








NJIPLA 33rd ANNUAL

PHARMACEUTICAL / CHEMICAL PATENT PRACTICE UPDATE

Wednesday, November 20, 2019, 12:00 PM - 5:30 PM
APA Woodbridge Hotel, Iselin, New Jersey

SCHEDULE

- 12:00 - 12:45 Registration and Lunch
- 12:45 - 12:55 President's Introduction and Election of 2020 NJIPLA Board of Managers
Thomas A. Triolo, Regeneron Pharmaceuticals, Inc.
- 12:55 - 1:00 Opening Remarks by the Co-Chairs
J. Eric Thies, Merck & Co., Inc. and **Suja Vathyam**, Botos Churchill IP Law LLP
- 1:00 - 1:45  **Writing High-Quality Patent Applications for Effective Prosecution and Litigation: The District Court's Perspective**
KEYNOTE SPEAKER
The Honorable Stanley R. Chesler, *District Judge*,
U.S. District Court for the District of New Jersey
- 1:45 - 2:30  **Non-Statutory Double Patenting, as it Relates to Examination and How it Has Been Viewed in the Context of Patent Term Extension Under 35 USC 156**
Mary C. Till, *Senior Legal Advisor*,
United States Patent and Trademark Office
- 2:30 - 2:45 Refreshment Break
- 2:45 - 3:45   **Reaching Gender Parity in Innovation**
Serena Farquharson-Torres,
Bristol-Myers Squibb Company
Sarah Hooson, Merck & Co., Inc.
- 3:45 - 4:00 Refreshment Break
- 4:00 - 4:45   **Avoiding on Sale Bar Sins that Could Land Your Client in Patent Hell: Lessons from the *Helsinn* Case**
Priya G. Prasad, Exxon Mobil Corp.
Peter Tu, Signum Biosciences
- 4:45 - 5:30  **To Exclusivity and Beyond: The "Buzz" About FDA's Non-Patent Exclusivities**
Sara W. Koblitz, Hyman Phelps & McNamara

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Honorable
Stanley R. Chesler
Biography

Judge Chesler is a United States District Judge for the District of New Jersey. He has served in the federal judiciary for over 30 years. He began his service as a United States Magistrate Judge in 1987. In 2002, Judge Chesler was appointed as a United States District Judge. He chairs the District of New Jersey's Local Patent Rules Committee.

Before his appointment to the bench, Judge Chesler served as a federal prosecutor and a state prosecutor. Between 1980 and 1987, he worked as an attorney with the U.S. Department of Justice Organized Crime Strike Force and as an Assistant U.S. Attorney. He was the Deputy Chief of the Newark Organized Crime Strike Force between 1984 and 1986. As a federal prosecutor, Judge Chesler specialized in the investigation and prosecution of complex labor racketeering cases. Judge Chesler was an Assistant District Attorney with the Bronx County (New York) District Attorney's Office from 1974 to 1980. As a state prosecutor, he acted at various times as Chief of the office's Investigations Bureau and the Chief of its Narcotics/Rackets Bureau. Judge Chesler received his J.D. from St. John's University School of Law *magna cum laude* in 1974.

Title of presentation:

Writing High-Quality Patent Applications for Effective Prosecution and Litigation

The Honorable Stanley R. Chesler, United States District Judge, United States District Court for the District of New Jersey

Summary: This Keynote presentation by Judge Stanley R. Chesler at NJIPLA's "33rd Annual Pharmaceutical / Chemical Patent Practice Update" on November 20, 2019, will address issues that arise during patent litigation, from the perspective of a District Court Judge who has actually ruled on such issues when hearing patent cases before him. Judge Chesler will speak extemporaneously without relying on a slide presentation.

Judge Chesler will emphasize that high-quality patent applications not only provide for more effective prosecution to obtain a granted patent, but also enhance the strength of such patent during patent litigation. Many of the issues that are contested in patent litigation could have been avoided by using appropriate terminology when writing the patent application in the first place.

Judge Chesler's presentation will provide concrete and tangible suggestions on how patent prosecutors can make a patent "Federal Judge Proof." For example, Judge Chesler's will advise that the use of apparently simple words are a potential trap for the unwary ... even words such as "and" or "or" can be problematic!

