



Strategic Considerations in View of the USPTO's Proposed Rules

Part IV: Supplemental Examination

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AIA Webinar Series

<u>Date</u>	<u>Topic</u>
March 27, 2012	Inter Partes Review Part I: Pre-Trial
April 3, 2012	Inter Partes Review Part II: Trial
April 10, 2012	Inter Partes Review Part III: Post-Trial
April 17, 2012	Supplemental Examination
April 24, 2012	Derivation and PGR

Agenda

- FR Purpose Of Supplemental Examination
- FR Procedural Particulars
- FR Handling By The PTO
- FR Application Post-*Therasense*
- FR Hypotheticals

Background

- ❖ 35 U.S.C. § 257
- ❖ Request that the PTO “consider, reconsider, or correct information believed to be relevant to the patent, in accordance with such requirements as the Director may establish”.
- ❖ Effective September 16, 2012
- ❖ Applies to any patent issued before, on, or after the effective date

Purpose

- ❖ Supplemental examination – voluntary proceeding for patentee to inoculate patent against charges of inequitable conduct

(1) IN GENERAL- A patent shall not be held unenforceable on the basis of conduct relating to information that had not been considered, was inadequately considered, or was incorrect in a prior examination of the patent if the information was considered, reconsidered, or corrected during a supplemental examination of the patent.

Purpose

- ❖ “clean up” prior art
 - Office actions / other art surfacing in co-pending applications
 - Art surfacing in foreign counterpart applications
 - Allows you to avoid filing chain of RCE’s to disclose this art

- ❖ unavailable for already-asserted art

Procedural Particulars

- ❖ Who Can File?
 - Patent Owner Only

- ❖ What Can Be Filed?
 - Any information to be considered, reconsidered or corrected
 - **10 Item Limit**

Procedural Particulars

- ❖ Content Of Request
 - Each issue raised by each item of information
 - How each item of information is relevant to each aspect of patent to be examined

- ❖ Page Limits:
 - Extra fees for each document > 20 pages in length
 - Summary of relevant portions for documents > 50 pages

Procedural Particulars

- ❖ When Can It Be Filed?
 - September 16, 2012

- ❖ Against Which Patents Can It Be Filed Against?
 - All (retroactive and prospective)

Supplemental Examination By PTO

- ❖ PTO Reviews for compliance
 - Patent owner notified of non-compliant request and given limited opportunity to render compliant
 - Non-compliant requests not given filing date unless and until patent owner renders compliant

Supplemental Examination By PTO

- ❖ PTO conducts supplemental examination
 - Must occur within 3 months of receiving compliant request
 - Mandated by statute
 - Substantial New Question of Patentability (SNQ) Standard
 - PTO determines if any item of information in the request raises SNQ affecting any claim of the patent
 - Generally limited to issues identified in request

Supplemental Examination By PTO

- ❖ Supplemental Examination Certificate
 - Indicates if PTO determined that an SNQ was raised
 - If SNQ found, *ex parte* reexamination ordered
 - *Ex parte* reexam according to existing procedures, except
 - Basis not limited to patents or printed publications
 - Patent owner may not file statement under 35 U.S.C. § 304 (statement responding to PTO finding of SNQ before reexamination)

Effect of Supplemental Reexamination

FR **Limited Amnesty** 35 U.S.C. § 257(c)(1)

FR Patent may not be held unenforceable for conduct relating to information that:

- had not been considered,
- was inadequately consider, or
- was incorrect in the prior examination

if the information was considered, reconsidered, or corrected during a supplemental examination.

Effect of Supplemental Reexamination

Exception:

- No amnesty in action brought before conclusion of supplemental exam (and any resulting *ex parte* reexam)
- No amnesty allegations pled *with particularity* in an ANDA certification received before date of request for supplemental exam

Items Of Information That Can Be Considered

37 C.F.R. §1.605

- ❖ Not limited to patents and printed publication
- ❖ Any supporting document containing information believed relevant to patent that patent owner request PTO to consider, reconsider or correct.
 - Journal articles and patents
 - Video and audio recording transcripts
 - Declarations and affidavits
 - E-mails

Items Of Information That Can Be Considered

37 C.F.R. §1.605

- ❖ Information must be in writing:
 - Submit written transcripts of audio and video recordings
 - May also include selected images from video, with explanation of their correlation to transcript
 - If no supporting document, discuss in body of request
 - *E.g.*, Information concerning issue under 35 U.S.C. § 101
 - Still counted as an “item of information”

“Items of Information”

- ❖ Ten item limit per request
 - must file additional requests if ten items not sufficient
 - No limit on number of requests one can file for a patent
 - *But*, processing / reexam fees required for each request

“Items of Information”

- ❖ Each supporting document counted as a separate item
 - Where combination of items must be considered (*e.g.*, for obviousness), each item counted separately
 - Exception for non-English language documents and translations
 - If information not based on or contained in supporting document:
 - Discussion in request counted as separate item of information

Preparing the Request: What to Include

- ❖ Formal Requirements
 - Cover sheet itemizing each component submitted
 - *E.g.*, certificate of mailing, each supporting document, *etc.*
 - Table of Contents

Preparing the Request: What to Include

- ❖ Identify the patent and each aspect for supplemental exam
 - By: Patent number, issue date, first-named inventor (§1.601(b)(3))
 - Attach copy to the request
 - Include any certificates of correction, disclaimer, extension, reexam, *etc.*

