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Supplemental Examinations to Consider, Reconsider, or Correct Patent-Related Information: A Tangled Web Indeed

Lisa A. Dolak*

A pending legislative proposal would authorize 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.” It would further bar the federal courts from holding a patent unenforceable “on the basis of conduct relating to information” considered during supplemental examination.

The obvious intent of the proposal is to constrain the federal courts’ power to entertain inequitable conduct-based challenges. Its emergence is unsurprising, given the mounting dissatisfaction with the courts’ application of the inequitable conduct doctrine. However, because the bill proposes to provide patent owners a forum for effectively purging the taint associated with intentionally undermining the integrity of the patent procurement process, it raises a number of interesting questions.

This essay examines ethics-related implications of the supplemental examinations proposal. “Ethics” is broadly defined here to extend beyond potential ethics and discipline-related considerations for practitioners to related implications for the USPTO, the courts, and the patent system generally.

* Angela S. Cooney Professor of Law, Syracuse University College of Law. This discussion draft was prepared for the Aug. 12-13, 2010 10th Annual Intellectual Property Scholars Conference in Berkeley, California. It is a pre-publication work in progress which outlines preliminary analysis of a significant legislative proposal. Further work, including additional analysis and the provision of appropriate supporting citation, is planned. Comments and critiques would be appreciated. I can be reached at ladolak@law.syr.edu.
I. INTRODUCTION

Enough about the “plague”!¹ Judges,² business representatives,³ legislators,⁴ and commentators⁵ (this commentator included⁶) have spilled volumes of ink decrying the

¹ 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 preserves 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.”).

² See, e.g., id.

³ 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. [hereinafter “Hearings on H.R. 1908”] 43-44 (2007) (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.”).

⁴ See, e.g., Hatch Makes Inequitable Conduct Defense, NAT’L J. TECH DAILY DOSE, Mar. 18, 2009, available at http://techdailydose.nationaljournal.com/2009/03/hatch-makes-inequitable-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)).

⁵ See, e.g., Chris Mammen, A Call to Reform Inequitable Conduct This Year, IPWATCHDOG, Apr. 9, 2009, http://www.ipwatchdog.com/2009/04/09/a-call-to-reform-inequitable-conduct-this-year/id=2482/ (“Reform of the inequitable conduct doctrine is needed.”); Kate McElhone, Inequitable Conduct: Shifting Standards for Patent Applicants, Prosecutors, and Litigators, 17 TEX. INTELL. PROP. L.J. 385, 387-88 (2009) (“To settle the law of inequitable conduct and provide definitive guidance in this area, Congress should overrule recent Federal Circuit precedent and
current state of inequitable conduct law. This paper, instead, discusses some implications of one proposed inequitable conduct reform: the “[s]upplemental examination[] to consider, reconsider, or correct information” delineated in the March 4, 2010 Manager’s Amendment of S. 515, the currently-pending Senate patent reform bill (“Manager’s Amendment”) Patent Reform Act of 2010.\(^7\) The proposed supplemental examination procedure would afford patent owners the opportunity secure USPTO consideration of information that might otherwise give rise to an inequitable conduct challenge.

Prospects for enactment of the provisions of the Manager’s Amendment are uncertain, at best.\(^8\) Meanwhile, judicial reform of the patent system continues, the PTO’s proposed rules by amending the Patent Act.”); Arti K. Rai, *Growing Pains in the Administrative State: The Patent Office’s Troubled Quest for Managerial Control*, 157 U. PA. L. REV. 2051, 2079 (2009) (“The progress that could be achieved through inequitable-conduct reform is difficult to overstate.”).