Judge Chesler will analogize the drafting of a patent (which protects intellectual property) to the drafting of a legal deed (for conveyance of real property). Judge Chesler will suggest that, as with any other writing endeavors, an author of a patent application should set their work product aside for a while, then revisit it to ensure that it would make sense when read by a judge during future patent litigation. Judge Chesler will draw upon his years of experience on the bench when providing practical advice to attorneys who are preparing and litigating patent applications. In disseminating the foregoing legal guidance, Judge Chesler will refer to applicable patent case law from the Court of Appeals for the Federal Circuit and the US Supreme Court.

Judge Chesler is a sitting Federal District Court judge for the District of New Jersey who has heard numerous patent cases, so he is uniquely qualified to provide guidance and practical suggestions for patent attorneys who are writing and litigating patents.

Mary C. Till

Mary C. Till received a B.S. in Chemistry from Gannon University and her M.S. in Organic Chemistry from Virginia Tech. She began her career in patent law in 1993 serving as a patent examiner in what is now Technology Center 1600, examining patent applications in the field of organic chemistry, in particular, small molecules. Beginning in 1997, she worked in private practice at Foley & Lardner in Washington, DC. In private practice, Ms. Till was actively engaged in procuring patent protection for various life science corporations and universities, counseling the entities regarding product launches and providing opinions of counsel on freedom to operate, validity, infringement, invalidity and due diligence issues. While working as a patent agent, Ms. Till earned her J.D. from American University's Washington College of Law, cum laude. Ms. Till rejoined the USPTO in 2005 and is now a Senior Legal Advisor in the Office of Patent Legal Administration (OPLA) at the USPTO. Ms. Till is primarily responsible for administration of the Hatch-Waxman Act provisions found in 35 U.S.C. 156 on behalf of the USPTO. Ms. Till was involved with various aspects of implementation of the America Invents Act, focusing on the First Inventor to File provisions, having co-drafted the guidance on first inventor to file. She worked on all phases of implementing the first inventor to file provisions at the USPTO, including examiner training and IT implementation. Her additional duties in the Office of Patent Legal Administration involve implementing case law and pilot programs to the examining corps, drafting responses and position papers on White House Executive Actions, acting as liaison with the Office of Data Management, updating the MPEP, providing input and analysis on various congressional inquiries/proposed legislation and briefing USPTO executives for congressional testimony, and providing assistance to the examining corps as necessary. During her tenure as a senior legal advisor in OPLA, she has received a Department of Commerce Gold Medal Award in 2015, a Department of Commerce Silver Medal Award in 2013, a Department of Commerce Bronze Medal Award in 2014, and an Exceptional Career Award from the USPTO in 2016.

She is admitted to the bar of Virginia and to practice before the United States Patent and Trademark Office.

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**Nonstatutory double patenting, as it relates
to examination and how it has been viewed
in the context of 35 USC 156**

Mary C. Till

November 20, 2019

UNITED STATES
PATENT AND TRADEMARK OFFICE



Policy behind the doctrine of double patenting

- Seeks to prevent the unjustified extension of patent exclusivity beyond the term of a patent.
- Seeks to prevent the possibility of multiple suits against an accused infringer by different assignees of patent claiming patentably indistinct variation of the same invention
- MPEP 804

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Nonstatutory double patenting

- A NSDP rejection is proper when conflicting claims are not identical, but at least one examined claim is not patentably distinct from a reference claim because the examined claims is either **anticipated by** or **obvious over** the reference claim(s).
- MPEP 804

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Evolution of NSDP jurisprudence

- Pre-2014
 - Focus was on respective issue dates
 - Claim of later-issued patent could be rejected/invalid over claim of earlier-issued patent
- 2014: **Gilead v. Natco** and **Abbvie v. Kennedy**
 - Federal Circuit held that expiration dates should control, not issuance dates
 - Are claims of later-expiring patent mere obvious variants of earlier expiring claims?
 - Gilead Sciences, Inc. v. Natco Pharma Ltd, 753 F.3d 1208 (Fed. Cir. 2014)
 - AbbVie, Inc. v. Kennedy Institute of Rheumatology, 764 F.3d 1366 (Fed. Cir. 2014)



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Evolution of NSDP jurisprudence

