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Information Disclosure in Patent Prosecution: IDS Filings, Key Considerations, Strategies for Disclosure

THURSDAY, DECEMBER 16, 2021

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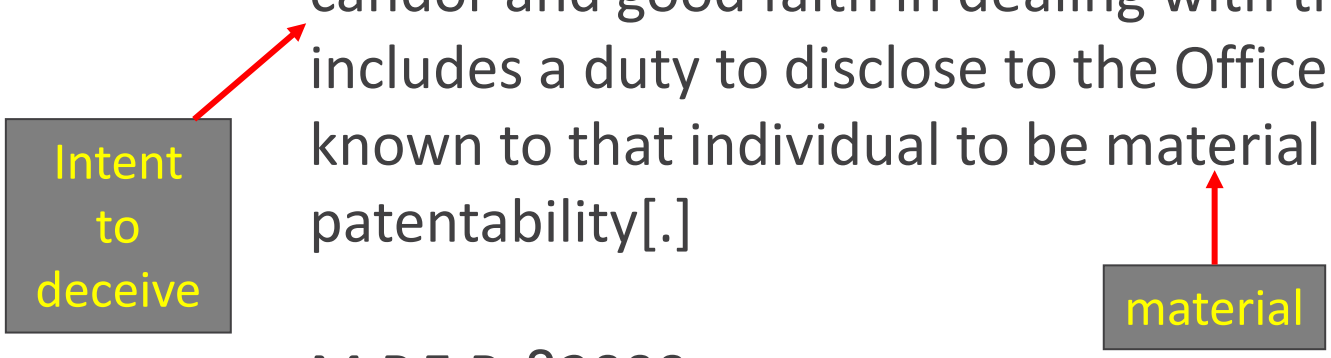
Outline

1. Duty of disclosure
2. IDS filings: brief overview
3. Considerations for elements of the IDS filing
    1. IDS pleas
    2. Form PTO/SB/08a
    3. Form PTO/SB/08b
    4. Timing
4. Other considerations
    1. PTAs
    2. Continuing applications
    3. National phase applications
5. Best practices for disclosure

- *What considerations for Form PTO/SB/08a or Form PTO/SB/08b should patent counsel keep in mind?*
- *What should be disclosed related to a continuing application?*
- *What role do IDSs play in a supplemental examination?*
- *What strategies should counsel employ when determining whether and when to disclose?*

Duty Of Disclosure

- Everyone involved in drafting and prosecuting US patent application owes a duty of disclosure to the USPTO (even though Rule 56 has been suspended, it is germane).
- 37 C.F.R. §1.56: Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability[.]
- M.P.E.P. §2000



Who Has A Rule 56 Duty?

- Individuals associated with the filing or prosecution of a patent application are:
  - **Inventors**
  - **attorney or agent** and
  - **every other person who is substantively involved** in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application.

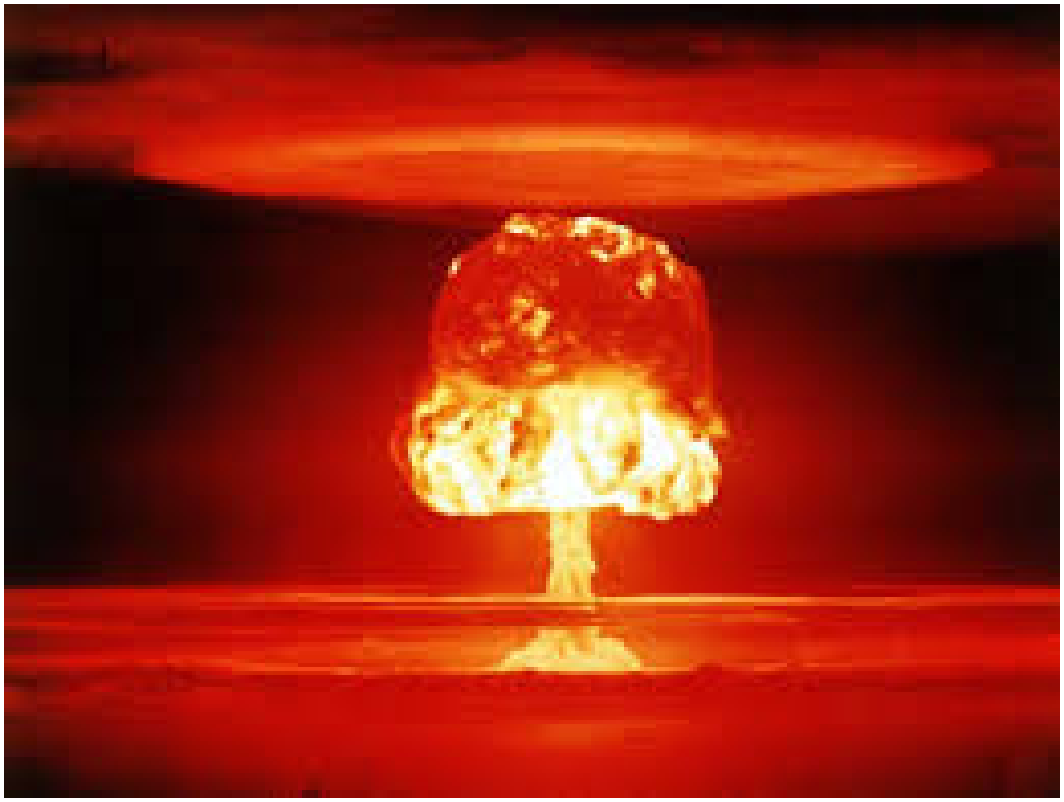
How Long Does Duty Last?

- Through issuance (unless back before USPTO via reexam/IPR/PGR or reissue). *But see also 3D Medical* case on the next slide.

- But perhaps not during patent term extension - See *Schering Corp. v. Mylan Pharmaceuticals, Inc.*, Slip Copy, 2011 WL 1885709 (D.N.J. May 17, 2011) (unpublished)
  - "in view of the specific allegations at issue in this motion, the Court does not interpret the duty of candor and good faith identified in §1.765 to require the disclosure of potentially invalidating prior art relating to the '721 patent. The Court therefore concludes that Schering's alleged failure to disclose such information during the term extension proceedings would not support a finding of inequitable conduct[.]"

Failure to Fulfill Duty

- Entire patent held unenforceable.



Therasense, Inc. v. Becton, Dickinson & Co.,

649 F.3d 1276 (Fed. Cir. 2011) (*en banc*)

- Majority (6-5) on Rehearing En Banc:

- **"but for" materiality** = if the PTO would not have allowed a claim had it been aware of the undisclosed prior art.

- **"affirmative egregious misconduct" exception** = no "but-for" materiality but it would otherwise be unjust to allow the patentee to enforce the patent. Example: filing of an unmistakably false affidavit. Does not include mere nondisclosure of prior art references.

- That majority was lost when Judge Rader departed.

Therasense: Standard For Intent

- Majority on Rehearing En Banc:
  - **specific intent to deceive** = single most reasonable inference that one with a Rule 56 duty "knew of the reference, knew that it was material, and made a deliberate decision to withhold it." No more "should have known" standard for intent (no disagreement from dissent or concurring opinions). Absence of a good faith explanation for failure to disclose a material reference (which was the case in Therasense) does not, by itself, constitute intent to deceive.
  - Explicitly forbade inferring intent solely from materiality and abandoned the "sliding scale". (No disagreement in the dissenting or concurring opinions).

Recent Example

- *ShenZhen JingPinCheng Elec. Tech. Co. v. Blisslights, LLC*, 2021 U.S. Dist. LEXIS 217972 (S.D. Cal. Nov. 10, 2021)
  - ShenZhen sought declaratory judgment of, inter alia, unenforceability based on inequitable conduct.
    - Defendant and its counsel failed to disclose relevant and material prior art in the prosecution of the '045 Patent by not filing an IDS.
    - During the prosecution of the '345 Patent, the parent patent of the '045 Patent, Defendant and counsel filed an IDS with the Patent Office disclosing some relevant prior art references.
    - Defendant prosecuted the '045 Patent as a child of the '345 Patent in order to intentionally hide prior art references from the Patent Office because it was eager to monopolize the market.
  - Blisslights filed motion to dismiss for failure to plead sufficiently under *Exergen*.

Recent Example

- *ShenZhen* (con't)
  - Defendant: MPEP § 609.02(I) provides that, "[w]hen filing a continuing application …, it will not be necessary for the applicant to submit an information disclosure statement in the continuing application that lists the prior art cited by the examiner in the parent application unless the applicant desires the information to be printed on the patent issuing from the continuing application …. The examiner of the continuing application will consider information which has been considered by the Office in the parent application." (emphasis in original)
    - "considered" because on cited on face of '345 patent.
  - Plaintiff: MPEP, § 609.02 provides that where information previously submitted but not "considered" by the Patent Office in a parent application, the applicant must resubmit the information in the continuing application.
    - "considered" means initialed.
  - DC: Denied motion to dismiss because "unable to determine as a matter of law whether the examiner of the '345 Patent 'considered' the prior art references at issue in this case because there is a disputed issue of fact what 'considered' means."

