

Supplemental Examination Requests: Benefits and Limitations, Strategic Use

Assessing Enforceability of Patent Portfolios, Evaluating the High Burden

WEDNESDAY, MAY 9, 2018

1pm Eastern | 12pm Central | 11am Mountain | 10am Pacific

Today's faculty features:

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A Need For Supplemental Examination To Clear The Path To Enforceability?

- Cleaning up own patent portfolio/health check.
- Due diligence investigation.
 - If there is a possible issue, is SE an option?
 - Also check if SE request filed and if the information submitted was then used as basis for challenge in PTAB or court. If not, may be a vulnerability (SE protects from inequitable conduct only, not from using item submitted as basis for patentability/validity challenge!)
- Prior to or when listing in the OB, assess whether requesting SE is an appropriate strategy.
 - Owners of Orange Book-listed patents may be able to make reasonably accurate predictions of when they will receive patent validity challenges → may be well-suited to submit an appropriate request for supplemental examination before their patents become involved in a potential litigation or IPR.

Remember

- (1) SE is no guarantee that you will not need to worry about inequitable conduct; may generate a new inequitable conduct claim based on statements in the SE proceeding.
- (2) SE provides a route for effectively seeking a reexam on information that cannot be considered in a conventional reexam.

“Consider, Reconsider, Or Correct”

Relevant Information

35 U.S.C. 257 Supplemental examinations to consider, reconsider, or correct information.

- (a) REQUEST FOR SUPPLEMENTAL EXAMINATION.—A patent owner may request supplemental examination of a patent in the Office to **consider, reconsider, or correct information believed to be relevant to the patent**, in accordance with such requirements as the Director may establish. Within 3 months ...the Director shall ...issu[e] a certificate indicating whether the information presented in the request raises a substantial new question of patentability.”
- (b) REEXAMINATION ORDERED.—If the certificate issued under subsection (a) indicates that a substantial new question of patentability is raised by 1 or more items of information in the request, the Director shall order reexamination of the patent. ... During the reexamination, the Director shall address each substantial new question of patentability identified during the supplemental examination, notwithstanding the limitations in chapter 30 relating to patents and printed publication or any other provision of such chapter.

not limited to patents and printed publications

Effect: Insulate Patent for Enforceability

35 U.S.C. 257 Supplemental examinations to consider, reconsider, or correct information.

- c) EFFECT.—
 - (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. The making of a request under subsection (a), or the absence thereof, shall **not** be relevant to enforceability of the patent under section 282.

Does not insulate from unpatentability though

during the "SE" not the reexam - insulated whether or not SNQ is found!

Exceptions: Already Pled or in Para. iv Notice

35 U.S.C. 257 Supplemental examinations to consider, reconsider, or correct information.

- c) EFFECT.—

- 2) EXCEPTIONS.—

- (A) PRIOR ALLEGATIONS.—Paragraph (1) shall not apply to an allegation pled with particularity in a civil action, or set forth with particularity in a notice received by the patent owner under section 505(j) (2)(B)(iv)(II) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j) (2)(B)(iv)(II)), **before the date of a supplemental examination request** under subsection (a) to consider, reconsider, or correct information forming the basis for the allegation.
- (B) PATENT ENFORCEMENT ACTIONS.—In an action brought under section 337(a) of the Tariff Act of 1930 (19 U.S.C. 1337(a)), or section 281, paragraph (1) shall not apply to any defense raised in the action that is based upon information that was considered, reconsidered, or corrected pursuant to a supplemental examination request under subsection (a), unless the **supplemental examination, and any reexamination ordered pursuant to the request, are concluded before the date on which the action is brought.**

Burden On Patent Owners For Supplemental Examination

- Steep fee, § 1.20(k) Supplemental Examination
 - \$4,400 for request + \$12,100 if reexam ordered
 - \$180 per nonpatent document 21–50 pages in length + \$280 per page above 50 pages
- Patent owner admissions
 - § 1.610(b) A request for supplemental examination **must** include:
 - (5) **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.**
- Limit to number of items that a patent owner may raise in a request for supplemental examination.
 - § 1.605 No more than **12** items believed to be relevant to the patent.
- §1.620: (e) No interviews and (f) no amendments.

Fraud Reported to AG

35 U.S.C. 257 Supplemental examinations to consider, reconsider, or correct information.

- (e) FRAUD.—If the Director becomes aware, during the course of a supplemental examination or reexamination proceeding ordered under this section, that a **material fraud on the Office may have been committed** in connection with the patent that is the subject of the supplemental examination, then in addition to any other actions the Director is authorized to take, including the cancellation of any claims found to be invalid under section 307 as a result of a reexamination ordered under this section, **the Director shall also refer the matter to the Attorney General for such further action as the Attorney General may deem appropriate**. Any such referral shall be treated as confidential, shall not be included in the file of the patent, and shall not be disclosed to the public unless the United States charges a person with a criminal offense in connection with such referral.

Other Sanctions

35 U.S.C. 257 Supplemental examinations to consider, reconsider, or correct information.

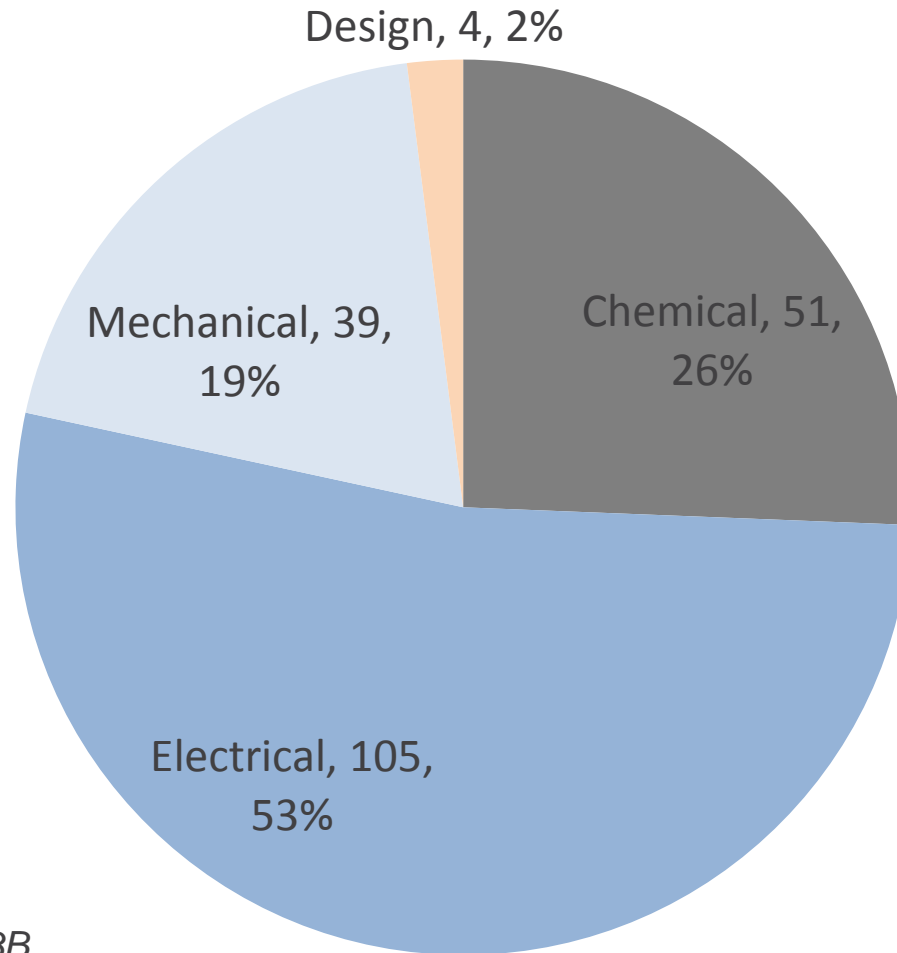
- (f) RULE OF CONSTRUCTION.—Nothing in this section shall be construed—
 - (1) to preclude **the imposition of sanctions based upon criminal or antitrust laws** (including section 1001(a) of title 18, the first section of the Clayton Act, and section 5 of the Federal Trade Commission Act to the extent that section relates to unfair methods of competition);
 - (2) to limit the authority of the Director to **investigate issues of possible misconduct and impose sanctions for misconduct** in connection with matters or proceedings before the Office; or
 - (3) to limit the authority of the Director to issue regulations under chapter 3 relating to sanctions for misconduct by representatives practicing before the Office.

M.P.E.P.

- Chapter 2800.
- SE requests may only be filed by the patent owner (of the entire right, title, and interest in the patent).
- May be filed at any time during the period of enforceability of a patent.
- No third-party participation allowed.
- Public access to SE requests and accompanying material only available once the request is granted a filing date.
- §2811.01: “The patent owner must explain, for each claim requested to be examined, either (1) what the item of information teaches with respect to that claims, or (2) which teaching contained in the item of information may be considered by an examiner to be **important** when determining the patentability of that claim.
 - See also, §2816.02 and §2816.03 using same language for examiner determinations.

