Supplemental Examination and Inequitable Conduct: Protection and Pitfalls

Daniel Parrish

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SUPPLEMENTAL EXAMINATION AND INEQUITABLE CONDUCT:
PROTECTION AND PITFALLS

DANIEL PARRISH

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I. SUPPLEMENTAL EXAMINATION: A NEW POST-ISSUANCE PROCEEDING TO REMEDY THE “PLAGUE” OF INEQUITABLE CONDUCT OVER-PLEADING

A unique aspect of patent litigation is that the prosecuting attorney often faces charges on par with the alleged infringer. Approximately one-third of all patent infringement lawsuits allege that the prosecuting attorney acted inequitably while obtaining a patent, putting both the patent at risk of being held unenforceable and the attorney at risk of losing his or her license to practice before the United States Patent and Trademark Office (USPTO or the Office). This is a scary proposition for the patent practitioner and patent owner, who could both be at risk of losing their livelihood.

Congress recently enacted the Leahy-Smith America Invents Act (AIA), introducing a new procedure that allows patent owners to, inter alia, preemptively reduce the likelihood of inequitable conduct claims during future litigation. Statutorily, 35 U.S.C. § 257 provides a new post-issuance proceeding called supplemental examination, which allows a patent owner to remedy potential flaws accumulated in the course of prosecution of the patent application upon which the issued patent is based. Common flaws include prior art that was not cited and other information that was not adequately considered during prosecution.

With this first-pass procedure, the patent owner submits the relevant information to the examiner for consideration in view of the existing patent claims. If the examiner determines that no substantial new questions of patentability (SNQP) exist, the patent is “bulletproof” against inequitable conduct claims during future litigation. On the other hand, if the examiner believes an SNQP exists, ex parte reexamination is ordered to further analyze the information. If an SNQP exists, the statutory immunity with respect to the

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1 Christian E. Mammen, Controlling the “Plague”: Reforming the Doctrine of Inequitable Conduct, 24 BERKELEY TECH. L.J. 1329, 1358 (2009) (highlighting table with column C showing fraction of district court patent infringement proceedings where inequitable conduct was pled reached forty percent of filings in 2007 and 2008).
4 See id. § 257(a) (West 2012) (requesting that in a supplemental examination the Office “consider, reconsider, or correct information believed to be relevant to the patent.”).
5 See id. § 257(c)(1) (West 2012) (stating that a patent shall not be held unenforceable if the information was considered during supplemental examination).
6 See id. § 257(b) (West 2012) (stating that if supplemental examination raises a SNQP, the Director shall order ex parte reexamination).
submitted information is still granted and the patent itself may be strengthened or weakened during the subsequent *ex parte* reexamination.7

In early 2012, the USPTO proposed rules for supplemental examination, opening a public-comment period.8 After consideration, the USPTO responded to the comments and published final rules outlining the specific requirements and steps to supplemental examination.9

This article begins with a discussion of inequitable conduct10 and follows with a summary of the supplemental examination rules and comments.11 Next, two major components of supplemental examination are discussed in depth. First, the USPTO’s reference to a recent Federal Circuit ruling12 to define “material fraud” is analyzed to provide specificity regarding its application in practice.13 Second, the supplemental examination rules are explored for potential holes where a practitioner could either cleanse a patent of actual inequitable conduct or create new grounds for inequitable conduct.14 Finally, statutory amendments are proposed that could increase access to supplemental examination and reduce uncertainty.15

II. INEQUITABLE CONDUCT AND CONGRESSIONAL MOTIVATION FOR CHANGE

Patents, by their very nature, affect the public by providing the owner with a legal monopoly on the invention. To increase the likelihood of granting patent protection to only novel, useful, and non-obvious inventions, the USPTO requires

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7 See id. § 257(c)(1) (West 2012) (stating that statutory immunity to inequitable conduct is only awarded “if the information was considered, reconsidered, or corrected during a supplemental examination of the patent.”) (emphasis added).


10 See infra Part II.

11 See infra Part III.


13 See infra Part IV.

14 See infra Part V.

15 See infra Part VI.
applicants to disclose “all information material to patentability.” The underlying policy is that the applicant is in the best position to have full knowledge of the art and disclosure of this information leads to higher quality examination.

In this section, the “duty of candor” is introduced with respect to inequitable conduct and the doctrine of “unclean hands.” Next, inequitable conduct is discussed as a litigation strategy, including how the perceived benefits have led to over-pleading and quantitative research supporting this view. Taken together, these trends provided the congressional motivation to enact supplemental examination.

A. Duty of Candor and Inequitable Conduct

An inventor applying for a patent has a duty of candor and good faith in dealing with the USPTO, including the obligation to disclose all information material to patentability. Common “material” information includes references cited by a foreign patent office while prosecuting a counterpart application and statements regarding the patentability of the invention (e.g., arguments made to a foreign patent office).

The duty of candor applies to all parties associated with the filing and prosecution of a patent application, including the attorney or agent representing the inventor. Known as “Rule 56,” a failure to meet this obligation may result in an unenforceable patent if the breach exceeds the threshold of inequitable conduct.

16 37 C.F.R. § 1.56(a) (2012) (charging each individual associated with the patent with a duty of candor and good faith, including the duty to disclose all information material to patentability).

17 See infra Part II.A.

18 See infra Part II.B.

19 See infra Part II.C.

20 See 37 C.F.R. § 1.56(b) (stating that information is material if it is not cumulative to the record and either establishes a prima facie case of unpatentability or is inconsistent with an argument of patentability).

21 See id. § 1.56(a)(1–2) (encouraging applicants to carefully examine prior art cited in search reports of a foreign patent office in a counterpart application).

22 See id. § 1.56(c)(2) (charging “[e]ach attorney or agent who prepares or prosecutes the application” with the duty of candor and good faith).

23 Therasense, Inc. v. Beecton, Dickinson & Co., 649 F.3d 1276, 1292 (Fed. Cir. 2011) (cautioning that because of the severity of punishment, inequitable conduct should only be applied if the penalty is commensurate with the violation).

24 Am. Hoist & Derrick Co. v. Sowa & Sons, Inc., 725 F.2d 1350, 1364 (Fed. Cir. 1984) (“[A]n applicant’s misrepresentation or failure to meet his ‘duty to disclose’ . . . will not in itself render a patent invalid or unenforceable [but] . . . may be determined [under the appropriate standard].”).
Inequitable conduct refers to a legal principle “that is different from, but related to, the duty of disclosure.” The principle is rooted in the doctrine of “unclean hands,” where a patent owner seeking judicial enforcement of a patent is barred from remedies if the patent was obtained using disreputable means. “Unclean hands” applies to applicants who, with the intent to mislead or deceive the examiner, withhold material information or submit materially false information to the USPTO during patent prosecution. These two elements—intent to deceive and materiality of information—comprise the two-prong test for inequitable conduct.

Successful inequitable conduct claims provide alleged infringers with the valid affirmative defense of unenforceability. This is the “atomic bomb” of patent litigation because it makes the patent valueless and even provides for recovery of attorney fees. Thus, failing to fulfill the duty of disclosure could spell devastation for the patent owner and his representatives, providing a windfall to any competitors. It is no wonder that pleading inequitable conduct is a key strategy in many patent litigation cases.