- Post-2014
 - Earlier-expiring patent can be Obviousness Type Double Patenting (OTDP) reference against patent with same priority date but later expiring due to PTA
 - Magna Electronics, Inc. v. TRW Automotive Holdings Corp, No. 1:12-cv-654 (WD Mich, 2015)
 - “[I]f a patent, under its pre-PTE expiration date, is valid under all other provisions of law, then it is entitled to the full term of its PTE”
 - Novartis AG v. Ezra Ventures LLC, 909 F.3d 1367 (Fed. Cir. 2018)
 - Post-URAA patent can not be an OTDP reference against pre-URAA patent
 - Novartis v. Breckenridge, 909 F.3d 1355 (Fed. Cir. 2018)



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Types of nonstatutory double patenting

- Based on anticipation analysis
- Based on obviousness analysis
- Equitable principle against unjustified timewise extension of patent rights
- MPEP 804

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Nonstatutory double patenting

- Anticipation analysis:
 - A claim can be rejected under NSDP if the claim under examination is not patentably distinct from the reference claim if the claim under examination is anticipated by the reference claim. This type of NSDP comes about when the examined claim is generic to a species or sub-genus claimed in a conflicting patent or application

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Nonstatutory double patenting

- Where the examined claim: (1) is directed to a species or subgenus covered by a conflicting generic claim in a patent or application, or (2) overlaps in scope with a conflicting patent or application claim; the potentially conflicting claim cannot be said to anticipate the examined claim. Both situations would require an obviousness analysis UNLESS one can, upon reading the potentially conflicting patent or application CLAIMS, “at once envisage” the invention claimed in the examined application. This means it is still an ANTICIPATION ANALYSIS.
- MPEP 804



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Nonstatutory double patenting

- Obviousness analysis
- Analogous to 35 U.S.C. 103 analysis but analysis is limited to the reference patent or application claims
 - Determine the scope and content of the patent/copending application claim relative to a claim in issue.
 - Ascertain the differences between the patent/copending application claim relative to a claim in issue.
 - Resolve the level of ordinary skill in the art.
 - Evaluate evidence of secondary considerations.

See: MPEP 804(II)(B)(2)



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NSDP obviousness: Written rejection

- A NSDP obviousness rejection is analogous to a 35 U.S.C. 103 rejection and should address the following:
 - The differences between a claim in the examined application compared to a claim in the conflicting patent or copending application.
 - The rationale for concluding that the invention defined in the claim at issue would have been an obvious variation of the invention defined in a claim in the conflicting patent or copending application.

See: MPEP 804(II)(B)(2)



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Balancing invention and obviousness

- If a claimed invention is a non-obvious variant of what was previously patented, described, or known and is not subject to double patenting, the claim should be allowed (subject to compliance with 35 U.S.C. 101 and 112).
- If claimed invention is an obvious variant of what was previously patented, described, or known, there are multiple tools that might be used to reject the claim(s)
 - 35 U.S.C. 103
 - Non-statutory double patenting



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Requirements for NSDP rejections

- The application under examination and the reference patent or copending application have conflicting claims, AND:
 1. Have the same inventive entity, or
 2. Have a common inventor, or
 3. Have a common assignee/owner, or
 4. Be subject to a joint research agreement as set forth in 35 U.S.C. 102(c) or pre-AIA 35 U.S.C. 103(c)(2) and (3)

See: MPEP 804



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Provisional vs. nonprovisional rejections

- Provisional rejections are based on one or more copending applications.
- Nonprovisional rejections are based on one or more issued patents.

See: MPEP 804(I)



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Tips for applications having the same effective U.S. filing date

- To overcome provisional NSDP rejections (absent an effective amendment), where both applications have the same effective U.S. filing date, the provisional NSDP rejection made in each of the applications should be maintained until a showing that the claims are patentably distinct or filing a terminal disclaimer in both applications.

See: MPEP 804(I)(B)(1)



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Remember, it is about the claims!

- Compare the **claims** of the application under examination to the **claims** of a patent or co-pending application.
 - Same scope = Statutory DP (35 U.S.C. 101 DP)
 - Obvious variant = NSDP
- **Withdrawn claims** in a **co-pending application** can be considered.
- **Withdrawn claims** in **the application under examination** should not be considered.

See: MPEP 804



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Remember, it's about the claims!

