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America Invents the Supplemental Examination, But Retains the Duty of Candor: Questions and Implications

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AMERICA INVENTS THE SUPPLEMENTAL EXAMINATION, BUT RETAINS THE DUTY OF CANDOR: QUESTIONS AND IMPLICATIONS

Lisa A. Dolak∗

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I. INTRODUCTION

The America Invents Act1 ("AIA") authorizes the U.S. Patent and Trademark Office ("USPTO") to undertake a "supplemental examination" of an issued patent to "consider, reconsider, or correct information believed to be relevant to the patent."2 It further bars the federal courts from holding a patent unenforceable "on the basis of conduct relating to information" considered during supplemental examination.3

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2. See infra notes 16-21 and accompanying text.
3. See infra notes 35-38 and accompanying text.
One obvious purpose underlying supplemental examination is to constrain the federal courts' power to entertain inequitable conduct-based challenges. Many such challenges are unsuccessful, if not unfounded.\textsuperscript{4} Supplemental examination will afford patent owners the opportunity to dispense with anticipated inequitable conduct charges,\textsuperscript{5} in some cases by demonstrating the immateriality of the information at issue.\textsuperscript{6} However, supplemental examination will obviate inequitable conduct challenges even if patent applicants have withheld or misrepresented material information with the intent to deceive the USPTO.\textsuperscript{7}

In this respect and in others, the introduction of supplemental examination into the patent system raises a number of questions. In particular, the new law includes a requirement that the USPTO refer incidents of suspected prosecution-related fraud to the Attorney General for investigation if the USPTO becomes aware of such circumstances.\textsuperscript{8} Registered practitioners are not only duty-bound, however, to refrain from fraud.\textsuperscript{9} They, as well as inventors and others who participate substantively in patent prosecution and reexamination, have a broader duty of candor.\textsuperscript{10} Under pre-AIA law, both the patent owner and the responsible practitioner could be penalized as a result of an intentional violation of the duty of candor.\textsuperscript{11} Using supplemental examination, however, an owner can decouple the enforceability of the patent from a prior candor violation, leaving the practitioner who is alleged or suspected to have committed the violation to face any potential consequences.\textsuperscript{12} These changes create implementation issues for the USPTO, potential ethics and tactical issues for practitioners, and questions about the impact of the new proceeding on the patent system, generally.

\textsuperscript{4} See, e.g., Thomas F. Cotter, An Economic Analysis of Patent Law's Inequitable Conduct Doctrine, 53 Ariz. L. Rev. 735, 737 n.2 (2011) (collecting studies relating to the frequency with which the defense is pled); Lee Petherbridge, Jason Rantanen & Ali Mojibi, The Federal Circuit and Inequitable Conduct, 84 S. Cal. L. Rev. 1293, 1308-09 (2011) (reporting the frequency with which patent owners succeed on the issue of inequitable conduct in written Federal Circuit decisions).

\textsuperscript{5} See infra notes 69-70 and accompanying text.

\textsuperscript{6} See infra notes 33-34 and accompanying text.

\textsuperscript{7} See infra notes 79-85 and accompanying text.

\textsuperscript{8} See infra notes 49-50, 86-90 and accompanying text.

\textsuperscript{9} 37 C.F.R. § 10.23(b)(4) (2012).

\textsuperscript{10} See 37 C.F.R. §§ 1.56, 1.555 (2012).


\textsuperscript{12} See infra Part III.B.3.
For example, what role, if any, will the USPTO Office of Enrollment and Discipline play in policing candor violations suggested by requests for supplemental examination? How might this new opportunity to liberate a patent from the consequences of possible misconduct in its procurement affect the attorney-client relationship and the practitioner who originally prosecuted the patent? Will patent owners embrace supplemental examination, or will they avoid it either because other post-grant opportunities now exist for the consideration of information that might ground an inequitable conduct charge, or out of concern that supplemental examination requests might invite unwanted scrutiny?

This paper considers these duty-of-candor-related issues—issues that the USPTO, the courts, patent owners, and patent challengers may face in the wake of the enactment of the AIA’s provisions relating to supplemental examination. But first, by way of background, Part II presents an overview of the legislation relating to supplemental examination and explores how supplemental examination might operate, in light of its apparent goals. Part III considers questions relating to the overlay of supplemental examination on the existing U.S. patent application and enforcement regime, with particular focus on its interplay with the applicant’s duty of candor. As that section illustrates, the focal point of that examination is the supplemental examination request. Accordingly, Part III introduces the discussion of the candor-related questions raised by supplemental examination by considering the range and nature of information such requests may contain. Part IV concludes.

II. SUPPLEMENTAL EXAMINATION: LEGISLATIVE FRAMEWORK, GOALS, AND OPERATION

A. Supplemental Examination in the AIA

The new supplemental examination proceeding will afford patent owners the opportunity to secure USPTO consideration of information that might otherwise give rise to an inequitable conduct challenge. In particular, section 12 of the AIA establishes a new section 257 in Title 35, U.S. Code, with six principal subsections, entitled “Request for Supplemental Examination,” “Reexamination Ordered,” “Effect,” “Fees

and Regulations," "Fraud," and "Rule of Construction." Subpart (a) introduces supplemental examination, as follows:

(a) Request for Supplemental Examination— 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.

Thus, the AIA creates a new USPTO proceeding designated as a "supplemental examination." The purpose is "to consider, reconsider, or correct information believed to be relevant to the patent" that is the subject of the request. The USPTO is charged with evaluating the information presented in the request under the familiar reexamination standard: "whether [it] raises a substantial new question of patentability," and it will have three months to make that determination. Only the patent owner will be able to request a supplemental examination.

The next section of the legislation sets forth the consequences of a USPTO determination that the request raises a substantial new question of patentability:

(b) Reexamination Ordered— 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. The reexamination shall be conducted according to procedures established by chapter 30, except that the

17. Id. at 325.
18. See id.
19. See id.
20. "If . . . the Director finds that a substantial new question of patentability affecting any claim of a patent is raised, the determination will include an order for reexamination of the patent for resolution of the question." 35 U.S.C.A. § 304 (West 2011). See, e.g., In re Swanson, 540 F.3d 1368, 1375 (Fed. Cir. 2008) (noting that "[t]he ‘substantial new question of patentability’ requirement prevents potential harassment of patentees by ‘act[ing] to bar reconsideration of any argument already decided by the [USPTO], whether during the original examination or an earlier reexamination.’" (quoting H.R. REP. NO. 96-1307(I) (1980); U.S. CODE CONG. & ADMIN. NEWS 6460, 6466 (1980)).
22. See id.
patent owner shall not have the right to file a statement pursuant to section 304. During the reexamination, the Director shall address each substantial new question of patentability identified during the supplemental examination, notwithstanding the limitations in chapter 30 relating to patents and printed publication or any other provision of such chapter.23

According to the new law, the consequence of a USPTO determination that any of the information in the request for supplemental examination raises a substantial new question of patentability will be a reexamination proceeding which differs from the usual ex parte reexamination in two principal respects. First, the patent owner (who filed the request for supplemental examination in the first place) will be barred from submitting a statement.24 Second, and significantly, the restriction limiting reexamination to consideration of “patents and printed publications”25 will not apply, and “information” is not otherwise limited or defined in the legislation. Accordingly, a patent owner will be able to use supplemental examination not only to bring to the attention of the USPTO prior art patents and printed publications, but also non-print prior art (such as pre-critical date sales and public uses) and non-prior art information of the kind the Federal Circuit had held to be material for purposes of the inequitable conduct defense, prior to its recent en banc decision overhauling that doctrine.26 Such non-prior art information includes:

- unpublished notes taken by a non-inventor, co-employee at a poster presentation,27
- a non-prior art article relevant to whether the claims at issue were enabled,28
- a third-party’s patent application (in the inventor’s possession) and information regarding the third-party’s

23. Id.
24. Having filed the supplemental examination request in the first place, the patent owner will presumably have had its say.
25. 35 U.S.C.A. § 302 (West 2011) authorizes “[a]ny person [to] file a request for reexamination . . . of any claim of a patent on the basis of any prior art cited under the provisions of section 301,” which authorizes the citation of “prior art consisting of patents or printed publications.” See id.
model of his own invention (which the inventor had seen),

- "intentional falsehoods, misrepresentations, and nondisclosures" relating to inventorship,
- a false statement in a Petition to Make Special, and
- unjustified claims to small entity status.