\(^{8}\) See, e.g. Lawrence B. Ebert, *What’s really going to happen with S. 515’s version of patent reform*, IPBIZ, Mar. 16, 2010, http://ipbiz.blogspot.com/2010/03/whats-really-going-to-happen-with-s515s.html (“[F]or all the hoopla, amended S. 515 is not going to become a law anytime soon.”); Fish & Richardson, *2010 Patent Law Reform Updates*, Apr. 30, 2010, http://www.fr.com/2010-Patent-Law-Reform-Update/ (“If none of the 100 Senators places a “hold” on the bill, it would be approved as amended without any floor debate in the Senate and then would move to the House of Representatives. However, as of this week, a few Senators prefer to attach their pet amendments to the bill. As a result, the leadership probably be faced with the task of finding time for debate on the Senate floor, in competition with other important bills and confirmations of Presidential appointments.”); Peter Zura, *Leahy Post-Bilski Comments and Patent Reform*, THE 271 PATENT BLOG, July 1, 2010, http://271patent.blogspot.com/2010/07/leahy-post-bilski-comments-and-patent.html (“As the summer recess approaches, it is all but certain that Congress will (again) postpone efforts to enact patent reform. Since the manager’s amendment (S. 515) was forwarded to the Senate in April, very little has been done in advancing the legislation.”).
including, perhaps, momentous potential revisions to the inequitable conduct doctrine. Accordingly, judicial developments may overtake the pending proposal for supplemental examinations. Nevertheless, the proposal has some interesting potential implications for the patent system, practitioners, and the U.S. Patent & Trademark Office ("USPTO") that are worth considering, given that supplemental examinations could be included in future legislative proposals, if not enacted this year. Those implications are

On April 26, 2010, the Federal Circuit agreed to rehear en banc the appeal in Therasense, Inc. v. Becton, Dickinson and Co., 593 F.3d 1289 (Fed. Cir. 2010). Therasense, Inc. v. Becton, Dickinson & Co., No. 08-1511 (Fed. Cir., April 26, 2010) (en banc Order). The court asked the parties to brief six categories of questions, and invited the participation of amici curiae. Id. at *2-3. Specifically, the court requested input as follows:

1. Should the materiality-intent-balancing framework for inequitable conduct be modified or replaced?


3. What is the proper standard for materiality? What role should the United States Patent and Trademark Office’s rules play in defining materiality? Should a finding of materiality require that but for the alleged misconduct, one or more claims would not have issued?


5. Should the balancing inquiry (balancing materiality and intent) be abandoned?

6. Whether the standards for materiality and intent in other federal agency contexts or at common law shed light on the appropriate standards to be applied in the patent context.

examined below, following a section-by-section breakdown of the proposal as set forth in the S. 515 Manager’s Amendment.

II. THE LEGISLATIVE PROPOSAL

The pending Senate bill would establish a new section 257, with five principal subsections, entitled “In General”, “Reexamination Ordered”, “Effect”, “Fees and Regulations”, and “Rule of Construction”, as follows:

(a) **In General.**—A patent owner may request supplemental examination of a patent to consider, reconsider, or correct information believed to be relevant to the patent. Within 3 months of the date a request for supplemental examination meeting the requirements of this section is received, the Director shall conclude the supplemental examination by issuing a certificate indicating whether the information presented in the request raises a substantial new question of patentability.

The legislation would create a new USPTO proceeding designated 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 would be 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 would have three months to make that determination. Only the patent owner could request supplemental examination.

(b) **Reexamination Ordered.**—If 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

10 “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. § 304. 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 1980, pp. 6460, 6466.).
be conducted according to procedures established by chapter 30, except that the 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 therein relating to patents and printed publication or any other provision of chapter 30.

The consequence of a USPTO determination that any of the information in the request for supplemental examination raises a substantial new question of patentability would 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) would be barred from submitting a statement.\(^{11}\) Second, and significantly, the restriction limiting reexamination to consideration of “patents and printed publications”\(^{12}\) would not apply, and “information” is not otherwise limited or defined in the proposal. Accordingly, supplemental examination could be used, presumably, not only to bring to the attention of the USPTO non-print prior art (such as pre-critical date sales and public uses), but also non-prior art information of the kind the Federal Circuit has held to be material, such as:

- unpublished notes taken by a non-inventor co-employee at a poster presentation;\(^{13}\)
- a non-prior art article relevant to whether the claims at issue were enabled;\(^{14}\)
- a third-party’s patent application (in the inventor’s possession) and information regarding the third-party’s model of his own invention (which the inventor had seen).\(^{15}\)

\(^{11}\) Having filed the supplemental examination request in the first place, the patent owner would presumably have had its say.

\(^{12}\) 35 U.S.C. § 302 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 35 U.S.C. §§ 301, 301.

\(^{13}\) Monsanto Co. v. Bayer Biosciences N.V., 514 F.3d 1229, 1235 (Fed. Cir. 2008).

