

## Using Supplemental Examination Effectively to Strengthen the Value of Your Patents

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Imagine as a patent owner or the patent owner's counsel, you are reviewing a patent involved in a business deal or potential litigation. As you move deeper in your analysis you find a piece of information that was not brought to the attention of the U.S. Patent and Trademark Office during prosecution of the underlying application.

While the information may not be sufficient to invalidate any of the claims in your patent, it could be used to raise questions of inequitable conduct that can interfere with your enforcement efforts or even potentially kill your deal. What to do?

The recently enacted Leahy-Smith America Invents Act provides a cost-effective and practicable answer: supplemental examination.

Supplemental examination provides patent owners with an avenue to ask the USPTO to consider, reconsider, or correct information that they believe is relevant to an issued patent. While the USPTO has yet to issue regulations governing the form, content and other requirements of requests for supplemental examination, this article considers three potential situations where supplemental examination, as laid out in the new legislation, may help patent owners maximize the value of their patents.

### **How It Works**

We recommend considering supplemental examination in at least three situations. First, a patent owner can use supplemental examination to address certain types of information that come to its attention between allowance and issuance of a patent. Second, the patent owner may also use supplemental examination to address the concerns of investors or potential partners during a due diligence investigation. Third, supplemental examination can effectively complement other strategies during a prelitigation phase.

The new provision allows the patent owner to ask the USPTO to consider any information, not just prior art publications, that the patent owner believes is relevant to the patent and was not brought to the USPTO's attention during prosecution. Within three months after the date a patent owner requests the supplemental examination, the USPTO will issue a certificate indicating whether the information raises a substantial new question of patentability. If it does, the USPTO automatically declares an ex parte reexamination and carries it out according to regular reexamination procedure, with the caveat that the patent owner will not have the right to file a statement pursuant to 35 U.S.C. §304.

Thus, the patent owner entering ex parte reexamination through supplemental examination does not have the opportunity to provide the USPTO with amendments or new claims it may wish to propose, at the beginning of the procedure. If the USPTO does not find a substantial new question of patentability, the supplemental examination concludes and an accused infringer cannot challenge the enforceability of the patent in subsequent litigation on the basis that the information was not presented to the USPTO during the initial examination.

Supplemental examination not only effectively shields enabling patent owners from inequitable conduct allegations arising from information not submitted to the USPTO during initial examination, it also provides patent owners with other strategic benefits over patent-owner-initiated ex parte reexamination proceedings. For example, the patent owner can obtain the benefit of supplemental examination without having extensive assertions in the record as to the relevance and applicability of the art.

### **Strategic Benefits**

Specifically, unlike a request for ex parte reexamination that must set forth the potential substantial new question of patentability, the pertinency and manner of applying cited prior art to every claim for which reexamination is requested, the statutory provision for supplemental examination does not include this requirement. See 35 U.S.C. § 302 (describing the statutory requirements for a request for reexamination). Therefore, with supplemental examination, even if the USPTO declares a reexamination, the patent owner has not made any admissions or characterized the relationship of the information to the claims.

Supplemental examination also benefits the patent owner because it implicitly widens the scope of material that can enter the reexamination process by allowing submission of much more than prior art printed publications and patents. Thus, the universe of information that a patent owner can present may include unpublished papers, notebook data, prosecution in related non-published applications, or even information raising question of a potential on-sale or prior use bar.

### **Timing**

To take advantage of the shielding effect of the provision, the patent owner must request supplemental examination before a patent challenger raises an allegation of inequitable conduct in a declaratory judgment action or an Abbreviated New Drug Application (ANDA) notice. The burden

increases when the patent owner brings an enforcement action in district court or at the International Trade Commission.

In these instances, the patent owner must not only request supplemental examination, but it must also wait for the USPTO to conclude the supplemental examination (and any declared reexamination), before the shielding effect will protect it against a possible inequitable conduct claim in that proceeding.

The provision continues to recognize the importance of the patent applicants' duty of candor to the USPTO by making supplemental examination unavailable where actual fraud had been committed during the initial examination of the patent. In fact, the new provision allows the USPTO to refer matters involving fraud discovered during the course of the supplemental examination to the attorney general for possible prosecution.

### **Between Allowance and Issuance**

In light of this background, we propose three areas where supplemental examination can complement existing strategies, or perhaps create new ways to maximize patent value. As one scenario, a patent owner may consider using supplemental examination as an alternative to an information disclosure statement (IDS) after it becomes aware of new likely-cumulative or less relevant information after the USPTO has allowed the application, but before a patent has been issued.

While the patent owner may feel confident that the information will not impact patentability or validity, nevertheless the mere existence of the information may be sufficient for a potential infringer to build a claim of inequitable conduct. Once the USPTO issues a final office action or a notice of allowance, patent applicants generally file a request for continued examination (RCE) in order to file an IDS, incurring both significant fees and delay in prosecution.