Some such non prior-art information (without more) clearly will not raise a "substantial new question of patentability," and even more clearly will not satisfy the Federal Circuit's new "but-for" materiality standard. However, at least where there is doubt about how a court might regard information—prior art or otherwise—that was (or was arguably) not considered (or inadequately considered) by the USPTO during original (or a prior) prosecution, a patent owner might well elect to pursue supplemental examination. New section 257(c) of the Patent Act sets forth the preemptive protection a patent owner can obtain via supplemental examination:

(c) Effect-

(1) IN GENERAL— 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. The making of a request under subsection (a), or the absence thereof, shall not be relevant to enforceability of the patent under section 282.33

This is the key provision in the supplemental examination portion of the AIA. Except as discussed below, the legislation strips the courts of the power to hold patents unenforceable for inequitable conduct in cases where the patentee has previously secured, via supplemental examination, USPTO consideration of the information the patent challenger alleges was withheld or misrepresented.36 A patent owner will be able to use supplemental examination to “consider, reconsider, or correct” information it knows or believes was not considered, was “inadequately considered, or was incorrect” during the initial examination or during a post-grant examination, such as reexamination.37 That a supplemental examination request was filed (or was not filed) will not otherwise bear on the patent’s enforceability.38

The injunction against a determination of unenforceability will not operate if either of two statutory exceptions applies:

(2) EXCEPTIONS—

(A) PRIOR ALLEGATIONS— Paragraph (1) shall not apply to an allegation pled with particularity in a civil action, or set forth with particularity in a notice received by the patent owner under section 505(j)(2)(B)(iv)(II) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(2)(B)(iv)(II)), before the date of a supplemental examination request under subsection (a) to consider, reconsider, or correct information forming the basis for the allegation.

(B) PATENT ENFORCEMENT ACTIONS— In an action brought under section 337(a) of the Tariff Act of 1930 (19 U.S.C. 1337(a)), or section 281 of this title, paragraph (1) shall not apply to any defense raised in the action that is based upon information that was considered, reconsidered, or corrected pursuant to a supplemental examination request under subsection (a), unless the supplemental examination, and any reexamination ordered pursuant to the request, are concluded before the date on which the action is brought.39

36. See id.
37. Id.
38. See id.
39. Id. at 326.
These exceptions relate to timing, and will be triggered by specified events. Under section 257(c)(2)(B), a patent owner contemplating an enforcement action (either in the district courts or in the International Trade Commission) and seeking to head off an anticipated inequitable conduct charge based on particular information, will only obtain the benefit of the section 257(c)(1) protection if the USPTO has concluded its supplemental examination of that information (at the patent owner’s request) and any resulting reexamination before the patent owner files its enforcement action. 40

The exception in new section 257(c)(2)(A) will apply when the patent challenger (as opposed to the patent owner) makes the first move, for example, by filing a declaratory judgment action or answer to complaint containing particularized allegations of inequitable conduct, or by sending the patent owner a Paragraph IV letter41 before the patent owner files a supplemental examination request. 42 In such a case, supplemental examination will not preclude litigation of the inequitable conduct defense at issue.43

40. See id.


(I) that such [Orange Book] patent information has not been filed, (II) that such patent has expired, (III) . . . the date on which such patent will expire, or (IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted . . . .


Under 35 U.S.C. § 271(e)(2)(A) (2006), the filing of an ANDA “for a drug claimed in a patent” constitutes an act of patent infringement if the ANDA applicant seeks approval to market the generic drug before the expiration of the patent(s) at issue (i.e., files a “Paragraph IV” certification). If the patent owner does not file suit against the ANDA applicant within forty-five days after receiving the required notice of the ANDA filing, the FDA is authorized to approve the ANDA. 21 U.S.C. § 355(j)(5)(B)(iii) (2006). However, if/when the ANDA application commences marketing the generic drug product, the patent owner is free to sue the ANDA for infringement.

42. Other commentators appear to have read section 257(c)(2) somewhat differently. See Bruce M. Wexler, Preston K. Ratliff II & Jason T. Christiansen, Will Inequitable Conduct Finally Be Reformed?, LAW 360 (June 29, 2010), http://www.law360.com/articles/172626 (discussing corresponding provisions in an earlier version of the legislation).

43. See 125 Stat. at 326.
These two exceptions will operate to encourage patent owners to seek (and complete) supplemental examination (and any resulting reexamination) regarding any potentially problematic information before filing suit. A patent challenger who wants to press an inequitable conduct defense, on the other hand, will have to assert that defense—in a declaratory judgment complaint, an answer to an infringement complaint, or a Paragraph IV letter—before the patentee initiates a supplemental examination. Note that in either case, the patentee will retain control over the situation because the patentee will decide when to file suit or take another enforcement-related step that will constitute the kind of "affirmative act" necessary to trigger declaratory judgment jurisdiction\(^44\) or list its patent(s) in the FDA Orange Book.\(^45\)

The AIA includes provisions relating to fee-setting and rule-making:

(d) Fees and Regulations-

(1) FEES— The Director shall, by regulation, establish fees for the submission of a request for supplemental examination of a patent, and to consider each item of information submitted in the request. If reexamination is ordered under subsection (b), fees established and applicable to ex parte reexamination proceedings under chapter 30 shall be paid, in addition to fees applicable to supplemental examination.

(2) REGULATIONS— The Director shall issue regulations governing the form, content, and other requirements of requests for supplemental examination, and establishing procedures for reviewing information submitted in such requests.\(^46\)

This section requires the USPTO to set fees for the filing and consideration of supplemental examination requests, and in addition, to collect the fees applicable to ex parte reexamination where reexamination is ordered.\(^47\) It also requires the USPTO to establish rules governing the submission and processing of such requests.\(^48\)

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\(^{44}\) See SanDisk Corp. v. STMicroelectronics, Inc., 480 F.3d 1372, 1380-81 (Fed. Cir. 2007) ("[J]urisdiction generally will not arise merely on the basis that a party learns of the existence of a patent owned by another or even perceives such a patent to pose a risk of infringement, without some affirmative act by the patentee.").

\(^{45}\) See supra note 41.

\(^{46}\) 125 Stat. at 326.

\(^{47}\) See id.

