* "Defendant's Answer and Affirmative Defenses," Hodgdon Powder Company, Inc. v. Clean Shot Technologies, Inc., Case No. 00-8394-Civ-HURLEY/LYNCH (S.D. Fla.), filed June 28, 2000.
57. The available data suggest that district courts make a substantive determination on inequitable conduct claims about 25-35 times a year. *See* Inequitable Conduct Defense in Patent Litigation (2005–2010) *supra* note 14 (reporting that district courts made a substantive determination on inequitable conduct in 200 cases between January 1, 2005 and May 31, 2010); Katherine Nolan-Stevaux, Note, *Inequitable Conduct Claims in the 21st Century: Combating the Plague*, 20 Berkeley Tech. L.J.147 (2005) (estimating that 244 allegations of inequitable conduct were decided in district courts between January 1, 1995 and December 31, 2004).
58. *See Therasense*, 649 F.3d at 1289.

twelve-and-a-half times a year on average.[59] Determinations that inequitable conduct was actually committed were even rarer: prior to *Therasense*, the Federal Circuit reached an ultimate conclusion of inequitable conduct around 2.5 times per year.[60]

Since *Therasense*, determinations that inequitable conduct occurred have become, if anything, even more infrequent: in the twenty-two months since *Therasense* issued, the Federal Circuit has issued written opinions addressing inequitable conduct only nine times.[61]

Of these nine opinions, in only one did the Federal Circuit reach an ultimate conclusion that inequitable conduct had been committed - in that case, the Federal Circuit affirmed a district court's finding of inequitable conduct.[62] While these numbers are small, given the recentness of *Therasense*, it appears that at the Federal Circuit level, inequitable conduct determinations are likely to remain rare and ultimate conclusions of inequitable conduct even rarer.

III. What Can Be Done

As the example discussed above illustrates, empirical legal studies present a dilemma: on the one hand, they are fundamentally necessary to answer questions about the effect of legal doctrines; on the other, they may be subject to misuse and error. What can be done to shrink the bull's horns? In this section, I raise several suggestions that in many fields are fundamental components of empirical research yet tend to be often overlooked in legal studies.

As a starting point, study authors themselves are in the best position to ensure that their studies are valid. Authors can follow a number of procedures to ensure the quality of their studies. First, in designing and carrying out their studies, authors can follow a set of methodological best practices, such as those suggested by Hall & Wright in their seminal

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59. This number was arrived at by dividing 338 cases involving inequitable conduct, the number reported by Petherbridge, Rantanen, & Mojibi, *supra* note 1, at 1305 n.40, by 27, by the number of years that study covered. In contrast, the Federal Circuit has historically addressed the issue of obviousness about 23 times per year. *See* Lee Petherbridge & R. Polk Wagner, *The Federal Circuit and Patentability: An Empirical Assessment of the Law of Obviousness*, 85 Tex. L. Rev. 2051, 2072 (2006) (reporting 362 identified Federal Circuit opinions on obviousness for the period January 1, 1990 to June 1, 2005). Note that not all of these determinations resulted in a final disposition of the issue; in some cases, the case was remanded for further proceedings.

60. Petherbridge, Rantanen, & Mojibi, *supra* note 1, at 1340.

61. In re Rosuvastatin Calcium Patent Litigation, 703 F.3d 511 (Fed. Cir. 2012); Outside the Box Innovations, LLC v. Travel Caddy, Inc., 695 F.3d 1285 (Fed. Cir. 2012); 1st Media, LLC v. Elec. Arts, Inc., 694 F.3d 1367 (Fed. Cir. 2012); Santarus, Inc. v. Par Pharmaceutical, Inc., 694 F.3d 1344 (Fed. Cir. 2012); Aventis Pharma S.A. v. Hospira, Inc., 675 F.3d 1324 (Fed. Cir. 2012); Powell v. Home Depot USA, Inc., 663 F.3d 1221 (Fed. Cir 2011); Cordis Corp. v. Boston Scientific Corp., 658 F.3d 1347 (Fed. Cir. 2011); August Tech. Corp. v. Camtek, Ltd., 655 F.3d 1278 (Fed. Cir. 2011); American Calcar, Inc. v. American Honda Motor Co., Inc., 651 F.3d 1318 (Fed. Cir. 2011).