\(^{14}\) Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc., 326 F.3d 1226, 1234-35 (Fed. Cir. 2003).

\(^{15}\) GFI, Inc. v. Franklin Corp., 265 F.3d 1268, 1274-75 (Fed. Cir. 2001).
“intentional falsehoods, misrepresentations, and nondisclosures” relating to inventorship;16
• a false statement in a Petition to Make Special;17
• unjustified claims to small entity status.18

As will become apparent, the fact that some such non prior-art information (without more) clearly would not raise a “substantial new question of patentability” would not discourage patentees from filing requests for supplemental examination. In fact, as next discussed, the opportunity to submit such information – and all information that could ground an inequitable conduct charge – to the USPTO via the supplemental examination proceeding is what would make it attractive to patentees.

(c) Effect.—

(1) In General.—A patent shall not be held unenforceable under section 282 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.

This is the key provision in the supplemental examination proposal. Except as discussed below, the legislation would strip the courts of the power to hold patents unenforceable for inequitable conduct in cases where the patentee had previously secured via supplemental examination USPTO consideration of the information the patent challenger alleges was withheld or misrepresented. A patent owner could 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.


supplemental examination request was filed (or was not filed) would not otherwise bear on the patent’s enforceability.

The injunction against a judicial unenforceability determination would not operate if either of two statutory exceptions applied:

(2) EXCEPTIONS.—

(A) PRIOR APPLICATIONS.—This subsection shall not apply to an allegation pled with particularity under section 282, 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 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, this subsection shall not apply to any defense raised based upon information that was considered, reconsidered or corrected pursuant to a request under subsection (a) unless the supplemental examination, and any reexamination ordered pursuant to the request, are concluded prior to the date on which the action is brought.

These exceptions relate to timing, and would be triggered by specified events. The meaning and relationship between the two exceptions are not entirely clear. Under proposed 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 could only obtain the benefit of the Section 257(c)(1) protection if the USPTO had concluded its supplemental examination of that information (at the patent owner’s request) and any resulting reexamination before the patent owner filed its enforcement action.

The intended application of Section 257(c)(2)(A) is less clear. It may be that Section 257(c)(2)(A) would apply when the patent challenger (as opposed to the patent owner) makes the first move, i.e., by filing a declaratory judgment action or getting a
Paragraph IV certification\(^{19}\) containing particularized allegations of inequitable conduct into the hands of the patent owner before the patent owner files a supplemental examination request,\(^{20}\) although the literal language of the section would also include defensive allegations pled (i.e., in an answer to a complaint) in a patent infringement action. In such a case, the patent challenger could pursue the defense.

If this is the correct understanding of these two exceptions,\(^{21}\) they would operate to encourage patent owners to seek (and complete) supplemental examination (and any

\(^{19}\) Pursuant to portions of the Drug Price Competition and Patent Term Restoration Act of 1984, Pub.L. No. 98-417, 98 Stat. 1585 (codified at 21 U.S.C. §§ 355, 360cc and 35 U.S.C. §§ 156, 271, 282 (2003)), a brand-name drug manufacturer who has obtained Food & Drug Administration (“FDA”) marketing approval for its drug product through the FDA “New Drug Application” (“NDA”) approval process must notify the FDA of all patents that “claim[] the drug for which the [NDA] applicant submitted the application . . . and with respect to which a claim of patent infringement could reasonably be asserted . . . .” 21 U.S.C. §355(b)(1), (c)(2). The FDA publication that identifies such patents is known as the “Orange Book.” A generic drug manufacturer who wishes to utilize the FDA’s “Abbreviated New Drug Application” process (and thereby obtain marketing approval for the generic drug product by virtue of its bioequivalence with the NDA-approved drug) must certify that “(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 . . . .” 21 U.S.C. §355(j)(2)(A)(vii)(I-IV).

Under 35 U.S.C. § 271(e)(2)(A), 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 45 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). However, if/when the ANDA application commences marketing the generic drug product, the patent owner is free to sue the ANDA for infringement.