IDS Filings: Brief Overview

- 37 CFR 1.98 and MPEP 609.04(a) Content Requirements
  - List of all patents, publications, U.S. applications, or other information.
    - See MPEP § 707.05(e), for more information on data that should be used when citing publications and electronic documents.
    - Must be separate from the specification.
  - Legible copies of each foreign patent; each publication or that portion which caused it to be listed, other than U.S. patents and U.S. patent application publications; each cited pending unpublished U.S. application unless the cited pending U.S. application is stored in the Image File Wrapper (IFW) system.
  - A concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information listed that is not in the English language.
    - And a copy of any readily available translation.

Not Admission Of Prior Art

- Merely listing reference in IDS may not be treated as an admission of prior art.
  - *Abbott Laboratories v. Baxter Pharmaceutical Products Inc.*, 334 F.3d 1274 (Fed. Cir. 2003): listing of references in an IDS only indicates that references in the disclosure may be material to prosecution of the pending claims.
  - *Riverwood Int'l Corp. v. R.A. Jones & Co.*, 324 F.3d 1346, 1355 (Fed. Cir. 2003): "One's own work may not be considered prior art in the absence of a statutory basis, and a patentee should not be 'punished' for being as inclusive as possible and referencing his own work in an IDS."
  - See 37 C.F.R. §1.97(h).

Be Careful About Characterizations

- *Valve Corp. v. Ironburg Inventions Ltd.*, 8 F.4th 1364 (Fed. Cir. 2021)
  - PTAB: Mixed FWDs.
    - '688 patent: 9 claims unpatentable as anticipated, 5 not shown to be obvious over the Burns article.
  - Issue whether Burns article publicly accessible as of Oct. 20, 2010.
  - Cited by the examiner and described it as published Oct. 20, 2010.
  - Applicants did not dispute and stated the date in an IDS.
  - Ironburg: "including the Burns article in its IDS does not mean that the Burns article is prior art because including a reference in an IDS is not 'an admission that any reference is prior art.' …. The IDS is significant here, not because of its inclusion of the Burns article by the applicant, but because of the applicant's characterization of the Burns article as being dated 2010, which is before the critical date of each patent …."
  - FC: Affirmed-in-part, reversed-in-part, vacated-in-part, remand.
    - Valve established by overwhelming evidence that the Exhibit is a copy of an online article that was publicly accessible on October 20, 2010, that the Board could not find otherwise, and therefore the Exhibit is prior art. We reverse the Board's determination that the Exhibit was not prior art, vacate the Board's determination that [5] claims … were not shown to be unpatentable, and remand for the Board to consider Valve's arguments that relied on the Exhibit as to those claims.

Citation May Support Inference of Knowledge

- *Longhorn Vaccines & Diagnostics & Diagnostics, LLC v. Spectrum Sols. LLC*, -- F.Supp.3d__ (D. Utah Sept. 23, 2021)
  - Longhorn sued Spectrum for infringement, alleging that Spectrum knew of the Asserted Patents at least since April 11, 2018, when it cited "one or more" of them in an IDS.
  - Spectrum moved to dismiss, arguing that "citations to a patent in an IDS do not support a reasonable inference that an alleged infringer had actual knowledge of it."
  - DC:
    - "no reason to conclude that citations to a patent in an IDS cannot support an inference that the party who submitted the IDS had knowledge of that patent. … [T]he act of citing a patent in an IDS necessarily implies that the one preparing and submitting it possesses some degree of knowledge regarding that patent and its contents."
    - "Because Spectrum appears to be the applicant who submitted the IDS, it is reasonable to infer, at least at this stage of the case, that it was sufficiently connected to the IDS to have knowledge of what it contained. Thus, drawing all reasonable inferences in favor of Longhorn, and for the reasons discussed above, Longhorn has plausibly alleged that Spectrum had pre-filing knowledge of those patents."

See also, Lytone Enter. v. Agrofresh Solutions, 2021 U.S. Dist. LEXIS 26922 (D. Del. Feb. 12, 2021)

Considerations for Elements of the IDS Filing

MPEP 609

"In nonprovisional applications, applicants and other individuals substantively involved with the preparation and/or prosecution of the application have a duty to submit to the Office information which is material to patentability as defined in 37 CFR 1.56. The provisions of 37 CFR 1.97 and 37 CFR 1.98 provide a mechanism by which patent applicants may comply with the duty of disclosure provided in 37 CFR 1.56. …

Third parties (individuals not covered by 37 CFR 1.56(c)) cannot file information disclosure statements under 37 CFR 1.97 and 37 CFR 1.98. …

An information disclosure statement filed in accordance with the provisions of 37 CFR 1.97 and 37 CFR 1.98 will be considered by the examiner assigned to the application. ….

The filing of an information disclosure statement shall not be construed as a representation that a search has been made. 37 CFR 1.97(g). There is no requirement that an applicant for a patent make a patentability search. Further, the filing of an information disclosure statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in 37 CFR 1.56(b). 37 CFR 1.97(h). See MPEP § 2129 regarding admissions by applicant."

Form PTO/SB/08

Information Disclosure Statement

Select the description to view each form in your browser	Updated	Code
Information Disclosure Statement by Applicant - EFS-Web auto-load version **This EFS-Web version of the SB/08 is the RECOMMENDED version** • Instructions [DOC]	02/2018	SB/08a - EFS-Web
Information Disclosure Statement by Applicant [page 1]	06/2015	SB/08a
Information Disclosure Statement by Applicant [page 2]	06/2015	SB/08b
Certification and Request for Consideration of an Information Disclosure Statement Filed After Payment of the Issue Fee Under the QPIDS Pilot Program • More information	12/2016	SB/09
Patent Term Adjustment Statement Under 37 CFR 1.704(d)	05/2018	SB/133

Form PTO/SB/08a (electronic)

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (02-18)
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	Filing Date	
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CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature		Date (YYYY-MM-DD)	
Name/Print		Registration Number	

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Examiner Name	
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Examiner Signature		Date Considered	

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1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Form PTO/SB/09

Doc Code: QPIDS.REQ
Document Description: QuickPath Information Disclosure Statement

PTO/SB/09 (09-18)

CERTIFICATION AND REQUEST FOR CONSIDERATION OF AN INFORMATION DISCLOSURE STATEMENT FILED AFTER PAYMENT OF THE ISSUE FEE UNDER THE QPIDS PROGRAM

Non-Provisional Application Number:	Filing Date:
First Named Inventor:	Title of Invention:

THE UNDERSIGNED HEREBY CERTIFIES AND REQUESTS THE FOLLOWING FOR THE ABOVE-IDENTIFIED APPLICATION.

1. Consideration is requested of the information disclosure statement (IDS) submitted herewith, which is being filed after payment of the issue fee.
2. Check the box next to the appropriate selection:
   ☐ Each item of information contained in the IDS was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the IDS. See 37 CFR 1.97(e)(1).
   OR
   ☐ No item of information contained in the IDS was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the IDS was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the IDS. See 37 CFR 1.97(e)(2).
   OR
   ☐ See attached certification statement in compliance with 37 CFR 1.97(e).
3. Please charge the IDS fee set forth in 37 CFR 1.17(p) to Deposit Account No. _____.
4. A Petition to Withdraw from Issue After Payment of the Issue Fee (37 CFR 1.313(c)(2)), including the petition fee set forth in 37 CFR 1.17(h), is submitted herewith as a **Web-based ePetition**.
   WARNING: Do not submit the petition as a follow-on paper via EFS-Web. Submit the petition as a Web-based ePetition by signing on to EFS-Web as a registered user, selecting the radio button next to "Existing application/patent," and then selecting the radio button next to "ePetition (for automatic processing and immediate grant, if all petitions requirements are met)." Failure to use the Web-based ePetition interface will result in automatic entry of the RCE.
5. A request for continued examination (RCE) under 37 CFR 1.114 and the RCE fee under 37 CFR 1.17(e) are submitted herewith.
6. The RCE will be treated as a "conditional" RCE. In the event the examiner determines that any item of information contained in the IDS necessitates the reopening of prosecution in the application, the undersigned understands that (i) the RCE will be processed and treated as an RCE under 37 CFR 1.114 and therefore (ii) the IDS fee under 37 CFR 1.17(p) will be returned in accordance with 37 CFR 1.97(b)(4). In the event that no item of information in the IDS necessitates reopening prosecution, the undersigned understands that the RCE will not be processed and the RCE fee under 37 CFR 1.17(e) will be returned.
7. This certification and request is being filed as a **Web-based ePetition** and is not accompanied by an amendment to the application. Inclusion of an amendment will result in automatic entry of the RCE.

Signature	Date
Name (Print/Typed)	Practitioner Registration Number (If applicable)

Note: *Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required in accordance with 37 CFR 1.33 and 11.18. Please see 37 CFR 1.4(d) for the form of the signature. If necessary, submit multiple forms for more than one signature, see below.**

☐ *Total of _____ forms are submitted.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

IDS Timing Rules

- To have an IDS considered by the Office, the IDS must satisfy 37 C.F.R. § 1.98 (specifying the required content of an IDS) and section (b), (c), or (d) of 37 C.F.R. § 1.97.

- Sections (b), (c), and (d) of § 1.97 specify different time periods and conditions under which an IDS may be filed.

- If an IDS does not comply with § 1.97 or § 1.98, it will be placed in the file, but will not be considered by the Office. 37 C.F.R. § 1.97(i).

- See MPEP 609.04(b).