First, unenforceability applies not only to the accused claims, but the entire patent and potentially related patents in which the same information was withheld. Thus, one inequitable conduct claim could wipe out an entire patent portfolio. A second advantage to the party asserting the claim is that both the

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26 Mammen, supra note 1, at 1334 (“[A] patentee seeking to enforce its patent rights must not come before the court with unclean hands due to his intentional misleading of the PTO in order to obtain the patent.”); see also Robert J. Goldman, Evolution of the Inequitable Conduct Defense in Patent Litigation, 7 HARV. J.L. & TECH. 37, 49–50 (1993).
27 Norian Corp. v. Stryker Corp., 363 F.3d 1321, 1330 (Fed. Cir. 2004).
28 35 U.S.C.A. § 282(b)(1) (West 2012) (“The following shall be defenses in any action involving the validity or infringement of a patent and shall be pleaded: (1) . . . unenforceability.”).
29 Aventis Pharma S.A. v. Amphastar Pharm., Inc., 525 F.3d 1334, 1349 (Fed. Cir. 2008) (Rader, J., dissenting) (“The threat of inequitable conduct, with its ‘atomic bomb’ remedy of unenforceability, ensures that candor and truthfulness.”); see also Ningling Wang & Thomas L. Irving, Whither Therasense?, FINNEGAN (May 16, 2012), http://www.finnegan.com/FCWSite/abc.aspx?url=http%3a%2f%2fwww.finnegan.com%2fnews%2fnewspdf.aspx%3fnews%3d08f8e827-0cee-4886-abb4-3e41ca27be99%26pdf%3dtrue (stating that alleged infringers will continue to assert inequitable conduct so long as the cost is minimal, the burden on the patentee is high, and the payoff is the “atomic bomb”).
31 Therasense, Inc. v. Becton, Dickinson & Co., 649 F.3d 1276, 1292 (Fed. Cir. 2011) (“[I]nequitable conduct renders an entire patent (or even a patent family) unenforceable . . . .”).
inventor and the patent practitioner will likely be subject to deposition covering any relevant documents. This provides a unique window into the prosecution history and blurs the attorney-client privilege. A third advantage is that the asserting party can paint the inventor as deceitful, in contrast with the typical narrative of an opportunist scientist. Thus, the accused infringer has an incentive to plead inequitable conduct at the slightest opportunity because the strategic and technical advantages are “too attractive to ignore.”

B. Inequitable Conduct as a “Plague”

Inequitable conduct over-pleading was first characterized as a “plague” by the Federal Circuit in 1988. Since then, it has not disappeared and has in fact increased, leading some commentators to call for curtailment of Rule 56, refinement of the duty of disclosure to include keywords for examiner searches, and even the abolition of inequitable conduct as an affirmative defense.

Between 2000 and 2008, inequitable conduct pleadings at the district court level rose in a near-linear fashion from around four to forty percent. Conspicuously divergent from this trend is a relatively stable fraction of cases that actually uphold inequitable conduct claims at the Federal Circuit. This “ultimate success rate” hovers around 0.50% for the same period, though some factors are

32 Mammen, supra note 1, at 1332 (“[M]ost relevant documents will come from the files of the inventor and the patent attorney who prosecuted the patent, and those individuals will likely be subject to deposition.”).

33 Id. (citing an “asymmetrical discovery burden”).

34 Id. (stating that the accused infringer can “impugn the character of the inventor and her counsel, providing a counterbalance to the patentee's likely narrative at trial of the inventor as an idealized genius.”).


36 Burlington Indus., Inc. v. Dayco Corp., 849 F.2d 1418, 1422 (Fed. Cir. 1988) (“[T]he habit of charging inequitable conduct in almost every major patent case has become an absolute plague. Reputable lawyers seem to feel compelled to make the charge against other reputable lawyers on the slenderest grounds, to represent their client’s interests adequately, perhaps.”).

37 See, e.g., Erstling, supra note 30, at 365 (“Short of abolishing the duty of candor altogether, an alternative would be to follow the model of the European Patent Office (“EPO”). Under such a system, no duty of disclosure would be imposed on an applicant unless an examiner determined that information was needed but the examiner was unable to access it herself.”).


40 See Mammen, supra note 1, at 1358–60 (outlining a table and corresponding graphic illustrating trends in inequitable conduct pleading).
not considered. These factors include the number of settled cases where inequitable conduct claims played a role in the decision to settle, cases that were not appealed, and cases where inequitable conduct was not addressed on appeal. Nonetheless, the steady increase of inequitable conduct pleadings supports the categorization of inequitable conduct over-pleading as a “plague.”

C. Congressional Motivations

Supplemental examination blossomed from Senator Orrin Hatch’s advocacy to restrict the inequitable conduct doctrine due to its ever-increasing burden on patent litigation.

Discovery in any litigation is costly and inequitable conduct claims are no different. In 2011, the median cost to reach the end of discovery was one-and-a-half-million dollars for a patent infringement case seeking one to twenty-five million dollars in damages. If a patent suit includes an inequitable conduct claim, this requires both sides to spend a substantial sum to explore these allegations, which only adds to the cost.

The risk of defending inequitable conduct claims often deters investors, especially because an inequitable conduct finding could render a portion of the patent portfolio unenforceable, wiping out the entire investment. Congress included supplemental examination in the AIA to resolve such uncertainties with respect to patents. This should increase patent-driven innovation with all of the ensuing economic benefits.

In essence, Congress sought to provide an expedited procedure for a patent owner to eliminate uncertainty, at least with respect to potential flaws in patent prosecution. In theory, this would be useful to convince a skeptical investor by

41 Id. (illustrating trends in inequitable conduct success on appeal).
42 Id. at 1360.
43 Joe Matel, A Guide To The Legislative History Of The America Invents Act: Part II of II, 21 FED. CIR. B. J. 539, 546 (2011) (“Senator Hatch continued to pursue inequitable-conduct reform, arguing that the defense has been overpleaded and ‘has become a drag on the litigation process.’” (citing 153 CONG. REC. S4691 (daily ed. Apr. 18, 2007) (statement of Sen. Hatch))).
46 See id.
47 See id. (“[S]upplemental examination will result in path-breaking inventions being developed and brought to market that otherwise would have lingered on the shelf because of legal uncertainty . . . .”)
48 Id. (“Currently, even minor and inadvertent errors in the patent application process can lead to expensive and very unpredictable and very inequitable conduct litigation.”).
“bulletproofing” a patent in view of an inconsistent position or prior art not presented to the USPTO.49

III. FINAL SUPPLEMENTAL EXAMINATION RULES AND COMMENTS

The new 35 U.S.C. § 257 provides the statutory basis for supplemental examination,50 and recently the USPTO issued final supplemental examination rules outlining the filing process.51 A supplemental examination request must comply with formal requirements, including joinder of all parties, a fee, up to twelve items of information, and any optional explanations.52 During supplemental examination, the examiner will determine if the submitted information raises a SNQP or uncovers any material fraud.53 Upon conclusion, the USPTO will publish a supplemental examination certificate and may order ex parte reexamination if an SNQP arises.54 Interspersed within the discussion of these rules that follow in the next few sections are relevant public comments.

A. Statutory Basis

Supplemental examination under 35 U.S.C. § 257 became available to patent owners on September 16, 2012.55 Section 257(a) describes the supplemental examination request and places a three-month statutory deadline for the USPTO to issue a supplemental examination certificate, which indicates whether the information raises an SNQP.56 Section 257(b) states that ex parte reexamination is required if any item of information raises an SNQP.57 Under § 257(c), the patent cannot be held unenforceable in view of information considered during

49 Id. (“It is often the case that startup companies or university researchers cannot afford to hire the very best patent lawyers. . . . Later, when more legally sophisticated investors evaluate the patent for potential investment or purchase, these minor flaws in prosecution can deter the investor from purchasing or funding the development of the invention.”).
50 See infra Part III.A.
51 See infra Part III.B.
52 See infra Part III.C.
53 See infra Part III.D.
54 See infra Part III.E.
56 See id. § 257(a) (West 2012) (“A patent owner may request supplemental examination of a patent in the Office to consider, reconsider, or correct information believed to be relevant to the patent . . . . Within 3 months after the date a request for supplemental examination meeting the requirements of this section is received, the Director shall conduct the supplemental examination and shall conclude such examination by issuing a certificate indicating whether the information presented in the request raises a substantial new question of patentability.”)
57 See id. § 257(b) (West 2012) (“If the certificate issued under subsection (a) indicates that a substantial new question of patentability is raised by 1 or more items of information in the request, the Director shall order reexamination of the patent.”).
supplemental examination. 58 This protection extends to the request itself. 59 Exceptions exist where supplemental examination does not preempt a civil suit claim filed prior to the supplemental examination request. 60 Similarly, the benefits of supplemental examination do not extend to patent enforcement actions until all proceedings are concluded. 61 Next, § 257(d) gives the USPTO the authority to establish fees and regulations. 62 Finally, if the Office learns of a material fraud, § 257(e) directs the Director to refer the matter to the Attorney General. 63

B. Filing a Supplemental Examination Request

1. Filing of Papers

   a. All Parties of Any Interest Must Join the Request

   A patent owner may request supplemental examination at any time during the period of enforceability of a patent. 64 The USPTO deems any party with an ownership interest in a patent a “patent owner.” 65 Since the result of supplemental

58 See id. § 257(c)(1) (West 2012) (“A patent shall not be held unenforceable on the basis of conduct relating to information that had not been considered, was inadequately considered, or was incorrect in a prior examination of the patent if the information was considered, reconsidered, or corrected during a supplemental examination of the patent.”).