\(^{21}\) The applicability of Section 257(c)(2)(A) to declaratory judgment claimants is not entirely clear. On the one hand, it is not restricted to inequitable conduct “defenses”; rather, it applies to inequitable conduct “allegation[s]”, and in that respect would appear to be triggered by preemptive allegations pled in a declaratory judgment complaint. On the other hand, Section 257(c)(2)(A) references “allegation[s] pled with particularity under section 282”, which section relates to “defenses in any action involving the validity or infringement of a patent”, and it is not clear that allegations supporting declaratory judgment claims qualify as “defenses”. However,
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, would 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 retains control over the situation because it decides when to file suit or take another enforcement-related step that would constitute the kind of “affirmative act” necessary to trigger declaratory judgment jurisdiction\(^\text{22}\) or lists its patent(s) in the FDA Orange Book.\(^\text{23}\)

\((d)\) **FEES AND REGULATIONS.**—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 pursuant to subsection \((a)\), fees established and applicable to ex parte reexamination proceedings under chapter 30 shall be paid in addition to fees applicable to supplemental examination. The Director shall promulgate regulations governing the form, content, and other requirements of requests for supplemental examination, and establishing procedures for conducting review of information submitted in such requests.

This section would require the USPTO to set fees for the filing and consideration of supplemental examination requests, and to collect, in addition, the fees applicable to ex parte reexamination where reexamination is ordered. It also would require the USPTO to establish rules governing the submission and processing of such requests.

Interpreting the two sections as proposed herein makes sense, given their juxtaposition and the fact that unless \((2)(B)\) is read as applicable to suits initiated by the patentee and \((2)(A)\) as including challenges initiated by the accused or would-be infringement defendant, the two sections appear to confusingly overlap.

\(^\text{22}\) **See** SanDisk Corp. v. STMicroelectronics, Inc., 480 F.3d 1372, 1380-81 (Fed. Cir. 2007) (“Jurisdiction 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.”).

\(^\text{23}\) **See supra** note 19.
(e) **Rule of Construction.**—Nothing in this section shall be construed—

(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 promulgate regulations under chapter 3 relating to sanctions for misconduct by representatives practicing before the Office.

Finally, section (e) would expressly disavow any effect on the existing law relating to criminal and antitrust liability, and preserve the USPTO’s power to regulate the conduct of those who practice before the Office and to investigate and impose sanctions for misconduct.

New Section 257 would take effect “1 year after the date of enactment” of the legislation and would “apply to patents issued before, on, or after that date.” Thus while patent owners would have to wait one year before they could take advantage of the new supplemental examination proceeding, once it is in effect they could use it to anticipatorily defeat potential inequitable conduct charges relating to any of their issued, pending, or future patents.

### III. Considerations and Implications

#### A. Supplemental Examination: Goals and Operation

The obvious goal of the supplemental examination proposal is to limit the viability of inequitable conduct allegations in patent litigation. It seeks to accomplish this by providing patent owners a vehicle through which they can preempt inequitable conduct challenges and all of the associated uncertainty, expense, and *in terrorem* effects. A patent owner who identifies information that was (or arguably was) incorrect, not considered, or inadequately considered during original (or another prior) prosecution could 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.

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 would 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, it is in a substantially better position than had it proceeded against the defendant without first taking advantage of supplemental examination. 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 the anticipated litigation.

It has also effectively obtained consideration of the submitted information under a “but for” materiality standard. The Federal Circuit’s decision to employ broader standards, such as the “reasonable examiner” standard and even the “new Rule 56” materiality standard instead of applying a rule that information could only be material if “but for” the fact that the USPTO hadn’t had the opportunity to consider it during prosecution a claim would not have issued, has drawn fire from some who argue that inequitable conduct is too easily injected into and proven in litigation.

The proposed supplemental examination procedure is actually much better, from the point of view of a patent owner, than a “but for” materiality standard for inequitable conduct, because a “but for” materiality finding in litigation could still culminate in a determination of utter unenforceability. In contrast, a patent could survive a “but for” determination in supplemental examination/reexamination, emerging with narrower, but invigorated claims that still read on the products of potential infringement defendants. Moreover, even if a “but for” standard governed in litigation, the supplemental examination procedure would afford 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 of by a lay jury in a hotly contested inter partes action in federal court.