Before supplemental examination, the patent applicant had only one other, and much less desirable option—making a statement essentially indicating when the reference was first cited in foreign prosecution, or when it was first known to those involved in prosecution. Once the applicant pays the issue fee, the patent owner can only submit an IDS after withdrawing the application from issue. Accordingly, a submission of additional information after a notice of allowance can result in substantive cost for the patent owner, both in legal fees associated with reopening prosecution and in the delay.

Moreover, prior to supplemental examination, attorneys would also spend significant time and energy expanding their analysis of the reference, to also determine whether a future challenger could argue that the information arising after allowance is highly relevant and not cumulative over other prior cited references, and evaluating the strengths and weaknesses of a future challenger's potential arguments. With supplemental examination as an option, the patent owner could focus the initial assessment to determine if reasonable arguments exist that the document is not relevant or cumulative over prior-cited documents.

Then, if concerns of potential inequitable conduct remain, the patent owner could allow the patent to issue, and follow with a supplemental examination request. By following this approach the patent owner can better manage legal costs at the end of the prosecution of the patent, while also benefiting from the protection from a potential inequitable conduct charge during potential litigation.

Furthermore, since the USPTO should decide whether a substantial new question of patentability exists within three months, adopting the suggested approach may also be substantially more efficient than the alternative of pursuing an RCE.

Of course, the patent owner faces the risk that the USPTO would declare a reexamination. To address that concern the patent owner could, for example, identify in the request the specific references that are cumulative. This strategy would be an ideal approach when a patent owner receives an office action in another jurisdiction or a related U.S. application citing the same or substantially the same art, but making different arguments regarding patentability.

### **Part of Due Diligence**

The due diligence context offers another opportunity for the patent owner to use supplemental examination. In a due diligence investigation, the attorneys for an investor or potential partner try to determine whether any information should have been cited in an IDS and was not. Before supplemental examination, encountering potentially material and non-cited information may bring the negotiation efforts to a halt or significantly reduce the monetary value of the patent.

The patent owner can respond to the concerns of the investor or potential partner by providing the information in a supplemental examination request. If the USPTO determines that the information does not raise a substantial new question of patentability, this can appease the concerns of the investor or potential partner within a very short time frame. If the USPTO declares a reexamination, the patent owner has an opportunity to argue for the patentability of the claimed invention over the art (or amend the claims to avoid the art).

If the parties are eager to conclude a deal immediately, using these procedures as milestones in an agreement provides the parties with flexibility and appropriate economic rewards. For example, the parties can set a milestone payment for the date the USPTO declares that the information does not raise a substantial new question of patentability, with an alternative milestone for the conclusion of a reexamination with granting of claims covering the intended subject matter of the transaction.

Allowing for subsequent or incremental payments promotes both parties' interests. Thus, using supplemental examination, and incorporating it into license agreements, provides an attractive option, especially in comparison to delaying a deal or terminating negotiations.

### **Part of Prelitigation Strategy**

Supplemental examination can also provide a powerful tool for addressing concerns during a prelitigation analysis. While many patent owners have engaged in a robust prelitigation analysis,

including identification of any information that it may have inadvertently omitted from an IDS, the availability of supplemental examination should incentivize all patent owners to carefully scrutinize this area before bringing suit.

Furthermore, since the new law establishes a very clear time limitation, patentees should take these steps as early as possible to avoid either having to delay an enforcement action or lose the shielding effect of the procedure if the USPTO has not concluded the supplemental examination (or subsequent reexamination) at the time the action is brought.

Giving patent owners the ability to "clean-up" the patent and prevent inequitable conduct charges may result in a stronger prelitigation investigation that identifies and addresses potential issues out of court, thus minimizing litigation costs.

Finally, patent owners should note that while in the past a potential infringer may have hinted about the basis for an unenforceability claim during prelitigation negotiations, potential infringers will be much less likely to do so now.

### **Looking Ahead**

As the rulemaking process begins, we will learn more about the USPTO procedures for supplemental examination and how the USPTO will address the different interests of the parties involved. We look forward to learning what fees the USPTO will charge for the process, and the allocation of the supplemental examination workload.

In terms of efficiency, it would make sense to have the same examiner who conducted the prosecution study the additional references to determine whether they affect the patentability of the issued claims; however, given the potential for a reexamination, the Central Reexamination Unit may also play a role in the process.

We also look forward to the USPTO requirements for the form of the request, and whether the USPTO permits or requires any comments regarding the documents submitted. While the idea of having a submission with minimal remarks may appeal to patent owners from the points of view of litigation strategy and expense in preparing the request, the USPTO may require some further assessment of the document, especially to ensure an efficient turnaround that meets the statutory timeline of three months.

While we await further details on this procedure from the USPTO, the new legislation provides a powerful tool to address potential problems with issued patents.

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