59 See id. § 257(c)(1) (West 2012) (“The making of a request under subsection (a), or the absence thereof, shall not be relevant to enforceability of the patent under section 282 [presumption of validity; defenses].”)

60 See id. § 257(c)(2)(A) (West 2012) (“Paragraph (1) shall not apply to an allegation pled with particularity in a civil action . . . before the date of a supplemental examination request . . .”).

61 See id. § 257(c)(2)(B) (West 2012) (“[P]aragraph (1) shall not apply to any defense raised in [a patent enforcement] action . . . unless the supplemental examination, and any reexamination ordered pursuant to the request, are concluded before the date on which the action is brought.”).

62 See id. § 257(d) (West 2012).

63 See id. § 257(e) (West 2012) (“If the Director becomes aware . . . that a material fraud on the Office may have been committed in connection with the patent that is the subject of the supplemental examination . . . the Director shall . . . refer the matter to the Attorney General for such further action as the Attorney General may deem appropriate.”).


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examination is binding on the entire patent, all owners are required to join. Non-patent owners (e.g., third parties) cannot participate in supplemental examination proceedings and are barred from filing any papers or other submissions related thereto.

b. Fees Due at Filing

i. Rule

Effective March 19, 2013, the request must include $16,500, covering both the cost of the supplemental examination and the potential ex parte reexamination filing fees: $4,400 and $12,100, respectively, with the latter fee being refunded if no SNQP is raised. Recent legislation will reduce these fees for small and micro entities, potentially because of the widespread public response.

ii. Commentary

A number of public comments expressed some form of sticker shock. This is understandable because the cost of pre-AIA ex parte reexamination was just $2,520. The USPTO appears to justify this fee increase to “encourage applicants to provide all relevant information during initial examination, which facilitates compact prosecution.” Yet this logic is faulty because the motivation behind supplemental examination was to provide an avenue to avoid spending resources in litigation debating inequitable conduct claims.

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66 Supplemental Examination Provisions of the AIA, 77 Fed. Reg. at 48,832 (to be codified at 37 C.F.R. § 1.601(a)) (“A request for supplemental examination of a patent must be filed by the owner(s) of the entire right, title, and interest in the patent.”).
67 Id. at 48,852 (to be codified at 37 C.F.R. § 1.601(b)).
69 Supplemental Examination Provisions of the AIA, 77 Fed. Reg. at 48,851 (to be codified at 37 C.F.R. § 1.26(c)).
70 Setting and Adjusting Patent Fees—Final Rule, 78 Fed. Reg. at 4,232 (displaying Table 19 that shows a sixty-one and eighty-one percent fee reduction for small and micro entities, respectively).
71 37 C.F.R. § 1.20(c)(1) (2010).
A discrepancy arises when a patent owner seeks to submit fewer than twelve items yet pays the flat rate for up to twelve items. This illustrates the disparity between the fee calculation and the actual cost of administering supplemental examination. This is unfortunate because “Congress has provided a new avenue to remove inequitable conduct issues, but the PTO immediately sets fees to deter the use of the procedure.”

c. Filing Date Awarded upon Perfection of Request

Upon perfection of the supplemental examination request, a filing date will be awarded, though a patent owner will be given time to submit missing parts to an incomplete request. At that time, the three-month statutory clock begins, during which the USPTO must complete the supplemental examination. The supplemental examination request will be available in the public Patent Application Information Retrieval (PAIR) system only after the request is perfected in order to avoid a “race to the court.”

C. Content of Request

1. Request Limited to Twelve Items of Information

a. Rule

A supplemental examination request is limited to twelve items of information, although more than twelve items can be presented by filing multiple requests. An item is broadly defined as anything relevant to patentability, including patents,

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76 Supplemental Examination Provisions of the AIA, 77 Fed. Reg. at 48,852 (to be codified at 37 C.F.R. § 1.610(d)).
77 35 U.S.C.A. § 257(a) (West 20012) (“Within 3 months after the date a request for supplemental examination meeting the requirements of this section is received, the Director shall conduct the supplemental examination and shall conclude such examination by issuing a certificate . . . .”).
78 Supplemental Examination Provisions of the AIA, 77 Fed. Reg. at 48,830 (“The Office, however, is establishing a procedure in which the request, and any other papers or information submitted as part of or accompanying the request, will not be available in Public PAIR until the request meets the conditions to be entitled to a filing date.”).
79 Id. at 48,842 (USPTO response to comment 23).
80 Id. at 48,852 (to be codified at 37 C.F.R. § 1.605(a)).
printed publications, audio or video recordings, and evidence of a prior sale. The Office “reserves its option to merge supplemental examination proceedings as circumstances arise.”

b. Commentary

Although the Office received suggestions to use a sliding scale, it chose a flat fee to comply with the statutorily mandated three-month reply period. The Office provided additional justification for the twelve-item limit, reporting that ninety-three percent of ex parte reexamination requests in 2011 included twelve items or fewer. This is unfortunate for patent owners wishing to submit more than twelve items because the thirteenth item doubles the cost, but due to economies of scale, almost certainly does not double the burden. This situation provides a windfall to the Office.

Submissions with more than twelve items may be commonplace if supplemental examination is used to “cleanse” a patent portfolio prior to acquisition, especially if patents in the portfolio were not prosecuted with sophisticated counsel. This is especially relevant considering that a single successful inequitable conduct charge can tarnish an entire patent family.

Another commentator noted that during discovery, “literally dozens of potential inequitable conduct allegations are pursued, particularly during discovery, in hopes of finding a subset of such issues to pursue and present at

81 See id. at 48,852 (to be codified at 37 C.F.R. § 1.605(b)); see also id. at 48,833 (discussion of Rule 1.605(b)).
82 See id. at 48,839 (USPTO response to comment 9 regarding merger).
84 David Kappos, The Role of Submission Limits in Timely Completion of Supplemental Examination, DIRECTOR’S FORUM: A BLOG FROM USPTO’S LEADERSHIP (Apr. 27, 2012), http://www.uspto.gov/blog/director/entry/the_role_of_submission_limits (describing the conflict between providing a quick (three-month period) yet decisive examination of overlooked items and the inevitable complexity that too many items invites).
87 Therasense, Inc. v. Becton, Dickinson & Co., 649 F.3d 1276, 1292 (“[I]nequitable conduct renders an entire patent (or even a patent family) unenforceable . . . .”).
Thus, although fewer than twelve items may be presented in court, many more are likely to be alleged pre-trial. This runs counter to the USPTO rationale that “[inequitable conduct . . . during patent litigation . . . typically concern[s] far fewer than twelve items of information.”

One irony is that Congress enacted the three-month limit to expedite the supplemental examination process. Yet there is no time limit on any subsequent ex parte reexamination proceedings. Thus, for any supplemental examinations that proceed to ex parte reexamination, the three-month turnaround may be of minor importance compared to the uncertain duration of reexamination.

2. Other Content Requirements

In addition to including the items of information relevant to patentability, multiple other content requirements exist. Notably, the request must identify the patent claims for which supplemental examination is requested and include a “separate, detailed explanation of the relevance and manner of applying each item of information to each claim of the patent for which supplemental examination is requested.” This is important because it implies that the patent owner may limit the scope of supplemental examination to specific claims as opposed to the patent as a whole. Furthermore, the patent owner can frame any relevant issues in favorable light, or guide the examiner away from sensitive issues, as discussed in section V below.

3. Request May Include Additional Explanations

Although not required, the patent owner may submit additional explanations to the examiner. This may assist the examiner in focusing on the relevant issues, though it may also raise potential problems if the patent owner steers the examiner away from difficult or problematic aspects of the reference. Again, this is discussed in section V below.

D. Supplemental Examination Proceedings

88 Letter from Robert A Armitage, supra note 83, at 2 n.1 (commenting on placing a limitation on the number of items).
90 Id. at 48,852 (to be codified at 37 C.F.R. § 1.610(b)) (listing nine separate requirements to the supplemental examination request).
91 Id. at 48,852 (to be codified at 37 C.F.R. § 1.610(b)(4)–(5)).
92 Id. at 48,852 (to be codified at 37 C.F.R. § 1.610(c)(3)–(4)) (stating that the owner may include “[a]n explanation of how the claims patentably distinguish over the items of information” and “[a]n explanation of why each item of information submitted with the request does or does not raise a substantial new question of patentability.”).
After a filing date is awarded, the Office has three months to determine if an SNQP exists.93 The Office will examine the information provided in view of the applicable claims, however, the precise scope of the proceedings is ambiguous.94 The Office will also search for any indications of material fraud.