Furthermore – and with particular relevance to the ethics and disciplinary implications of the proposal – nothing in the proposed legislation requires the USPTO to
consider whether the information submitted in a supplemental examination request was withheld or misrepresented with deceptive intent during the first or prior prosecution. Deceptive intent is simply not relevant. Thus, patent owners could use the supplemental examination procedure to head off everything from frivolous potential inequitable conduct allegations to utterly meritorious charges that a patent was secured through outright fraud.\textsuperscript{24}

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 doesn’t 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

\textsuperscript{24} It is undeniable that serious breaches of the duty of candor occur. See, e.g., Applied Materials, Inc. v. Multimetrixs, LLC, 2008 WL 2892453 (N.D. Cal. July 22, 2008) (holding patent unenforceable for inequitable conduct based on the submission of signature forged after the inventor’s death); Armament Systems & Procedures, Inc. v. IQ Hong Kong Ltd., No. 00-C-1257, 2007 WL 2154237, at *22 (E.D. Wis. July 24, 2007) (concluding 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 Industries, Inc., 499 F. Supp. 844 (D. Del. 1980) (holding 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).

It is also (to this commentator) mind-boggling that Congress would permit patents procured in such a manner to be “scrubbed” for future potential enforcement.
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 – provable with clearly and convincing evidence – that the patent was procured via inequitable conduct. The patent owner has managed to expunge its inequitable conduct – something that it cannot do under existing law.  

The supplemental examination procedure would 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 proposal is commendable in several respects. It could protect innocent patent owners and practitioners against baseless, but costly and damaging, charges of prosecution misconduct. It could 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 would 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.  

25 See Hewlett-Packard Co. v. Bausch & Lomb Inc., 882 F.3d 1556, 1564 (Fed. Cir. 1989) (citing In re Clark, 522 F.2d 623, 627 (Pa. Commw. Ct. 1975) (“[r]eissue is not available to rescue a patentee who had presented claims limited to avoid particular prior art and then had failed to disclose that prior art (the examiner not having cited it) after that failure to disclose has resulted in the invalidating of the claims”). See also Golden Valley Microwave Foods, Inc. v. Weaver Popcorn Co., Inc., 837 F. Supp. 1444, 1478 (N.D. Ind. 1992) (“[w]here inequitable conduct has occurred during prosecution, it cannot be purged or cured after the patent has issued”). But see Litton Systems, Inc. v. Honeywell, Inc., 87 F.3d 1559 (Fed. Cir. 1996) (reversing district court determination of inequitable conduct based on the patentee’s failure to disclose a reference during original prosecution, in part because the examiner’s receipt and consideration of the reference during reissue mitigated any failure to disclose it during original prosecution).

26 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. Such is clearly
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 where the patent owner uses the proceeding to avoid the consequences of its prior misconduct, the proposed regime has the benefit of streamlining the enforcement litigation.

The proposal for supplemental examinations is an improvement over prior proposals to strip the courts of jurisdiction to adjudicate inequitable conduct defenses, in that it would 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.

It also raises a number of questions, including questions with potential ethics- and discipline-related implications. Courts, litigants, practitioners, and the USPTO would all be affected, and every patent system-stakeholder should consider the potential ramifications of the supplemental examinations proposal.

B. Questions and Implications for the Patent System, Generally

1. **How much detail would/should the USPTO require the patent owner to provide in its request for supplemental examination?**

As noted above, it appears that the proposal’s authors aim to render irrelevant any deceptive intent underlying the original disclosure failure or misstatement.27

contemplated by the proponents of supplemental examination; otherwise, the proposal would make no sense.

27 As noted above, the Manager’s Amendment provisions pertaining to supplemental examination make no mention of intent. In fact, the Manager’s Amendment would render deceptive intent irrelevant to validity in numerous other respects. See Draft substitute, supra note 7.
Presumably, then, the patent owner would not be required to explain why the omission or misrepresentation was made.

However, the proposal would require the USPTO to determine whether the information contained in a supplemental examination request raises “a substantial new question of patentability.” Under current law, when a patent owner or third party requests ex parte reexamination, “[t]he request must set forth the pertinency and manner of applying cited prior art to every claim for which reexamination is requested”28 in order to facilitate the USPTO’s determination of “whether a substantial new question of patentability affecting any claim of the patent concerned is raised by the request”.29 Given the parallels between the supplemental examination and ex parte reexamination proceedings, it seems reasonable to assume that the USPTO might want to see a similar explanation of the potential relevance (vel non) of the information disclosed in a request for supplemental examination. And yet while reexamination requests are required by statute to explain the “pertinency and manner of applying” the information contained therein, the supplemental examination proposal does not include any such requirement.