37 C.F.R. § 1.97(b): An IDS Shall Be Considered By The Office If Filed By The Applicant:

(1) Within three months of the filing date of a national application;

(2) Within three months of the date of entry of the national stage in an international application;

(3) Before the mailing of a first Office action on the merits;

(4) Before the mailing of a first Office action after the filing of a request for continued examination under § 1.114; or

(5) Within three months of the date of publication of the international registration under Hague Agreement Article 10(3) in an international design application.

37 C.F.R. § 1.97(c) and (d)

- (c) An IDS shall be considered by the Office if filed by the applicant after the period specified in paragraph (b), provided that the IDS is filed before the mailing date of a final OA, a Notice of Allowance, or an action that otherwise closes prosecution in the application, and it is accompanied by one of:
  - (1) The statement specified in paragraph (e) of this section; or
  - (2) The fee set forth in § 1.17(p).

- (d) An information disclosure statement shall be considered by the Office if filed by the applicant after the period specified in paragraph (c) of this section, provided that the information disclosure statement is filed on or before payment of the issue fee and is accompanied by:
  - (1) The statement specified in paragraph (e)of this section; and
  - (2) The fee set forth in § 1.17(p).

The Statement under § 1.97(e)

- (1) Each item of information in the IDS was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the IDS; or

- (2) No item of information contained in the IDS was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the IDS was known to any individual designated in § 1.56(c) more than three months prior to the filing of the IDS.

Filing an IDS After Allowance, Before Paying Issue Fee

- If a statement under § 1.97(e) can be made, then file the IDS under § 1.97(d) with the statement and fee.

- If a statement under § 1.97(e) cannot be made, then file an RCE and the IDS under § 1.97(b).

- IDS qualifies as the required "submission" that must be filed with an RCE. 37 C.F.R. § 1.114.

37 C.F.R. § 1.97(f) - (i)

f) No extensions of time for filing an information disclosure statement are permitted under§ 1.136. If a bona fide attempt is made to comply with § 1.98, but part of the required content is inadvertently omitted, additional time may be given to enable full compliance.

g) An information disclosure statement filed in accordance with this section shall not be construed as a representation that a search has been made.

h) The filing of an information disclosure statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in § 1.56(b).

i) If an information disclosure statement does not comply with either this section or § 1.98, it will be placed in the file but will not be considered by the Office.

Filing an IDS After Paying Issue Fee

- Doesn't fall under section (b), (c), or (d) of § 1.97.
- RCE must be filed prior to payment of the issue fee unless filed with a Petition to Withdraw from Issue under § 1.313.
- RCE requires a fee.
- Filing a Petition to Withdraw after issue fee paid and filing of RCE will likely delay prosecution.
- Another option is currently available: File a Quick Path IDS (QPIDS)

QPIDS Requirements

- Eliminates the requirement of processing an RCE with an IDS after payment of the issue fee.
- If the Examiner determines that no item of information in the IDS necessitates reopening prosecution, the Office will issue a corrected Notice of Allowability.
- Program made permanent Sept. 28, 2018.
- *FAQ at https://www.uspto.gov/patent/initiatives/quick-path-information-disclosure-statement-qpids*

Quick Path IDS (QPIDS)

- Must be a utility or reissue application.
- Design and plant applications do not qualify for the program.
- All papers must be filed via electronically via EFS-Web.
- All fees must be paid by authorization to charge a deposit account.

QPIDS Submission

- A QPIDS submission must include:
  1) a transmittal form that designates the submission as a QPIDS submission;
  2) an IDS accompanied by a timeliness statement set forth in § 1.97(e), with the IDS fee set forth in § 1.17(p);
  3) a Web-based ePetition to withdraw from issue under § 1.313(c)(2), with the petition fee set forth in § 1.17(h); and
  4) an RCE, which will be treated as a "conditional" RCE, with the RCE fee under § 1.17(e).

What Happens After a QPIDS is Filed?

- A compliant ePetition to Withdraw from Issue will be granted immediately upon submission.
- The IDS submission will be placed on the examiner's ''expedited'' docket for consideration.
- A non-compliant QPIDS submission that otherwise complies with the RCE requirements will be treated as an RCE.
- For example, a submission that includes an amendment is non-compliant and will be processed as an RCE.

What Happens After a QPIDS is Filed?

- If the examiner determines no item of information in the IDS necessitates reopening prosecution, the examiner will issue a corrected Notice of Allowability.

- RCE will not be processed and the RCE fee will be automatically returned.
  - The IDS and petition fees will not be returned.

- A new notice of allowance and fee(s) due (i.e., PTOL–85) will not be issued.

What Happens After a QPIDS is Filed?

- If the examiner determines any item of information in the IDS necessitates reopening prosecution, the RCE will be processed and placed on the examiner's docket.

- The IDS fee will be automatically returned.
  - The petition fee will not be returned.

- PTO will send a form (PTO-2300) notifying the applicant that prosecution is being reopened and include a copy of the submitted IDS listing (e.g., form PTO/SB/08) as considered by the examiner.

Filing a QPIDS

- Same process as filing an ePetition to Withdraw from Issue.
- The ePetition is web-based (i.e., the petition is filled out using EFS-Web).
- Submit the same items that are submitted with an ePetition to Withdraw from Issue:
  - RCE and IDS.
  - Plus, submit a QPIDS form.

Form PTO/SB/09

Doc Code: QPIDS.REQ
Document Description: QuickPath Information Disclosure Statement

PTO/SB/09 (09-18)

CERTIFICATION AND REQUEST FOR CONSIDERATION OF AN INFORMATION DISCLOSURE STATEMENT FILED AFTER PAYMENT OF THE ISSUE FEE UNDER THE QPIDS PROGRAM

Non-Provisional Application Number:	Filing Date:
First Named Inventor:	Title of Invention:

THE UNDERSIGNED HEREBY CERTIFIES AND REQUESTS THE FOLLOWING FOR THE ABOVE-IDENTIFIED APPLICATION.

1. Consideration is requested of the information disclosure statement (IDS) submitted herewith, which is being filed after payment of the issue fee.
2. Check the box next to the appropriate selection:

   ☐ Each item of information contained in the IDS was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the IDS. See 37 CFR 1.97(e)(1).

   OR

   ☐ No item of information contained in the IDS was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the IDS was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the IDS. See 37 CFR 1.97(e)(2).

   OR

   ☐ See attached certification statement in compliance with 37 CFR 1.97(e).
3. Please charge the IDS fee set forth in 37 CFR 1.17(p) to Deposit Account No. _____.
4. A Petition to Withdraw from Issue After Payment of the Issue Fee (37 CFR 1.313(c)(2)), including the petition fee set forth in 37 CFR 1.17(h), is submitted herewith as a **Web-based ePetition**.

Form PTO/SB/09 (con't)

WARNING: Do not submit the petition as a follow-on paper via EFS-Web. Submit the petition as a Web-based ePetition by signing on to EFS-Web as a registered user, selecting the radio button next to "Existing application/patent," and then selecting the radio button next to "ePetition (for automatic processing and immediate grant, if all petitions requirements are met)." Failure to use the Web-based ePetition interface will result in automatic entry of the RCE.

5. A request for continued examination (RCE) under 37 CFR 1.114 and the RCE fee under 37 CFR 1.17(e) are submitted herewith.
6. The RCE will be treated as a "conditional" RCE. In the event the examiner determines that any item of information contained in the IDS necessitates the reopening of prosecution in the application, the undersigned understands that (i) the RCE will be processed and treated as an RCE under 37 CFR 1.114 and therefore (ii) the IDS fee under 37 CFR 1.17(p) will be returned in accordance with 37 CFR 1.97(b)(4). In the event that no item of information in the IDS necessitates reopening prosecution, the undersigned understands that the RCE will not be processed and the RCE fee under 37 CFR 1.17(e) will be returned.
7. This certification and request is being filed as a **Web-based ePetition** and is not accompanied by an amendment to the application. Inclusion of an amendment will result in automatic entry of the RCE.

Signature	Date
Name (Print/Typed)	Practitioner Registration Number (If applicable)

Note: *Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required in accordance with 37 CFR 1.33 and 11.18. Please see 37 CFR 1.4(d) for the form of the signature. If necessary, submit multiple forms for more than one signature, see below.**

☐ *Total of _____ forms are submitted.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

File an ePetition…

Select a web-based ePetition to Withdraw from Issue

PDF-based ePetitions

Filing instructions: Download and complete the respective EFS-Web Fillable PDF Form and attach it to the ePetition submission. See the Resources page for additional information.