1. Scope of Proceedings

“Within three months after the filing date of a request for supplemental examination, the Office will determine whether a substantial new question of patentability affecting any claim of the patent is raised by any of the items of information presented in the request.”95 It is important to note how the “any-any” language encompasses any claim and any item. Yet the next sentence in the rule appears to limit this all inclusive language: “The determination will generally be limited to a review of the item(s) of information identified in the request as applied to the identified claim(s) of the patent.”96 This potential mismatch in scope is discussed in Part V below.

Although a SNQP is never defined in a statute, the MPEP states that “[a] prior art patent or printed publication raises a substantial question of patentability where there is a substantial likelihood that a reasonable examiner would consider the prior art patent or printed publication important in deciding whether or not the claim is patentable.”97 There is no reason to believe this definition would not apply to information submitted during a supplemental examination.

2. Material Fraud

If the Office uncovers any fraud, the matter will be referred to the U.S. Attorney General in accordance with 35 U.S.C. § 257(e), though the Office anticipates that such instances will be rare.98 Although not incorporated into § 1.620, the Office defined “material fraud” as narrower in scope than the inequitable conduct in Therasense.99

3. Other Limitations

94 See infra Part V.A.1.
95 Supplemental Examination Provisions of the AIA, 77 Fed. Reg. at 48,852 (to be codified at 37 C.F.R. § 1.620(a)) (emphasis added).
96 Id. (emphasis added).
97 MPEP, supra note 65, § 2242(I) (although a SNQP will not be found if the “same question of patentability has already been decided as to the claim in a final holding of invalidity by the Federal court system or by the Office in a previous examination.”) A common example is cumulative prior art already considered. Id.
98 Supplemental Examination Provisions of the AIA, 77 Fed. Reg. at 48,853 (to be codified at 37 C.F.R. § 1.620(g)) (providing guidance for how the USPTO should handle fraud).
99 Id. at 48,829; see also infra Part IV (discussing material fraud in view of Therasense).
The rules provide no options for communicating with the Office outside of the supplemental examination request. For example, substantive interviews with the examiner are prohibited, and amendments cannot be filed.

E. Conclusion from the Supplemental Examination Analysis

By the end of the three-month statutory period, the Office will issue a supplemental examination certificate indicating whether a SNQP exists.

1. If a SNQP Exists

If the Office finds a SNQP in light of one or more items of information, the examiner will order ex parte reexamination in accordance with § 257(b). Although the ensuing ex parte reexamination is limited to items included in the supplemental examination request, any claim in the patent may be examined. Interestingly, although the ex parte reexamination must address each SNQP identified during supplemental examination, the rules give the examiner the freedom to raise new SNQPs and consider items of information that did not previously raise a SNQP. The supplemental examination certificate will only indicate that a SNQP was raised, and an ex parte reexamination certificate will publish when the matter concludes.

2. If no SNQP Exists

If the Office finds that no SNQP exists, the electronic supplemental examination certificate will issue, ex parte reexamination will not be ordered, and the fee will be refunded. The supplemental examination certificate will indicate that no SNQP was raised by any of the items of information considered.

100 Id. at 48,853 (to be codified at 37 C.F.R. § 1.620(e)).
101 Id. (to be codified at 37 C.F.R. § 1.620(f)).
102 Id. (to be codified at 37 C.F.R. § 1.625(a)–(c)).
103 Id. (to be codified at 37 C.F.R. § 1.625(b)).
104 Id. (to be codified at 37 C.F.R. § 1.625(d)(2)) (“Reexamination of any claim of the patent may be conducted on the basis of any item of information as set forth in § 1.605.” (emphasis added)).
105 35 U.S.C.A. § 257(b) (West 2012) (“[T]he Director shall address each substantial new question of patentability identified during the supplemental examination . . . .”).
106 Supplemental Examination Provisions of the AIA, 77 Fed. Reg. at 48,853 (to be codified at 37 C.F.R. § 1.625(d)(2–3)) (“(2) Reexamination of any claim of the patent may be conducted on the basis of any item of information; . . . (3) Issues in addition to those raised by patents and printed publications . . . may be considered and resolved . . . .”).
107 See id. at 48,853 (to be codified at 37 C.F.R. § 1.625(b)).
108 See id. at 48,853 (to be codified at 37 C.F.R. § 1.625(c)) (stating that if there is no SNQP, then the reexamination fee is refunded in accordance with 37 C.F.R. § 1.26(c)).
109 Id. (stating that the certificate will indicate whether any item considered raised a SNQP).
Regardless of whether a SNQP arises, supplemental examination, by itself, is enough to grant the patent immunity with respect to the items considered. Thus, unless an exception applies, the patent cannot be held unenforceable in view of the information considered during supplemental examination.

Nonetheless, there is some risk during every supplemental examination that the Office may determine that the new information presents evidence of material fraud. While finalizing the AIA, Senator Kyl recommended that the standard for judging material fraud should be in line with Therasense, persuading the Office to use this standard as the lower boundary for material fraud. Of course, this standard is subject to judicial interpretation.

**IV. MATERIAL FRAUD IN VIEW OF THERASENSE**

Although supplemental examination is supposed to shield a patent owner from inequitable conduct claims, the Office could actually uncover material fraud during supplemental examination. The Office refers to inequitable conduct in Therasense to define the lower boundary of material fraud. The Therasense court shifted inequitable conduct jurisprudence towards a stricter standard. The interplay between supplemental examination and Therasense is likely to be minimal because the standard requires egregious deception, the applicant controls which documents are reviewed, and third party submissions are excluded.

**A. Defining Material Fraud and Inequitable Conduct**

The Office states that "material fraud" is narrower than inequitable conduct as defined in Therasense. Inequitable conduct requires two elements: (1) intent to deceive and (2) materiality of the reference with respect to patentability. Under

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110 35 U.S.C.A. § 257(c)(1) (West 2012) (stating that a patent shall not be held unenforceable if the information was considered during supplemental examination).
112 157 CONG. REC. S5429 (daily ed. Sept. 8, 2011) (statement of Sen. Kyl). (suggesting that the Director should use the standard in Therasense to determine whether a fraud is “material”).
113 See infra Part IV.A.
114 See infra Part IV.B.
115 See infra Part IV.C.
117 See Star Scientific, Inc. v. R.J. Reynolds Tobacco Co., 537 F.3d 1357, 1365 (Fed. Cir. 2008) (“To successfully prove inequitable conduct, the accused infringer must present ‘evidence that the applicant (1) made an affirmative misrepresentation of material fact, failed to disclose material information, or submitted false material information, and (2) intended to deceive the
the current Rule 56, information is material to patentability if it establishes, by itself or in combination, a *prima facie* case of unpatentability, or is inconsistent with an applicant’s assertion to the Office.\(^{118}\)

Prior to *Therasense*, these two elements were weighed on a “sliding scale,” where a patent could be held unenforceable by a strong showing of materiality and a minimal showing of intent, and vice versa.\(^{119}\) The *Therasense* court narrowed this definition by requiring both elements and setting higher thresholds for each.