\(^{48}\) Id.
The next section of the legislation specifies what is to happen if the Director "becomes aware . . . that a material fraud on the Office may have been committed in connection with the [subject] patent":

(e) Fraud— If the Director becomes aware, during the course of a supplemental examination or reexamination proceeding ordered under this section, that a material fraud on the Office may have been committed in connection with the patent that is the subject of the supplemental examination, then in addition to any other actions the Director is authorized to take, including the cancellation of any claims found to be invalid under section 307 as a result of a reexamination ordered under this section, the Director shall also refer the matter to the Attorney General for such further action as the Attorney General may deem appropriate. Any such referral shall be treated as confidential, shall not be included in the file of the patent, and shall not be disclosed to the public unless the United States charges a person with a criminal offense in connection with such referral.49

The consequences of such a determination by the Director include "the cancellation of any [invalid] claims" and a confidential referral of "the matter to the Attorney General for such further action as the Attorney General may deem appropriate," "in addition to any other actions the Director is authorized to take . . . ."50

This section was not included in the original legislative proposal relating to supplemental examination.51 A subsequent proposal would have barred supplemental examination "regarding . . . an application or patent in connection with which fraud on the Office was practiced or attempted."52 No such bar was included in the version that became law, which instead directs the USPTO to refer cases of suspected fraud to the Attorney General.53

The AIA also includes several provisions relating to aspects of the law that are unaffected by the introduction of supplemental examination:

(f) Rule of Construction— Nothing in this section shall be construed—

49. Id. at 326-27.
50. Id.
52. H.R. REP. NO. 112-098 (2011) ("No supplemental examination may be commenced by the Director on, and any pending supplemental examination shall be immediately terminated regarding, an application or patent in connection with which fraud on the Office was practiced or attempted.").
53. See 125 Stat. at 326-27. The provision relating to fraud is discussed further infra notes 86-90 and accompanying text.
(1) to preclude the imposition of sanctions based upon criminal or antitrust laws (including section 1001(a) of title 18, the first section of the Clayton Act, and section 5 of the Federal Trade Commission Act to the extent that section relates to unfair methods of competition);

(2) to limit the authority of the Director to investigate issues of possible misconduct and impose sanctions for misconduct in connection with matters or proceedings before the Office; or

(3) to limit the authority of the Director to issue regulations under chapter 3 relating to sanctions for misconduct by representatives practicing before the Office. 54

In particular, new section 257(f) expressly disavows any effect on the existing law relating to criminal and antitrust liability, and preserves the USPTO’s power to regulate the conduct of those who practice before the Office and to investigate and impose sanctions for misconduct. 55

New section 257 will take effect “upon the expiration of the 1-year period beginning on the date of the enactment” of the AIA—i.e., on September 16, 2012, and will “apply to any patent issued before, on, or after that date.” 56 Thus, once the supplemental examinations provisions are in effect patent owners can use them to anticipatorily defeat potential inequitable conduct charges relating to any of their issued, pending, or future patents.

B. Supplemental Examination in Context

The emergence of the supplemental examination concept in the legislative lead-up to the enactment of the AIA 57 was unsurprising, given the then-increasing dissatisfaction with the courts’ application of the inequitable conduct doctrine. Business representatives, 58 legislators, 59 commentators 60 (this commentator included), 61 and even

54. Id. at 327.
55. See id.
56. Id.
57. See supra notes 51-53 and accompanying text.
58. See, e.g., The Patent Reform Act of 2007: Hearings on H.R. 1908 Before the Subcomm. on Courts, the Internet, and Intellectual Property of the H. Comm. on the Judiciary, 110th Cong. 43-44 (2007) [hereinafter “Hearings on H.R. 1908”] (statement of Kevin Sharer, CEO and Chairman of the Board of Amgen, Inc.) (“When a patent is litigated, the most innocent statements, or failures to disclose the smallest thing, can become the bases for charges of inequitable conduct.”).
the judges having the power to shape the doctrine had spilled volumes of ink analyzing and critiquing developments in inequitable conduct law. The foment led, ultimately, to the Federal Circuit’s reconsideration en banc of the inequitable conduct doctrine in *Therasense, Inc. v. Becton, Dickinson & Co.* In its May 2011 *Therasense* decision, the court adopted a heightened standard for evaluating the materiality of information alleged to have been withheld from or misrepresented to the USPTO reiterating that deceptive intent cannot be inferred from circumstantial evidence unless it is ‘‘the single most reasonable inference able to be drawn from the evidence,’’ and held that ‘‘[a] district court should not use a ‘sliding scale’ where a weak showing of

conduc.php (‘‘The inequitable conduct defense is frequently pled, rarely proven, and always drives up the cost of litigation, [Senator Hatch] said. If an inequitable conduct claim wins, a valid patent will be held entirely void, and the infringer walks away without any liability, he added. There is ‘virtually no downside for the infringer to raise this type of attack.’’) (quoting Sen. Orrin Hatch, R-Utah).


62. See, e.g., Larson Mfg. Co. v. Aluminart Prod. Ltd., 559 F.3d 1317, 1342 (Fed. Cir. 2009) (Linn, J., dissenting) (‘‘[O]ur precedent has significantly diverged from the Supreme Court’s treatment of inequitable conduct and perpetuates what was once referred to as a ‘plague’ that our en banc court sought to cure in *Kingsdown Medical Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 876 n.15 (Fed. Cir. 1988) (en banc) (quoting 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.’’)); McKesson Info. Solutions, Inc. v. Bridge Med., Inc., 487 F.3d 897, 926-27 (Fed. Cir. 2007) (Newman, J., dissenting) (‘‘This court returns to the ‘plague’ of encouraging unwarranted charges of inequitable conduct, spawning the opportunistic litigation that here succeeded despite consistently contrary precedent.’’); Ferring B.V. v. Barr Lab., Inc., 437 F.3d 1181, 1196-97 (Fed. Cir. 2006) (Newman, J., dissenting) (‘‘The panel majority, steeped in adverse inferences, holds that good faith is irrelevant and presumes bad faith. Thus the court resurrects the plague of the past, ignoring the *Kingsdown* requirements of clear and convincing evidence of a misrepresentation or omission material to patentability, made intentionally and for the purpose of deception.’’)).


64. *Id.* at 1291 (‘‘[A]s a general matter, the materiality required to establish inequitable conduct is but-for materiality.’’).

65. *Id.* at 1290 (quoting *Star Scientific Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1366 (Fed. Cir. 2008)).
intent may be found sufficient based on a strong showing of materiality, and vice versa." 66 These changes should make it more difficult for patent challengers to establish inequitable conduct in the future.

Despite the intervening developments in Therasense, the proposal for supplemental examination remained in the pending patent reform legislation and was ultimately included in the AIA as enacted, albeit in somewhat-revised form. 67 The structure and content of the legislation's provisions relating to supplemental examination suggest that it will operate as discussed in the next section.

C. Supplemental Examination in Operation

The obvious goals of the supplemental examination provision are to provide patent owners a forum for vetting information that might otherwise ground an inequitable conduct defense to the enforcement of their patents, and a vehicle they can use to deprive the courts of the power they would otherwise have to hold even a patent that had been reexamined by the USPTO unenforceable for inequitable conduct. 68 Patent owners can use supplemental examination to preempt inequitable conduct challenges and all of the associated uncertainty, expense, and in terrorem effects. 69 A patent owner who identifies information that was (or arguably was) incorrect, not considered, or inadequately considered during original (or another prior) prosecution can effectively take the issue of inequitable conduct relating to that information off the table before either filing suit or taking other steps to enforce the patent. 70