- The claims of the patent or copending application can form the basis of a double patenting rejection regardless of the availability of the patent or copending application as a prior art reference.



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Use of the specification in NSDP

- Use of the specification of the potentially conflicting patent or application as prior art is prohibited unless the potentially conflicting patent or (published) application qualifies as prior art
- However, the specification may be used for **claim interpretation**:
 - Using the specification as a dictionary for claim terminology
 - Relying on portions of the disclosure which provide support for the claims to determine the proper scope of a claim (e.g., to interpret 35 U.S.C. 112(f) language or a special definition) in the potentially conflicting patent or application

See: MPEP 804(II)(B)(2)(a) and *In re Vogel*



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Use of the specification in NSDP

- Examples of **proper** use of the specification from the potentially conflicting application or patent to support an ODP rejection:
 - Reliance on a definition for a claim term to demonstrate that the potentially conflicting claims meet limitations of the claims under examination.
 - Reliance on teachings with respect to the conflicting claims to show that the claim under examination would have been an immediately envisaged embodiment of the genus defined by the potentially conflicting claims.
 - Reliance on the specification to show that the present method claims are a contemplated utility of the product described by the potentially conflicting claims.
 - Reliance on the specification to show that a claim under examination is an obvious variation of an invention disclosed and claimed in the patent.

See: MPEP 804(II)(B)(1) and MPEP 804(II)(B)(2)(a)



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Use of the specification in NSDP

- Examples of **improper** use of the specification from the potentially conflicting application or patent to support an ODP rejection:
 - Reliance on teachings in the specification showing nothing more than that the conflicting claims dominate the claims under examination.
 - Reliance on disclosure in the specification that the species under examination represents an embodiment of the potentially conflicting claims where certain variables are selected, without providing a rationale for why those selections would have been obvious.
 - Reliance on disclosure in the specification that the claimed method under examination is a contemplated method of making the product defined by the copending claims.

See: MPEP 804(II)(B)(2)(a)



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Nonstatutory double patenting

- Genus-species situations:

- The analysis required is different in situations where the claim in the application being examined (1) is directed to a species or sub-genus covered by a generic claim in a potentially conflicting patent or application, or (2) overlaps in scope with a claim in a potentially conflicting patent or application but the potentially conflicting claims cannot be said to anticipate the examined claims. Both of these situations require an obviousness analysis unless one of ordinary skill in the art would, on reading the potentially conflicting patent or application, at once envisage the invention claimed in the examined application. See *AbbVie Inc. v. Kennedy Institute of Rheumatology Trust*, 764 F.3d 1366, 112 USPQ2d 1001 (Fed. Cir. 2014). For example, in the genus-species situation, the examiner **typically should explain why** it would have been obvious to select the claimed species or sub-genus given the genus claimed in the potentially conflicting patent or application.

See: MPEP 804 (II)(B)(1)



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Nonstautory double patenting

- Generic claims presented in a separate application after issuance of species claims:

- If a generic claim is presented in a separate application after the issuance of a patent claiming one or more species within the scope of the generic claim, the Office may reject the generic claim on the grounds of nonstatutory double patenting when the patent and application have at least one common inventor and/or are either (1) commonly assigned/owned or (2) non-commonly assigned/owned but subject to a joint research agreement as set forth in 35 U.S.C. 102(c) or pre-AIA 35 U.S.C. 103(c)(2) and (3). Applicant may overcome such a rejection by filing a terminal disclaimer. MPEP 806.04(i)



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Overcoming NSDP Rejections

- Argue rejection on the merits
 - Show evidence of non-obviousness
- Amend the claims
- File a terminal disclaimer
 - Requires common ownership between application and NSDP reference
 - Stipulates that application is only enforceable upon maintenance of common ownership of application and NSDP reference
 - Cannot disclaim single claims, only an application in its entirety
 - TD cannot be withdrawn after issuance of application
 - TD cannot overcome an NSDP rejection over an expired patent



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Terminal disclaimers and 35 USC 156

- The extended term of a patent can be affected by a terminal disclaimer filed against a later issued earlier expiring patent. *Gilead Scis., Inc. v. Natco Pharma Ltd.*, 753 F.3d 1208, 110 USPQ2d 1551 (Fed. Cir. 2014).