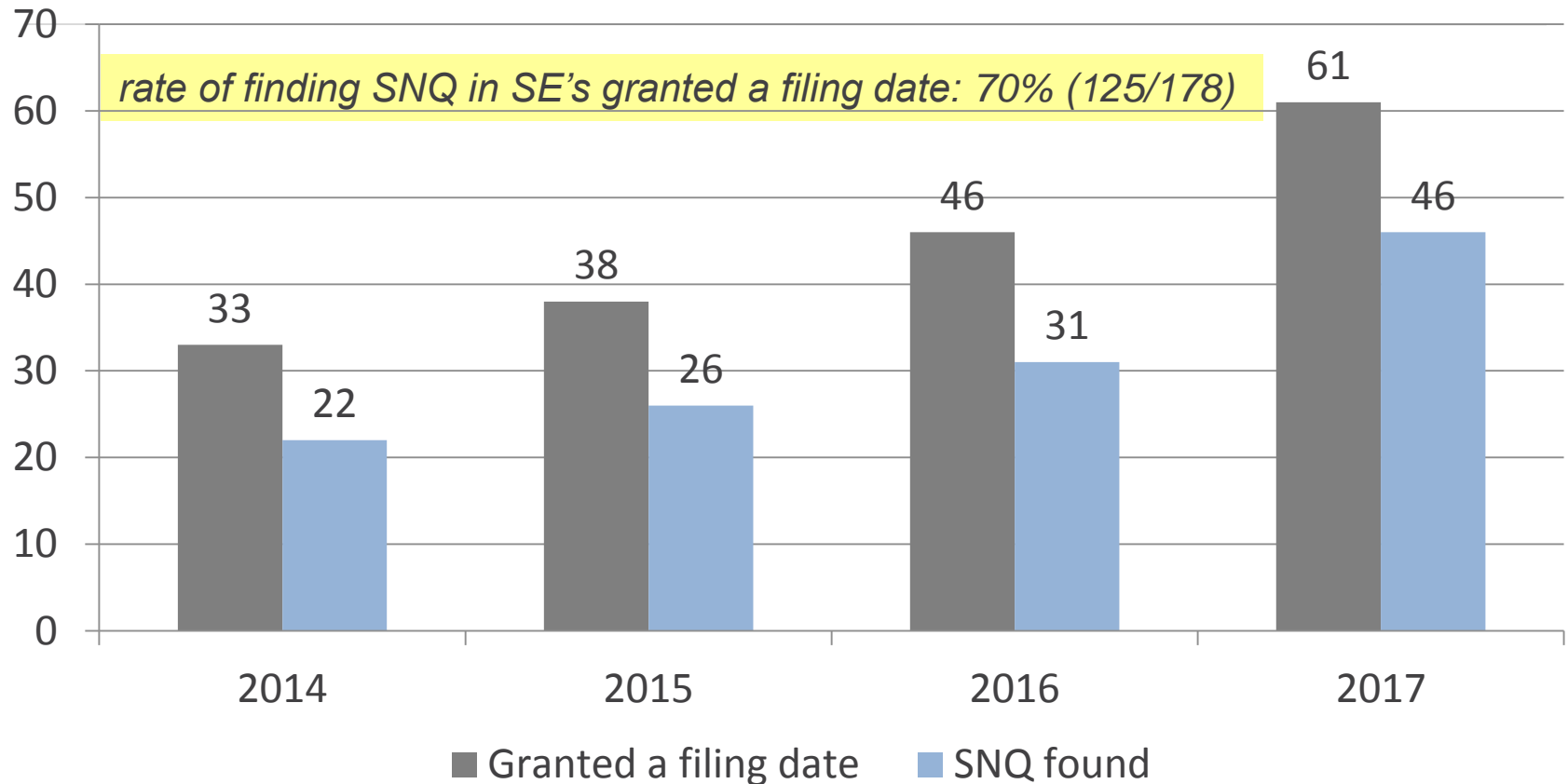
Supplemental Examination Stats

SE Requests Filed (2014-2017)



Source: USPTO 2017
Annual Report, Table 13B

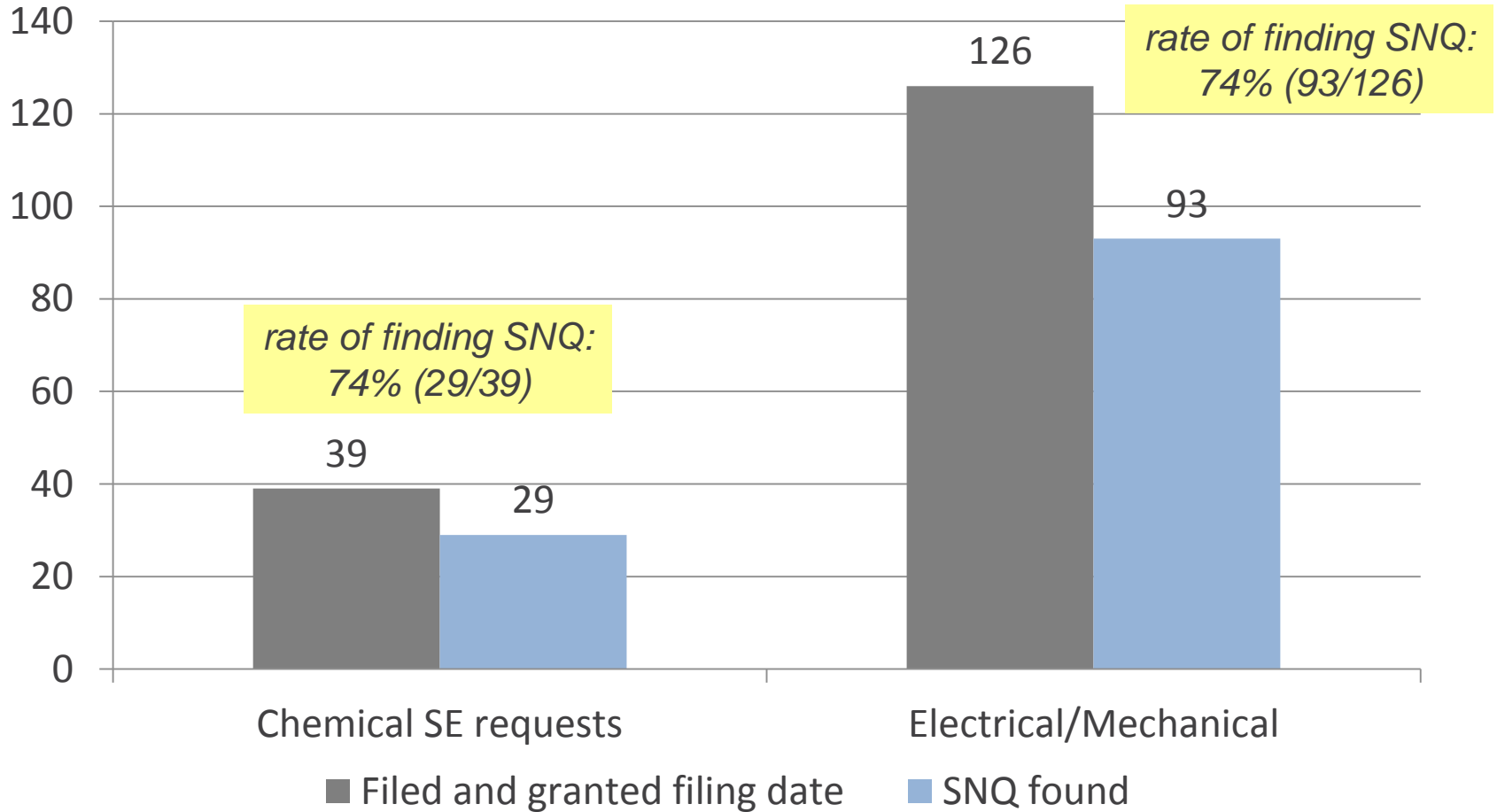
Supplemental Examination Stats (2014-2017)



Source: USPTO 2017
Annual Report, Table 13B

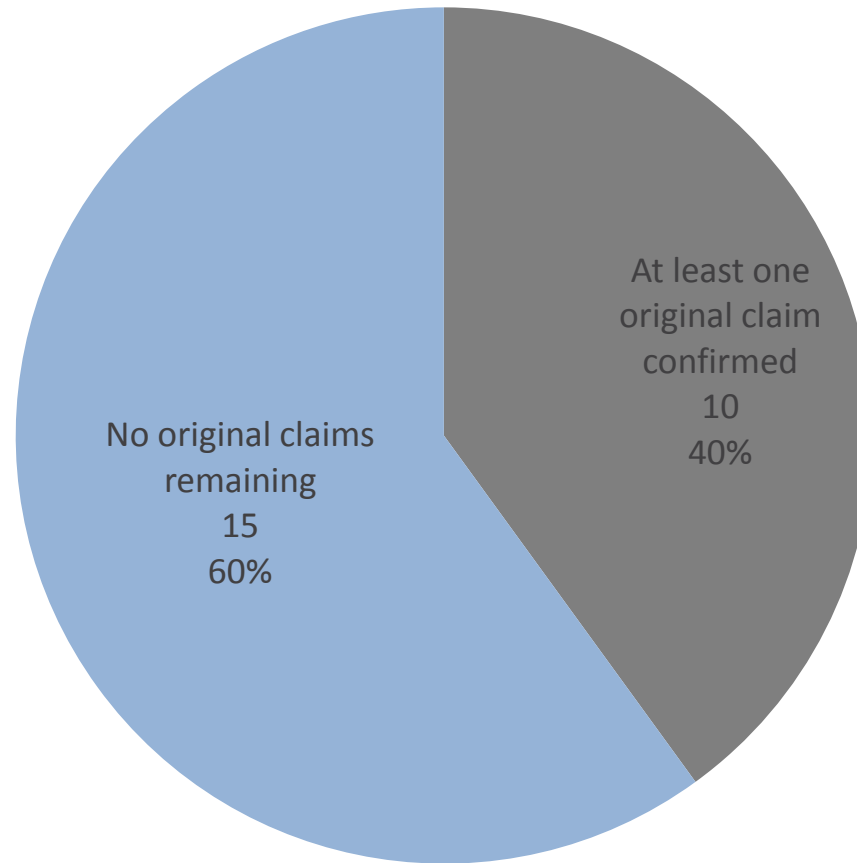
SNQ Findings By Technology

(2014-2017)



Source: 165 SE requests granted a filing date

Closer Look At The Chemical SE Requests Where SNQ Found (2014-2017)



In the chemical Supplemental Examination Petitions for which a SNQ was found, 25 have had a reexamination certificate issued.

