

INEQUITABLE CONDUCT AND SUPPLEMENTAL EXAMINATION: PROMISE, PROCEDURE, AND PARTICULARS

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ABSTRACT

The America Invents Act, signed into law on September 16, 2011, ushered in an array of patent reforms. One overlooked procedure, Supplemental Examination, seeks to purge putative instances of inequitable conduct prior to litigation by allowing patent owners to submit prior art and short statements to the USPTO after patent issuance. Few parties have used it. We analyze the law of inequitable conduct, explain the Supplemental Examination procedure, and discuss potential reasons for its lack of popularity among patent owners.

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The defense of inequitable conduct, one of the most powerful litigation tools available to an accused infringer, ensures against the fraudulent procurement of patents. Every person associated with the filing and prosecution of a U.S. patent application owes to the USPTO a duty of candor and good faith. If an accused infringer has evidence to suggest that the patent owner breached his duty, he may raise a defense of inequitable conduct. When found, inequitable conduct renders the patent unenforceable against all past, present, and future infringers, even potentially affecting the enforceability of related patents. The Damocles' sword of unenforceability due to inequitable conduct drastically complicates patent valuation and investment in cutting-edge technology.

The AIA offers patent owners an opportunity to reduce uncertainty through a new procedure called supplemental examination.⁴ This new procedure allows any patent owner to request that the USPTO consider, reconsider, or correct information in the patent or its file history. Within three months, the Director will determine whether information in the request raises a substantial new question of patentability. If so, he will order *ex parte* reexamination in view of the submitted evidence, during which the patent owner can argue for patentability of the claimed invention. Importantly, anything considered in the request for supplemental examination or the ensuing *ex parte* reexamination is, by statute, barred as the basis for a later finding of inequitable conduct.

Still, there are important limitations to what supplemental examination can accomplish. First, supplemental examination becomes unavailable once inequitable conduct has been raised in either a paragraph IV notice letter⁵ or a pending litigation.⁶ The cleansing effect of supplemental examination occurs only once the proceeding and any *ex parte* reexamination ordered therefrom has drawn to a close. So, if the patent becomes involved in litigation before the USPTO completes its review, the accused infringer may raise an inequitable conduct defense regarding any information that the patent owner asked the USPTO to consider in its request for supplemental

⁴ 35 U.S.C. § 257; See Janet Gongola, *Tips for Filing a Complaint Supplemental Examination Request* USPTO (Dec. 19, 2012, 5:18 PM), http://www.uspto.gov/blog/aia/entry/from_janet_gongola_patent_reform.

⁵ The term "paragraph IV notice letter" refers to a notice received by a 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) (2013)), notifying the patent owner that a generic pharmaceutical company has filed an Abbreviated New Drug Application ("ANDA") requesting FDA approval to market a generic version of a patent-protected drug.

⁶ 35 U.S.C. § 257(c)(2)(A).