Instead, the proposal requires the USPTO to “promulgate regulations governing the form, content, and other requirements of requests for supplemental examination”. Accordingly, the issue of what patent owners would have to say would be left to the USPTO.

This issue has particular significance given the proposal’s design. The entire 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. To fulfill this purpose, the request should 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 would 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.” If for no other reasons, the USPTO should require, at a minimum, essentially the same kind of showing for supplemental examination requests. Patent owners should be required to “set forth the pertinency


and manner of applying the information submitted to every claim for which supplemental examination is requested.\textsuperscript{30}

The issue of what patent owners should have to say is complicated, however, by the fact that supplemental examination would not be limited to patents and printed publications. 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 would disclose patents and printed publications, patent owners could be expected to use the procedure to bring to the attention of the USPTO all kinds of other information, prior art and non-prior art.

For example, patent owners would likely seek to disclose pre-critical date sales and public uses, information relating to inventorship, unpublished 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 would 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, all that should be required is enough information to make clear that the information has no bearing on substantive patentability. In other situations, however, the USPTO would 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 U.S.), and a description of what was on sale. Sales outside the U.S., 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 patentability.

\textsuperscript{30} Because patentability is determined claim-by-claim, supplemental examination, like reexamination, should be so conducted.
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.

In some cases, perhaps, the USPTO would, at the request of the patent owner, be willing to proceed for purposes of its evaluation under the assumption that the sale qualified as prior art. Still, though, the patent owner would have to disclose what was sold, and even this description would necessarily entail characterizations. The point is that some supplemental examination requests would include detailed descriptions of products, events, and other facts. This, in turn, raises other questions.

2. How much litigation would 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 would 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 would 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, what we know for sure is that litigation opponents will battle over the quality and scope of the patent owner’s disclosure in supplemental examination.

31 If so, another interesting question concerns whether the patent owner should be free to later contest the prior art status of such information in enforcement litigation.
3. **What if the patent owner does omit important information or otherwise mislead the USPTO in supplemental examination?**

Under the terms of the proposed 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 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 proposed 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.

4. **Would the availability of supplemental examinations corrupt the system?**

Another key question, of course, is whether the very existence of the supplemental examination opportunity would itself 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 might deter potential market competitors and their investors, to the public detriment. 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

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32 At least if the first supplemental examination led to a reexamination, or if the courts construe “a prior examination of the patent” in proposed Section 257(c)(1) to include supplemental examinations that do not result in reexamination.
that the patent owner can control whether and when litigation begins, even publicly available information would potentially be subject to fraudulent misuse. Aside from the unseemliness of implementing, by statute, a regime that could encourage deliberate misconduct on the part of patent applicants – and, in the process, conscript the USPTO into the business of “white-washing” dirty patents – careful consideration should be given to the potential for exacerbation of the real or perceived patent quality and patent “troll” problems.

C. Particular Implications for the USPTO and Practitioners

As noted above, the proposed supplemental examinations regime has the potential to directly enlist the USPTO in laundering violations of the duty of candor. But both the USPTO and practitioners may wish to consider another interesting issue raised by the proposal: **Would – or should – the USPTO initiate disciplinary investigations based on information disclosed in supplemental examination requests?**

Consistent with the design of the proposal, 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, in many cases, the request could consist of an identification, or, where necessary, a description, of the information the patent owner contends “had not been considered, was inadequately considered, or was incorrect in a prior examination of the patent.” For example, where the information in question is a previously-undisclosed prior art reference, the request could, 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 (subject to the potential litigation challenges discussed above) obviated an inequitable conduct challenge based on the previously-undisclosed reference.

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

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33 Along with whatever additional information or analysis the USPTO requires, by regulation.
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.

**Would (could) the USPTO simply ignore the “bad facts” presented in the request?** In 1988, the agency announced that it was disbanding the “fraud squad”, i.e., that it would no longer investigate possible instances of inequitable conduct that came to its attention. However, the USPTO’s misconduct investigation at that time was focused on the issue of whether claims should be rejected because the applicant had procured or attempted to procure them via fraud. The supplemental examinations proposal, in contrast, is 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 that’s a separate issue from whether the USPTO, with 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 Professional Responsibility (“USPTO Code”),

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34 Assume, for purposes of this hypothetical, that these have to be disclosed in order to make the data and its potential significance comprehensible.