Example of No SNQ Found: 96/000,008

- U.S. Pat. 8,017,344 Claim 1. A method of screening for an inhibitor of the binding between a CAR and a CARL, which comprises the steps of:
 - a) contacting...; (b) detecting...; (c) comparing...; and (d) selecting...wherein the CARL is a protein that binds to a natural CAR and is the protein of any one of: (1)...; (2)...; (3)...; (4)...; (5)...; or (6)...; and wherein the CAR is a protein that binds to a polypeptide comprising the amino acid sequence of SEQ ID NO: 1 or 2, and is a protein comprising an amino acid sequence of any one of: (7)...; (8)...; or (9)... .
- Items requested to be considered:
 - 1) Japanese Office Action;
 - 2) Wan article; and
 - 3) Response to Japanese Office Action.

Example of No SNQ Found: 96/000,008

- Patent Owner's characterization:
 - Wan discloses the human CAR protein, nucleotide sequence encoding the human CAR protein, and was the basis for the obviousness rejection of claims 3 and 4 in corresponding Japanese patent's Japanese Office Action.
 - Those claims were canceled to overcome the rejection, and the US patent does not contain corresponding claims.
 - “Nonetheless, the ‘CAR’ protein recited in claim 1 ...encompasses the human CAR protein disclosed in Wan... . As a result, when applying Wan and the Japanese Office Action and the response to the Japanese Office Action to claim 1..., all of the references can be seen to disclose or refer to the ‘CAR’ component of the claim. This constitutes the potential relevance and manner of applying the items of information to claim 1... .”

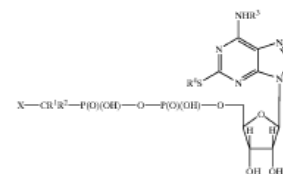
Example of No SNQ Found: 96/000,008

USPTO: “The JPO office action and the patent owner’s response to the JPO Office action, as presented in the request, do not raise a substantial new question of patentability. These items of information show how the Japanese Patent Office characterized the Wan reference. However, 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 with respect to claims 1–3 of the ‘344 patent. 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.”

N.B. the statute says “relevant” not “important”

Example of SNQ Found: 96/000,021

- U.S. Pat. 6,114,313 Independent claim: 1. A pharmaceutical composition comprising a nucleotide analog, mannitol and a modifying additive which is sodium chloride or a polyol, wherein the nucleotide is a compound of formula



- wherein R_1 and R_2 independently represent hydrogen or halogen, R_3 and R_4 independently represent phenyl, or C_{1-6} -alkyl optionally substituted by one or more substituents selected from OR_5 , C_{1-6} -alkylthio, NR_6 , R_7 , phenyl, $COOR_8$ and halogen, R_5 , R_6 , R_7 and R_8 independently represent hydrogen or C_{1-6} -alkyl, and X represents an acidic moiety, or a pharmaceutically acceptable salt thereof.
- Items requested to be considered:
 - WO 94/18216 (the '216 publication)
 - JP 58-74696 ('the 696 publication)

Example of SNQ Found: 96/000,021

- Patent Owner characterization:
 - The '216 publication was cited in the specification of the '313 patent but not in an IDS or by the examiner during prosecution of the '313 patent.
 - The '696 publication was not cited in an IDS or by the examiner during prosecution of the '313 patent.
 - Cited portions of publication in chart covering 6 pages that related to claim limitations, though stated “The chart is not to be construed as an admission that the features of the prior art referenced therein contain the limitations of the claims.”

Example of SNQ Found: 96/000,021

USPTO: “The ‘216 publication discloses that solutions containing a compound of formula I may be evaporated by freeze drying or spray drying to give a solid composition, The ‘696 publication discloses method of stabilization of [ATP] in a lyophilized state...[and] that the saccharides used in the invention include []... and one of these saccharides or a combination of two or more of them can be used...The ‘696 publication teaches that the concentration of the stabilizer should be 3% of higher... .

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.”

N.B. the statute says “relevant” not “important”

But Things May Not Always Go Smoothly!

October 2012: Request filed, 96/000,005

- U.S. Pat. 8,145,578 Claim 1. A system for remotely determining measurements of a roof, comprising:
 - a computer including an input means, a display means and a non-transitory memory; and
 - a roof estimation software program in the non-transitory memory and operable to cause a processor of the computer to:
 - receive location information...; receive image files...; determine, measurements of the roof including size, dimensions, and pitch of the plurality of distinct roof sections of the roof of said building based solely on the received image files; and
 - outputting a report having the determined measurements therein.

But Things May Not Always Go Smoothly!

- Items requested to be considered and why relevant:
 - 1) EP 1,010,966 patent
 - “it relates to using image files in determining roof measurements” “but does not teach or suggest at least the following feature of claims 1, ‘determine measurements of the roof ... *based solely* on the received image files” (emphasis in original).
 - “it is cumulative to one or more other references already considered” during prosecution.
 - 2) CA 2,191,954
 - “it relates to using image files in determining measurements” but “does not include any new, non-cumulative technical teaching that was not previously considered by the Office” during prosecution.
 - 3) DE 198,57,667
 - “it relates to using image files in determining roof measurements” but “does not include any new, non-cumulative technical teaching that was not previously considered by the Office” during prosecution.

But Things May Not Always Go Smoothly!

- Items requested to be considered and why relevant:
 - 4) U.S. 6,333,749
 - “it relates to determining dimensions of objects” but “fails to teach or suggest several important elements of claims 1-52[,] including, for example [the ‘determine’ limitation].”
 - “it is not a roof estimation software program”
 - 5) website page, www.aerodach.de
 - shows the commercial product of the ‘966 patent (item #1)
 - “does not include any new, non-cumulative technical teaching that was not previously considered by the Office” during prosecution.
 - 6) website page, <https://aerowest.de>
 - “does not include any new, non-cumulative technical teaching that was not previously considered by the Office” during prosecution.

But Things May Not Always Go Smoothly!

- Items requested to be considered and why relevant:
 - 7) AeroDach® Online Roof Analysis
 - it uses “image files in determining roof measurements that may be included in a roof report”
 - uses the ‘966 patent process; cumulative
 - 8) U.S. 2006/0137736
 - “it relates to determining roof shape.”
 - Ground of rejection in related application.
 - “does not contain any new, non-cumulative technical teaching that was not previously considered by the Office”
 - 9) article
 - “it relates to determining shapes of buildings using images.”
 - Ground of rejection in related application.

But Things May Not Always Go Smoothly!

- SNQ found on 8 of 9 items submitted, SE certificate issued.
- Reasons for SNQ determination based on items 1 and 3–9.
 - Items 1, 3–9 teach “to determine measurements of the roof...based solely on the received image files as recited by claim 1[.]”
 - “a reasonable examiner would consider important”
 - N.B. the statute says “relevant” not “important”
- No SNQ based on item #2 (Canadian patent application) because it “expressly discloses that processing constructions such as buildings is a feature for further development. Therefore, ...fails to teach any of the ‘roof estimation’ features recited by claim 1.”

But Things May Not Always Go Smoothly!

- 187 additional items then submitted in IDS.
- Reexam ordered.
- Remember: reexam can deal with any of §§ 101, 102, 103, and 112
- **All claims rejected for failure to comply with 35 U.S.C. §112 (a).**
 - Claims rejected for failing to comply with enablement requirement.
 - “By reciting a generic verb such as ‘determining’ or ‘constructing’ and describing the result, rather than the process, the claims define an invention which is substantially broader than the disclosed invention and would encompass inventions which Applicants have neither disclosed nor invented.”
 - The specification failed to “disclose substantial technical details related to 1) the calibration feature, module, or steps; 2) a method of ‘determining’ roof dimensions ‘based solely’ on the received image files; or 3) the ‘proprietary algorithms that construct the three-dimensional geometry of a roof ‘based solely’ on the received image files.”
 - “the gap between the state of the prior art and the claimed invention involves the combination and improvement of many disparate technologies rather than an incremental advance of the prior art.”
 - No working examples.
 - Undue experimentation – “no reasonably detailed guidance”

But Things May Not Always Go Smoothly!

- **All claims rejected for failure to comply with 35 U.S.C. §112(b).**
 - Claims also rejected for vague and indefinite language under §112(b).
 - meaning unknown: “image files representing a plurality of distinct roof sections aerial images of the roof”
- With respect to items 1, 3–9:
 - “The Examiner agrees with Patent Owner’s remarks...that none of the Items of Information discloses how to determine measurements of the roof ‘based solely’ on the received image files[.]”
 - “Accordingly, the prior art references...fail to teach or suggest the claimed inventions.”
 - “However, Patent Owner is notified that claim amendments to require a calibration module, step, or feature, would likely necessitate new prior art rejections under 35 U.S.C. §§ 102 or 103, since this amendment would eliminate a feature relied upon to distinguish over the prior art.”
 - “Therefore, if Patent Owner chooses to amend the claim language in response to the [§ 112] rejections ..., Patent Owner is requested to carefully consider whether than amended claim language would be patentable over the Items of Information, alone or in combination.”