66. Id.
67. See supra notes 51-53 and accompanying text.
68. Pre-Therasense, the Federal Circuit had refused to allow patent owners to "cure" inequitable conduct via USPTO consideration of the information at issue in reexamination or reissue. See, e.g., Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc., 326 F.3d 1226, 1241 (Fed. Cir. 2003) (holding that a patent owner's "disclosure [of material information] during reissue is irrelevant to the inquiry of whether [it] acquired the [patent in question] by engaging in inequitable conduct").
69. See supra notes 35-38 and accompanying text. See also Lisa A. Dolak, The Inequitable Conduct Doctrine: Lessons from Recent Cases, 84 J. PAT. & TRADEMARK OFF. SOC'Y 719 (2002) ("[E]ven well before the summary judgment or trial phases of litigation, the in terrorem effects of any colorable inequitable conduct allegation can significantly alter the balance between the litigants."); Philip Abromats, Nondisclosure of Preexisting Works in Software Copyright Registrations: Inequitable Conduct in Need of a Remedy, 32 JURIMETRICS J. 571, 581 (1992) ("Because of its unsettled nature, some have assailed the inequitable conduct defense in patent law. The most common criticism is that it is impossible to determine in advance which types of conduct will be held inequitable, leading to an in terrorem effect on patent holders and encouraging defendants to raise the defense in virtually every case.")
70. See supra notes 35-38 and accompanying text.
Of course, if the information the patent owner submits raises "a substantial new question of patentability" regarding one or more of the claims of the patent, the patent will be ordered into reexamination, where the patent owner could be required to cancel or amend one or more claims in light of the submitted information. But, assuming that the patent owner emerges with one or more claims that are potentially infringed by the putative defendant, the patent owner is in a substantially better position than had it proceeded against the defendant without first taking advantage of supplemental examination, even if intervening rights have attached. In the latter circumstance, the patent owner risked a judicial determination that all claims of the patent—even those that were valid and infringed—were unenforceable. By first invoking supplemental examination, instead, the patent owner has stronger claims that are immune from attack on the basis that the patent owner had previously withheld or misrepresented the newly considered information with the intent to deceive the USPTO. It has blunted the threat of unenforceability and significantly diminished its opponent's leverage in this respect in the anticipated litigation.

It has also effectively obtained consideration of the submitted information under a "but-for" materiality standard. The supplemental examination proceeding is actually better, from the point of view of a patent owner, than the "but-for" materiality standard for inequitable conduct because a "but-for" materiality finding in litigation could still

72. See 35 U.S.C.A. § 307(b) (West 2011) ("Any proposed amended or new claim determined to be patentable and incorporated into a patent following a reexamination proceeding will have the same effect as that specified in section 252 of this title for reissued patents on the right of any person who made, purchased, or used within the United States, or imported into the United States, anything patented by such proposed amended or new claim, or who made substantial preparation for the same, prior to issuance of a certificate under the provisions of subsection (a) of this section.").
73. Therasense, 649 F.3d at 1288 ("[I]n-equitable conduct regarding any single claim renders the entire patent unenforceable.") (citing Kingsdown Med. Consultants, Ltd. v. Hollister Inc., 863 F.2d 867, 877 (Fed. Cir. 1988)).
74. See Tremesha S. Willis, Note, Patent Reexamination Post Litigation: It’s Time to Set the Rules Straight, 12 J. INTELL PROP. L. 597, 601-02 (2005) ("If a patent passes reexamination muster and maintains its validity, the patentee will have a stronger patent. . .").
75. See supra notes 35-38 and accompanying text.
76. See, e.g., William C. Rooklidge & Alyson G. Barker, Reform of a Fast-Moving Target: The Development of Patent Law Since the 2004 National Academies Report, 91 J. PAT. & TRADEMARK OFF. SOC’Y 153 (2009) ("[T]he [inequitable conduct] defense injects significant cost, complexity and uncertainty in patent infringement lawsuits that accused infringers find valuable as leverage in seeking favorable settlements with patent owners or, when the allegations prove successful, avoiding paying damages on otherwise valid and infringed patents.").
culminate in a determination of unenforceability. In contrast, a patent could survive a “but-for” determination in supplemental examination/reexamination, and emerge with claims that are narrower but invigorated, and that still read on the products of potential infringement defendants. Moreover, the supplemental examination proceeding affords the patent owner the opportunity to have the “but-for-ness” of the information evaluated in an ex parte proceeding by a technically-trained expert in the USPTO instead, potentially, by a lay jury in a hotly contested inter partes action in federal court.78

Furthermore, supplemental examination is available not only to “consider, reconsider, or correct information” that was innocently or negligently withheld or misrepresented during a prior prosecution, but also to “cure” actual inequitable conduct.79 Even, in other words, where the patent owner knew of, participated in or orchestrated the withholding or misrepresentation of material information and did so with the intent to deceive the USPTO, the patent owner can utilize supplemental examination to “scrub” the patent in anticipation of enforcement.80 This is because the legislation makes deceptive intent in the procurement of patent rights irrelevant,81 except where and to the extent that “the Director becomes aware, during the course of a supplemental examination [or associated reexamination], that a material fraud on the Office may have been committed in connection with the patent that is the subject of the supplemental examination.”82

78. Either way, under Therasense, the materiality determination is to be made under the “preponderance of the evidence” evidentiary burden and the “broadest reasonable construction” claim construction. See Therasense, 649 F.3d at 1291-92.

79. America Invents Act, Pub. L. No. 112-29, sec. 12, § 257, 125 Stat. 284, 325-27 (2011). See also Gerald M. Murphy, Jr., Ethical Considerations in Post-Grant Proceedings, 1078 PLU/PAT 151, 176 (2012) (“Supplemental Examination provides a “cure” for any inequitable conduct that may have occurred.”).

80. Serious breaches of the duty of candor have occurred. See, e.g., Applied Materials, Inc. v. Multimetrixs, LLC, No. C 06-07372 MHP, 2008 WL 2892453 (N.D. Cal. July 22, 2008) (holding a patent unenforceable for inequitable conduct based on the submission of a signature forged after the inventor’s death); Armament Sys. & Procedures, Inc. v. IQ Hong Kong Ltd., No. 00-C-1257, 2007 WL 2154237, at *22 (E.D. Wis. July 24, 2007) (finding that a drawing submitted as part of a Rule 131 declaration and dated 1997 was actually drawn in 2002, and holding the affected patent unenforceable); Grefco, Inc. v. Kewanee Indus., Inc., 499 F. Supp. 844 (D. Del. 1980) (holding a patent unenforceable as procured through fraud where the patentee misrepresented test results and told the examiner that the invention had been successfully tested when in fact it had actually failed two tests), aff’d without publ. opinion, 671 F.2d 495 (3d Cir. 1981).

81. Robert A. Armitage, The Role of the America Invents Act in Ending the Plague of “Inequitable Conduct” Allegations, 4 No. 3 LANDSLIDE 1 (2012) (“All references to “deceptive intent” are stripped out of the patent statute. Remedial measures that have been heretofore dependent upon the ability to show absence of deceptive intent are no more.”).

82. 125 Stat. at 326-27.
For example, suppose that a patent owner (or an attorney or agent acting on the owner's behalf) purposefully concealed a highly material prior art reference during original examination. The patent owner knew that the reference would have precluded the issuance of the broadest claim—claim 1—of the patent, and for that reason did not disclose the reference. Now comes time to enforce the patent. The patent owner conducts an infringement analysis, and determines that the infringement target's products infringe the narrowest claims of the patent, and likely infringe the claims of medium scope. And further assume, that in any event, the broad claim does not enhance the patentee's infringement position; the limitations that might preclude a finding of infringement of the claims of medium scope are found, as well, in claim 1.

The supplemental examination proceeding is ideally suited for such a patentee. Before filing suit or engaging in any sword-rattling vis-à-vis the target, the patent owner can submit the previously-withheld reference in a request for supplemental examination. In the above hypothetical, the submission would trigger reexamination, because surely a previously unconsidered reference that anticipates or renders obvious claim 1 of the patent raises "a substantial new question of patentability." Further, in reexamination, the USPTO would (correctly) reject claim 1 as unpatentable, forcing the patent owner to either cancel or narrow it. But for the reasons stated above, the patent owner's infringement position is unaffected by the amendment, and its validity position has been enhanced. And the courts are, by statute, precluded from considering the target's charge that the patent was procured via inequitable conduct, even if provable with clearly and convincing evidence. The patent owner has managed to expunge its inequitable conduct—something that it cannot do under existing law.

The only exception is where the "the Director becomes aware, during the course of a supplemental examination [or associated reexamination], that a material fraud on the Office may have been committed in connection with the patent that is the subject of the supplemental examination." But this exception is narrow in stated scope, and likely even narrower in actual practice.