**B. Federal Circuit Ruling in Therasense**

1. Background

*Therasense, Inc. v. Becton, Dickinson & Co.*, involves disposable blood glucose strips used to help diabetics measure the glucose levels in their blood.\(^{120}\) An electrochemical reaction on the strip generates an electrical current corresponding to the glucose concentration.\(^{121}\) *Therasense* (now Abbott Laboratories (Abbott)), owns U.S. Patents 5,820,551 (‘551) and 4,545,382 (‘382).\(^{122}\) The alleged novelty of the ‘551 patent was that the reaction occurred without an intervening membrane, whereas the ‘382 patent required a membrane.\(^{123}\)

As pointed out by the examiner, the ‘382 patent specification disclosed that a protective membrane was optional, yet not required: “*Optionally, but preferably* when being used on live blood, a protective membrane surrounds both the enzyme and the mediator layers, permeable to water and glucose molecules.”\(^{124}\)

In order to overcome this reference, the examiner required a qualified scientist’s declaration swearing that one skilled in the art would read this description as requiring a membrane.\(^{125}\) Abbott did exactly this, asserting that the

\(^{118}\) 37 C.F.R. § 1.56(b) (2010).
\(^{119}\) Am. Hoist & Derrick Co. v. Sowa & Sons, Inc., 725 F.2d 1350, 1363 (Fed. Cir. 1984) (“Thus, for example, where an objective “but-for” inquiry is satisfied . . . a lesser showing of facts from which intent can be inferred may be sufficient to justify holding the patent invalid or unenforceable, in whole or in part.”).
\(^{120}\) 649 F.3d 1276, 1282 (Fed. Cir. 2011).
\(^{121}\) *Id.*
\(^{122}\) *Id.* at 1283.
\(^{123}\) *Id.*
\(^{124}\) *Id.* (citing U.S. Patent No. 4,545,382 (col. 4 at ll. 63–66) (filed Oct. 22, 1982)) (emphasis added).
\(^{125}\) *Id.*
“optionally, but preferably” language was mere “patent phraseology.” The examiner allowed the patent and on the day of issuance Abbott asserted it against a competitor in an infringement action. Unfortunately for Abbott, this language was inconsistent with a prior assertion in a sibling case prosecuted at the European Patent Office (EPO).

2. EPO Prosecution

The '382 patent application’s European counterpart issued as European Patent 0,078,636 ('636). During prosecution, Abbott made assertions that were exactly opposite to the assertions made at the USPTO. For example, with respect to the same “optionally, but preferably” language: “It is submitted that this disclosure is unequivocally clear. The protective membrane is optional, however, it is preferred when used on live blood in order to prevent the larger constituents of the blood, in particular erythrocytes from interfering with the electrode sensor.”

The Applicant never submitted the EPO assertion to the USPTO. The USPTO examiner only allowed the contested patent after an affidavit was filed in which an expert asserted a specific interpretation of the prior art. Becton pled inequitable conduct on the grounds that this interpretation was inconsistent with representations in the application prosecuted before the EPO.

3. Narrower Inequitable Conduct Standard in Therasense

In one fell swoop, the Therasense court shifted inequitable conduct jurisprudence towards a stricter standard. The decision pivoted on how much weight to give the assertions made to the EPO, which were withheld from the USPTO and inconsistent with an affidavit filed with the USPTO just prior to issuance.

The en banc panel affirmed that inequitable conduct requires intent to deceive and materiality of the reference, but went further, holding that omitted information is only material if “but-for” its exclusion the claim or patent would not have issued. Similarly, the court affirmed that the standard for intent to

126 Id.
128 See Therasense, 649 F.3d at 1284 (referring to J.A. 6585) (emphasis added).
129 Id. at 1291 (“When an applicant fails to disclose prior art to the PTO, that prior art is but-for material if the PTO would not have allowed a claim had it been aware of the undisclosed prior art.”). But see id. at 1292 (“This court recognizes an exception in cases of affirmative egregious misconduct. . . . [For example,] ‘deliberately planned and carefully executed scheme[s]” to defraud the PTO and the courts.” (quoting Hazel-Atlas Glass Co. v. Hartford-Empire Co., 322 U.S. 238, 245 (1944))).
deceive also requires a threshold level of “clear and convincing” evidence. The court went even further, holding that both elements must exceed the clear and convincing evidence standard, as compared to the previously applied lower standard of a preponderance of the evidence, and that they should not be weighed on a sliding scale. A claim rejection is a USPTO judgment subject to review by the courts. “But-for” materiality means that the omitted information renders the claim invalid because the USPTO would not have allowed the claim if it had been aware of the reference. This case-within-a-case invalidity is indeed far more difficult to prove.

The court vacated and remanded the Therasense case with respect to the inequitable conduct claims. With respect to materiality, the district court was charged with determining whether the USPTO “would not have granted the patent but for Abbott’s failure to disclose the EPO briefs.” With respect to intent to deceive, the district court was charged with determining whether the practitioners knew of the briefs and their materiality and “made the conscious decision not to disclose them in order to deceive the PTO.”

4. District Court Findings upon Remand

In March 2012, the district court applied this new stricter standard and nonetheless found Abbott’s ’551 patent unenforceable due to inequitable conduct. Citing the same evidence as above, the court found that the USPTO would not have allowed the patent if it had been made aware of the EPO brief.

The court also found that Abbott knew that the withheld assertion was material and that the attorneys in question intentionally withheld this assertion because it would seriously undermine the patentability of the invention. The court found that the intent to deceive was especially strong in light of the infringement suit filed the same day as issuance.

130 Id. at 1290 (stating that the accused infringer must prove that the patent owner acted with the specific intent to deceive the PTO (citing Star Scientific, Inc. v. R.J. Reynolds Tobacco Co., 537 F.3d 1357, 1366 (Fed. Cir. 2008)).

131 Therasense, 649 F.3d at 1290 (“A district court should not use a ‘sliding scale,’ where a weak showing of intent may be found sufficient based on a strong showing of materiality, and vice versa.”).

132 Id. at 1296.
133 Id.
134 Id.
136 See id. at 868.
137 Id. at 865.
138 Id. at 868.
Today, the disputed patent is unenforceable, as the appeal was dismissed and attorney fees awarded. This provides an important example of what constitutes inequitable conduct under the Federal Circuit’s stricter standard, since it was applied to the very facts upon which the new standard was based. Nonetheless, it is not entirely clear how an examiner would apply the Federal Circuit’s *Therasense* inequitable conduct standard to material fraud during supplemental examination.

**C. Interplay Between Supplemental Examination and Therasense**

Dictum in the Federal Circuit’s opinion in *Therasense* appears to predict a reduction in inequitable conduct pleadings following the implementation of a stricter standard. Although it may be too soon to assess the accuracy of this prediction, supplemental examination provides an additional route for patent owners to bypass these claims. Since the *Therasense* standard is the minimum threshold for material fraud in supplemental examination, the holding has additional impact beyond the courts. Supplemental examination should allow patent owners to cleanse a patent from innocent oversights while still detecting fraud. Yet given the statutory protection granted to the supplemental examination request, the applicant’s control over the scope of examination, the *Therasense* standard, and the exclusion of third parties, the Office will rarely uncover material fraud. If material fraud is suspected, errors of commission will likely be treated harsher than errors of omission.

1. **The USPTO Could Uncover Material Fraud During Ex Parte Reexamination**

During supplemental examination, a patent owner is limited to submitting a request, which “shall not be relevant to enforceability of the patent.” During the actual examination, statements, interviews, and amendments are not allowed. Thus, a patent owner’s actions are limited to the submission request which “shall
not be relevant to enforceability,” essentially a form of statutory immunity. Nonetheless, the Office must contemplate some situation where the supplemental examination itself would uncover material fraud because it provided the *Therasense* standard. Since the supplemental examination request has statutory immunity, an *ex parte* reexamination ordered after supplemental examination could reveal evidence of material fraud, though this is unlikely.

The request itself contains only information selected by the patent owner, giving the applicant complete control over what information is reviewed. If the prosecuting attorney is filing the supplemental examination request, he or she is unlikely to volunteer information that could be considered material fraud since this would put both the patent and the attorney’s license at risk. But patent practitioners might think twice about “airing their dirty laundry.”

Furthermore, if the patent owner changes representation and the new attorney suspects material fraud during the prosecution, the attorney will likely advise against supplemental examination since the patent could be declared invalid during the *ex parte* reexamination. This disincentive to submit particularly harmful information is aided by the exclusion of third parties whom may have the most to gain from invalidating the patent. Thus, if the Office uncovers material fraud, it will most likely be from a small subset of unsuspecting practitioners or those with a high-risk tolerance. If this does happen, *Therasense* provides a concrete example of the minimum level of conduct that could lead to material fraud in practice.