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Example 1a: Is a NSDP rejection proper?

<p>Examined Application (Inventors A and B): Claim 1. A compound having the formula: $R^1-(CH_2CH_2)_n-R^2$ wherein R^1 is a saturated or unsaturated alkoxy, aryloxy, alkylcarboxy or heteroaryloxy, R^2 is an unsubstituted phenyl or substituted aryl, heterocyclyl or heteroaryl, and n is 1-10.</p>	<p>Patent X,XXX,XXX (Inventors A and B): Filed before but issued after the effective filing date of the examined application Claim 10. A compound having the following formula: $CH_3O(CH_2)_6$-Phenyl or $CH_3OCH_2CH_2CH_2CH_2$-Phenyl.</p>
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Note: No restriction made, no common assignee, and no JRA



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Example 1a: Question and analysis

- Is a NSDP rejection proper here?
 - A NSDP rejection would be appropriate because:
 - The two applications have the same inventive entity.
 - The scope of Claim 1 of the application being examined is broader than and fully encompasses the two species claimed in claim 10 of the patent.
 - Therefore, a NSDP-anticipatory rejection of Claim 1 of the application over Claim 10 of the patent is appropriate.



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Example 1b: Is a NSDP rejection proper?

Examined Application (Inventors A and B): Claim 1. A compound having the following formula: $\text{CH}_3\text{O}(\text{CH}_2)_6\text{-Phenyl or}$ $\text{CH}_3\text{OCH}_2\text{CH}_2\text{CH}_2\text{CH}_2\text{-Phenyl.}$	Patent X,XXX,XXX (Inventors A and B): Filed before, but issued after the effective filing date of the examined application Claim 10. A compound having the formula: $\text{R}^1\text{-(CH}_2\text{CH}_2)_n\text{-R}^2$ wherein R¹ is a saturated or unsaturated alkoxy, aryloxy, alkylcarboxy or heteroaryloxy, R² is an unsubstituted phenyl or substituted aryl, heterocyclyl or heteroaryl, and n is 1-10.
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Note: No restriction made, no common assignee, and no JRA. The specification shows that the two compounds of Claim 1 under examination are disclosed in the patent specification and the POSITA would conclude that patented Claim 10 reads on those two compounds.



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Example 1b: Question and analysis

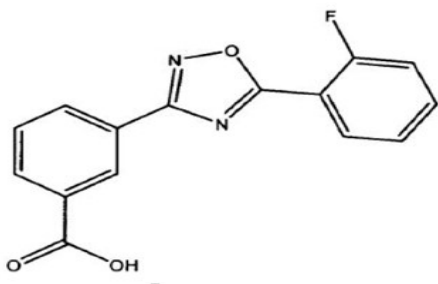
- Can a NSDP rejection be made here?
- Remember, how can we use the reference patent specification?
 - As a dictionary to learn the meaning of a term in a claim (*Toro Co. v. White Consol. Indus. Inc.*, 199 F.3d 1295 (Fed. Cir 1999)); to show that the claim under examination would have been an immediately envisaged embodiment of the genus defined by the potentially conflicting claims (*AbbVie Inc. v. Kennedy Institute of Rheumatology Trust*, 764 F.3d 1366 (Fed. Cir 2014)); to show that the examined method of use claims are a contemplated utility of the product described by the potentially conflicting claims (*Geneva Pharmaceuticals Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373 (Fed. Cir. 2003)) or to show that a claim under examination is an obvious variation of an invention disclosed and claimed in the potentially conflicting claims (*In re Vogel*, 422 F.2d 438 (CCPA 1970)).



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Example 2: Was a 35 USC 101 statutory double patenting rejection correct?