First, the universe of cases potentially implicated by this exception are those in which "a material fraud . . . may have been committed" on

84. See supra notes 35-38 and accompanying text.
85. 125 Stat. at 325-27.
86. Id. at 326-27.
the USPTO. Second, the exception only applies where “the Director becomes aware” of the possibility that such fraud occurred. For several reasons, even where a material fraud was perpetrated, the Director may well not “become aware” of it. It is also worth noting that triggering the “material fraud” exception does not adversely affect the enforceability of the patent at issue.

The supplemental examination proceeding will also serve, of course, to assist a patentee who discovers an innocent mistake during pre-enforcement review, or one who gets advance notice (in licensing negotiations, for example) of a potential defendant’s inequitable conduct theory.

The creation of supplemental examinations is commendable in several respects. It can protect innocent patent owners and practitioners against baseless, but costly and damaging, charges of prosecution misconduct. It can protect innocent patent owners from the consequences of practitioner misconduct, and innocent assignees and exclusive licensees from being left with an unenforceable patent as a result of negligent or intentional candor violations.

It will also encourage careful pre-enforcement review by patentees. The timing provisions tend to discourage the worst possible scenario; without them, a patent owner could knowingly flout its candor and disclosure obligations during prosecution and plan to use supplemental examination to clean up any problems identified by a future enforcement target. On the other hand, however, the timing provisions may discourage patent challengers from tendering potentially damaging information during license negotiations (to avoid tipping off the patent owner), and thus could make such negotiations less efficient.

In addition, by requiring the patentee to wait for the supplemental examination and any resulting reexamination proceeding to be concluded before filing suit as a condition of obtaining the preemptive protection, it avoids disrupting the litigation with the uncertainties associated with parallel USPTO proceedings and satellite disputes regarding litigation stays. And even in the above-described hypothetical

87. Id.
88. Id.
89. Id.
90. See supra notes 49-50 and accompanying text.
91. To be sure, such a patent owner—and any patent owner who would initiate supplemental examination—would risk loss of claim scope or even the entire patent in a potential follow-on reexamination. However, as discussed above, in some cases the patent owner would be able to “thread the needle”, i.e., eliminate the threat of unenforceability by disclosing the previously un- or inadequately-disclosed information while preserving claims of valuable scope.
where the patent owner uses the proceeding to avoid the consequences of its prior misconduct, the new regime has the benefit of streamlining the enforcement litigation.

The creation of supplemental examinations is an improvement over prior proposals to strip the courts of jurisdiction to adjudicate inequitable conduct defenses,\(^{92}\) in that it will require patent owners to take affirmative, risk-entailing, patent-quality-enhancing steps to obtain its benefits. It does, however, reflect a viewpoint that all that matters is validity, i.e., that claims that the USPTO decides are patentable should not be held unenforceable even if the applicant intentionally withheld or misrepresented material information during their procurement.

As discussed below, it also raises duty of candor-related questions for the USPTO, the courts, patent owners, challengers, and practitioners. These questions relate one way or another, ultimately, to the content of the supplemental examination request. The next section considers what such requests might include in particular circumstances and illustrates how supplemental examination requests might raise candor-related questions.

### III. SUPPLEMENTAL EXAMINATION REQUESTS: CONTEXT AND CANDOR-RELATED QUESTIONS AND IMPLICATIONS

#### A. A Substantial New Question of Patentability?

A number of the questions raised by the introduction of supplemental examinations relate to the content of supplemental examination requests. The USPTO has now issued proposed rules to implement these new proceedings, and those proposed rules include requirements for the inclusion of specific information and explanations in such requests.\(^{93}\)

As noted above, it appears that Congress intended to render irrelevant any deceptive intent underlying the original disclosure failure

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92. See, e.g., Patent Reform Act of 2005, H.R. 2795, 109th Cong. (1st Sess. 2005) ("No court or Federal department or agency other than the Office, and no other Federal or State governmental entity, may investigate or make a determination or an adjudication with respect to an alleged violation of the duty of candor and good faith under subsection (a) or with respect to an alleged fraud, inequitable conduct, or other misconduct in any proceeding before the Office involving a patent or in connection with the filing or examination of an application for patent, except as expressly permitted in this section.").

or misstatement, subject to the limited "material fraud" exception.94 Accordingly, the USPTO's proposed rules do not require the patent owner to explain why the omission or misrepresentation was made.95

However, the legislation does require the USPTO to determine whether the information contained in a supplemental examination request raises "a substantial new question of patentability."96 And, the new law requires the USPTO to promulgate "regulations governing the form, content, and other requirements of requests for supplemental examination."97 Accordingly, the issue of what patent owners will have to say has been left to the USPTO.

This issue has particular significance given the legislative design. The central purpose is to create an opportunity for the USPTO to consider information that the patent owner believes (or believes that a potential infringement defendant might assert) should have been considered by the USPTO in the original or another prior examination.98 To fulfill this purpose, it would seem necessary that the request present that information fairly and in enough specificity to facilitate the USPTO's evaluation of its effect on the patentability of the claims of the patent. Moreover, the USPTO will be required, in supplemental examination, to make the same determination it must make in response to the filing of an ex parte reexamination request: whether the information presented raises "a substantial new question of patentability"—and to do so within three months.99

The issue of what patent owners will have to say is complicated, however, by the fact that supplemental examination is not limited to patents and printed publications.100 A patent or printed publication reveals (at least to a person of ordinary skill in the art) its scope and content on its face; it speaks for itself, in that regard. And while some supplemental examination requests will disclose patents and printed publications, patent owners can be expected to use the proceeding to bring to the attention of the USPTO all kinds of other information, prior art and non-prior art.

For example, patent owners may seek to disclose pre-critical date sales and public uses, information relating to inventorship, unpublished

94. See supra notes 81-82 and accompanying text.
98. See supra notes 17-19 and accompanying text.
100. See supra note 26 and accompanying text.
notes, materials relevant to enablement, office actions and other
documents from co-pending applications, litigation papers and
proceedings, representations to foreign patent offices, and facts pertinent
to the interests and relationships of affiants, statements made in petitions
to make special, and the small-entity status of applicants and patent
owners. Depending on the circumstances, some of these might "speak for themselves" like patents and printed publications. But the
USPTO will need details and context relating to certain kinds of
information in order to evaluate its significance for the patentability of
the claims at issue.

For some categories of non-prior art information, such as erroneous
prior representations about small entity status, the USPTO would
presumably be able to readily conclude that such information has no
bearing on substantive patentability. In other situations, however, the
USPTO will not be able to make a call regarding the impact of the
information on patentability without some elaboration by the patent
owner.

Assume, for example, that the information pertains to a pre-critical
date sale. At a minimum, the USPTO would need the date of the sale (or
at least a statement that it occurred more than a year before the filing
date of the application in the United States), its location (whether or not
it occurred in the United States), and a description of what was on sale.
Sales outside the United States, or that occurred within a year before the
filing of the application per se cannot raise a substantial question of
patentability, and the USPTO would need to know what product or
service was on sale in order to determine its relevance under 35 U.S.C. §
102 or 35 U.S.C. § 103. Depending on the circumstances, additional
facts might matter. For example, the USPTO might need to know the
circumstances of the sale and/or the identities and relationship of the
parties. If the sale was transnational, further details might be required
to facilitate the USPTO's determination of whether it was or was not "in
this country." The stage of development of the invention at the time
of the sale (or as of the critical date) might make a difference. These are
just examples of the kinds of disclosures the patent owner might need or
might volunteer to make in a supplemental examination request.

101. See, e.g., supra notes 27-32 and accompanying text (identifying examples of information
on which inequitable conduct allegations have been based).