But Things May Not Always Go Smoothly!

- 251 additional items then submitted in IDS.
- 16 claims amended, 14 new claims added; more IDS's filed (44 items) and declarations.
 - Arguments to overcome enablement rejections.
 - Amendments to overcome indefiniteness rejection (printing error by USPTO)
 - New and amended claims not obvious, and submitted objective evidence of nonobviousness.
- Final rejection of all claims.
 - Declarations did not overcome enablement rejection because none was directed to the claimed invention, relied on extrinsic evidence for enabling disclosure, and none was supported with objective evidence.
 - New claim 59 rejected for indefiniteness.
- One claim amendment, arguments against the enablement rejection, and declarations requested for entry after final.
- Rejected – proposed amendments would not overcome rejection.

Re-Opens Prosecution!

- 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.’”

Re-Opens Prosecution!

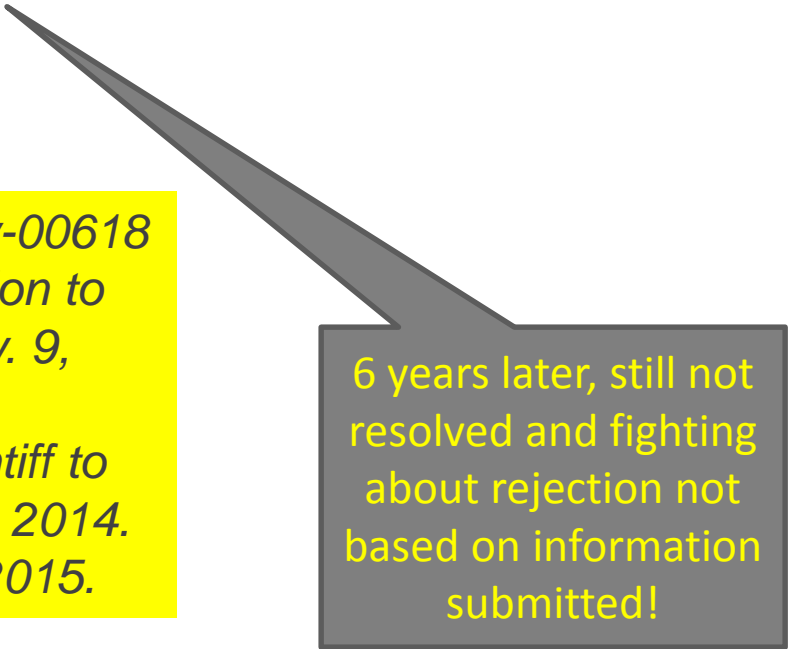
- Applicant amended claim to overcome definiteness and requested re-opening prosecution to address best mode; added two more new claims and inventor declarations.
- Another IDS (90 items)
- Final rejection for failure to disclose best mode.
 - Patent Owner did not overcome PTAB's presumption.
 - “[N]o 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).

Re-Opens Prosecution!

- Appeal filed.
- Oral hearing schedule for **Sept. 25, 2018**.

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.



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

Interplay with Other PTAB Proceedings

- 35 U.S.C. §315 / §325 Relation to other proceedings or actions
 - d) MULTIPLE PROCEEDINGS. – ...during the pendency of an inter partes review [any post-grant review under this chapter], if another proceeding or matter involving the patent is before the Office, the Director may determine the manner in which the inter partes review [post-grant review] or other proceeding or matter may proceed, including providing for stay, transfer, consolidation, or termination of any such matter or proceeding. ...

Interplay with IPRs

- Oct. 31, 2012: SE request filed for U.S. Pat. 7,909,641 claims 1–3 based on 7 items of information (96/000,007).
- Jan. 24, 2013: IPR petition filed on claims 1–6 (IPR2013–00122) based on references overlapping with SE request.
- Jan. 30, 2013: SE certificate, SNQ found based on all 7 items.
- April 1, 2013: reexam ordered.
- April 3, 2013: **PTAB suspended reexam pending outcome of IPR.**
 - “Conducting the reexamination concurrently with this proceeding would duplicate efforts within the Office and could potentially result in inconsistencies between the proceedings. **Notably, since claim 1–3 are the subject of both proceedings, the Patent Owner could amend those claims, which in turn could change the scope of the challenged claims while the Board is conducting its review. Further, the patentability of the three claims would be determined in both proceedings based on the same allegations of unpatentability.**”

Interplay with IPRs (con't)

- March 18, 2014: Patent Owner requested cancellation of claims 1–6 and requested adverse judgment.
- March 21, 2014: PTAB lifted suspension in reexam and entered judgment against Patent Owner.

Interplay with IPRs (con't)

- Dec. 30, 2014: Patent Owner filed petition to waive prohibition against filing claim amendments prior to an initial Office action on the merits.
 - “At present, no claims remain in U.S. Patent No. 7,909,641. Normally, the Patent Owner has the right to amend the claims in reexamination. However, MTI is prevented from filing any paper in a supplemental examination after a Reexamination Certificate has issued because of 37 CFR 1.625(d)(1), which provides that under such circumstances, the patent owner cannot file a paper as would normally be permitted under Rule 530. No action has issued from the Examiner since the inter partes review was terminated and the case was remanded, thus Patent Owner can file no amendment in response.
 - Accordingly, Petitioner seeks relief from 36 CFR 1.625(d)(1) and requests that it be permitted to file amended claims in accordance with 37 CFE 1.530 in order that the reexamination may proceed with claims to be considered.
 - Justice requires the waiver of this rule because Patent Owner is in an impossible situation. The inter partes review canceled all claims so there are no claims to be reexamined but Patent Owner cannot file new claims because of Rule 625(d)(1).

Interplay with IPRs (con't)

- Aug. 6, 2015: Petition dismissed and reexam terminated.
 - “[A]n inter partes review certificate cancelling all of the claims (i.e., claims 1–6) of the patent issued on July 11, 2014. For this reason, prosecution in the present reexamination proceeding is hereby terminated, and no ex parte reexamination certificate will issue, since the claims (i.e., claims 1–3 of the ‘641 patent) for which supplemental examination was requested, and of which reexamination was ordered, no longer exist.”

Example: 96/000,053

Claims Amended During Reexam

- U.S. Pat. 8,440,119 Claim 1. A method of making a fabric having a front side, a back side and an interior between the front side and the back side wherein the front side of the fabric is the side adjacent to the environment when the fabric is in use and the back side is the side adjacent to an object to be cooled when the fabric is in use, the method comprising the steps of:
 - a) forming the fabric with one or more fiber materials wherein at least one of the one or more fiber materials has a liquid diverting trait and wherein the at least one the fiber materials is positioned at the back side of the fabric; and
 - b) physically modifying the one or more fiber materials to establish a network of interstices in the interior of the fabric sufficient to slow the progression of liquid from the interior out of the fabric through the front side thereof.

Example: 96/000,053

Claims Amended During Reexam

- Items submitted
 - 1–8 are U.S. patents and applications
 - #9 is a PCT application
 - 10–11 are non-patent literature (article, chapter in publication).
- SNQ found with respect to 5 U.S. patents/applications and one article.
- No SNQ found with respect to other 5 items.
 - do “not provide any new teachings which an examiner would have found important in deciding whether or not claims 1–9 were patentable.”

Example: 96/000,053
Claims Amended During Reexam

- In response to rejections under §102(b) and §103, amended claims 1, 4 and 5; canceled 2, 3, 8 and 9; and added 10–20. (currently pending 1, 4–7, 10–20).
- Examiner found new claim 18 patentable and issued final rejection under §102(b) and §103 of claims 1, 4–7, 10–17, 19 and 20.
 - New claim 18 “because the prior art of record fails to provide a method of making a fabric of the present invention that comprises the step of weaving together a first yarn having a liquid diverting trait and a second yarn having a hydrophilic trait and the step of peaching the front and back sides of the fabric.”

Example: 96/000,053

Claims Amended During Reexam

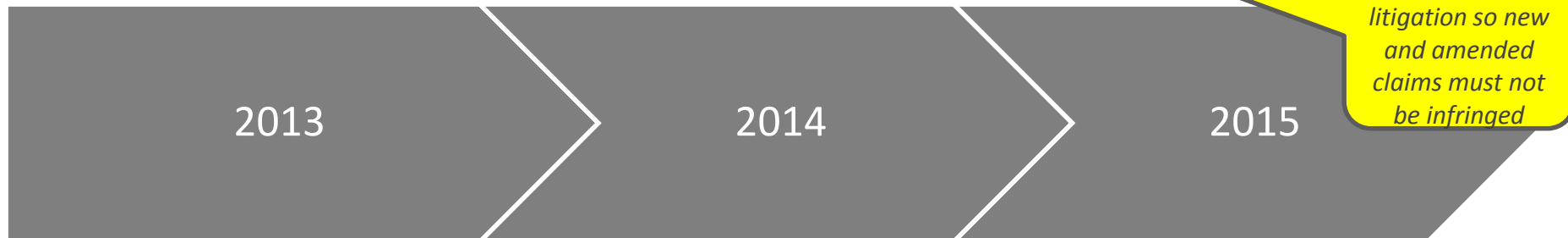
- Canceled claims 1–3 and 8–9, amended claims 4–7, new claims 10–15 added.
- Reexam Certificate issued.
 - New independent claim 10. A method of making a fabric having a front side, a back side and an interior between the front side and the back side, wherein the front side of the fabric is the side adjacent to the environment when the fabric is in use and the back side is the side adjacent to an object to be cooled when the fabric is in use, the method comprising the steps of:
 - a) providing a first yarn material having a liquid diverting trait, and a second yarn material having a hydrophilic trait;
 - b) weaving or knitting together the first yarn material and the second yarn material to form a woven or knitted fabric such that the first yarn material is positioned at the back side of the fabric to wick a liquid away from the object to be cooled so as to provide an evaporative cooling effect to the object, and such that the second yarn material is positioned at the front side of the fabric to restrict evaporation of the liquid through the front side of the fabric; and
 - c) peaching the front and back sides of the fabric to pull fibers of the first yarn material and fibers of the second yarn material into the interior of the fabric in an entangled fashion so as to establish a network of tortuous pathways amongst the entangled fibers sufficient to slow the progression of liquid through the interior of the fabric and out through the front side of the fabric.