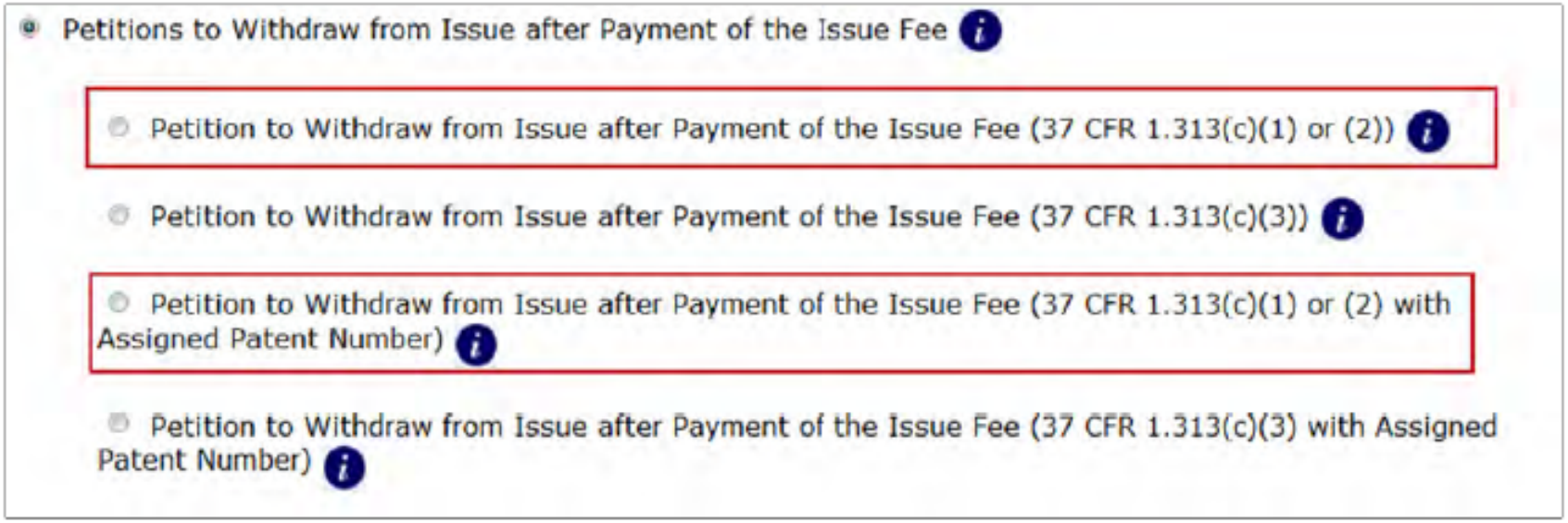
- Petition to make special based on age (37 CFR 1.102)
- Petition to Accept Unintentional Delayed Payment of the Maintenance Fee (37 CFR 1.378(c))

Web-based ePetitions

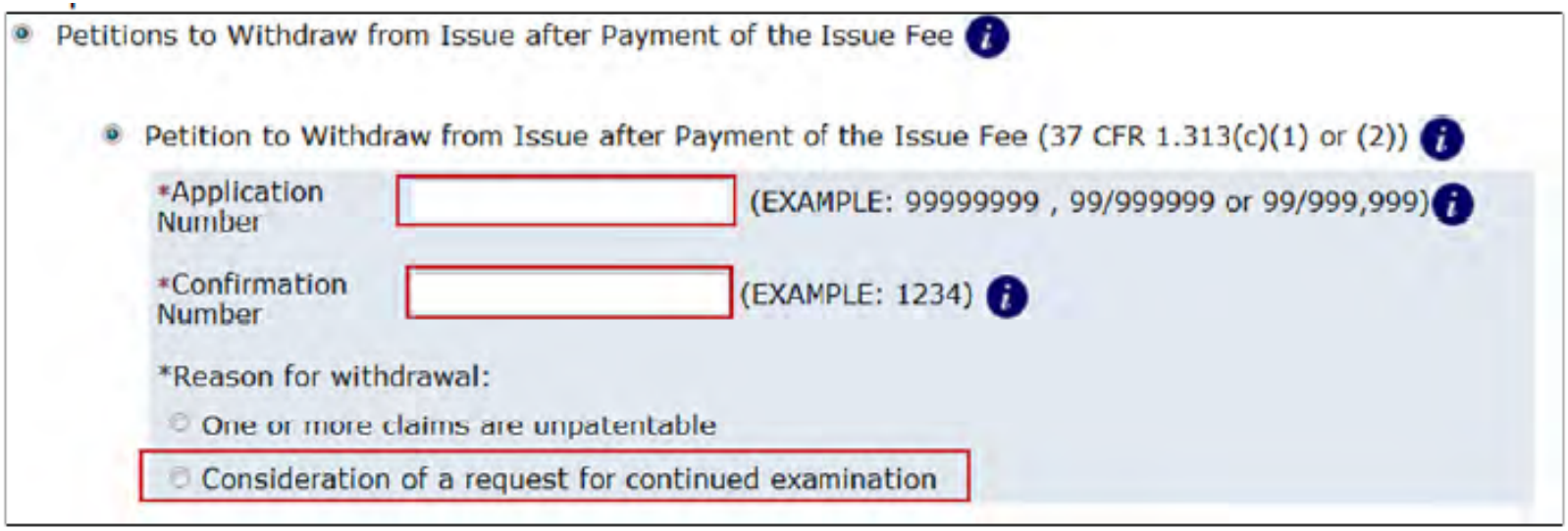
Filing instructions: The petition PDF Form is not required for the following ePetitions. Petition information will be entered directly into EFS-Web screens. See the Resources Page for additional information.

- Request for Withdrawal as Attorney or Agent of Record (37 CFR 1.36)
- Petitions to Withdraw from Issue after Payment of the Issue Fee
- Petitions for Revival
- Petition to Correct Assignee After Payment of Issue Fee (37 CFR 3.81(b))

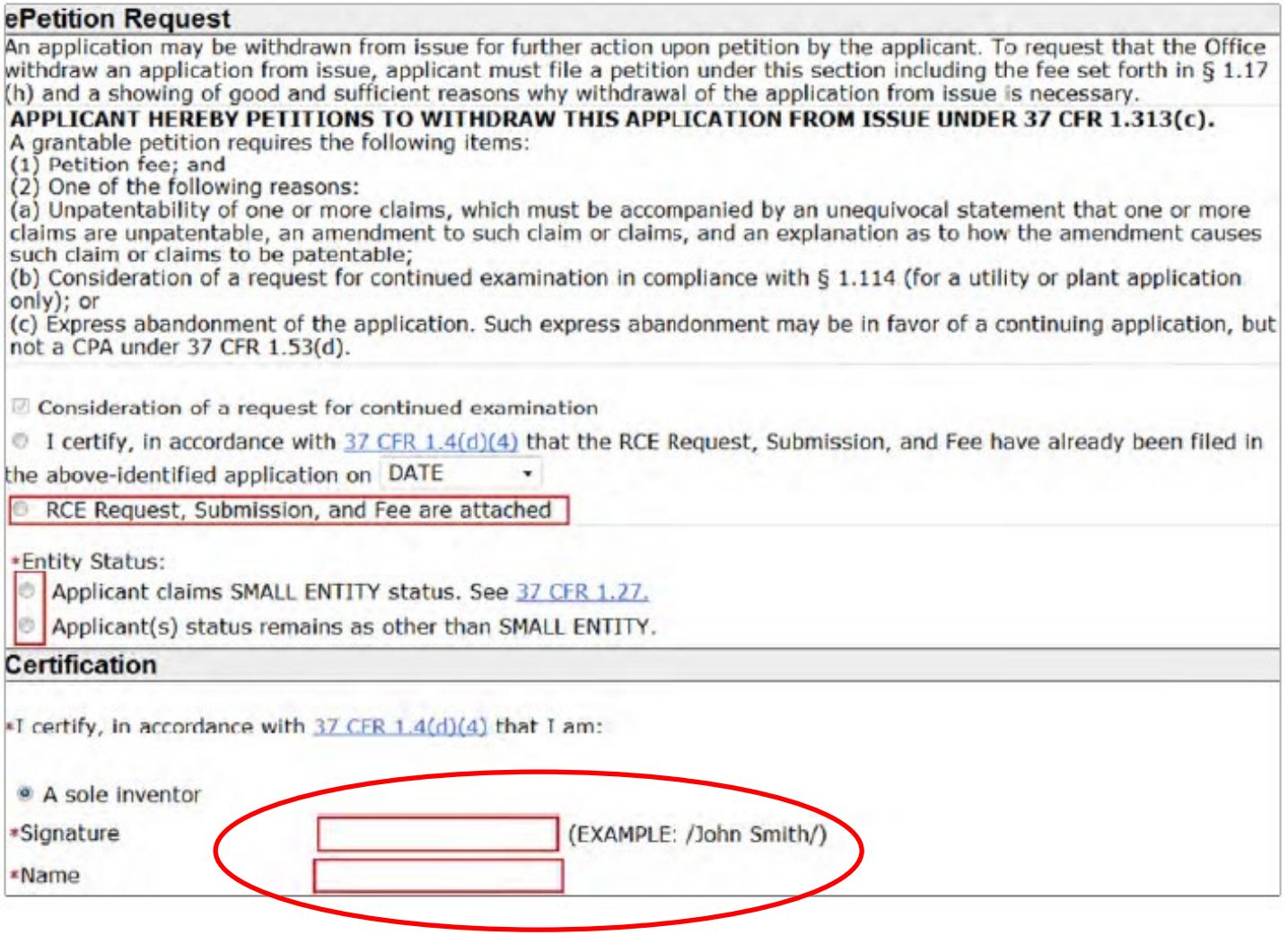
Select 1 of 2 Petition to Withdraw Options



Specify reason for withdrawal: Consideration of an RCE



ePetition Signature Requirement



ePetition Request

An application may be withdrawn from issue for further action upon petition by the applicant. To request that the Office withdraw an application from issue, applicant must file a petition under this section including the fee set forth in § 1.17 (h) and a showing of good and sufficient reasons why withdrawal of the application from issue is necessary.

