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Do your duty – disclose information to the USPTO during prosecution

Supplemental examination was largely created to reduce the overuse of inequitable conduct charges in patent litigation

The duty to disclose material information to the United States Patent and Trademark Office (USPTO) under 37 C.F.R. § 1.56 is a crucial requirement when prosecuting a patent application. The failure to disclose information can result in a later ruling of inequitable conduct rendering the patent unenforceable. With such high stakes, patent applicants and patent practitioners are often faced with difficult decisions related to the submission of various pieces of information. In this article, the topic of “over-disclosure” is discussed and the recent supplemental examination provision is briefly reviewed.

Over-disclosing information to the USPTO

Applicants and practitioners must disclose all known material prior art to the USPTO. According to the USPTO's current Information Disclosure Statement (IDS) requirements, there are no limits in terms of number of documents and page numbers of large documents. Where an applicant or practitioner is uncertain as to the materiality of the prior art, it is generally advisable to err on the side of caution and submit the information to the USPTO. In this way, the question of materiality is left to the patent examiner and not the applicant.

In very large IDS submissions (e.g., an IDS that includes a list of several hundred documents), applicants and practitioners may consider categorizing the documents. For example, where a patent application contains claims to methods and compositions comprising an antibody for treating various types of cancer, the IDS can highlight the references that primarily describe the categories of antibodies, cancers, treatment regimens, etc.

Because the cost of over-disclosure is minimal relative to the cost of under-disclosure (i.e., the risk of a finding of inequitable conduct), and because over-disclosing is often less expensive to an applicant than determining the materiality of every known reference, the tendency is to over-disclose information during patent application prosecution. Although there exists the risk that a patentee may be accused by an opponent during litigation of “burying” a highly-relevant reference in a submission of hundreds of less-relevant documents, it is generally advisable to over-disclose information for at least the reasons mentioned above.

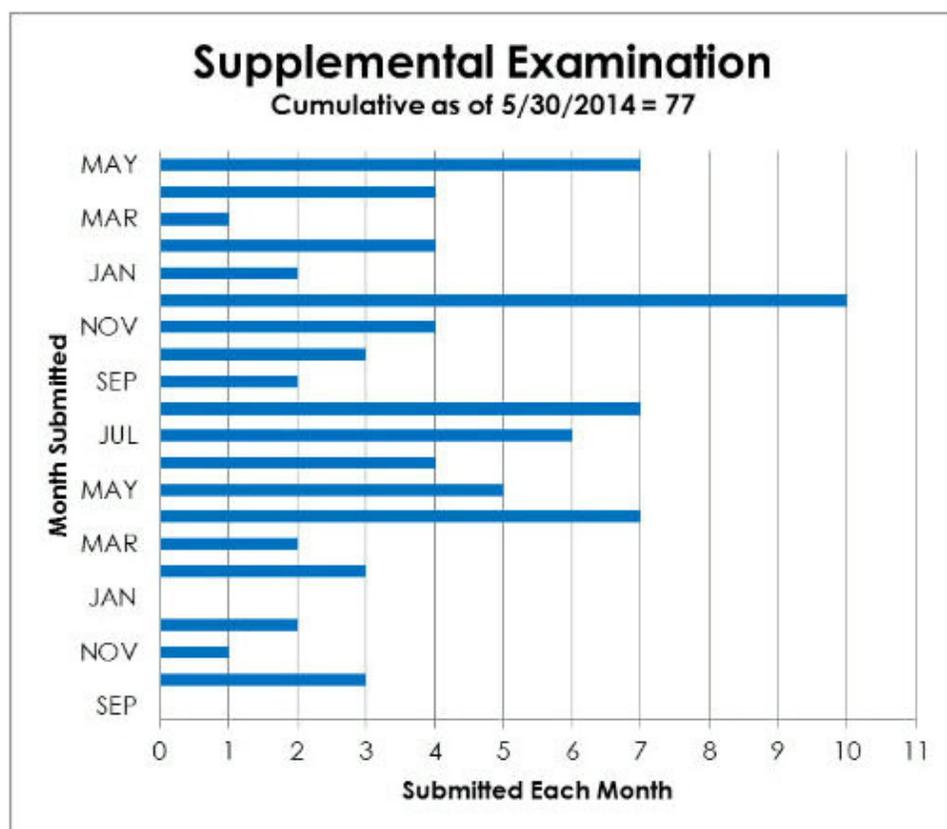
Supplemental examination – possible cure to a perceived under-disclosure

The Leahy-Smith America Invents Act (AIA), enacted in law September 16, 2011, with various effective dates, introduced several new proceedings applicable to issued patents (e.g., post-grant review, *inter partes* review, derivation proceedings and supplemental examination), modified some old proceedings (e.g., reissue patents and *ex parte* reexamination), and got rid entirely of other proceedings (e.g., *inter partes* reexamination and

interferences). Although not the subject of this article, reissue patents [were previously discussed](#) as a possible means to correct errors such as failure to perfect claims for priority (e.g., failure to properly claim a priority filing date of an earlier filed foreign or US patent application), defects in the drawings or specification, improper inventorship, and claiming more or less than what was proper to claim in the original patent.

Supplemental examination (SE) was largely created to reduce the overuse of inequitable conduct charges in patent litigation. Under the SE provision, a patent owner may request a SE of a patent so that the USPTO may consider, reconsider, or correct information believed to be relevant to the patent. The patent owner may present any information believed to be relevant to the patent, and the information is not limited to patents or printed publications, but instead may include information concerning any ground of patentability (i.e., patent eligible subject matter, anticipation, obviousness, written description, enablement, best mode, and indefiniteness).

Although SE can be a powerful tool to address problems with issued patents, the following statistics, which are available at the [USPTO's website](#), suggest that the SE provision has not yet been a popular mechanism for correcting perceived weaknesses in issued U.S. patents:



While recent case law has made it more difficult for accused infringers to successfully assert the inequitable conduct defense (see, e.g., *Exergen Corp. v. Wal-Mart Stores, Inc.* and *Therasense, Inc. v. Becton, Dickinson & Co.*, which heightened the pleading standard and raised the legal proof required for inequitable conduct, respectively), another explanation for the low number of SE filings is the high cost associated with the request for SE. A request for SE must be accompanied by a total fee of \$16,500 for a large entity (\$8,250 for small entity or \$4,125 for micro entity), broken down as a fee of \$4,400 for a large entity (\$2,200 for small entity or \$1,100 for micro entity) for processing and treating a request for supplemental examination; and a fee of \$12,100 for a large entity (\$6,050 for small entity or \$3,025 for micro entity) for ex parte reexamination ordered as a result of a supplemental examination proceeding.

Notwithstanding the high costs, SE is expected to be an important part of a pre-litigation strategy, as it can give patentees an opportunity to reduce or eliminate known weaknesses in their patents prior to initiating a patent infringement action. One such known weakness may be, for example, the realization that the patentee should have disclosed a prior art reference in an IDS during patent application prosecution.

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