1. A compound, **3-[5-(2-Fluorophenyl)-[1,2,4]oxadiazol-3-yl]benzoic acid** having the structure:



22. A compound selected from the group consisting of:

3-[5-(4-Chloromethyl-phenyl)-[1,2,4]oxadiazol-3-yl]benzoic acid;

3-[5-(2-Fluorophenyl)-[1,2,4]oxadiazol-3-yl]benzoic acid;

3-[5-(3,4-Difluoro-phenyl)-[1,2,4]oxadiazol-3-yl]benzoic acid;

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Example 2: Question and analysis

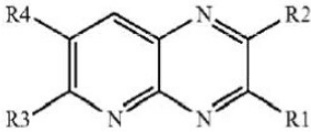
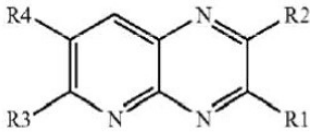
- Claim 1 is provisionally rejected under statutory double patenting (35 U.S.C. 101 DP) as claiming the same invention as that of Claim 22 of copending Application No. xx/xxx,xxx.
- Q. Was the statutory double patenting rejection correct?
 - No
- A 35 U.S.C. 101 double patenting rejection should not be made here as Claim 22 is of different scope than Claim 1 as Claim 22 has more than just Compound A1. However, a nonstatutory double patenting rejection would have been appropriate with an anticipation analysis. One can “at once envisage” all the members of the prior art claim and the claim under examination is one of those species.

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Example 3: Product claim vs. method of use claim

Claims under examination	Patent Claims and Specification
<p>1. A method of modulating function of a kinase, comprising: administering to a subject in need thereof a compound according to formula I,</p>  <p>In which the substituents R1-R4 have the following meaning: R1 and R2 are independently of one another: (i) hydrogen, (ii) hydroxyl, (iii) halogen</p>	<p>1. A pyrido[2,3-b]pyrazine compound of general Formula,</p>  <p>In which the substituents R1-R4 have the following meaning: R1 and R2 are independently of one another: (i) hydrogen, (ii) hydroxyl, (iii) halogen</p> <p>The invention relates to kinase modulators of the pyrido[2,3-b]pyrazine type and to the preparation and use thereof</p>

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Example 3: Question and analysis

- Claim 1 is rejected under nonstatutory double patenting over claim 1 of the patent.
- Q1: Was the NonStatutory Double Patenting rejection correct?
 - Yes
- Q2: Should claim 1 be rejected if no 121 bar exists?
 - Yes
- Q3: Do you need a secondary reference?
 - No
- A nonstatutory double patenting rejection is proper for rejection of claims to methods of use over claims to a compound based on an unjustified timewise extension rationale. *Geneva Pharmaceuticals, Inc. v. GlaxoSmithKline PLC*.

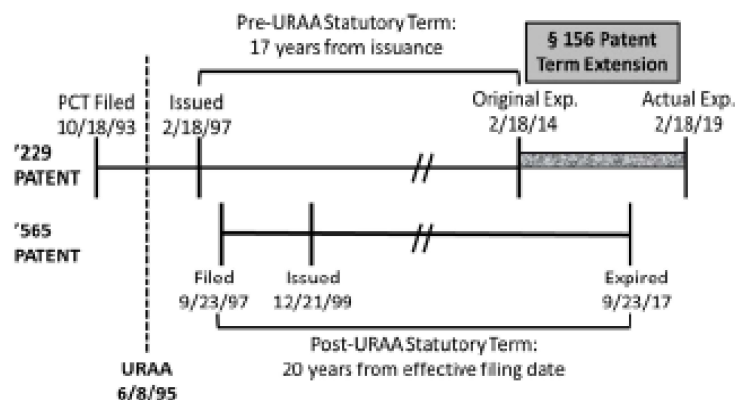
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Impact of PTE on OTDP: Novartis v. Ezra

"229 Patent covers API;" 565 Patent covers method of using the API



In this scenario, public would not be free to use the method claimed in the earlier-expiring patent until expiry of the compound patent:
How does this square with OTDP public policy rationale?



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Impact of PTE on OTDP: Novartis v. Ezra

- The CAFC found in favor of Novartis and reasoned that *Merck & Co. v. Hi-Tech Pharmacal Co.*, 482 F.3d 1317 (Fed. Cir. 2007) applied. In doing so, "as a logical extension" of Merck, ODP "does not invalidate a validly obtained PTE[:]" "[I]f a patent, under its pre-PTE expiration date, is valid under all other provisions of law, then it is entitled to the full term of its PTE."
- Significantly, the Federal Circuit in Ezra also noted that "agreeing with Ezra would mean that a judge-made doctrine [ODP] would cut off a statutorily-authorized time extension." They "decline[d] to do so."