Timeline of Example: 96/000,053

Claims Amended During Reexam

- May 14, 2013: U.S. 8,440,119 issued
- July 30 and 31, 2013: Infringement litigations filed.

- Jan. 21, 2015: Stipulated dismissal without prejudice of second litigation.
- Feb. 12, 2015: Reexam certificate issued.



- Jan. 24, 2014: Initial SE request filed.
- Feb. 13 and 24, 2014: district court litigations stayed pending outcome of SE request.
- March 21, 2014: Corrected SE request in view of 11 items:
- April 11, 2014 and May 26, 2014: requests for ex parte reexamination
- May 16, 2014: SE Certificate, SNQ found based on 6 items.
- May 21, 2014: Reexam ordered.
- June 24, 2014: Proceedings merged.
- July 10, 2014: OA rejecting claims as anticipated under §102(b) and §103.
- Aug 11, 2014: Claims amended.
- Oct. 21, 2014: Final rejection
- Nov. 20, 2014: Stipulated dismissal without prejudice of one litigation.
- Dec. 22, 2014: Amendment after final.

Example: 96/000,018

Litigation Brought After SE/Reexam Finished

- U.S. 7,631,671 Claim 1. A method for in-line blending of gasoline and butane comprising:
 - a) providing a continuously flowing gasoline stream that comprises:
 - i. a plurality of batches of different gasoline types;
 - ii. a gasoline flow rate that varies over time; and
 - iii. a plurality of gasoline vapor pressures;
 - b) providing an allowable vapor pressure;
 - c) providing a butane stream that comprises a butane vapor pressure;
 - d) periodically determining said gasoline vapor pressure;
 - e) periodically determining said gasoline flow rate;
 - f) calculating a blend ratio based upon said butane vapor pressure, said gasoline vapor pressure, and said allowable vapor pressure; and
 - g) blending said butane stream and said gasoline stream at a blending unit at said blend ratio to provide a blended gasoline stream having a blended vapor pressure less than or equal to said allowable vapor pressure.
- Items of information
 - butane blending instrument air diagram; and
 - declaration regarding operation of butane blending plant.

example of how items of information do not have to be a patent or printed publication

Example: 96/000,018

Litigation Brought After SE/Reexam Finished

- Patent Owner: priority date of claims is Feb. 9, 2001 and construction of blending station not completed until June 2004, so any potential public use can be antedated.
- SNQ found with respect to claims 6, 14, 15, 17–21, 24, 25, 50 and 51:
 - claims not entitled to priority filing date;
 - plant contains most of the claimed structure;
 - sale of gasoline blended according to claimed invention is a commercial exploitation of the patent;
 - SE request shows public use on the date that the blended gasoline was delivered from the plant;
 - “a reasonable examiner would consider the [declaration and diagram] to be important in determining whether claims 6, 14, 15, 17–21, 24, 25, 50 and 51... are patentable.”
- SNQ not found for claims 1–5, 7–13, 16, 22, 23, 26–49, 52–54:
 - items of information do not qualify as prior art because claims entitled to priority filing date.
 - claim limitation not met in several of these claims.

Example: 96/000,018
Litigation Brought After SE/Reexam Finished

- Claims 6, 14, 15, 17–21, 24, 25, 50 and 51 rejected for public use or sale.
 - the plant contained all of the claims elements.
 - “[T]he sale of gasoline blended according to the claimed invention is seen as commercial exploitation... [t]hus, there was public use of the ...claims on the date that the blended gasoline was delivered from the ...plant.”
 - Processes at plant occurred prior to 2006.
 - Claims effective filing date is April 20, 2006 (because not entitled to priority date).
- All claims canceled and reexam certificate issued.
- Patent owner filed infringement action based on remaining claims.
- Defendant raised defense of unenforceability for inequitable conduct before the USPTO on 11 bases including that the diagram and declaration submitted in the SE was false.

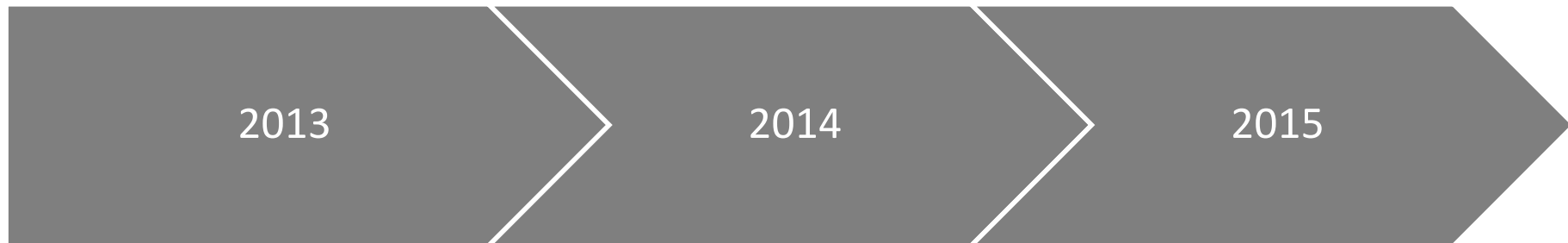
Example: 96/000,018
Litigation Brought After SE/Reexam Finished

- Aug. 22, 2017: motion to bifurcate inequitable conduct.
- Oct. 16, 2017: motion for summary judgment of no inequitable conduct.
 - Argued no evidence of intent to deceive and that declaration statements were accurate.
- Nov. 29, 2017: Judge ordered all pending motions stricken without prejudice except three Daubert challenges.
- Jan. 12, 2018: motion for summary judgment of no inequitable conduct (same arguments).
- April 10, 2018: status hearing set for June 6, 2018.

Example: 96/000,018

Litigation Brought After SE/Reexam Finished

- Aug. 27, 2014 Reexam certificate issued

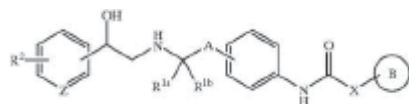


- Dec. 15, 2009 U.S. 7,631,671 issued
- April 12, 2013 initial SE request in view of 2 items (diagram and declaration – public use)
- July 5, 2013 corrected SE request
- Oct. 1, 2013 SE Certificate, SNQ for 12 of 54 issued claims.
- Oct. 29, 2013 Reexam ordered, for 12 of original claims, claims found not entitled to priority date and rejected.
- Nov. 26, 2013 claims in reexam canceled.
- Sept. 17, 2015, infringement litigation filed based on the remaining claims that had not been subject to ex parte reexamination.
- Defendants raised defense of unenforceability due to inequitable conduct, including that the declaration submitted with the SE request was false.
- (still pending as of April 10, 2018)

Example: 96/000,045

IPR After SE/Reexam Finished

U.S. 6,346,532 Claim 1. A compound of formula (I):



in the formula, each of the symbols means as follows:

- ring B is a heteroaryl group which is unsubstituted or substituted and is optionally fused with a benzene ring;
- X is a bond, or a lower alkylene or an alkenylene, both of which are unsubstituted or substituted with hydroxy or a lower alkyl group, or X is a carbonyl or a group represented by –NH–, and when X is a lower alkylene which is substituted with a lower alkyl group, a carbon atom of the ring B optionally bonds with the lower alkyl group so that a ring is formed;
- A is a lower alkylene or a group represented by –lower alkylene–O–;
- R^{1a}, R^{1b} are the same or different and each is a hydrogen atom or a lower alkyl group;
- R² is a hydrogen atom or a halogen atom; and
- Z is a group represented by =CH–; or a salt thereof.

Example: 96/000,045
IPR After SE/Reexam Finished

- Claims cover compounds useful as therapeutic agents for treating diabetes mellitus, but commercial embodiment, MYRBETRIQ® approved only for treating overactive bladder.
- Items of information:
 - 1) U.S. patent;
 - 2) Table of testing data for compounds disclosed in Item #1;
 - 3) Materials for in-house R&D meeting;
 - 4) Study report;
 - 5) R&D flowchart;
 - 6) monthly progress report;
 - 7) excerpts of prosecution for Item #1;
 - 8) JP '861;
 - 9) Blin article (not of record during prosecution);
 - 10) PCT publication;
 - 11) Thornber article (not of record during prosecution); and
 - 12) Rule 132 declaration.

