



## IP: U.S. Patent Office interprets the America Invents Act

NEW PROVISIONS DEAL WITH THE SUPPLEMENTAL EXAMINATION PROCESS

Who is in the details of the America Invents Act?

Some people say that the devil is in the details. Others say that God is in the details. It probably depends a lot on how you view the details. Do the details make things better (for you personally), or worse?

Passage of the America Invents Act (AIA) is a watershed event in U.S. patent law. The AIA seeks to harmonize the U.S. patent system with other patent systems. The AIA also seeks to shift the resolution of issues relating to patent validity and enforceability out of the U.S. courts and into the U.S. Patent and Trademark Office (USPTO). Further, the AIA seeks to streamline processes within and funding of the USPTO.

The America Invents Act was never intended to lay out the details. Instead, the AIA provides the broad framework. Eventually, U.S. courts will weigh in on the interpretation of the AIA. But first, the USPTO will need to put forth its interpretation of the AIA.

In January and February, the USPTO noticed at least 10 rulemakings that involve implementation of aspects of the AIA that have not yet become effective. The USPTO selected this timing to ensure that the rules would be in place prior to the September 2012 effective date for these changes. While the rules have not yet become final, it is clear that the rules take provisions of the AIA in directions that early commentary did not entirely expect.

For instance, the AIA included a new supplemental examination process, whereby applicants could remove issues of inequitable conduct through submission of information omitted, inadequately considered or incorrectly submitted. The submission could lead to reexamination of the patent, however. Additionally, the submission could not be used to address information raised in a civil action, an Abbreviated New Drug Application (ANDA) notice or an International Trade Commission (ITC) proceeding.

Certainly, some questioned whether such a procedure was necessary, because recent Federal

Circuit decisions seemed to take much of the sting out of the inequitable conduct defense. Others questioned whether patentees would simply start with reexamination (or reissue), instead of first passing through the supplemental examination phase. Still, it appeared that supplemental examination might provide a convenient approach for addressing simple errors in the original examination.

Then, the USPTO notice added several important details.

First, supplemental examination will be expensive. The patentee seeking supplemental examination can be expected to pay nearly \$21,000 in fees when the request is filed. While the USPTO may refund \$16,000 if reexamination is not required, the patentee must pay the full fee up front.

Second, the supplemental examination will require the patentee to characterize the information. The patentee cannot simply present the information, as it would in an Information Disclosure Statement. Instead, the patentee is required to:

- ♦ Identify each issue raised by each item of information
- ♦ Explain how each item raises the issue identified
- ♦ Explain why each item does or does not raise a substantial new question of patentability

Third, the supplemental examination will not even be *ex parte*—it will be conducted without patentee input after the request is filed. Once the request is filed, the patentee must sit and wait. There will be no ability to interview the examiner and provide further explanation, and there will be no ability to propose amendments.

These details may raise significant issues for patentees considering the suitability of supplemental examination:

- ♦ The up-front payment of the fee of \$20,000 seems out of proportion when it is considered that the patentee only had to pay approximately \$1,300 for the initial examination of the application
- ♦ The complexity of the required statement will add to the costs of the procedure. Certainly, some of the complexity may arise as the patentee's attorney works to ensure that the request does not itself create the basis for allegations of inequitable conduct.
- ♦ Without the ability to interact with the examiner, the patentee's attorney must anticipate issues in advance—always a difficult proposition

On the other hand, a potential infringer may view these details differently:

- ♦ The cost ensures that true issues are not simply glossed over because the USPTO lacks sufficient funds to carry out this important work
- ♦ The detailed statement further ensures that the USPTO can address all the relevant issues by placing the burden on those allegedly in the best position to explain the issues: the patentee and the patentee's attorney
- ♦ The elimination of interviews ensures that a complete written record supporting the determination of whether or not to initiate a reexamination is available to the public. This may be especially desirable in circumstances giving rise to supplemental examination, where the patentee is asking the USPTO to stop short of initiating a full post-grant reconsideration of the patent.

In the end, whether in the form of legislative act, administrative rule or judicial opinion, the law rarely satisfies all parties. Sometimes, the difference of opinion is set by the broad outlines of a new law; other times, the divergent views do not form until the nuances become apparent.

As we move toward September 2012, we should remember that while the passage of the AIA marked one set of endings, it also brought about a new set of beginnings, the implications of

which we are only starting to appreciate.

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