36 See id.


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including, for example, the prohibitions in 37 C.F.R. §§ 10.23(b)(4) and 10.23(c)(10) against “[e]ngag[ing] 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”. 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? At what cost to the integrity of the system?39

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,40 and other representatives of the patent owner may be so subject under particular circumstances,41 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 inequitable conduct; In re Kelber, No. 2006-13 (USPTO Dir. Sept. 23, 2008), available on the USPTO’s website, Office of Enrollment and Discipline home page, FOIA OED Initial Decision link (http://des.uspto.gov/Foia/DispatchOEDServlet?decisionType=&contractNo=&respName=kelber&txtInput_StartDate=&txtInput_EndDate=&docTextSearch=&page=60) (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 (see infra notes 42-45 and accompanying text), 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)).

39 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. 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.").

40 37 C.F.R. § 1.56(c)(1).

41 37 C.F.R. § 1.56(c)(3) (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.”).
Fed. R. Civ. P. 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 drafters of the S. 515 Manager’s Amendment ask that we accept the potential for that misconduct to go unpunished as a policy choice whose benefits outweigh its potential harms. 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 Manager’s Amendment also reflects the drafters’ recognition of the value of upholding standards when it comes to practitioner conduct. As noted above, the proposal 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 would change the existing law restricting OED from suspending or excluding practitioners if the conduct in question occurred more than five years before OED initiates disciplinary proceedings\(^{42}\) “where fraud, concealment or inequitable conduct is involved”.\(^{43}\) In such cases, “[t]he time period for instituting a proceeding under [35 U.S.C. § 32] shall not run . . . until information regarding the fraud, concealment, or inequitable conduct is made known to an officer or employee of the [USPTO] as prescribed in the regulations established under [35 U.S.C.] section 2(b)(2)(D)”,\(^ {44}\) i.e., the USPTO rules “govern[ing] the recognition and conduct of” practitioners.\(^ {45}\) That the bill advancing the creation of a new system for securing USPTO consideration of information that might otherwise ground an inequitable conduct allegation includes a proposal to toll the disciplinary statute of limitations until the USPTO learns of the potential misconduct indicates the drafters’ intent to hold practitioners accountable for candor violations and argues in favor of USPTO OED scrutiny of supplemental examination requests.

\(^{42}\) See Johnson v. SEC, 87 F.3d 484 (D.C. Cir. 1996); 3M Company v. Browner, 17 F.3d 1453 (D.C. Cir. 1994).

\(^{43}\) Draft substitute, \textit{supra} note 7.

\(^{44}\) \textit{Id.}

IV. CONCLUSION

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.”46 When it comes to the patent system, however, “the public”, includes more than just the patent owners47 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. It is from this holistic perspective that the proposal for supplemental examinations and its implications must be evaluated.

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47 Interestingly, the Intellectual Property Owners Association has come out in favor of the proposal for supplemental examinations but against the proposed change relating to the statute of limitations for disciplining practitioners. See IPO Board Resolution, “Supplemental Examination”, March 23, 2010, available at http://www.ipo.org/AM/Template.cfm?Section=IPO_Daily_News_&Template=/CM/HTMLDisplay.cfm&ContentID=25104 (“RESOLVED, IPO supports, in principle, legislation that would allow patent owners to request supplemental examination to consider, reconsider, or correct information relevant to their patents and provide that the patents shall not be held unenforceable on the basis of information so considered, reconsidered, or corrected. Specifically, IPO supports enactment of Section 10 of the draft substitute for S. 515 made public on March 4, 2010.”) and IPO Board Resolution, “Statute of Limitations”, March 23, 2010, available at http://www.ipo.org/AM/Template.cfm?Section=IPO_Daily_News_&Template=/CM/HTMLDisplay.cfm&ContentID=25104 (“RESOLVED, IPO supports, in principle, suspension or exclusion of patent practitioners from practice who commit fraud, concealment, or inequitable conduct in USPTO proceedings, but opposes legislation providing that the statute of limitations shall not run until information regarding the fraud, concealment, or inequitable conduct is made known to the USPTO.”).