2. Potential Examples of Material Fraud

   a. Errors of Commission

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145 See id. § 257(a) (West 2012).
146 Courtenay Brinckerhoff, *Supplemental Examination: Airing Your Dirty Laundry?*, PHARMAPATENTS (Feb. 1, 2012), http://www.pharmapatentsblog.com/2012/02/01/supplemental-examination-airing-your-dirty-laundry/#page=1 (“The new Supplemental Examination provisions have been described as a mechanism by which patent holders can ‘launter’ information that might otherwise render their patents unenforceable. Perhaps the price of being able to launder information to avoid inequitable conduct charges is having to air your dirty laundry in public.”).
148 Supplemental Examination Provisions of the AIA, 77 Fed. Reg. at 48,845 (to be codified at 37 C.F.R. § 1.601(b)).
An error of commission is a mistake where an actor does something wrong, as opposed to an error of omission where inaction is the mistake.\textsuperscript{149} Errors of commission can arise during patent prosecution when an applicant asserts knowingly false or inconsistent statements or arguments, for example, when an applicant refutes an examiner’s argument or makes an argument of patentability.\textsuperscript{150} Failing to disclose the relevant information can breach the Rule 56 duty of disclosure.\textsuperscript{151} For example, the losing party in \textit{Therasense} breached this duty because the EPO brief was inconsistent with the USPTO affidavit.\textsuperscript{152} Although this withholding could be viewed as an error of omission because the brief was not disclosed to the USPTO, it is more likely to be considered a false statement or an error of commission because the affidavit directly contradicted the EPO brief.

The USPTO and the courts treat errors of commission harsher than errors of omission because the applicant had to take affirmative steps to make the error.\textsuperscript{153} Furthermore, it is easier to prove that an applicant had intent to deceive if there are affirmative actions or statements, as opposed to inaction or silence. With respect to supplemental examination and any subsequent reexamination, the

\begin{footnotes}
\footnote{150}{37 C.F.R. § 1.56(b)(2)(i)-(ii) (2010) (“[I]nformation is material to patentability when it . . . is inconsistent with, a position the applicant takes in: (i) Opposing an argument of unpatentability relied on by the Office, or (ii) Asserting an argument of patentability.”).}
\footnote{151}{Id. § 1.56(a) (“The duty to disclose all information known to be material to patentability is deemed to be satisfied if all information known to be material to patentability of any claim issued in a patent was cited by the Office or submitted to the Office . . ..”).}
\footnote{152}{Id. § 1.56(b)(2)(i).}
\footnote{153}{Larson Mfg. Co. of S.D., Inc. v. AluminArt Prods. Ltd., 559 F.3d 1317, 1343 (Fed. Cir. 2009) (Linn, J., concurring) (“The Supreme Court's three inequitable conduct cases involved overt fraud, not equivocal acts of omission.” (citing Precision Instrument Mfg. Co. v. Auto Maint. Mach. Co., 324 U.S. 806, 809, 819 (1945))); see also Erstling, supra note 30, at 337–38 (“The seminal 1945 [Supreme Court] case of Precision Instrument Manufacturing Co. . . . involved perjury and fraud in an interference proceeding. During the proceeding’s discovery phase, the patentee learned that the opponent had lied by submitting false affidavits about the dates of conception and disclosure of the invention as well as about inventorship. Rather than reporting the fraud, the patentee settled the interference and received rights to both the patents in question. When the patentee attempted to enforce the patents in a subsequent infringement action, the district court refused to do so, and the Supreme Court ultimately agreed, arguing that not only the doctrine of unclean hands, but also the public interest, precluded the enforcement of ‘perjury-tainted patents.’” (footnotes omitted) (citing Precision Instrument Mfg. Co., 324 U.S. at 816)).}
\end{footnotes}
USPTO is more likely to find material fraud if it uncovers an error of commission.

b. Errors of Omission

During international patent prosecution, foreign offices often cite references not cited by the USPTO. Practitioners will typically file an information disclosure statement (IDS) with the Office to provide this reference to the examiner for consideration in the prosecution of the U.S. patent. This can create a complex web of references, especially when prosecuting multiple patents in multiple jurisdictions and different languages. Supplemental examination can likely remedy an inadvertent omission, especially if the reference is similar to references previously raised by the USPTO.

If the Therasense court instead considered a common error of omission, it is difficult to see how the court would have found intent to deceive. For example, if a reference was cited during the EPO prosecution and that reference was never submitted to the USPTO, it would be difficult to prove that Abbott had specific intent to deceive, especially under the clear and convincing evidence standard. Thus, this error of omission would most likely be viewed in a more favorable light.

Nonetheless, problems may arise, particularly if the reference was used to bar patent rights in a foreign jurisdiction or significantly narrow the claims compared to the U.S. counterpart. A savvy litigator could plant seeds of doubt that the patent practitioner intentionally withheld the reference.

Based on the strict standard in Therasense, the Office is unlikely to uncover material fraud during supplemental examination. This is because the request has statutory immunity, the patent owner selects what information is considered, third parties are excluded, and the standard requires particularly egregious conduct. This is illustrated by the historical preference to find inequitable conduct in acts of commission compared with acts of omission. Since filing a supplemental examination request is by definition an act (as opposed to an omission), questions invariably arise regarding whether supplemental examination could create new grounds for inequitable conduct. The answer is an uncomfortable maybe.

154 37 C.F.R. § 1.98 (2010) (“Any information disclosure statement . . . shall include . . . (1) A list of all patents, publications, applications, or other information submitted for consideration by the Office.”).
155 See 35 U.S.C.A. § 257(c)(1) (West 2012) (stating that if the information raises no SNQP, the patent cannot be held unenforceable).
V. SCOPE OF SUPPLEMENTAL EXAMINATION VS. SCOPE OF IMMUNITY: COULD A PATENTEE REMAIN VULNERABLE TO INEQUITABLE CONDUCT CLAIMS AFTER SUPPLEMENTAL EXAMINATION?

Academic and public commentary illuminated potential mismatches between the scope of immunity and the scope of the supplemental examination. This may manifest in at least three fact patterns. First, assuming blanket immunity, a disreputable patent owner may try to mislead the examiner by limiting the scope of the identified issues, steering the examination away from sensitive subject matter. Second, if a court limits immunity to the scope of examination, a patent owner that does not fully recognize all possibilities may present a limited case, opening the door to, albeit narrower, inequitable conduct claims. Third, a position taken during supplemental examination, if contrary to prior assertions, may create fodder for future inequitable conduct claims.

A. Immunity Awarded to Undeserving Patent due to Mischaracterization by a Mistaken or Disreputable Applicant

Many comments, and at least two law review articles, pointed out a potential loophole in the law where, whether by mistake or unethical behavior, an undeserving patent may obtain “amnesty” from inequitable conduct claims. This possibility is rooted in the potential disconnect between the scope of the examination and the scope of rights awarded by supplemental examination.

1. Scope of Supplemental Examination

At first glance, the scope of the supplemental examination is identical to the scope of rights awarded because the examination explores all information

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156 See generally White, supra note 39.
157 See infra Part V.A.1–2.
158 See infra Part V.A.4.
159 See infra Part V.B.
160 Jason Rantanen & Lee Petherbridge, Toward a System of Invention Registration: The Leahy-Smith America Invents Act, 110 Mich. L. Rev. First Impressions 24, 25 (2011) (describing supplemental examination as a patent amnesty program, “encourag[ing] patent applicants to use any number of strategies that would never have been countenanced under pre-AIA law to obtain patents, and it offers to cure all but the most extreme through filing a supplemental examination request.”); see also Jason Rantanen et al., America Invents, More or Less?, 160 U. Pa. L. Rev. Penumbra 229, 231 (2012) (“Another change that carries the potential to reduce patent-encouraged innovation is the AIA’s supplemental examination provision, which immunizes patents from charges that applicants deceived the Patent Office into allowing patents that do not satisfy the requirements for patentability.” (citing 35 U.S.C.A. § 257 (West 2012))).
presented, and the immunity applies to the entire patent with respect to that information.\textsuperscript{161}

The statute compels the Director to indicate whether the “information presented in the request raises a substantial new question of patentability.”\textsuperscript{162} There is no reason to believe that “information” should be interpreted differently from the Rule 56 duty of disclosure in patent cases, which requires that patent owners disclose information material to any claim.\textsuperscript{163} Material information is somewhat circularly defined as anything “material to patentability.”\textsuperscript{164} This includes patents and printed publications but also prior public uses, sales, offers to sell, and prior invention by another. Thus, in theory, all “information” is considered when determining if a SNQP exists. In practice though, the rules allow a patent owner to mislead the examiner, whether intentionally or accidentally. The rules require that the supplemental examination request contain “[a] separate, detailed explanation of the relevance and manner of applying each item of information to each claim of the patent for which supplemental examination is requested.”\textsuperscript{165}

Thus, supplemental examination may not examine all claims in a patent. The option to limit which claims are examined is reiterated: “The determination will generally be limited to a review of the item(s) of information identified in the request as applied to the identified claim(s) of the patent.”\textsuperscript{166}

Optionally, a patent owner may attempt to frame the issues by including “an explanation of how the claims patentably distinguish over the items of information”\textsuperscript{167} or an “explanation of why each item of information submitted with the request does or does not raise a substantial new question of patentability.”\textsuperscript{168} The Office most likely implemented these mechanisms in order to reduce the burden on the examiners by forcing the patent owner to focus on the relevant issues and pertinent claims. Yet this can introduce significant bias.