Example: 96/000,045

IPR After SE/Reexam Finished

- Why relevant:
 - Items 2, 3, 4, and 12 include information not available until mid-2003, so was not before the USPTO during prosecution of the claims, which issued Feb. 12, 2002.
 - Items 2, 3, 5-7, and 12 include initial screening data that may cover the scope of the claims but did not satisfy internal screening criteria so was not before the USPTO; specification did not correctly describe the test employed for assessment; statement in specification may not be correct for all claimed compounds.
 - Japanese application '778 may not provide sufficient written description support for full scope of all of the claims, and therefore JP '861 may be prima facie prior art.
 - Item 9 in combination with Item 8 may raise prima facie case of obviousness.
 - Item 10 in view of 8 and 11 may raise prima facie case of obviousness.

Example: 96/000,045
IPR After SE/Reexam Finished

Note comment in original SE request:

“None of the current claims is limited to cover only Astellas’ commercialized product, mirabegron. Should the Patent and Trademark Office order ex parte reexamination of the claims of the ‘532 patent in connection with this request for supplemental examination, Astellas intends to amend the claims of the ‘532 patent to cover only mirabegron and its salts.”

Example: 96/000,045

IPR After SE/Reexam Finished

- Items raising a SNQ:
 - 8 (JP '861) discloses a compound with selective stimulatory effects on the adrenergic receptor and...anti-obesity effects and anti-hyperlipidemia effects....As such, a reasonable examiner would consider these teachings...important in deciding whether [the] claims ...are patentable.”
 - 8 in combination with 9 and in combination with 9-11 would be considered important in deciding patentability.
- Items not raising a SNQ:
 - 2, 3, 4, and 12: “Since claims [all relate to a] compound of formula (I), a reasonable examiner would not consider...Items 2-4 and 12, particularly the 2003 results of the clinical trials for treating diabetes mellitus, important in deciding the patentability of the claims[.]”
 - 2, 3, 5-7, 12: “the Testing Data Table shows that most of the claimed compounds exhibit selective β_3 receptor activity, consistent with the disclosure of the specification. As such, a reasonable examiner would not consider the information provided...important in deciding whether claims 1-14 are patentable.”

Example: 96/000,045

IPR After SE/Reexam Finished

- Claims 1–5, 7–11, 13 and 14 rejected.
 - Japanese patent application does not support claims; not entitled to priority date.
 - Claims rejected for obviousness over JP'861 in view of articles and PCT publication.
- Amended claims 1, 3–5, 11.
 - Claim 1 amended “to better reflect the subject matter disclosed” the priority Japanese application “and to better define the intended invention.”
- Canceled claims 2, 7–8, 16–17.
- Claims 9–10, 13–14 unchanged.
- Added claims 15–19.
- Claim 6, 12 not subject to reexam.
- With the priority date, Item 8 (JP '861) is not prior art.

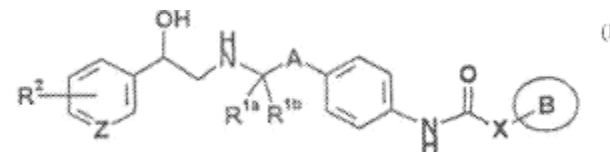
Example: 96/000,045
IPR After SE/Reexam Finished

- Interview
- Supplemental amendment cancelling claims 16-17.
- Reexam certificate issued.
 - Claims 2, 7, 8 canceled
 - Claims 1, 3-5, 9-11, 13-14 amended
 - New claims 15-17
 - Claims 6 and 12 not reexamined.

Example: 96/000,045

IPR After SE/Reexam Finished

- Amended claim 1: A compound of formula (I):



in the formula, each of the symbols means as follows:

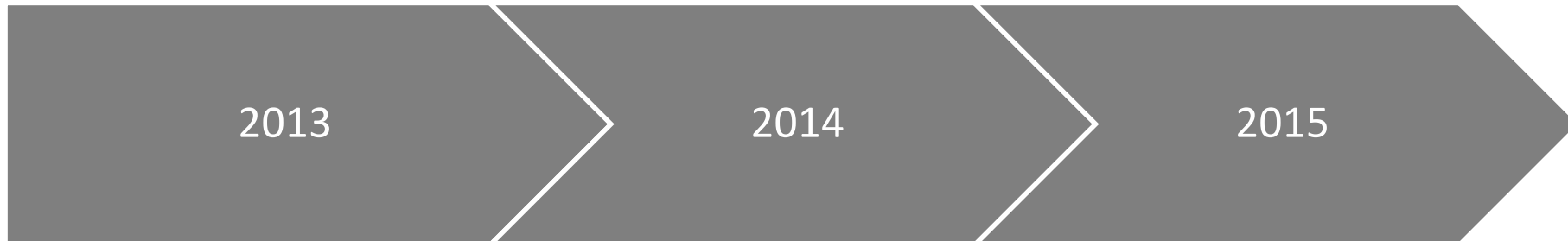
- ring B is a **nitrogen-containing** heteroaryl group which is unsubstituted or substituted and is optionally fused with a benzene ring;
- X is [a bond, or] a lower alkylene or an alkenylene, both of which are unsubstituted or substituted with hydroxy or a lower alkyl group, or X is a carbonyl or a group represented by –NH–, and when X is a lower alkylene which is substituted with a lower alkyl group, a carbon atom of the ring B optionally bonds with the lower alkyl group so that a ring is formed;
- A is [a lower alkylene] **methylene, ethylene**, or a group represented by [–lower alkylene–O–] **–CH₂O–**;
- R^{1a}, R^{1b} are the same or different and each is a hydrogen atom or a lower alkyl group;
- R² is a hydrogen atom or a halogen atom; and
- Z is a group represented by =CH–; or a salt thereof.

Example: 96/000,045

IPR After SE/Reexam Finished

- Feb. 12, 2002: U.S. 6,346,532 issued
- Nov. 21, 2013: SE request filed based on 12 items.

- Feb. 24, 2015: Reexam certificate issued with 3 claims canceled, 9 claims amended, 3 claims added, 2 original claims (not reexamined).



- Jan. 31, 2014: SE Certificate, SNQ for 12 of the 14 claims in view of 8 items.
- Mar. 6, 2014: Reexam ordered, claims rejected.
- April 16, 2014: interview.
- May 6, 2014: Claims amended.

*Oct. 2016 infringement litigations filed.
Mar. 2017 litigations consolidated,
pending.
Oct. 16, 2017 IPR petition filed (IPR2018-00079) - includes reference on which SNQ was found and reexam ordered (Blin), although in different combination of art.
Feb. 8, 2018: POPR argued 325(d) for reference that was already considered in prosecution, SE, and reexam.
Patent also in litigations filed Oct. 2016.*

Example: 96/000,071
Claim Canceled in Reexam Survived IPR

- U.S. 7,229,509 Claim 10. A rolled product comprising an aluminum alloy according to claim 1, with a thickness of at least about 3 inches, exhibiting in a solution heat-treated, quenched, stress-relieved and artificially aged condition, at least one set of properties selected from the group consisting of: [(a) – (f)].
- Claim 1. An aluminum alloy having improved strength and fracture toughness, said alloy comprising the following alloying elements added thereto:...; and wherein the balance is Al and normal and/or inevitable elements and impurities.
- Issued with 16 claims. Claims 1–9 and 11–16 disclaimed on Nov. 11, 2011.

Example: 96/000,071
Claim Canceled in Reexam Survived IPR

- Items of information:

- 1) Balmuth article
- 2) semi-annual report (NASA)
- 3) U.S. Patent 5,234,662 (Balmuth)
- 4) U.S. Patent 5,211,910 (Pickens)
- 5) U.S. Patent 5,389,154 (Cho)
- 6) Chellman and Balmuth vol 1.
- 7) Chellman and Balmuth vol 2.
- 8) Starke declaration (filed in IPR2014-01002)
- 9) Balmuth declaration (filed in IPR2014-01002)
- 10) Starke final report
- 11) Reynolds and Crooks article

- Claim chart provides explanation of relevance of each item by mapping each item to claim 10. “[S]hould *not* be construed as an admission[.]”

Example: 96/000,071
Claim Canceled in Reexam Survived IPR

- Items raising a SNQ:
 - 1: Balmouth discloses Al-Li alloys which overlap compositions recited in claim 10.
 - 2: NASA discloses a rolled product comprising Al-Li alloys which overlap the compositions recited in claim 10.
 - 3: Balmuth patent discloses Al-Li alloys which overlap the compositions recited in claim 10.
 - 4: Pickens patent discloses Al-Li alloys which overlap the compositions recited in claim 10.
 - 5. Cho patent discloses Al-Li alloys which overlap the compositions recited in claim 10.
 - 10. Starke final report discloses Al-Li alloys which overlap the compositions recited in claim 10.
 - 11. Reynolds article discloses Al-Li alloys which overlap the compositions recited in claim 10.

Example: 96/000,071
Claim Canceled in Reexam Survived IPR

- Items not raising a SNQ:
 - 6: Chellman and Balmuth vol 1 Al-Li alloys do not fall within the scope of claim 10.
 - 7: Chellman and Balmuth vol 2 Al-Li alloys do not fall within the scope of claim 10.
 - 8 and 9: “These items of information merely speak to how the declarants characterize various prior art references and the state of the art. These items of information do not qualify as prior art..., nor do they contain information that raises any other issues of patentability with respect to claim 10[.]”

Example: 96/000,071
Claim Canceled in Reexam Survived IPR

- Claim 10 rejected as obvious over Bamouth, NASA, Starke final report, Reynolds, and combination of.
 - Pickens and Cho considered cumulative or less pertinent.
- Claim 10 canceled, new claims 17–30 added.
 - Cited references do not teach or suggest subject matter in new claims (“a rolled product with a thickness of at least about 3 inches of the claimed alloy achieving the claims properties”)
 - Objective evidence of nonobviousness.
 - Expert declarations submitted.
- Added claims found patentable; cited references teach .09”.