1999) (examining its precedent relating to sales between related entities for purposes of the on sale
bar of 35 U.S.C. § 102(b) (2011)).

103. 35 U.S.C.A. § 102(b) (West 2011).
Even if the patent owner admitted that the sale qualified as prior art, the USPTO would need to know what was sold, and even this description would necessarily entail characterizations. The point is that some supplemental examination requests will include detailed descriptions of products, events, and other facts.

The USPTO’s proposed rules reflect these realities. Under the proposal, the patent owner would be required, for example, to include in its supplemental examination request:

- a statement that: (1) Identifies each item of information that was not considered in the prior examination of the patent, and explains why consideration of the item is being requested; (2) identifies each item of information that was not adequately considered in the prior examination of the patent, and explains why reconsideration of the item of information is being requested; and (3) identifies each item of information that was incorrect in the prior examination of the patent, and explains how it is being corrected.

In addition, the USPTO is proposing to require:

- “an identification of each issue of patentability raised by each item of information” and
- “a separate, detailed explanation for each identified issue of patentability, in order to determine whether the submitted items of information are appropriate for supplemental examination, and to better analyze the information submitted with the request.”

Whatever decisions the USPTO makes regarding the content of supplemental examination requests and its handling of situations where it does not have the information it needs to make a “substantial new question of patentability” determination, the availability of supplemental examination suggests a number of candor-related issues and considerations. Some of these questions are considered in the next section.

105. Id. at 3670-71.
B. Duty of Candor-Related Questions and Implications

1. Will the Availability of Supplemental Examinations Corrupt the System?

A key question, of course, is whether the very existence of the supplemental examination opportunity will foster candor violations during prosecution or subsequent examination. Some patent owners or their representatives might be tempted to try to maximize claim scope by intentionally suppressing or misrepresenting material information during prosecution if they know they can potentially “clean-up” the violation later during supplemental examination while still preserving viable claim scope. Even absent enforcement efforts on the part of the patentee, the unmerited claim scope has the potential to deter market competitors and their investors, to the public detriment. \(^{106}\) Information not readily accessed via search, such as prior art sales and public uses, or which lies within the exclusive control of the patent owner, such as undisclosed or misrepresented test results, or information improperly withheld relating to inventorship, poses the greatest risk in this regard. However, given that the patent owner can control whether and when litigation begins, even publicly available information could potentially be subject to fraudulent misuse. Congress has presumably considered and rejected these concerns, but time will tell whether some patent owners might seek to exploit this opportunity.

2. How will the USPTO Handle Supplemental Examination Requests that Suggest that Fraud or a Candor Violation Occurred During a Prior Prosecution?

As noted above, the new supplemental examinations regime has the potential to permit patent owners to “cure” candor- and fraud-related enforceability defects in patents. Both the USPTO and practitioners may

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\(^{106}\) See, e.g., Joseph Scott Miller, Joint Defense or Research Joint Venture? Reassessing the Patent-Challenge-Bloc’s Antitrust Status, 2011 STAN. TECH. L. REV. 5, 29 (2011) ("even an invalid patent continued to have an \textit{in terrorem} effect against other potential defendants: faced with the choice, ‘prospective defendants will often decide that paying royalties under a license or other settlement is preferable to the costly burden of challenging the patent,’ notwithstanding the other alleged infringer’s success at invalidating the patent.” (discussing and quoting Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found., 402 U.S. 313, 338 (1971)); Glynn S. Lunney, Jr., E-Obviousness, 7 MICH. TELECOMM. & TECH. L. REV. 363, 384 (2001) ("[F]ailing to resolve the validity issue, where raised, permits potentially invalid claims to ‘remain in terrorem of the art’ and to serve as a basis for enabling the patent holder to extract license fees, if not monopoly rents.” (quoting Royal Typewriter Co. v. Remington Rand, 168 F.2d 691 (2d Cir. 1948)).
wish to consider another interesting issue raised by the new law: How will the USPTO handle supplemental examination requests that suggest that fraud or a candor violation occurred during a prior prosecution?

Consistent with the design of the legislation, many, if not most requests for supplemental examination would presumably not implicate the patent owner or its prosecution counsel in any wrongdoing. The legislative text requires no disclosure beyond the "information believed to be relevant to the patent." Thus, although the patent owner will be required to provide the information and explanations the USPTO ultimately requires, a request disclosing a previously-undisclosed prior art reference would, in essence, say to the USPTO: "Here is Reference X. Please consider whether it raises a substantial new question of patentability." The USPTO would conduct that evaluation, and either initiate reexamination or issue its determination that the information does not substantially implicate patentability. Either way, assuming that the patent emerges (amended or not) from any resulting reexamination, the patent owner would have obviated an inequitable conduct challenge based on the previously-undisclosed reference (subject to the potential litigation challenges discussed above).

However, there may be situations in which the content of the request would inherently raise an issue of misconduct on the part of the patent owner (or its predecessor in interest), or the prosecuting attorney or agent. For example, the request might disclose unfavorable test data, and the conditions of the testing strongly suggest that tests in question must have been done at the same time as the testing that generated the favorable data the then-applicant relied on to secure the patent in the first place. Or, suppose that the disclosure of pre-critical date sales activity in a supplemental examination request makes it clear that the failure to disclose the activity during original prosecution constituted a candor violation. Or, what if a supplemental examination request is based on a previously-uncited, but highly material, rejection in a co-pending application contemporaneously prosecuted by the same attorney who prosecuted the patent undergoing supplemental examination? And, besides situations that imply that misconduct may have occurred, some requestors might outright (on purpose or by accident) state facts demonstrating that the applicant or its prosecution counsel knowingly violated its/his/her disclosure obligations.

108. Assume, for purposes of this hypothetical, that these have to be disclosed in order to make the data and its potential significance comprehensible.
As to circumstances reasonably suggesting that "fraud may have occurred," the statute imposes an obligation on the USPTO to refer the matter to the Attorney General. But, nothing in the statute requires the Office to create a fraud investigation unit. And, given the USPTO's workload and resource constraints, it seems unlikely that it will undertake to investigate suspected fraud.

But, what if, even absent such investigation, a supplemental examination request reasonably suggests that a candor violation (even if not an actual fraud) occurred during prosecution? Would (could) the USPTO simply ignore the "bad facts"? It is true that the USPTO has previously determined that it is ill-equipped to investigate whether claims should be rejected because the applicant had procured or attempted to procure them via fraud. And further, the supplemental examination proceeding is apparently designed to make any actual or alleged past misconduct on the part of the patent owner or its representative irrelevant to its right to patent protection. But, as evidenced by the legislation's "carve out" for USPTO-detected "material fraud," the issue of whether the patent is enforceable is a separate issue from the obligations of registered practitioners, inventors, and others who participate substantively in patent prosecution to disclose (and refrain from misrepresenting) known material information to the USPTO.

The statute provides (at least on its face) an avenue for investigating and prosecuting material fraud on the part of any individual—practitioner, inventor, or other person. But, will (should) that avenue supplant the existing regime for disciplining practitioners? The USPTO has a duty of candor on the books, and an Office of Enrollment and Discipline ("OED") charged with "[i]nvestigat[ing] grievances alleging unethical conduct by registered patent attorneys and agents" in operation. OED has the authority to investigate and punish inequitable conduct and other violations of the USPTO Code of

110. See id.
112. See id.
113. As discussed supra note 81 and accompanying text, deceptive intent is simply not relevant to a patentee's ability to use supplemental examination.
Professional Responsibility ("USPTO Code"), including, for example, the prohibitions in 37 C.F.R. §§ 10.23(b)(4) and 10.23(c)(10) against "[e]ngaging in conduct involving dishonesty, fraud, deceit, or misrepresentation" and "[k]nowingly violating or causing to be violated the requirements of § 1.56 or § 1.555." And registered practitioners assume the special duty to comply with those rules along with the privilege of representing inventors and assignees before the USPTO. Consistent with its mission and authority, could OED legitimately ignore apparent violations of the USPTO’s regulations relating to candor and professional responsibility disclosed in requests for supplemental examination?