APPLICANT HEREBY PETITIONS TO WITHDRAW THIS APPLICATION FROM ISSUE UNDER 37 CFR 1.313(c).

A grantable petition requires the following items:
(1) Petition fee; and
(2) One of the following reasons:
(a) Unpatentability of one or more claims, which must be accompanied by an unequivocal statement that one or more claims are unpatentable, an amendment to such claim or claims, and an explanation as to how the amendment causes such claim or claims to be patentable;
(b) Consideration of a request for continued examination in compliance with § 1.114 (for a utility or plant application only); or
(c) Express abandonment of the application. Such express abandonment may be in favor of a continuing application, but not a CPA under 37 CFR 1.53(d).

☑ Consideration of a request for continued examination

○ I certify, in accordance with 37 CFR 1.4(d)(4) that the RCE Request, Submission, and Fee have already been filed in the above-identified application on DATE

○ RCE Request, Submission, and Fee are attached

*Entity Status:

○ Applicant claims SMALL ENTITY status. See 37 CFR 1.27.

○ Applicant(s) status remains as other than SMALL ENTITY.

Certification

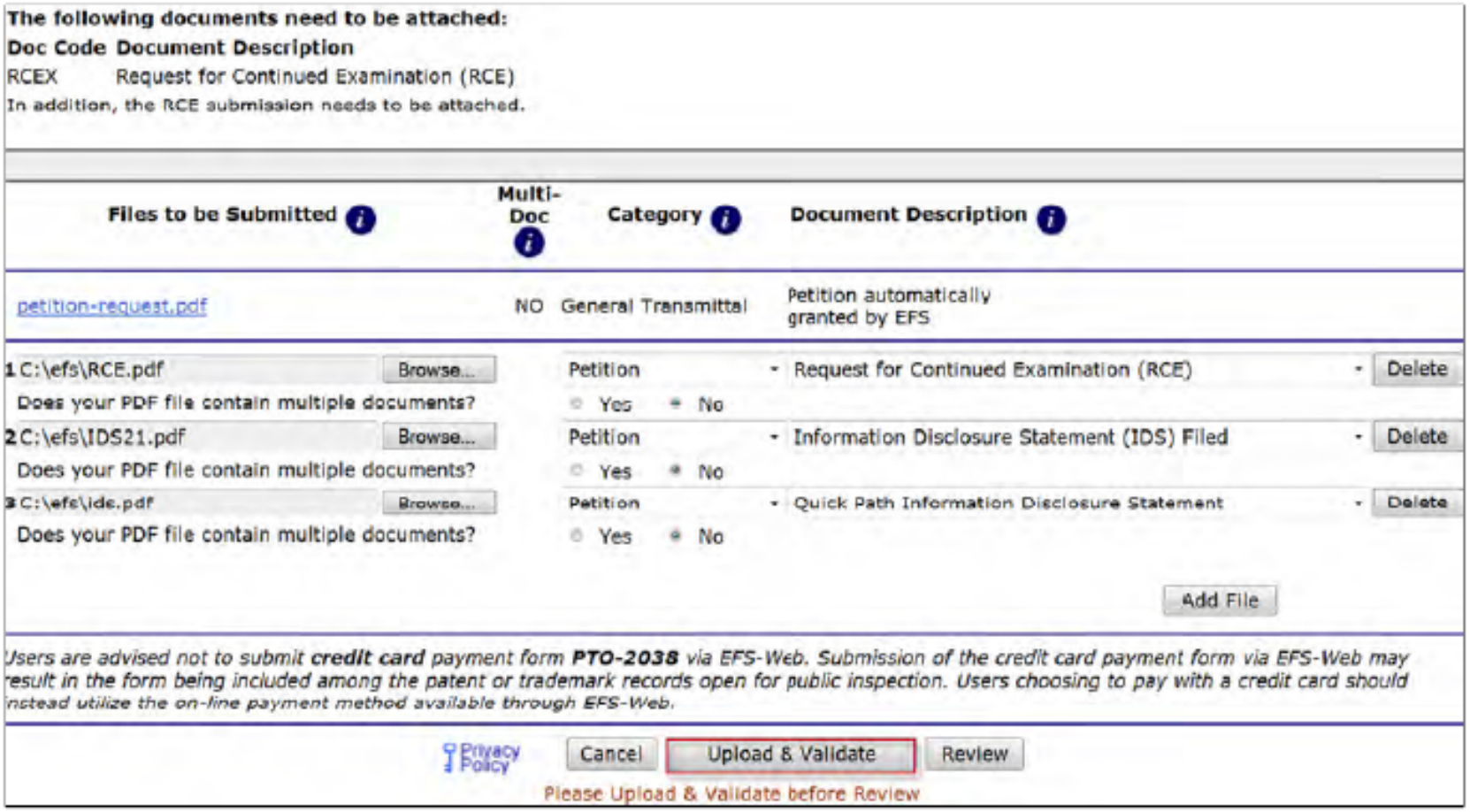
*I certify, in accordance with 37 CFR 1.4(d)(4) that I am:

◉ A sole inventor

*Signature (EXAMPLE: /John Smith/)

*Name

Attach RCE, IDS, and QPIDS Form

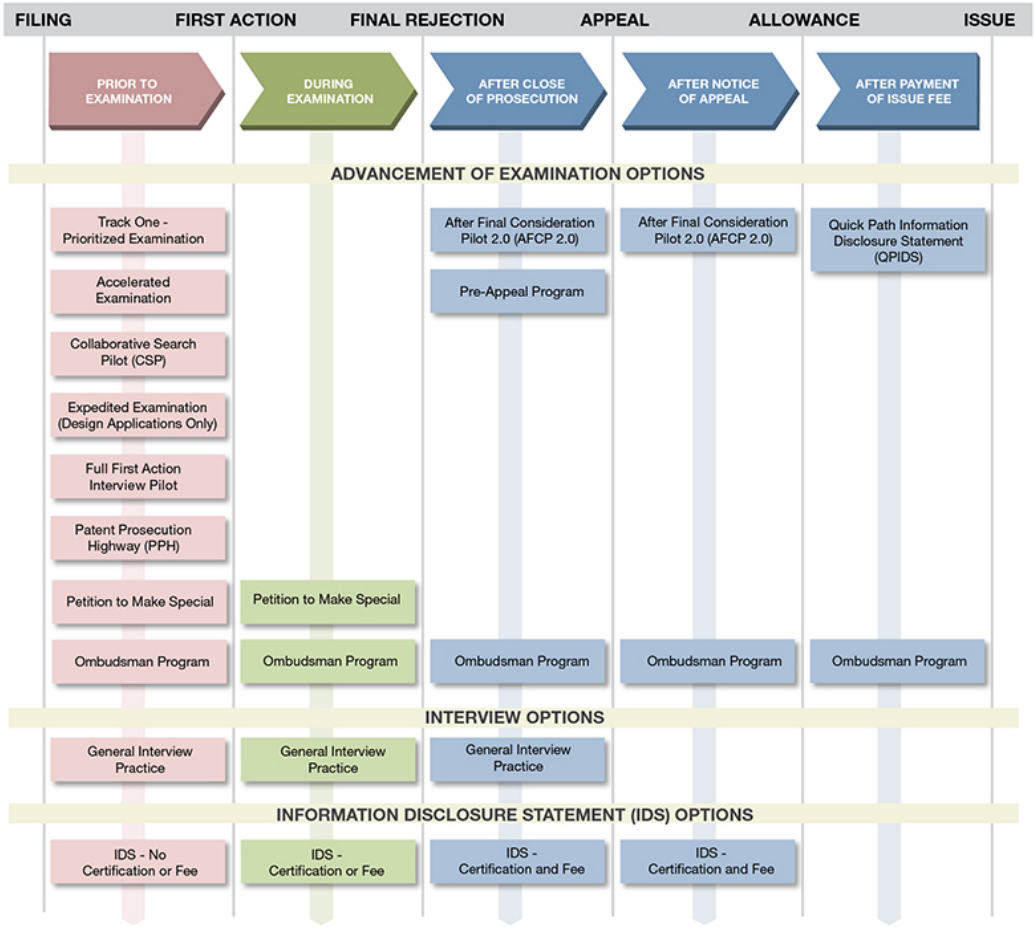


PTO's Initiatives Timeline and Matrix

- **Patent Application Initiatives Timeline** identifies when various initiatives are available during each phase of the prosecution process.
  - See next slide.