Preparing the Request: What to Include

- ❖ Identify all other post patent “Office proceedings” ((§1.601(b)(5))
 - *E.g.*, *Ex parte* reexams, *inter partes* review, post-grant review, *etc.* (past and present)
 - No explicit requirement to identify proceedings outside PTO (*E.g.*, Federal court or ITC proceedings)

Preparing the Request: What to Include

- ◆ Identify each “aspect” of the patent to be examined ((§1.601(b)(6))
 - *E.g.*, Claims (specify which ones), specification, abstract, drawings or priority benefit
 - For means-plus-function claims – identify structures, materials or acts in specification corresponding to each means-plus-function element

Preparing the Request: Substantive Contents

- ◆ List of each item of information requested to be considered, reconsidered or corrected. 37 C.F.R. §1.610(b)(4)
 - Include publication date, when applicable
 - For each item not considered in prior examination
 - Identify and explain why consideration requested
 - For each item of information not adequately considered in prior examination
 - Identify and explain why reconsideration requested
 - For each item of information that was incorrect in prior examination
 - Identify and explain how it is being corrected

Preparing the Request: Substantive Contents

- ❖ Examples Of Information:
 - Prior art not considered during prior exam
 - Prior art not considered in combination with another, new reference during prior exam
 - Declaration submitted in prior exam (*e.g.*, evidence of unexpected results) found to contain analytical error

Preparing the Request: Identifying Each “Issue of Patentability”

- ◆ Request must identify each “issue of patentability” raised by each submitted item of information. 37 C.F.R. §1.610(b)(7)
 - Item of information may raise more than one “issue of patentability”
 - “Issue of patentability” not defined. Different from SNQ?

Preparing the Request: Identifying Each “Issue of Patentability”

- ❖ For each issue identified, a separate, detailed explanation of:
 - Relevance to each aspect of the patent identified for examination (*e.g.*, to specific claims)
 - How each item of information raises the issue, including
 - For §101 and §112 issues: support in specification for each claim limitation
 - For §102/ §103/double patenting: how each claim limitation is met (or not met) by each item of information
 - May include explanation of how/why claims distinguish over the information

Preparing the Request: Attachments

- ❖ The patent
 - Include any/all disclaimers and any/all certificates of correction, extension, reexamination, *etc.*
- ❖ Each “item of information” (*i.e.*, each supporting document)
 - With translations of pertinent parts of non-English documents (at least those parts specifically discussed in the request)
 - *Exceptions*: Not required to submit
 - U.S. patents and U.S. patent application publications
 - Items of information forming part of body of the request
 - All papers must comply with PTO rules for formatting papers
 - Non-patent “literature” and court documents may be redacted
- ❖ Summaries
 - Required for relevant portions of each submitted document >50 pages (with citations to specific pages)

Non-Compliant Requests for Supplemental Exam

- ❖ Non-compliant request will not be granted filing date
- ❖ Patent owner notified of non-compliant request, limited time to correct. 37 C.F.R. § 1.610(e)
 - Length of “limited time” not specified
- ❖ Failure to correct
 - Request for supplemental reexamination denied
 - Fee for *ex parte* reexamination refunded
- ❖ Timely filing of correction
 - Patent owner must timely file compliant request, correcting all defects identified in notice
 - Filing date is receipt date corrected request

Handling by PTO

- ❖ PTO must decide within three months of filing date
 - Mandated by statute
- ❖ Determines whether any SNQ raised by information in Request
 - Same standard as for *ex parte* reexamination:
 - Substantial likelihood reasonable examiner would consider the information important in determining patentability (M.P.E.P. § 2242)
 - “Generally” limited to review of issues identified in request, applied to aspects of patent (*e.g.*, specific claims) identified
- ❖ Amendments or interviews allowed if and when re-exam ordered

Handling by PTO

- ❖ Material Fraud referred to U.S. Attorney General
 - Required by statute
 - Proposed rules do not define “material fraud”
 - PTO regards as narrower than inequitable conduct

Fees

- ❖ Processing fee: **\$5,180**
 - Fee for *ex parte* reexamination: **\$16,120**
 - Must be paid with request for Supplemental Exam
 - Refundable if reexamination not ordered

- ❖ Excess page fees
 - For each non-patent document 21-50 pages: **\$170**
 - For each additional 50 sheets (or fraction thereof): **\$280**

Hypotheticals

FR § 101 / *Post-Prometheus* / *Post-Bilski*

FR §§ 102 / 103

FR § 112

FR Inequitable Conduct

Application Post-*Therasense v. Becton*

FR “This court now tightens the standards for finding both intent and materiality in order to redirect a doctrine that has been overused to the detriment of the public.”

United States Court of Appeals
for the Federal Circuit

THERASENSE, INC. (NOW KNOWN AS ABBOTT
DIABETES CARE, INC.)
AND ABBOTT LABORATORIES,
Plaintiffs-Appellants,

v.

BECTON, DICKINSON AND COMPANY,
AND NOVA BIOMEDICAL CORPORATION,
Defendants-Appellees,

AND

BAYER HEALTHCARE LLC,
Defendant-Appellee.

2008-1511, -1512, -1513, -1514, -1595

Appeals from the United States District Court for the
Northern District of California in consolidated case nos.
04-CV-2123, 04-CV-3327, 04-CV-3732, and 05-CV-3117,
Judge William H. Alsup.

Decided: May 25, 2011

JOHN M. WHEALAN, of Silver Spring, Maryland argued
for plaintiffs-appellants on rehearing en banc. With him
on the brief were ROHIT K. SINGLA and PETER A. DETRE,

Questions?



Thank You!



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