Critics might argue that such scrutiny is inappropriate because, as OED asserts, "[t]he disciplinary system is designed to protect the public, not punish practitioners." In the context of the patent system, however, "the public" includes more than just the patent owners whose interests registered practitioners are duty-bound to advance. It includes the courts, the competitors, and potential competitors of patent owners, and the investors, employees, consumers for whose benefit the patent system was established. Accordingly, the implementation of supplemental examination should prompt consideration of the potential adverse impact of under-enforcement of stated disciplinary norms on these interests as well as the interests of registered practitioners.

115. See, e.g., Brief for Lawrence S. Pope at 2, 6, Therasense, Inc. v. Becton, Dickinson and Co., 593 F.3d 1289 (Fed. Cir. 2010) (Nos. 2008-1511, 2008-1512, 2008-1513, 2008-1514, 2008-1595), rehe'g en banc granted, op. vacated by 2010 WL 1655391 (Fed. Cir. Apr. 26, 2010), available at http://www.patentlyo.com/lawrence_20s._20pope s 20motion_20for_20leave20to_20intervene-1.pdf (arguing for leave to intervene on appeal in part because counsel faces disciplinary inquiries from OED as a result of a district court determination of inequitable conduct); In re Kelber, No. 2006-13 (USPTO Dir. Sept. 23, 2008), available at http://des.uspto.gov/Foia/DispatchOEDServlet?decisionType=&contractNo=&respName=kelber&txtInput_StartDate=&txtInput_EndDate=&docTextSearch=&page=60 (follow "FOIA OED Initial Decision" link) (advising practitioner that OED would take no disciplinary action against him based on a U.S. International Trade Commission determination of inequitable conduct because the conduct in question occurred outside the applicable statute of limitations, but taking that inequitable conduct into account as "[w]eighing against any reduction in sanction" for his violation of 37 C.F.R. §§10.23(b)(4) and 10.23(c)(2)(ii) (2008)).


118. See, e.g., Benjamin H. Barton, The ABA, the Rules, and Professionalism: The Mechanics of Self-Defeat and a Call for a Return to the Ethical, Moral, and Practical Approach of the Canons, 83 N.C. L. REV. 411, 424 (2005) (collecting authorities discussing the fallout from disciplinary under-enforcement and decrying the "boundary-seeking" approach of modern disciplinary regimes ("Lawyers are trained not only to determine the boundaries of the law but also to consider the worst-case scenario of violating any given law, i.e. the odds of being caught and the likely punishment."

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Of course, to the extent that supplemental examination requests reveal or imply past misconduct, it may be difficult to determine whose misconduct it was. While inventors are subject to the Rule 56 disclosure duty, and other representatives of the patent owner may be so subject under particular circumstances, they are not bound by the USPTO Code and are not subject to OED discipline. And although the USPTO has the power to sanction non-practitioners for violations of 37 C.F.R. § 10.18—its version of Federal Rule of Civil Procedure 11—it appears that rule would not apply to the kind of misconduct that may be suggested or revealed in many, at least, supplemental examination requests. Thus, in cases where non-practitioners were responsible for knowingly withholding or misrepresenting information, the AIA appears to contemplate that an Attorney General referral is the potential remedy. But, as long as there is a USPTO duty of candor, a professional responsibility code, and a body charged with disciplinary enforcement, practitioners should (and do, at least theoretically) stand on a different footing from their clients.

Ironically, the AIA also reflects the drafters’ recognition of the value of upholding the standards that govern practitioner conduct. As noted above, the AIA expressly preserves the USPTO’s power to regulate the conduct of those who practice before the Office and to investigate and impose sanctions for misconduct. And, it altered the prior law restricting OED from suspending or excluding practitioners if the conduct in question occurred more than five years before OED initiates disciplinary proceedings. In particular, the AIA amended 35 U.S.C. § 32—the statute that authorizes the USPTO to suspend or exclude registered practitioners, including for misconduct—to recite:

A proceeding under this section shall be commenced not later than the earlier of either the date that is 10 years after the date on which the misconduct forming the basis for the proceeding occurred, or 1 year after the date on which the misconduct forming the basis for the

Here the drafters’ choice to emphasize the boundary-seeking heuristic is particularly devastating because the minimum Rules governing lawyers are, in fact, notoriously under-enforced.

120. 37 C.F.R. § 1.56(c)(3) (2000) (imposing the duty to disclose information material to patentability on "[e]very other person substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application.").
122. See Johnson v. SEC, 87 F.3d 484 (D.C. Cir. 1996); 3M Co. v. Browner, 17 F.3d 1453 (D.C. Cir. 1994).
proceeding is made known to an officer or employee of the Office

Thus although the USPTO now has only one year to initiate a disciplinary proceeding after "the misconduct . . . is made known to [a USPTO] officer or employee," subject to that limitation it can act as to conduct that occurred up to ten years before the proceeding occurred. In this sense, the limitations period has been extended, a change which appears to reflect a congressional determination that the prior, shorter "look-back" period was inadequate. That the legislative enactment creating a new system for securing USPTO consideration of information that might otherwise ground an inequitable conduct allegation includes a provision that extends the disciplinary look-back period indicates the drafters' intent to hold practitioners accountable for candor violations and militates in favor of USPTO-OED scrutiny of supplemental examination requests.

The bottom line is that the USPTO has imposed on practitioners and applicants a duty of candor, including an affirmative duty to disclose information material to patentability. Although some have called for its abolition, the USPTO evidently believes that the disclosure duty serves to promote the advancement of its objectives. It defended its broad disclosure standard in the Therasense litigation, and has proposed in the wake of that litigation to retain, but align its disclosure duty requirements with the materiality standard announced in Therasense. Furthermore, in its post-Therasense notice of proposed rulemaking, the USPTO contemplates and even encourages the submission of more information than the rule requires.

123. 125 Stat. at 291.
124. Id.
125. 37 C.F.R. § 1.56 (2000).
129. Id. at 43633.
The Federal Circuit has now revised but retained the inequitable conduct defense. In the AIA, Congress expressly reaffirmed the authority of the USPTO to regulate practitioner conduct, extended the look-back period for investigating practitioner misconduct, and included in the provisions relating to supplemental examination a requirement for referral of suspected "material fraud" to the Attorney General. And the USPTO has encouraged applicants to continue to broadly construe their disclosure obligations even as it has proposed to conform its disclosure rule with the Federal Circuit's inequitable conduct law. Accordingly, there appears to be a commitment to retaining and enforcing the duty of disclosure on the part of the Court, the Congress, and the USPTO. Whether and how that commitment will manifest under Therasense and the AIA remains to be seen.

3. How will Supplemental Examination Affect the Practitioner-Client Relationship?

Although much about how practitioners might be affected by supplemental examination proceedings is uncertain, their introduction may prompt new thinking about the practitioner-client relationship on the part of both patent owners and practitioners.

As noted above, inherent in the design of supplemental examinations is the opportunity for the patent owner to liberate the property right from any taint resulting from misconduct in its procurement. It is this dissociation in particular that has the potential to impact the client-practitioner relationship.

From the perspective of the patent owner, supplemental examination provides an opportunity to have the USPTO consider, reconsider, or correct information relating to patentability, and to remove that information as a potential basis for a viable inequitable conduct challenge in the courts. In some cases, at least, it can be expected that the patent owner's primary or even sole consideration, then, will be the "cleansing" of the patent.