- **Patent Application Initiatives Matrix** presents a detailed explanation of the various initiatives for comparison.
  - https://www.uspto.gov/patent/initiatives/patent-application-initiatives/uspto-patent-application-initiatives-prior

Patent Application Initiatives Timeline



Patent Application Initiatives Matrix

USPTO Patent Application Initiatives - After Close of Prosecution

	After Final Consideration Pilot 2.0 (AFCP 2.0)	Pre-Appeal Program	General Interview Practice	Quick Path Information Disclosure Statement (QPIDS)	Ombudsman Program
Description	AFCP 2.0 authorizes additional time for examiners to search and/or consider responses after final rejection.	An avenue to request that a panel of examiners formally review the legal and factual basis of the rejections in their application prior to the filing of an appeal brief.	The USPTO encourages examiners to take a proactive approach to examination by reaching out and engaging our stakeholders in an effort to resolve issues and shorten prosecution.	QPIDS eliminates the requirement for filing an RCE with an IDS filed after payment of the issue fee in order for the IDS to be considered by the examiner.	The Patents Ombudsman Program enhances the USPTO's ability to assist applicants or their representatives with issues that arise during patent application prosecution.
Program Start Date	05/2013	07/2005		05/2012	04/2010
Currently Active (accepting applications)	Yes	Yes	Yes	Yes	Yes
Petition / Request	Request	Request	Request	Submitted Via EFS-Web as e-petition	Request

Other Considerations

- PTAs
- Continuing applications
- National phase applications

Form PTO/SB/133

PTO/SB/133 (05-18)

PATENT TERM ADJUSTMENT STATEMENT UNDER 37 CFR 1.704(d)		
	Application Number	
	Filing Date	
	First Named Inventor	
	Art Unit	
	Examiner Name	
	Practitioner Docket No.	

APPLICANT HEREBY STATES THE FOLLOWING (please review 37 CFR 1.704(d) before filing this form):

☐ Each item of information contained in the information disclosure statement was first cited in any communication from a patent office in a counterpart foreign or international application or from the Office, and this communication was not received by any individual designated in 37 CFR 1.56(c) more than thirty days prior to the filing of the information disclosure statement.

AND/OR

☐ Each item of information contained in the information disclosure statement is a communication that was issued by a patent office in a counterpart foreign or international application or by the Office, and this communication was not received by any individual designated in 37 CFR 1.56(c) more than thirty days prior to the filing of the information disclosure statement.

INSTRUCTIONS:

- **This form will not satisfy the requirement of 37 CFR 1.97(e).** The present statement is filed under 37 CFR 1.704(d) and will not substitute for compliance with any of the requirements of 37 CFR 1.97 and 1.98. For an information disclosure statement to comply with 37 CFR 1.97(c) or (d), the information disclosure statement must be accompanied by a statement under 37 CFR 1.97(e) notwithstanding any statement filed under 37 CFR 1.704(d).
- The present form (PTO/SB/133) should be filed concurrently with the information disclosure statement to derive benefit under 37 CFR 1.704(d).

Signature		Date	
Typed or Printed Name		Practitioner Registration Number	

***Note**: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required in accordance with 37 CFR 1.33 and 11.18. Please see 37 CFR 1.4(d) for the form of the signature. If necessary, submit multiple forms for more than one signature, see below*.*

☐ *Total of _____ forms are submitted.

Patent Term Adjustment

- Request recalculation of the patent term adjustment with respect to IDS's accompanied by a proper safe harbor statement under 37 CFR. 1.704(d).
  - (d)(1) A paper containing only an information disclosure statement in compliance with §§ 1.97 and 1.98 will not be considered a failure to engage in reasonable efforts to conclude prosecution(processing or examination) of the application under paragraphs (c)(6), (c)(8), (c)(9), or (c)(10) of this section, and a request for continued examination incompliance with § 1.114 with no submission other than an information disclosure statement incompliance with §§ 1.97 and 1.98 will not be considered a failure to engage in reasonable efforts to conclude prosecution (processing or examination)of the application under paragraph (c)(12) of this section, if the paper or request for continued examination is accompanied by a statement that each item of information contained in the information disclosure statement:
    - (i) Was first cited in any communication from a patent office in a counterpart foreign or international application or from the USPTO, and this communication was not received by any individual designated in 37 CFR 1.56(c) more than thirty days prior to the filing of the information disclosure statement; **or**
    - (ii) is a communication that was issued by a patent office in a counterpart foreign or international application or by the USPTO, and this communication was not received by any individual designated in 37 CFR 1.56(c) more than thirty days prior to the filing of the information disclosure statement.
  - (2) The thirty-day period set forth in paragraph (d)(1) of this section is not extendable.

Patent Term Adjustment

- **Either of these statements *or both* may be needed.**
- 37 C.F.R. §1.704(d)(i) relates to "information… first cited in any communication."
  - Relates to the references cited in the communication from a patent office in a counterpart application.
- 37 C.F.R. §1.704(d)(ii) relates to "a communication that was issued by a patent office in a counterpart foreign or international application or by the USPTO."
  - Relates to, for example, the search report or the office action.
- If an Office Action is issued in a counterpart application containing first cited references, within 30 days, the Office Action ***and*** the references are filed in an IDS and to be properly certified under 37 C.F.R. §1.704(d), ***both boxes*** in Form PTO/SB/133 must be checked.
- Failure to properly certify may lead to the loss of patent term adjustment even if Form PTO/SB/133 is filed on a timely basis.

Continuing Applications

- MPEP 609.02
  - Continuing application that claims benefit under 35 U.S.C. 120 to a parent application (other than an international application that designated the U.S.) – **no IDS necessary.**
  - Continuing application that claims benefit under 35 U.S.C. 120 to an international application that designated the U.S. – **IDS necessary.**

Continuing Applications: IDS That Has Been Considered (1) in the Parent Application, or (2) Prior to the Filing of a Request for Continued Examination (RCE)

- MPEP 609.02
  - Continued Prosecution Applications (CPAs) Filed Under 37 CFR 1.53(d)
    - need not be resubmitted.
  - Continuation Applications, Divisional Applications, or Continuation-in-Part Applications Filed Under 37 CFR 1.53(b)
    - need not be resubmitted.

- "If resubmitting a listing of the information, applicant should submit a new listing that complies with the format requirements in 37 CFR 1.98(a)(1) and the timing requirements of 37 CFR 1.97. Applicants are strongly discouraged from submitting a list that includes copies of PTO/SB/08 or PTO-892 forms from other applications."

  - Requests for Continued Examination (RCE) Under 37 CFR 1.114
    - need not be resubmitted.

*Continuing Applications: IDS That Has **Not** Been Considered (1) in the Parent Application, or (2) Prior to the Filing of a Request for Continued Examination*

- MPEP 609.02
  - Continued Prosecution Applications Filed Under 37 CFR 1.53(d)
    - No specific request from the applicant that the previously submitted information be considered by the examiner is required.
  - Continuation Applications, Divisional Applications, or Continuation-In-Part Applications Filed Under 37 CFR 1.53(b)
    - Resubmit the information in the continuing application in compliance with 37 CFR 1.97 and 37 CFR 1.98.

- "When resubmitting a listing of the information, applicant should submit a new listing that complies with the format requirements in 37 CFR 1.98(a)(1). Applicants are strongly discouraged from submitting a list that includes copies of PTO/SB/08 or PTO-892 forms from other applications."

Continuing Applications: Requests for Continued Examination Under 37 CFR 1.114

- MPEP 609.02
  - Requests for Continued Examination Under 37 CFR 1.114
    - "Information filed in the application in compliance with the content requirements of 37 CFR 1.98 before the filing of a RCE will be considered by the examiner after the filing of the RCE."

National Phase Applications

- MPEP 609.03 Information Disclosure Statements in National Stage Applications
  - "When examining a PCT national stage application, the examiner will consider all U.S. patents, U.S. patent application publications, and U.S. pending applications cited in the international search report that are stored electronically in the USPTO's Image File Wrapper (IFW) system. The examiner will consider other documents cited in the international search report when the Form PCT/DO/EO/903 in the national stage application indicates that both the international search report and the copies of the documents are present in the national stage file."

App. No. 10/430,435

- Interview Summary:
  - "Substance of Interview…: Mr Irving called to verify that, in addition to the IDS documents, the Supplemental Notices of Related Litigations (SNRLs) had been considered. Exr affirmed that over the course of prosecution, all NRLs, up to and including the 7th and 8th SNRLs had been considered. …"

App. No. 10/430,435

- Interview Summary:
  - "Substance of Interview…: Mr Irving called to notify exr that the 9th SNRL and 10th suppl. IDS had been scanned and was ready for review. Exr indicated that the submissions would be reviewed. …"

App. No. 10/430,435

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation
LCM	P00424	Public Version of Amphastar's Memorandum of Points and Authorities in Support of Motion for Summary Judgment or, in the Alternative, Summary Adjudication Re Prior Art Invalidity Pursuant to 35 USC § 102, dated March 14, 2005, including Exhibit A.	
LCM	P00425	Public Version of Amphastar's Statement of Uncontroverted Facts and Conclusions of Law in Support of Amphastar's Motion for Summary Judgment or, in the Alternative, Summary Adjudication Re Prior Art Invalidity Pursuant to 35 USC § 102, dated March 14, 2005.	
LCM	P00426	Defendant Amphastar Pharmaceuticals, Inc.'s Notice of Motion and Motion for Summary Judgment, or in the Alternative, Summary Adjudication of Issues, Re Prior Art Invalidity Pursuant to 35 USC § 102, dated March 14, 2005.	
LCM	P00427	Public Version of Declaration of Steven M. Hanle in Support of Amphastar's Motion for Summary Judgment, or in the Alternative Summary Adjudication of Invalidity Pursuant to 35 USC § 102, dated March 14, 2005.	
LCM	P00428	Public Version of Declaration of Geert-Jan Boons in Support of Amphastar's Motion for Summary Judgment, or in the Alternative, Summary Adjudication of Invalidity Pursuant to 35 USC § 102, dated March 7, 2005.	
LCM	P00429	Public Version of Declaration of Alma Mack in Support of Amphastar's Motion for Summary Judgment, or in the Alternative, Summary Adjudication of Invalidity Pursuant to 35 USC § 102, dated March 8, 2005.	