62. Aventis Pharma S.A. v. Hospira, Inc., 675 F.3d 1324 (Fed. Cir. 2012).

Essay *Systematic Content Analysis of Judicial Opinions*.[63] Second, authors can describe those methodologies in full detail in the Essay itself or in an accompanying appendix, as Mammen did in the study discussed in this article. By "full detail" I mean replicable detail: in sufficient detail to enable another researcher to replicate every step of the methodology (although not necessarily the precise results) of the study.[64] Third, they can make their datasets available for subsequent review and analysis.[65] Authors can also seek out and obtain peer review of the study methodology *before* beginning to code the data, so as to avoid making a design error in the early stages of the project. Finally, and perhaps most importantly, in many instances study authors may have great success working in teams, producing efficiencies and checks on one another while minimizing the risk of premature disclosure.[66] While in some cases it may simply not be feasible to engage in multi-author scholarship, the advantages provided by this approach go beyond simply the effect on the methodological approach itself.[67]

Beyond engaging directly with the study author during the project itself, third-party scholars can also play a significant role in ensuring the quality of empirical legal studies by carefully reviewing those studies that are produced and published, and engaging in a productive dialogue about those studies. While there are scholars who provide useful post-publication commentary and criticism,[68] the quality of empirical legal studies has the potential to be greatly improved by even greater engagement and critical review of published studies. Law reviews today offer a tremendous opportunity for exactly this type of commentary through the online supplements that nearly every major law review offers.[69]

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63. Mark A. Hall and Ronald F. Wright, *Systematic Content Analysis of Judicial Opinions*, 96 Cal. L. Rev. 63, 100-120 (2008).
64. Even with a fully replicable methodology, it may often be impossible for subsequent researchers to precisely duplicate the results because case coding frequently involves at least some level of judgment, and different people can reasonably disagree, especially over close calls. This may be particularly true in the case of actual "content analysis" studies, in which the coder is assessing (frequently as an expert) the judicial reasoning employed by the court. This does not mean that the empirical study is invalid; rather, that uncertainty is simply a recognized part of the analysis.
65. When datasets are available, subsequent researchers gain the ability to precisely duplicate the results from the analysis-stage forward, mitigating the limitation discussed in the preceding footnote.
66. *See, e.g.,* Petherbridge, Rantanen & Mojibi, *supra* note 1.
67. *See* Christopher Anthony Cotropia & Lee Petherbridge, *The Dominance of Teams in the Production of Legal Knowledge*, available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2212431 (providing empirical evidence that team research is on average more frequently cited than individual research and that teams are more likely than individuals to produce exceptionally high impact research).
68. One notable recent example is the commentary following the publication of Colleen Chien's *Predicting Patent Litigation*, 90 Texas L. Rev. 283 (2011). *See* Lee Petherbridge, On Predicting Patent Litigation, 90 Texas L. Rev. See Also 75 (2012); Jay P. Kesan, David Schartz & Ted Sichelman, *Paving the Path to Accurately Predicting Legal Outcomes: A Comment on Professor Chien's Predicting Patent Litigation*, 90 Texas L. Rev. See Also 97 (2012).
69. *See, e.g.,* Stanford Law Review Online at www.stanfordlawreview.org/online; Michigan Law Review *First Impressions*, at www.michiganlawreview.org/first-impressions.

Nor should scholars be the only ones to read empirical studies with a critical eye. The Mammen study was appropriately transparent; its methodology was clearly laid out in an almost fully reproducible fashion.[70] The Committee Position Essay discussed in the introduction, and cited by the Federal Circuit in *Therasense* as a study that "estimated that eighty percent of patent infringement cases included allegations of inequitable conduct,"[71] presents an even more extreme example in that it reports no actual data, let alone a methodology. While scholars have an important role to play in ensuring the quality of empirical studies themselves, courts and policy makers themselves need to assess empirical work from an objectively critical standpoint rather than blindly cite it even if it supports a preferred position.

The goal of these suggestions is not to cast aspersions on empirical legal work, but rather to improve its quality. Empirical legal studies are an important tool for legal commentators, courts, and policymakers.[72] They allow for the testing of empirical claims about the law and its effects, and provide evidence on which future decisionmakers can rely. Ensuring and improving the quality of empirical legal studies promotes both these goals: it allows the testing to be valid and increases the reliability of the evidence.

Conclusion

The primary purpose of this Essay is to critique and build upon Mammen's widely-invoked 2009 empirical study of the rate at which inequitable conduct was pled and found by the Federal Circuit, and to offer some suggestions as to how the problems identified here could be avoided in the future. The results of the examination described in this Essay suggest that claims of inequitable conduct did increase during the first two-thirds of the last decade, although they did so at a much more modest rate than previously understood. More importantly, since 2008, the rate at which accused infringers have pled inequitable conduct has dropped precipitously. These results are significant, in that they call into question the extent to which previously-held assumptions about inequitable conduct were well-grounded in empirical reality, an important issue given recent developments by courts and the legislature to rein in the doctrine.

Given this landscape, there is a need for scholars to engage more closely with each others' empirical studies, both during development and after publication. Courts and policymakers, too, have a role to play in assessing empirical work with a discerning eye, as opposed to passively citing the results. ■

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70. One limitation on full reproducibility is the fundamental issue that database contents can grow over time as more materials are collected within the database. As discussed above in footnote 39, however, this appears to introduce only a relatively small variation for the periods studied.
71. *Therasense*, 649 F.3d at 1289.
72. Indeed, many questions in law are fundamentally empirical questions that can only be addressed by conducting an empirical study. Everyone likes to spin theories, but only through empirical testing can those theories be truly assessed.