Intellectual Property - USA

Non-prior art based supplemental examination requests

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Supplemental examinations

The America Invents Act includes a post-grant proceeding referred to as a 'supplemental examination request'. A supplemental examination request allows a patentee to present information to the US Patent and Trademark Office (USPTO) so that it can consider, reconsider or correct information believed to be relevant to the patent in an effort to avoid a determination in a later litigation of inequitable conduct based on that same information.(1) Any information considered, reconsidered or corrected during a supplemental examination request cannot be used to hold a patent unenforceable for inequitable conduct if the supplemental examination request and any resulting *ex parte* re-examination proceedings are completed before a civil action is brought.

'Information' under the statute is not limited to prior art patents and printed publications. However, since first becoming available, granted supplemental examination requests were based exclusively on such prior art that the patentee feared had not been provided to the USPTO under the patentee's duty of candour. That said, a recent supplemental examination request based on non-prior art 'information' is the first successfully filed and granted supplemental examination request to include such information. As this was the first supplement examination request of its kind, it was not known how the USPTO would interpret and implement the rules and regulations relating to the non-prior art information that the patentee wished to disclose to the USPTO.

Supplemental examination requests are complicated filings that require many difficult decisions. This update provides a short summary of several of the many issues that must be considered in drafting a supplemental examination request.

Challenges

A supplemental examination request must comply with the requirements of 37 Code of Federal Regulations (CFR) Sections 1601 and following in order to obtain a filing date and be considered by the USPTO. Many requirements and pitfalls must be overcome to comply. For example, a single supplemental examination request is limited to 12 items of information.(2) Determining the number of items in a supplemental examination request based on prior art patents and publications is fairly straightforward. Each document will typically count as one item. Trying to determine what constitutes one item for non-prior art is a considerably more complicated task, since each document submitted with the request may be deemed to constitute more than one item, depending on its nature. For example, if the information presented were data found in various laboratory notebooks, would each single piece of data count as one item? Would all data relating to each embodiment of the claimed invention count as one item? Or would each laboratory notebook count as one item? The answer differs depending on the specific circumstances of the case.

In addition to the strict limit on the number of items of information that may be submitted, each request must include a "separate, detailed explanation of the relevance and manner of applying each item of information to each claim of the patent for which supplemental examination is requested".(3) This detailed explanation must be carefully crafted. If the explanation is too vague, the USPTO may deem it insufficient to satisfy the rules and reject the request. Likewise, if the explanation is carelessly written, this could give rise to a finding of a substantial new question of patentability and a rejection of the claims in a subsequent reexamination. Therefore, great care must be taken in preparing the explanation; otherwise, a subsequent accused infringer could allege that the explanation itself is misleading and constitutes an act of inequitable conduct rendering the patent unenforceable.

Pros and cons

Although a patentee may believe that it is possible to overcome the various hurdles and comply with the USPTO requirements for a supplemental examination request, the decision to file a request is an important one which should be made carefully, bearing many factors in mind. Many pros and cons should be considered before filing a request.

Potential pros

A supplemental examination request may allow patentees to insulate themselves from potential inequitable conduct allegations. This was not possible prior to the enactment of the America Invents Act. Having the opportunity to address potential inequitable conduct issues prior to litigation may be highly desirable or necessary depending on the commercial importance of the patent and the products that it protects.

A supplemental examination request can be filed only by the patentee. To the extent the USPTO believes the information presents a substantial new question of patentability and orders a re-examination, no third parties can participate in the re-examination process. The supplemental examination process provides the patentee with the ability to present information that it wants the USPTO to consider and under circumstances where the submitter has control over how that information is presented.

To the extent that the re-examination is ordered, the patentee can amend the claims or add new narrower claims.

Potential cons

Supplemental examination requests become public once the filing requirements are met. By filing the request, a patentee is notifying the public of a potential inequitable conduct issue and provides a challenger with a potential roadmap for asserting inequitable conduct. This may encourage declaratory judgment actions before the supplemental examination request and any ensuing re-examination proceedings can be completed, preventing the patent from being immunised from inequitable conduct allegations based on the information presented in the request. Moreover, the request may contain admissions that a challenger could use as evidence to support its inequitable conduct allegations as to both intent to deceive the USPTO and materiality of the information.

In the realm of the Hatch-Waxman Act relating to generic pharmaceutical products,(4) a patentee may not have sufficient time to complete the supplemental examination request process before a generic files an abbreviated new drug application, forcing the patentee to file suit. Accordingly, any supplemental examination request should be filed well in advance of the expiration of any Food and Drug Administration exclusivity periods tied to the pharmaceutical product to allow sufficient time for the supplemental examination request to be granted and any ensuing re-examination proceedings to be completed. Failure to consider the timing could not only prevent a patentee from benefiting from the protection afforded against inequitable conduct allegations, but also strengthen a generic infringer's inequitable conduct allegations in future litigations.

By filing a supplemental examination request, a patentee may be deemed to be disclosing to the USPTO that a "material fraud on the Office may have been committed in connection with the patent".(5) If the USPTO determines there was a "material fraud," it will refer the matter, non-publicly, to the US attorney general for further action that it "may deem appropriate", which can include criminal charges. The comments to the final rules in the Federal Register state that 'material fraud' under this statue is "narrower in scope than inequitable conduct as defined by the [Federal Circuit] in *Therasense, Inc. v.*

Becton, Dickinson & Co., 649 F.3d 1276 (Fed. Cir. 2011)".[6] Although narrower, there is no additional guidance on what the USPTO will consider to be a material fraud, other than that the USPTO believes that instances of material fraud will be "rare".[7]

There is some indication that the USPTO may monitor supplemental examination requests and take disciplinary action against a registered practitioner if it feels that practitioner was guilty of misconduct during the original prosecution of the patent.

Supplement examination requests may lead to potential patent challengers more closely scrutinising the patent in search of other patentability problems – for example, a written description that otherwise might have gone unnoticed.

The fees for a supplemental examination request are substantial – currently $16,500 for a large entity. A patentee filing a supplemental examination request must pay the fee required to initiate a re-examination proceeding with the request, currently $12,100. If no substantial new question of patentability is found, some of the fee will be refunded. However, even with the refund, the fee is substantial.

Comment

Drafting a supplemental examination request based on non-prior art information presents a difficult and unique challenge. Understanding the complicated drafting requirements, along with the pros and cons of filing a request, is essential to successfully navigate this challenging process.

For further information on this topic please contact Simon Roberts, Jason Okun or Jason Johnson at Fitzpatrick, Cella, Harper & Scinto by telephone (+1 212 218 2100), fax (+1 212 218 2200) or email (sroberts@fchs.com, jokun@fchs.com or jjohnson@fchs.com). The Fitzpatrick, Cella, Harper & Scinto website can be accessed at www.fitzpatrickcella.com.

Endnotes

(1) See 35 United States Code (USC) Section 257.

(2) 37 Code of Federal Regulations (CFR) Section 1.605.

(3) 37 CFR Section 1.610(b)(5).

(4) See 21 USC Section 355.

(5) See 35 USC Section 257(e).

(6) Federal Register, Vol 77, No 157, August 14 2012, 48828 at 48829.

(7) *Id*.

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