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation
LCM	P00430	Public Version of Declaration of Dingyan Fei, a.k.a. Robert Fei in Support of Amphastar's Motion for Summary Judgment, or in the Alternative, Summary Adjudication of Invalidity Pursuant to 35 USC § 102, dated March 4, 2005.	
LCM	P00431	Public Version of Declaration of Paul Yu in Support of Amphastar's Motion for Summary Judgment, or in the Alternative, Summary Adjudication of Invalidity Pursuant to 35 USC § 102, dated March 7, 2005.	
LCM	P00432	Public Version of Declaration of Yu-Ying Chao in Support of Amphastar's Motion for Summary Judgment, or in the Alternative, Summary Adjudication of Invalidity Pursuant to 35 USC § 102, dated March 4, 2005.	
LCM	P00433	Public Version of Declaration of Stephen A. Campbell in Support of Amphastar's Motion for Summary Judgment, or in the Alternative, Summary Adjudication of Invalidity Pursuant to 35 USC § 102, dated March 7, 2005.	

App. No. 10/430,435

- Interview Summary:
  - "Substance of Interview…: To follow up on IDS, filed 1/26/05, Mr. Irving called to verify that references P00027 and P00246 (from a previous IDS) had indeed been considered. Exr confirmed that all documents in all submissions had been considered. The omission in initialling these entries was merely an oversight. The exr regrets the oversight and any confusion caused thereby. Additionally, the correspondence from Mr. Irving accompanying the IDS was also fully considered."

App. No. 10/430,435

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation
LCM	P00417	U.S. District Court Civil Docket (District of California; Aventis Pharma SA, et al. v. Amphastar Pharmaceut., et al.).	
LCM	P00418	Public Version of Defendant Amphastar's Rule 26(A)(2)(C) rebuttal to Expert Reports of Robert Linhardt and Jeffrey Weitz by Geert-Jan Boons, dated February 10, 2005.	
LCM	P00419	Public Version of Teva's Reply Expert Report of Dr. Richard Mateles, dated February 10, 2005.	
LCM	P00420	Public Version of Teva's Reply Expert Report of Michael Sofocleous, dated February 10, 2005.	
LCM	P00421	Amphastar's Rebuttal Expert Report of John T. Goolkasian, dated February 10, 2005, including Attachment A.	
LCM	P00422	Public Version of Teva's Reply Expert Report of Harry R. Buller, dated March 1, 2005, including Dr. Buller's Curriculum Vitae and list of documents reviewed by Dr. Buller.	

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TRANSMITTAL LETTER

Enclosed are the following documents:

1. ☒ Ninth Supplemental Notice of Related Litigations Under 37 C.F.R. § 1.178(b) (6 pages);

2. ☒ Tenth Supplemental Information Disclosure Statement (3 pages);
   - ☒ IDS Form PTO/SB/08 (2 pages);
   - ☒ 1 coversheet; and
   - ☒ 10 documents; and

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Sixth Supplemental Notice of Related Litigations Under 37 C.F.R. § 1.178(b)

Further to the Notice of Related Litigations ("NRL") filed on November 26, 2003, the Supplemental Notice of Related Litigations ("SNRL") filed on May 19, 2004, the Second Supplemental Notice of Related Litigations ("SSNRL") filed on May 20, 2004, the Third Supplemental Notice of Related Litigations ("TSNRL") filed on September 23, 2004, the Fourth Supplemental Notice of Related Litigations ("4SNRL") filed on November 8, 2004, and the Fifth Supplemental Notice of Related Litigations ("5SNRL") filed on November 12, 2004, wherein Applicant notified the U.S. Patent and Trademark Office ("PTO") under 37 C.F.R. § 1.178(b) that the '618 patent is involved in a litigation in the United States and that a foreign counterpart of the '618 patent is involved in judicial actions in Italy, Applicant hereby provides further information relating to the status of those proceedings. *See* MPEP 1442.04.

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A. New Issues

1) Inequitable Conduct Allegations

With respect to inequitable conduct, as will be recalled, the undersigned took the position in the November 12, 2004, 5SNRL that inequitable conduct allegations are not material, relying on MPEP 1448, 2010, and 2012. The undersigned, however, also pointed out that MPEP 2001.06(c) seems to suggest a contrary conclusion.

The undersigned took the position that there was no materiality and asked the PTO to let him know immediately if it disagreed. The next written communication the undersigned received was a Notice of Allowability dated December 16, 2004, leading the undersigned to conclude that the PTO agreed that there was no materiality.

On January 14, 2005, *Critikon, Inc. v. Becton Dickinson Vascular Access*, 120 F.3d 1253, 43 U.S.P.Q.2d (BNA) 1666 (Fed. Cir. 1997), was called to the undersigned's attention. That decision did not cite MPEP 1448, 2010, or 2012. With respect to inequitable conduct, it appears that the court interpreted MPEP 2001.06(c) as creating a duty in a reissue proceeding to bring to the PTO's attention not only that the original patent was involved in litigation but also that inequitable conduct was asserted against the patent. Applicant has already notified the PTO of the copending U.S. litigation and that invalidity and inequitable conduct have been asserted against the patent.

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However, in an abundance of caution, since prosecution is still open, and since *Critikon* has never been expressly overruled, Applicant is submitting herewith copies of documents from the litigation relating to, *inter alia*, allegations of inequitable conduct, with some confidential and clearly irrelevant information redacted. In many instances, the nature of the redacted information will be apparent from the context of the surrounding text (e.g., confidential lot numbers have been redacted). **If the Examiner believes that any of the redacted information is necessary or would like further information regarding the general nature of the redacted information, please let the undersigned know immediately.**

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In any event, as the Examiner will see, a number of the inequitable conduct allegations relate to Example 6 and/or experimental data presented during the original prosecution. As the undersigned has made abundantly clear, Applicant is not relying on Example 6 or any experimental data presented during the original prosecution. Rather, it has always been and still remains the Applicant's position in the reissue proceeding that the claims are not anticipated by, or prima facie obvious in view of, any of the art of record. The Notice of Allowability evidences the PTO's agreement.

RE42718

Dealing with FDA and Other Documents in an Application Covering Subject Matter that Finished Phase III Clinical Trials but Failed

RE 42,718, p. 3

Pre-IND Submission Meeting Briefing Document (Redacted) (2005).
Slide presented to FDA in Jul. 2010.

Weihan Zhang, "First Declaration under 37 C.F.R. § 1.132," dated Dec. 21, 2010.
Weihan Zhang, "Second Declaration under 37 C.F.R. § 1.132," dated Dec. 21, 2010.
Ex parte Subramanyam (BPAI, Mar. 29, 2010).
Final Office Action mailed Jun. 16, 2010, in U.S. Appl. No. 11/934,143.
Amendment and Reply under 37 U.S.C. § 1.114, in U.S. Appl. No. 11/934,143, filed Dec. 15, 2010.
Office Action mailed Jun. 16, 2010, in U.S. Appl. No. 11/674,557.
English translation of JP 2000034233 A—2000.*

* cited by examiner

William J. Sandborn, "Declaration of William J. Sandborn, M.D., under 37 C.F.R. § 1.132" with Exhibit 1, filed on Dec. 15, 2010, in U.S. Appl. No. 11/934,143.
Jianguo Ji, "Declaration under 37 C.F.R. § 1.132" with Exhibits 1-4, filed on Dec. 15, 2010, in U.S. Appl. No. 11/934,143.
Jifeng Duan, "Declaration under 37 C.F.R. § 1.132," filed on Dec. 15, 2010, in U.S. Appl. No. 11/934,143.
Li Wang, "Declaration under 37 C.F.R. § 1.132," filed on Dec. 15, 2010, in U.S. Appl. No. 11/934,143.
Zhiming Ma, "Declaration under 37 C.F.R. § 1.132," filed on Dec. 15, 2010, in U.S. Appl. No. 11/934,143.
Tao Wang, "Declaration under 37 C.F.R. § 1.132," filed on Dec. 15, 2010, in U.S. Appl. No. 11/934,143.
Weihan Zhang, "Declaration under 37 C.F.R. § 1.132," filed on Dec. 15, 2010, in U.S. Appl. No. 11/934,143.
Weihan Zhang, "First Declaration under 37 C.F.R. § 1.132," filed on Dec. 15, 2010, in U.S. Appl. No. 11/934,143.
Weihan Zhang, "Second Declaration under 37 C.F.R. § 1.132," filed on Dec. 15, 2010, in U.S. Appl. No. 11/934,143.
Xiaoqiang Yan, "Declaration under 37 C.F.R. § 1.132," filed on Dec. 15, 2010, in U.S. Appl. No. 11/934,143.
Xun Zhang, "Declaration under 37 C.F.R. § 1.132," filed on Dec. 15, 2010, in U.S. Appl. No. 11/934,143.
Yu Cai, "Declaration under 37 C.F.R. § 1.132," filed on Dec. 15, 2010, in U.S. Appl. No. 11/934,143.
Yuqing Wang, "Declaration under 37 C.F.R. § 1.132," filed on Dec. 15, 2010, in U.S. Application No. 11/934,143.
Jianguo Ji, "Declaration under 37 C.F.R. § 1.132" with Exhibits 1, dated Dec. 20, 2010.