Example: 96/000,071
Claim Canceled in Reexam Survived IPR

- Reexamined claim 17: A rolled product comprising an aluminum alloy, having improved strength and fracture toughness, said alloy comprising the following alloying elements added thereto:... ; and wherein the balance is Al and normal and/or inevitable elements and impurities, with a thickness of at least about 3 inches, wherein the rolled product exhibits in a solution heat-treated, quenched, stress-relieved and artificially aged condition, at least one set of properties selected from the group consisting of: [(e) –(f)].

Example: 96/000,071

Claim Canceled in Reexam Survived IPR

- June 12, 2007: U.S. 7,229,509 issued.
- Nov. 11, 2011: all but claim 10 canceled.
- Nov. 4, 2013: reissue application filed, canceling all but claim 10, amending claim 10, adding claims 17–28.
- June 20, 2014: IPR petition filed challenging claim 10 only based on references overlapping with SE request.
- July 3, 2014: SE request filed for claim 10 based on 11 items.
- July 3, 2014: amended IPR petition filed.
- Aug. 6, 2014 protest filed in reissue (by IPR petitioner’s counsel), citing items of information in SE
- Aug. 2014: SE Certificate, SNQ found in view of 7 items, reexam ordered.
- Oct. 23, 2014: PTO suspended reissue application.
- Oct. 31, 2014: claims rejected.
- Dec. 29, 2014: IPR instituted.

2014

2015

- Jan. 20, 2015 request to stay reexam and reissue, and request to stay IPR
- Feb. 19, 2015: denied all stay requests.
- **Feb. 28, 2015: canceled claim 10, new claims 17–30.**
- July 6, 2015, second protest filed (by IPR petitioner’s counsel) in reissue application.
- July 17, 2015: second notice of suspension of reissue application.
- **Nov. 2, 2015: Claim 10 not unpatentable.**
- **Nov. 12, 2015: Reexam cert. issued with new claims 17–30.**
- Dec. 9, 2015: reissue application abandoned.

Reissue Amendment

- Amendment to § § 251, 253:
 - Whenever any patent is , through error ~~without any deceptive intention~~, deemed wholly or partly inoperative or invalid, by reason of a defective specification or drawing, or by reason of the patentee claiming more or less than he had a right to claim in the patent, the Director shall, on the surrender of such patent and the payment of the fee required by law, reissue the patent.... [SEC. 20(d) and (e), 125 STAT. 333–334].
 - *Would one use a combination of Reissue and Supplemental Examination to insulate reissued claims from allegation of inequitable conduct? Or just reissue? Why?*

Note: 37 CFR 1.16(e) Basic fee for filing each application for the reissue of a patent is \$300! (with small/micro entity reductions available)

Inequitable Conduct Curable by Reissue?

- If the USPTO considers an item of information during a reissue proceeding and still reissues the patent, an accused infringer would be hard-pressed to argue that the item of information was “but for” material under the *Therasense* test for inequitable conduct.
- Thus, Congress’ removal of the “without deceptive intention” requirement from the reissue statute, in combination with the Federal Circuit’s *en banc* decision in *Therasense* requiring but-for materiality to establish inequitable conduct, arguably opens the door for patent owners to address the prong of but-for materiality of inequitable conduct via reissue.

Inequitable Conduct ≠ Error Curable by Reissue

- *Therasense, Inc. V. Becton, Dickinson and Co.*, 649 F.3d 1276, 1288 (Fed. Cir. 2011)
 - “Unlike other deficiencies, inequitable conduct cannot be cured by reissue,...or reexamination.” (*citing Aventis Pharma S.A. v. Amphastar Pharm. Inc.*, 525 F.3d 1334, 1341 (Fed. Cir. 2008), *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1182 (Fed. Cir. 1995)

But... SE as Tool

- A request for supplemental examination could provide a mechanism for such patent owners to strengthen their patents before litigation.
 - May be especially attractive for OB-listed patents because timing of Hatch–Waxman litigation may be predictable.

Timing

- Carefully consider the timing of any effort at supplemental examination if might soon seek to enforce the patent or if there is any indication that a third party might imminently file an IPR.
- While a decision on the request for supplemental examination must be made in three months, the patent could be tied up in the USPTO for at least a year if the Director orders *ex parte* reexamination or if a petition for IPR is filed and subsequently granted. And appealing an adverse decision in the *ex parte* reexamination could further delay any effort to enforce a patent

How to Balance The Benefits And Limitations of SE Before Filing Request?



- Potentially insulated claims.

- Have really good arguments to address any prior art or other items of information that you submit.

- If the PTO finds an SNQ, you're locked into ex parte reexamination before the CRU (not your original examiner)

- Only one bite at the apple (no RCEs), so you must appeal if you don't resolve everything with your response to the first OA.

*Questions To Ask :
Answers May Flush Out Information To Consider In Context Of
Supplemental Exam*

Were subjective evaluations presented as fact? Were assertions supported by science?

- Purdue Pharma L.P. v. Endo Pharms., Inc., 438 F.3d 1123 (Fed. Cir. 2006)

Is there any unsubmitted prior art?

Are there any unsubmitted pre- or post-filing date articles or publications related to the subject matter of the invention?

- Bristol-Myers Squibb Co. v. Rhône-Poulenc Rorer, Inc., 326 F.3d 1226 (Fed. Cir. 2003)

Questions To Ask :
Answers May Flush Out Information To Consider In Context Of
Supplemental Exam

Were all the experiments described performed as described?

- Hoffmann-LaRoche, Inc. v. Promega Corp., 323 F.3d 1354 (Fed. Cir. 2003)
- Novo Nordisk Pharmaceuticals, Inc. v. Bio-Technology General Corp., 424 F.3d 1347 (Fed. Cir. 2005)
- Pharmacia Corp. v. Par Pharmaceutical, Inc., 417 F.3d 1369 (Fed. Cir. 2005)
- Apotex, Inc. v. UCB, Inc., 763 F.3d 1354 (Fed. Cir. 2014)

Are there experiments and/or experiment details that were not included in the specification?

- Aventis Pharma S.A. v. Amphastar Pharmaceuticals, Inc., 525 F.3d 1334 (Fed. Cir. 2008)

*Questions To Ask :
Answers May Flush Out Information To Consider In Context Of
Supplemental Exam*

Are there undisclosed data?

- Cargill, Inc. v. Canbra Foods, Ltd., 476 F.3d 1359 (Fed. Cir. 2007)

Was data relied upon to establish patentability?

Questions To Ask :
Answers May Flush Out Information To Consider In Context Of
Supplemental Exam

Is there information in the files of those having a Rule 56 duty that is inconsistent with any data submitted? Inconsistent with arguments made?

- Monsanto Co. v. Bayer Bioscience N.V., 514 F.3d 1229 (Fed. Cir. 2008)
- Ferring B.V. v. Barr Labs., Inc., 437 F.3d 1181 (Fed. Cir. 2006)

*Questions To Ask :
Answers May Flush Out Information To Consider In Context Of
Supplemental Exam*

Are there any related applications? Uncited Office Actions in any related applications? Related patents? Litigation on related patents?

- McKesson Information Solutions, Inc. v. Bridge Medical, Inc., 487 F.3d 897 (Fed. Cir. 2007)
- Nilssen v. Osram Sylvania, Inc., 504 F.3d 1223 (Fed. Cir. 2007)
- Leviton Mfg. Co., Inc. v. Universal Sec. Instruments, Inc., 606 F.3d 1353 (Fed. Cir. 2010)

What About Unclean Hands?

Unclean Hands

- Equitable doctrine that denies a party relief if he has acted fraudulently or in bad faith.
- The big three Supreme Court “unclean hands” cases are:
 - Keystone Driller Co. v. Gen. Excavator Co., 290 U.S. 240 (1933): denying relief to patent owner who had suppressed evidence of a potentially invalidating prior use of the claimed invention to prevail in a patent infringement suit.
 - Hazel-Atlas Glass Co. v. Hartford-Empire Co., 322 U.S. 238 (1944): denying relief to patent owner who had fabricated a printed publication to overcome prior art rejection.
 - Precision Instrument Manufacturing Co. v. Automotive Maintenance Machinery Co., 324 U.S. 806 (1945): denying relief to patent owner who asserted patent after learning someone else invented first.

Unclean Hands

Gilead Sciences, Inc. v. Merck & Co, Inc., Case No. 13–cv–04057 (N.D. Cal.)

- Gilead filed declaratory judgment action for noninfringement and invalidity.
- Merck counterclaimed against Gilead for induced and contributory infringement, alleging that two of Merck's patents cover sofosbuvir, the active ingredient in Sovaldi[®] and Harvoni[®].
- DC: Summary judgment of infringement.
- Jury: patents valid; \$200 M damage award.
- **Gilead raised equitable defenses of waiver and unclean hands.**

Unclean Hands

Background:

- Merck and Pharmasset signed NDA that Merck “would not use Pharmasset's confidential information for any purpose other than for evaluating a potential collaboration with Pharmasset.”
- Merck created internal firewall “to protect Pharmasset's confidential structural information about its lead compound, PSI-6130.”
- Dr. Durette, an in-house Merck patent attorney working on a portfolio related to nucleoside analogs for treatment of HCV, participated in a due diligence call with Pharmasset.
 - Knew before the phone call, “that any information he learned about Pharmasset's PSI-6130 nucleoside analog compound would overlap with the subject matter of his patent prosecution docket for Merck, thereby creating a conflict.”
 - “Dr. Durette did not qualify as a firewalled individual; he was prosecuting patents from the Merck-Isis collaboration.”
 - Failed to tell Pharmasset that he was prosecuting patents in the same field of HCV nucleoside analogs and misrepresented that he was within the firewall.