\textsuperscript{161} 35 U.S.C.A. § 257(a), (c) (West 2012) (stating that “information” is examined with respect to a “patent” and the “patent” cannot be held unenforceable based on that “information”).

\textsuperscript{162} Id. § 257(a) (West 2012) (emphasis added).

\textsuperscript{163} 37 C.F.R. § 1.56(a) (2010).

\textsuperscript{164} MPEP, supra note 65, § 2001.04.


\textsuperscript{166} Id. (to be codified at 37 C.F.R. § 1.620(a)) (emphasis added).

\textsuperscript{167} Id. at 48,852 (to be codified at 37 C.F.R. § 1.610(c)(3)).

\textsuperscript{168} Id. at 48,852 (to be codified at 37 C.F.R. § 1.610(c)(4)).
Within these optional explanations, any relevant issues will most likely be framed in the light most favorable to the patent owner. Furthermore, by limiting the scope of the supplemental examination to the “claim[s] . . . requested,” the patent owner may sidestep the very questions of patentability that the information raises. This could create a brand new allegation of inequitable conduct. For example, the intentional misdirection of the examiner to avoid a valid SNQP could lay the grounds for future inequitable conduct claims even though the initial failure to submit the reference may not be inequitable.

Assuming not every conceivable issue is presented and examined, supplemental examination is unlikely to explore every aspect of the presented information in view of all allowed claims. The mismatch in scope of examination is paired with a mismatch in the scope of immunity.

2. Scope of Immunity

The statute compels the courts to provide full immunity to inequitable conduct claims stemming from references submitted for supplemental examination: “A patent shall not be held unenforceable on the basis of conduct relating to information” if that information is considered during supplemental examination. A plain reading of the statute implies that if an item of information is presented during supplemental examination a court has no choice but to dismiss all inequitable conduct claims “relating” to that information. This protection extends to the “patent” rather than just the patent claims scrutinized during supplemental examination. The clear statutory language provides minimal room to maneuver.

This presents an opportunity for a disreputable practitioner to obtain “amnesty” from actual inequitable behavior. As outlined in one comment, the patent owner could limit the examination to patent owner-identified issues of patentability yet claim the full statutory protection. Thus, a patent owner could

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169 Id. (to be codified at 37 C.F.R. § 1.610(b)(5)).
171 Id. § 257(c) (West 2012) (“shall” indicates that the court must dismiss claims “relating to information . . . considered . . . during a supplemental examination”).
172 Rantanen & Petherbridge, supra note 160, at 25.
173 Letter from William P. Berriedge, Oliff & Berriedge, PLC, to Cynthia L. Nessler, U.S. Patent & Trademark Office, Office of Patent Legal Admin., at 7 (Mar. 20, 2012) (on file with USPTO), available at http://www.uspto.gov/patents/law/comments/sup_exam/xs_d-oliff_20120320.pdf (“[T]he USPTO proposes to allow patent owners to determine the contours of supplemental information and limit the USPTO’s consideration of information to only patent owner-identified issues of patentability and claims, while providing those same patent owners with the full statutory exemption from inequitable conduct claims.”).
use supplemental examination as a shield such that the Office never addresses the actual issues of patentability.  

3. USPTO Response

The USPTO briefly addressed suggestions that supplemental examination should “entail a general reassessment of all issues of patentability” as opposed to only applicant-identified issues. The Office asserted that supplemental examination will be “generally limited to a review of the item(s) of information identified in the request with respect to the identified claim(s) of the patent.” By using the words “generally limited,” the Office reserves the right to broaden the scope of supplemental examination beyond the identified claims. Yet later in the response, the Office “put[s] the patent owner on notice that unless the patent owner identifies the particular claim(s) which the patent owner requests the Office to consider with respect to each item of information, the record may not reflect that these claim(s) were explicitly considered by the examiner.”

This appears to conflict with the broad statutory language that “information” considered during supplemental examination cannot be raised in an inequitable conduct claim. Nonetheless, citing the burden of completing an “accurate and comprehensive determination” within the three-month statutory window, the Office resolutely places the onus on the patent owner to call out all the claims related to any SNQP. The Office ends by noting that, contrary to the statutory language, the scope of immunity could be a judicial question “within the purview of the courts.”

4. An Incomplete Supplemental Examination May Leave Patentees Vulnerable to Limited Inequitable Conduct Claims

A court could limit the scope of inequitable conduct immunity to be commensurate with the scope of examination. This means that an item of information presented during supplemental examination could potentially be asserted in an inequitable conduct claim if it was not fully considered, for

174 Id. at 8 (“[T]he patent owner would have effectively used supplemental examination to protect itself against an allegation of inequitable conduct without the USPTO or the court actually analyzing relevant issues of patentability and relevant claims.”).


176 Id. (referring to proposed 37 C.F.R. § 1.620(a)) (emphasis added).

177 Id.

178 Id.

179 Id. (“As to the level of unenforceability protection, the issue of whether a court would be statutorily required to dismiss all allegations of inequitable conduct involving a particular item of information is within the purview of the courts.”).
example, if some claims are not examined or are incompletely examined. This runs contrary to the statutory language barring inequitable conduct claims “bas[ed] on conduct relating to information” considered during supplemental examination. Furthermore, this undoing of statutory immunity would likely complicate the litigation, raising costs and the burden on courts.

A judicial interpretation to allow inequitable conduct claims relating to information considered during supplemental examination would appear to undermine the statutory language. As noted above, a court “shall not” hold a patent unenforceable on grounds relating to information considered during supplemental examination. Thus, it is unlikely, but not inconceivable, that a court would limit the scope of immunity to anything less than the entire patent. If a court did indeed limit the immunity, it would most likely be commensurate with the scope of examination. Since the Office would have only examined the selected claims in view of the new information, it makes sense to extend statutory protection to the examined claims.

Thus, a safe route for both patent owners and practitioners is to request examination of all claims. Additionally, keeping the characterization of the invention and prior art to a minimum should reduce any practitioner-introduced bias. By keeping the scope of supplemental examination as broad as possible, the patent owner should, in theory, be awarded with broad immunity.

B. Supplemental Examination Could Create New Grounds for Inequitable Conduct Not Protected by Limited Immunity

Though unlikely, a patent could receive only limited protection after supplemental examination. If so, one question is whether conduct relating to the supplemental examination could create new grounds for inequitable conduct. For example, the written explanation of the “relevance and manner” in which the information relates to the claims could run contrary to a stance taken during prosecution. Furthermore, an unethical practitioner could avoid addressing the very SNQP that the information raises by limiting the scope to a less significant issue. Regardless of the nature, the statute appears to shield supplemental

181 Id.
182 Supplemental Examination Provisions of the AIA, 77 Fed. Reg. at 48,852 (to be codified at 37 C.F.R. § 1.610(b)(5)).
examinees from inequitable conduct claims relating to the supplemental examination request, though issues may arise during an ensuing reexamination.

After submitting a supplemental examination request, the patent owner is effectively barred from communicating with the Office regarding substantive matters in the supplemental examination. Prohibited actions include conducting interviews as well as submitting alternative claim language or proposed amendments. Even if ex parte reexamination is ordered after supplemental examination, the patent owner does not have the right to file a statement or proposed amendment.

Thus, outside of the initial supplemental examination request, there is little opportunity during supplemental examination for a patent owner to act inequitably. Yet, any number of issues could arise during the subsequent ex parte reexamination. “The Federal Circuit has held that the submission of information during reexamination . . . does not bar a subsequent inequitable conduct defense based on that information.”

Although the supplemental examination request is entitled to statutory immunity, § 257 grants no protection to the subsequent reexamination. Furthermore, any protection granted to the request is limited to inequitable conduct defenses under § 282. Thus, some conduct surrounding the request and any ex parte reexamination is still subject to Rule 56 sanctions. For example, if a practitioner attempts to avoid addressing a SNQP in a request by mischaracterizing a reference, the practitioner could be subject to Office disciplinary proceedings.