Supplemental Examination: Another Route for Getting Information Before the USPTO

Every case is very fact-specific.

Example of Related Foreign Proceedings: 96/000,008

- Items requested to be considered:
  - Japanese Office Action;
  - Wan article; and
  - Response to Japanese Office Action.

- No SNQ found.
  - USPTO: "…these items of information do not qualify as prior art under 35 U.S.C. 102 or 103, or contain information that raises any other issues of patentability …. For this reason, a reasonable examiner would not consider the JPO Office action or the patent owner's response to the JPO Office action important in determining whether claims 1-3 of the '344 patents are patentable."

- Bring foreign references to the USPTO.

- Patent owner had her cake and ate it too. Went for Supplemental Examination, but there was no SNQ. Yet still should escape from any inequitable conduct effect associated with the information submitted because the information submitted was considered "during" a SE. Win, win!

Example of *Related Foreign Proceedings: 96/000,021*

- Items requested to be considered:
  1) WO 94/18216 (the '216 publication)
  2) JP 58-74696 ('the 696 publication)

- SNQ found, reexam ordered.
  - USPTO: "A reasonable examiner would consider the teachings of the '216 publication and the '696 publication important in deciding whether claims 1-13 of the '313 patent are patentable."

- Reexamination certificate issued: claims canceled, amended claims, new claims.

- Use supplemental examination to amend claims and obtain new claims.

- Win, win to extent that patent owner gets amended claims and new claims, and those claims should be free of inequitable conduct charges based on the two items submitted for supplemental examination.

Example of SE Request Filed to Address an Inadvertent Failure to Cite Prior Art: 96/000,267

- U.S. Patent No. 8,859,504 includes 15 claims directed to compounds, crystalline forms, and a pharmaceutical composition.
- July 9, 2018: SE request only for crystalline form claims 6-14, in view of documents submitted by the applicant during prosecution (response to restriction requirement) and an expert declaration newly presented in the request for SE.
  - Expert declaration posited that crystalline form claims 6-14 recited a 5-membered ring, but, according to the declaration, the specification and by the peaks recited in the claims disclosed a 6-membered ring.
  - Millennium: the data discrepancies "may render the claims unclear, raising a potential indefiniteness issue[]" and may also create a potential issue of written description support.
- SNQ; ex parte reexamination ordered.
- Claims 6-14 rejected as indefinite, non-enabled, and lacking written description.
- Patent owner canceled claims 6-14 and also amended claims 1, 3, and 15, even though those claims were not mentioned in the Request for SE and were not rejected.
  - Corrected claim 3 to address an Office printing error and amended claims 1 and 5 "for clarity or to correct typographical error(s)."
- Dec. 20, 2018: Reexam Certificate issued; claims 1, 3, and 15 patentable as amended, confirmed patentability of claims 2 and 4-5, and canceled claims 6-14.
  - Cites MPEP 2816.01 as authorization to allow the Office to reexamine claims 1-5 and 15, despite not being the basis on which supplemental examination was requested.
  - 35 U.S.C. 257(a) and (c)(1), clearly and literally recite Supplemental Examination is "of a patent," not of claims of a patent.

Example of Inadvertent Failure To Cite Prior Art During Original Prosecution: 96/000,185

- Request for SE of U.S. Patent 9,428,647 claim 1-8.
  - Nine items of information, which the patent owner said "[t]hrough a clerical oversight, no Information Disclosure Citation was filed during prosecution of the original . . . application."
  - *Note, no explanation of what exactly the clerical oversight was, how it occurred, or when it was discovered, and the USPTO did not request any explanation during the resulting reexamination proceeding.*
- SNQ found based on two of the items of information submitted (Reference A and Reference B), and ex parte reexamination ordered.
- After non-final rejection, Patent Owner canceled claim 5 and amended claims 1, 2, 6, and 7 to incorporate limitations of claim 5 into independent claim 1, as clarifications.
  - Inventor declaration to claim entitlement to §102(b)(1) prior art exception.
- Reexam Certificate issued.
  - Office sua sponte held that the claims were distinguishable over References A and B (demonstrating that the §102(b)(1)(A) exception was not even necessary).
- Do everything possible to ensure that all prior art documents/information that are even possibly material to patentability and are known to at least one person with a Rule 56 duty, are submitted to the USPTO during original prosecution.
- But be prepared for the unexpected.
  - May not expect type of amendments have to make.
  - May take risk of filing declaration when not necessary.
  - Perhaps interview before committing to any course of action.

No Limit Once Reexam Ordered: 96/000,005

- SE Request for U.S. Pat. 8,145,578 on Oct. 4, 2012.
- SNQ found on 8 of 9 items submitted, SE certificate issued.
- **187 additional items then submitted in IDS.**
- All claims rejected for failure to comply with 35 U.S.C. §112 (a) (enablement) and for failure to comply with 35 U.S.C. §112(b).
- **251 additional items then submitted in IDS.**
- 16 claims amended, 14 new claims added; **more IDS's filed (44 items)** and declarations.
- Final rejection of all claims.
- One claim amendment, arguments, and declarations requested for entry after final.
- Rejected – proposed amendments would not overcome rejection.

96/000,005 (con't)

- Appeal filed.
- **Another IDS submitted** (20 references listed in an IPR filed on a related patent)
- PTAB:
  - Affirmed examiner's indefiniteness rejection of claim 59 (limitation lacked proper antecedent basis);
  - Overturned enablement rejection of all other claims (specification contains enabling disclosure); and
  - Added new rejection for failure to disclose best mode.
    - "Patent Owner describes an unspecified set of 'proprietary algorithms' as the method by which the invention is practiced, and then refers to a 'variety' of other algorithms which might be utilized. This gives rise to a presumption, in our minds, that Patent Owner withheld the 'best mode' for practicing the invention."
    - "Consequently we reject claims 1-66 with regard to the claimed 'calibration module,' the claimed step of 'calibrating,' and the claimed step of 'constructing a three-dimensional geometry of the roof based solely on the received image files' under 35 U.S.C. §112, first paragraph, for failing to set forth 'the best mode contemplated by the inventor of carrying out his invention.'"

96/000,005 (con't)

- Applicant amended claim to overcome definiteness and requested re-opening prosecution to address best mode; added two more new claims and inventor declarations.
- **Another IDS (90 items)**
- Final rejection for failure to disclose best mode.
  - Patent Owner did not overcome PTAB's presumption.
  - "[N]o corroborating factual evidence" to support statements of inventors.
- Response after final arguing against rejection.
  - Inventor notebooks support;
  - "[N]o evidence that a preferred algorithm was not disclosed."
- Advisory action that rejection will not be withdrawn.
- **Another IDS (30 items).**

96/000,005

Years later, still not resolved and fighting about rejection not based on information submitted!

- Appeal filed April 25, 2017.
- Board reversed, Ex parte Eagle View Technologies, Inc., Appeal No. 2018-003838 (Oct. 31, 2018).
  - Inventors were in possession of a best mode;
  - Expert declarations supported argument that the patent disclosed the best mode
- Reexam certificate issued Feb. 25, 2019: Claims 1-58 amended, newly added claims 53-68 patentable.

Meanwhile, in district court litigation, 2:12-cv-00618 filed April 11, 2012, the judge granted a motion to stay pending the supplemental exam on Nov. 9, 2012 (before a SNQ was found).
April 16, 2014, court lifted stay to allow Plaintiff to file motion for default. Motion denied Aug. 7, 2014.
Case dismissed without prejudice Aug. 31, 2015.

Lessons Learned: 96/000,005

- SE proved to be a way to resolve definiteness and best mode issues.
- No claims canceled; new claims added.
- "Car Wash" on the 9 items submitted with the SE.
- Is there a car wash on everything else (some **450 pieces of information**) submitted in the various IDS documents?
  - Does "during" the SE include any reexam ordered as a result of the SE request?

Polling Question No. 1

- A client would like to submit about 50 references in an IDS. The client believes about 10 to be more relevant and you want to make sure the Examiner is aware of that.

Do you

A. List without any explanation?
B. List and explain why the 10 should be given deeper consideration?
C. Simply fill in the "Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear" column on the SB/08 for those 10 references?

Polling Question No. 2

- A patent prosecutor characterizes the Flukum reference as prior art. But it is not prior art and the assignee said it was unaware of the prosecutor's characterization. Under *In re Nomiya*, is the assignee stuck with the characterization?

Yes or No?

Polling Question No. 3

- A cousin of Mr. Irving files what amounts to be 4 linear feet of information over several IDS documents. The Examiner acknowledges consideration of very document. In the litigation, Defendant accused Cuz Irving of burying the USPTO and thus committing inequitable conduct. Did Cuz Irving commit inequitable conduct?

Yes or No?

Polling Question No. 4

- In a Supplemental Examination, the patent owner submits information that clearly reveals intent to deceive during the original prosecution. Supplemental Examination is granted. In the ensuing reexamination, the Examiner finds that all claims, unamended, are patentable over all that information? Does the Supplemental Examination effectively car wash the misdoings during prosecution?

Yes or No?

Thank You!

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