Unclean Hands

Background (con't):

- Dr. Durette wrote “claims that targeted Pharmasset's work [and] were based on the information he learned on the March 17, 2004, patent due diligence call.”
- “The Court finds that Dr. Durette waited to amend the claims in the '499 Patent until Clark application was published to give the appearance that he learned it from a public source....Dr. Durette has admitted that he would not have been able to associate any structure in the Pharmasset application as the structure of PSI-6130 unless he knew the structure of PSI-6130 beforehand.”
- “Dr. Durette would not have written new claims to cover PSI-6130 in February 2005 but for his improper participation on the March 17, 2004 patent due diligence call and learning the structure of PSI-6130 ahead of the structure being published.”

Unclean Hands

DC: Patents unenforceable (2016 WL 3143943 (N.D. Cal. June 6, 2016))

- The “record, ...reflects a pervasive pattern of misconduct by Merck and its agents constituting unclean hands, which renders Merck's '499 and '712 Patents unenforceable against Gilead.”
- “Dr. Durette's changing and evasive explanations for why he narrowed the claims undermine his testimony. The Court finds his testimony to be not credible.”
- “Dr. Durette's claim that he amended the ... claims to focus on ‘get[ting] allowance on the subject matter that was most important to the [Merck–Isis collaboration]’ is contrary to the evidence and is not credible because Merck never tested any of the claimed compounds.”
- “The Court finds Dr. Durette's testimony that the two new, narrower claims he wrote ...were to protect Merck's “most important work” is not credible and is false.”

Unclean Hands v. Inequitable Conduct

DC: Patents unenforceable.

- The big three “unclean hands” cases are: Keystone Driller Co. v. Gen. Excavator Co., 290 U.S. 240, 241 (1933); Hazel-Atlas Glass Co. v. Hartford-Empire Co., 322 U.S. 238 (1944), overruled on other grounds by Standard Oil Co. v. United States, 429 U.S. 17 (1976); Precision Instrument Manufacturing Co. v. Automotive Maintenance Machinery Co., 324 U.S. 806 (1945).
 - Keystone Driller Co. v. Gen. Excavator Co.: “He who comes into equity must come with clean hands.”
 - Precision Instrument Manufacturing Co. v. Automotive Maintenance Machinery Co.: “Public interest demands that all facts relevant to such matters be submitted formally or informally to the Patent Office, which can then pass upon the sufficiency of the evidence. ... Such inequitable conduct impregnated Automotive's entire cause of action and justified dismissal by resort to the unclean hands doctrine.”
 - Hazel-Atlas Glass Co. v. Hartford-Empire Co.: “Every element of the fraud here disclosed demands the exercise of the historic power of equity to set aside fraudulently begotten judgments.”

Unclean Hands v. Inequitable Conduct

DC: Patents unenforceable.

- As explained in Therasense, Inc. v. Becton, Dickson & Co., 649 F.3d 1276 (Fed. Cir. 2011), “**unclean hands can involve improper conduct before either the Patent Office or the courts**, inequitable conduct relates solely to conduct before the Patent Office.” but “**unclean hands remains a viable defense, and does not require a finding of materiality[.]**”

‘Immediate and Necessary Relation’

DC: Patents unenforceable.

- “it is the Court's determination that, on balance, Merck's persistent misconduct involving repeated fabricated testimony and improper business conduct outweigh its right to maintain this suit against Gilead.”
- “In this case, ...Merck's misconduct includes lying to Pharmasset, misusing Pharmasset's confidential information, breaching confidentiality and firewall agreements, and lying under oath at deposition and trial. **Any one of these acts—lying, unethical business conduct, or litigation misconduct— would be sufficient to invoke the doctrine of unclean hands; but together, these acts unmistakably constitute egregious misconduct that equals or exceeds the misconduct previously found by other courts to constitute unclean hands.** Merck's acts are even more egregious because the main perpetrator of its misconduct was its attorney.”
- “there can be no doubt that Merck used this highly confidential information to benefit its own prosecution” and each of the foregoing unconscionable acts has an **‘immediate and necessary relation to...the matter in litigation’** because the patents that resulted from this series of unconscionable acts are now asserted against Gilead, Pharmasset's successor-in-interest.”

Jury Verdict Did Not Prevent Finding of Unclean Hands

Gilead argued invalidity under 35 U.S.C. §§102(f) and 102(g).

The jury found the patents were not invalid.

Merck argued that the jury's verdict prevents a finding of unclean hands.

- “According to Merck, the only unclean hands theory set forth in Gilead’s interrogatory responses is predicated on Merck’s derivation of the inventions claimed ...from Pharmasset’s confidential disclosures. Since the jury found the claims ...were not invalid for lack of written description or lack of enablement, the priority date of the asserted claims is January 18, 2002. As a result, Merck argues that it could not have derived the invention from Pharmasset in 2004 because its invention was completely conceived by January 18, 2002.

DC: “The Court disagrees with Merck’s view of Gilead’s interrogatory responses and the jury’s verdict. Gilead’s interrogatory responses made clear that its unclean hands defense is based on the belief that Merck improperly derived information about Pharmasset’s invention from Pharmasset’s confidential disclosures. These responses did not, as Merck argues, limit Gilead to a theory of unclean hands based on 35 U.S.C. § 102(f), also known ‘derivation,’ which states a person shall be entitled to a patent unless ‘he did not himself invent the subject matter.’ If Gilead’s unclean hands disclosure was interpreted as only disclosing a theory of unclean hands based strictly on § 102(f), it would be entirely redundant of Gilead’s § 102(f) invalidity defense. It would also allow Merck’s misconduct in obtaining Pharmasset’s confidential information during the 2004 phone call and subsequent litigation misconduct to go unchecked. Gilead’s responses, instead, provide Gilead the ability to pursue an unclean hands defense covering circumstances where Merck improperly received information from Pharmasset. Thus, **the jury’s verdict, which did foreclose a § 102(f) invalidity defense, does not prevent Gilead from pursuing a defense of unclean hands.**”

Attorney and Employer

DC: Patents unenforceable.

- “Candor and honesty define the contours of the legal system. **When a company allows and supports its own attorney to violate these principles, it shares the consequences of those actions.** Here, Merck's patent attorney, responsible for prosecuting the patents-in-suit, was dishonest and duplicitous in his actions with Pharmasset, with Gilead and with this Court, thus **crossing the line to egregious misconduct. Merck is guilty of unclean hands and forfeits its right to prosecute this action against Gilead.**”

Federal Circuit Affirms

Gilead Sciences, Inc. v. Merck & Co., Inc., --F.3d__ (Fed. Cir. April 25, 2018)(TARANTO, Clevenger, and Chen)

- Affirmed.
 - “[T]he connection of Pharmasset’s work on PSI-6130 with Dr. Durette, Merck, and Merck’s 2005 claim amendments for what became the ‘499 patent..., together with Dr. Durette’s eventual testimony about those connections, came to be the basis of the district court’s ultimate determination that Merck had unclean hands, precluding patent enforcement against Gilead.”

Federal Circuit Affirms (con't)

Supreme Court governing legal standard:

- Keystone Driller Co. v. General Excavation Co., 290 U.S. 240, 245 (1933) and Precision Instrument Mfg. Co. v. Automotive Maintenance Machinery Co., 324 U.S. 806, 814–15 (1945).
- “immediate and necessary relation” standard “must be met if the conduct normally would enhance the claimant’s position regarding legal rights that are important to the litigation if the impropriety is not discovered and corrected.”

Federal Circuit Affirms (con't)

“Nor is this a case involving alleged deficiencies in communications with the PTO during patent prosecution, for which this court’s inequitable–conduct decisions, e.g., Therasense ..., set important limits on conclusions of unenforceability through that doctrine.”

Reviewing for abuse of discretion, “the district court made findings that have adequate support in the evidence and that, taken together, justify the equitable determination of unclean hands as a defense to enforcement in this case.”

Federal Circuit Affirms (con't)

Immediately and necessarily related to the equity of giving Merck the relief of patent enforcement:

- Pre-litigation business misconduct
 - Dr. Durette violated firewall; and
 - Merck continued to use Dr. Durette in related patent prosecutions after the call.
- Litigation misconduct
 - Dr. Durette gave intentionally false testimony about participation in phone call; and
 - Dr. Durette gave intentionally false testimony about origin of Merck's 2005 amendment.
- Balancing of the equities
 - No abuse of discretion.
 - “The district court...had sufficient reason to find that both patents were tainted by the patentee's misconduct, especially the litigation misconduct.”

SE and Unclean Hands?

- Could patent owner use supplemental exam to purge basis of unclean hands allegation?
 - Statutory language is broad:
 - “A patent **shall not be held unenforceable** ... if the **information was considered, reconsidered, or corrected during a supplemental examination** of the patent.”
 - Basis for unclean hands allegation is that party acted fraudulently or in bad faith.
 - Exceptions under 35 U.S.C. 257(e) suggest “fraud” cannot be cured by supplemental examination.
 - But what if Director does not refer the matter to the Attorney General?
 - No reason to use “fraud” as a basis for limiting Supp Exam to inequitable conduct

THANK YOU

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