Supplemental examination provides a shield that only deflects inequitable conduct attacks in a courtroom. As such, patent owners should be on guard when

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185 Supplemental Examination Provisions of the AIA, 77 Fed. Reg. at 48,853 (to be codified at 37 C.F.R. § 1.620(e)).
186 Id. (to be codified at 37 C.F.R. § 1.620(f)); see also id. at 48,844 (stating in response to comment 30 that amendments could “create a cloud on the patent” if the Office determines that no SNQP exists).
189 35 U.S.C.A. § 257(b) (West 2012) (stating that if ex parte reexamination is ordered, the statute makes no mention of enforceability or lack thereof).
190 Id. § 257(c)(1) (West 2012) (“The making of a request . . . shall not be relevant to enforceability of the patent under section 282.”).
submitting a supplemental examination request. The statutory immunity during litigation is unlikely to apply to other proceedings in the Office. Although a supplemental examination request is unlikely to generate fodder for future inequitable conduct claims, a patent practitioner may still become ensnared in other Office matters if not careful.

VI. PROPOSED STATUTORY AND & REGULATORY CHANGES

As presently enacted, supplemental examination is unlikely to significantly reduce the number of inequitable conduct claims pled during patent infringement suits. This is because the cost is high, the scope of examination and immunity are uncertain, and patent attorneys will be hesitant to inadvertently create fodder for future inequitable conduct claims. Congress should amend § 257 to improve access to supplemental examination and reduce these uncertainties, aligning the proceedings with the congressional intent. Revised statutory language is proposed and discussed below.

A. Proposed Statutory Language

Congress should append the italicized language after the last sentence of 35 U.S.C. § 257(a):

A patent owner may request supplemental examination of a patent in the Office to consider, reconsider, or correct information believed to be relevant to the patent, in accordance with such requirements as the Director may establish. Within 3 months after the date a request for supplemental examination meeting the requirements of this section is received, the Director shall conduct the supplemental examination and shall conclude such examination by issuing a certificate indicating whether the information presented in the request raises a substantial new question of patentability. The Director may extend the three-month deadline at the request of the Applicant.

Congress should amend 35 U.S.C. § 257(c)(1) to incorporate the following italicized language:

A patent shall not be held unenforceable, with respect to a claim in the patent, on the basis of conduct relating to information that had not been considered, was inadequately considered, or was incorrect in a prior examination of the patent claim if the information was considered, reconsidered, or corrected during a supplemental examination of the patent claim. The making of a request under

\(^{191}\) See infra Part VI.A.

\(^{192}\) See infra Part VI.B–D.
subsection (a), or the absence thereof, shall not be relevant to enforceability of the patent under section 282 or 37 C.F.R. § 1.56.

B. Applicant-Initiated Exception to the Three-Month Limit Allows a Simpler Fee Structure.

The proposed amendment to § 257(a) enables an applicant to extend the three-month statutory limit, providing the USPTO with an avenue to create a simpler fee structure. This would enable a sliding scale fee approach because the Office would not be under the time pressure when considering thirteen items or more. Additionally, the sliding scale could have a lower limit of one item, so that the remedial cost for a single flaw in prosecution is less than twelve flaws. Overall, this is a step towards making the fees commensurate with the burden on the Office. Importantly, the USPTO would have to amend 37 C.F.R. §§ 1.605193 and 1.620194 accordingly for the statutory amendment to have an effect.

C. Limit the Scope of Immunity to the Claims Examined

The proposed amendments to § 257(c) regarding patent claims should clarify the scope of examination and immunity. The proposed amendment requires a claim to be considered during supplemental examination in order to qualify for statutory protection from inequitable conduct. This eliminates the loophole where a practitioner could direct the examiner to only one claim yet receive full statutory protection for the entire patent.

Unfortunately, this still leaves open the possibility that a disreputable practitioner may try to steer the examiner away from a sensitive issue. This is an acceptable compromise because it is unreasonable to expect the examiner to consider every conceivable way that an item of information could apply to a given claim. If the examiner is directed to both the claim and item of information, the examiner will likely scrutinize the reference at least as closely, if not closer, as during an initial patent prosecution. This should greatly reduce the likelihood that a significant issue slips past the examiner.

193 37 C.F.R. § 1.605(a) (2010) (proposed italicized language to be added after the first sentence: “Each request for supplemental examination may include no more than twelve items of information believed to be relevant to the patent. The Director may allow a supplemental examination request to include more than twelve items if the Applicant waives the three-month deadline for the Office to respond. More than one request for supplemental examination of the same patent may be filed at any time during the period of enforceability of the patent.”).

194 Id. § 1.620(a) (proposed italicized language to be added after the first sentence: “Within three months after the filing date of a request for supplemental examination, the Office will determine whether a substantial new question of patentability affecting any claim of the patent is raised by any of the items of information presented in the request. The Director may extend the three-month deadline at the request of the Applicant. The determination . . . .”).
D. Extend the Protection Given to the Request to Rule 56

The proposed amendment to § 257(c) extends the protection given to the supplemental examination request beyond inequitable conduct in court and to Rule 56 at the USPTO. Including Rule 56 immunity will eliminate the possibility that the request itself creates disciplinary grounds before the USPTO. If the Office believes that content in the request could be considered inequitable, reexamination can be ordered and any issues clarified. This is important because it will increase access to supplemental examination by reducing uncertainty. A patent practitioner will likely be hesitant to submit a supplemental examination request if it could lead to Rule 56 disciplinary proceedings. The proposed amendment aligns the interests of practitioners with the patent owner.

These proposed statutory amendments close loopholes in the supplemental examination proceedings and increase access. As more patents undergo the scrutiny of supplemental examination, fewer patents will be eligible for inequitable conduct claims in lawsuits, furthering the intent of Congress.

VII. CONCLUSION

Supplemental examination is a good start in the effort to stem the “plague” of inequitable conduct claims. As currently implemented, it is unlikely to be the panacea that Congress envisioned while drafting the AIA. Future amendments may increase access to the proceedings by making supplemental examination cheaper and reducing the risk that an honest practitioner inadvertently create evidence that could be used in future inequitable conduct claims.

Supplemental examination requires a patent owner to part with a large sum of money to examine up to twelve items, though a large fraction may be refunded. This fixed-fee structure unlinks the fee from the burden of examination. The Office could implement a sliding scale if Congress allowed exceptions to the three-month statutory turnaround time, lowering fees and simplifying examination of large portfolios.

The Office predicts scenarios where it may uncover material fraud during supplemental examination. To assist the examiners, the Office set the threshold for material fraud to be narrower than inequitable conduct in *Therasense*. Applicants’ actions will have to be especially egregious to exceed this strict standard. Given the limited interaction with the Office during supplemental examination, as well as statutory protection, the Office will rarely uncover material fraud. This will be reinforced by practitioners’ hesitancy to submit information that they know could be considered fraudulent.
The statutory language, especially in view of the USPTO rules, leaves room for judicial interpretation of whether the scope of supplemental examination matches the scope of protection from inequitable conduct proceedings. Depending on the statutory construction, at least three mechanisms exist where supplemental examination could give rise to inequitable conduct. First, a disreputable patent owner could mislead the examiner by steering the examination away from sensitive subject matter. Second, a patent owner that does not fully recognize all possibilities may present a limited case, opening the door to, albeit narrower, inequitable conduct claims. Third, a position taken during supplemental examination, if contrary to prior assertions, may create fodder for future inequitable conduct claims or Rule 56 violations. Statutory amendments could reduce the likelihood that these scenarios arise in practice.

Supplemental examination will likely become a niche arena like many of the other post-issuance proceedings. In some cases, it is likely to reduce claims of inequitable conduct, though many practitioners may hesitate to risk an issued patent and their clean record by acknowledging supposed flaws in prosecution. Supplemental examination will most likely be a precursor to most infringement suits because of the lower cost compared to litigation discovery. Furthermore, it will likely be used to expunge errors by less sophisticated counsel if technology based on a patent is pending purchase or further investment.

Though the future of supplemental examination is uncertain, these questions should resolve with time, and we will be able to better judge whether supplemental examination helped to reduce the “plague” of inequitable conduct pleadings.