130. See Therasense, 649 F.3d at 1282-96.
131. See supra note 54 and accompanying text.
132. See supra notes 123-24 and accompanying text.
133. See supra notes 49-50 and accompanying text.
134. See supra notes 128-30 and accompanying text.
135. See supra note 90 and accompanying text.
136. Notably, this opportunity is available even if the misconduct was committed by the patent owner himself or herself, or by a person (such as the inventor or an in-house attorney) employed directly by the patent owner.
However, as noted above, the very legislation that creates this opportunity for patent owners requires the USPTO to refer suspected material fraud to the Attorney General. 137 And, as is expressly preserved by the AIA, the USPTO retains its authority to discipline registered practitioners. 138 Thus, where misconduct such as an intentional candor violation did occur or might reasonably be suspected to have occurred, supplemental examination might lead to disciplinary—or even more serious—investigations and consequences for practitioners. Accordingly, the interests of patent owners and the practitioners who assisted in the procurement (or a prior examination) of the patent, as they relate to the use of supplemental examination, have the potential to diverge—significantly.

For those patent owners who are themselves not potentially subject to criminal or disciplinary investigation or sanction, this possibility should not present a problem. Patent owners are free, of course, to hire different counsel for supplemental examination than they used to prosecute the patent in the first place. And, given that deceptive intent is irrelevant to supplemental examination and that any consequences for misconduct unearthed in supplemental examination will affect only the person(s) suspected of being involved in that misconduct, a patent owner (it appears) need not be concerned about whether a supplemental examination request suggests such misconduct. But, practitioners may find such a situation disconcerting, as they may have concerns about being thrown under the proverbial bus, even where the patent owner did not so intend.

For one thing, by definition, a practitioner who is not engaged to participate in the preparation of a supplemental examination request that relates to a prior prosecution in which she was engaged will not have the opportunity to participate in the development of such a request. However, a practitioner who is engaged to file a supplemental examination request pertaining to an earlier prosecution in which he was involved may face an additional or different concern, namely, whether the circumstances create a conflict between his client’s interest in cleansing the patent and his personal interest in his reputation and good standing.

Much in this regard will depend on whether supplemental examinations ultimately lead to any conduct-related investigations or charges. In the meantime, the potential effects of supplemental

138. Id.
examination relating to the relationship between clients and practitioners are among the questions raised by this proceeding.

4. The Predicate Question: Will Patent Owners Utilize Supplemental Examination?

Ultimately, of course, the significance and impact of supplemental examination will depend on whether (and how) it is used by patentees. Ironically, its potential significance has been undercut even before it is available. By altering the materiality standard, *Therasense* facilitates the use of other post-grant options in some circumstances for patent owners concerned about potential future inequitable conduct allegations.

In particular, the materiality required to establish inequitable conduct is [now] but-for materiality. When an applicant fails to disclose prior art to the USPTO, that prior art is but-for material if the USPTO would not have allowed a claim had it been aware of the undisclosed prior art. Hence, in assessing the materiality of a withheld reference, the court must determine whether the USPTO would have allowed the claim if it had been aware of the undisclosed reference. In making this patentability determination, the court should apply the preponderance of the evidence standard and give claims their broadest reasonable construction.\[139\]

Thus, the inequitable conduct materiality standard now entails the same inquiry, in essence, as the patentability evaluation undertaken in reexamination and reissue. Accordingly, where a patent owner procures a patentability confirmation via reexamination or reissue, it has effectively secured evidence that the USPTO has determined that the information it considered in reexamination or reissue was not but-for material. Such a determination would not bind a court. However, it would, presumably, have evidentiary significance, as the confirmation of claims over the information that the USPTO considered in reexamination or reissue is inconsistent with the notion that the information was but-for material. Thus, although inequitable conduct could not previously be “cured” via reexamination or reissue, *Therasense* appears to have significantly enhanced the potential tactical

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\[139\] *Therasense*, 649 F.3d at 1291-92.
utility, in some circumstances, of such proceedings for patent owners who anticipate or face inequitable conduct charges.\textsuperscript{140}

Furthermore, of course, even without taking advantage of reexamination or reissue, patent owners now enjoy the heightened protection of the but-for materiality standard in inequitable conduct litigation. As a result, in some cases, patent owners will not find it necessary to seek a USPTO determination in a post-issuance proceeding. The but-for standard facilitates dealing directly with inequitable conduct allegations in the courts.

On the other hand, by going back to the USPTO (in an appropriate case), the patent owner can take advantage of the \textit{ex parte} nature of reexamination, reissue, or supplemental examination. And, only supplemental examination can provide a patent owner with a statutory immunity from an inequitable conduct determination.\textsuperscript{141} However, some patent owners may eschew supplemental examination to avoid opening up existing claims to reevaluation for compliance with other patentability requirements,\textsuperscript{142} or out of concern that supplemental examination requests might draw enhanced USPTO or litigation scrutiny.\textsuperscript{143}


\textsuperscript{141} See supra notes 75-76 and accompanying text.

\textsuperscript{142} See, e.g., McKeown, supra note 140.

\textsuperscript{143} Other questions relating to the supplemental examination and the duty of candor concern the potential for follow-on litigation. For example, to what extent will litigation ensue in enforcement actions filed following the completion of supplemental examinations on the issue of what information was disclosed in the request and is therefore “off the table” for judicial consideration? In some cases, no doubt, infringement defendants will try to recast the information disclosed by the patent owner, or argue that the patent owner’s disclosure was inaccurate, inadequate, or misleading, in order to get out from under the statutory preemption and have the opportunity to litigate inequitable conduct. In some, the patent owner might over-read what it disclosed to the USPTO in an attempt to extend the scope of the statutory preemption beyond that to which it is entitled. Given the contentious, high-stakes nature of patent litigation, it seems likely that litigation opponents will battle over the quality and scope of the patent owner’s disclosure in supplemental examination.

Such battles might take the form, in some cases, of disputes over whether the patent owner violated its duty of candor during the supplemental examination proceeding. Under the terms of the legislation, a patent owner could presumably file subsidiary requests for supplemental examination to have the USPTO “consider, reconsider, or correct” information that was “not . . . considered, was inadequately considered, or was incorrect” in the first or earlier supplemental examination(s), but only if the patent owner discovers the problem and initiates a supplemental examination before a potential defendant initiates a declaratory judgment or Paragraph IV challenge to the enforceability of the patent or initiates a supplemental examination which is concluded before filing suit. This reality provides a powerful incentive to infringement defendants sued following supplemental examination to argue in that litigation that the patent owner’s disclosure was...
IV. CONCLUSION

Supplemental examination is the AIA’s solution to the inequitable conduct problem—the legislative cure for “the plague.” Creative patent owners and challengers can be expected to carefully consider the strategic opportunities and challenges it offers. And, the USPTO and the courts will consider and adjudicate the consequences and significance of the choices and arguments that parties make regarding its use.

Congress was not writing on a blank slate, however. The insertion of this new procedure into the patent system, which is contemporaneously undergoing other significant AIA-related change, introduces issues beyond those which would otherwise arise from implementing a new procedure. One set of such issues relates to the relationship between the patent applicant’s duty of candor and the new supplemental examination, which can be used to “cleanse” a patent procured via an intentional breach of that duty. As discussed in this paper, the candor-related questions that lie at this intersection have the potential to affecting applicants, patent owners, their counsel, as well as the USPTO and the public, in new and unanticipated ways.

intentionally inadequate or misleading—in effect, that the patent owner committed inequitable conduct in supplemental examination—to attempt to cut off (under an interpretation of new section 257(c)(2)(A) that includes defenses pled in patent enforcement actions) the patentee’s ability to remedy the new alleged under- or mis-disclosure in a subsequent supplemental examination.