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Example 4

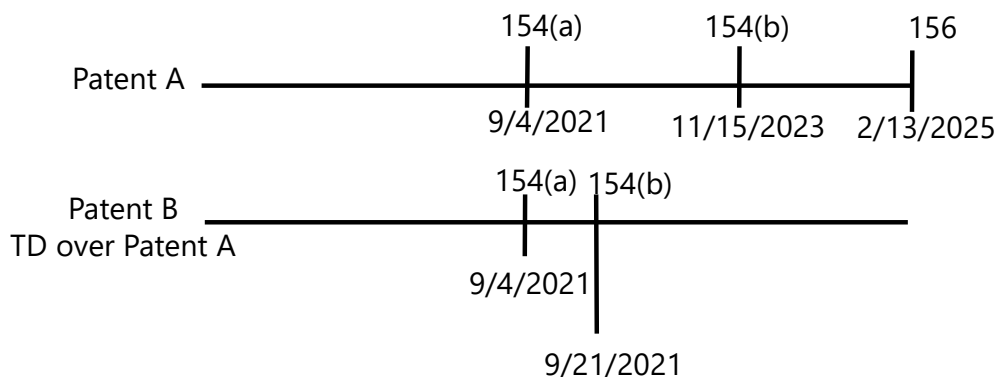
- Patent A — claims API and composition of API, issued 1st
 - 154(a) term ends September 4, 2021
 - 154(b) term is 801 days
 - Original expiration date: November 15, 2023 (154(a) + 154(b) term)
 - NDA Approval date is February 13, 2011
 - Calculated 156 term is 1,025 days, but this exceeds 14-year cap of 156(c)(3)
 - Entitled to extension of 456 days, extended expiry date February 13, 2025
- Patent B — claims specific composition of API, issued 2nd
 - 154(a) term ends September 4, 2021
 - 154(b) term is 17 days
 - Original expiration date: September 21, 2021 (154(a) + 154(b) term)
 - TD filed over patent A



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Example 4

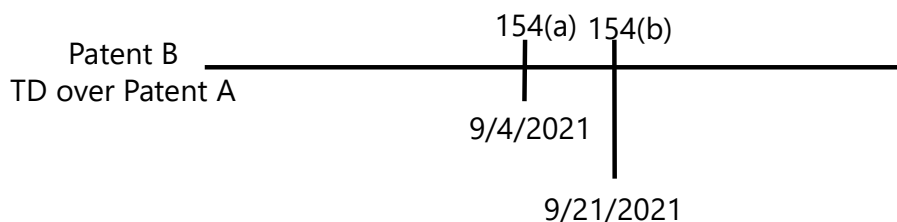
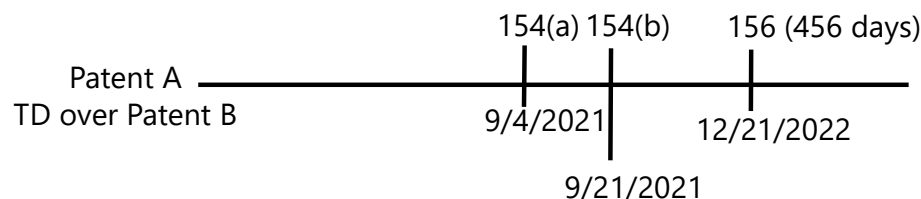
- Patent B was terminally disclaimed over patent A during prosecution. What would be the effect of a terminal disclaimer filed in patent A over patent B, to address OTDP concerns regarding a later issuing, earlier expiring patent?



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Example 4

- Terminal disclaimer of Patent A over Patent B. Their 154(a)+154(b) would expire on the same date and the 156 term would tack on, but instead of expiring on February 13, 2025, it expires December 21, 2022.



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Example 4

- Could Patent A be reissued to address the OTDP issue with patent B?
 - There must be a reissuable error.
 - Opening up patent to all bases of rejection
 - Original patent is surrendered upon grant of reissue (35 U.S.C. 252)
 - Reissue is for the unexpired part of the term of the original patent (35 U.S.C. 251)
 - Depends upon scope of claims in each patent, is there an argument for non-obviousness?

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Thank you!

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Serena Farquharson-Torres

Dr. Serena Farquharson-Torres is an innovation lawyer with over 19 years of experience. She is currently at Bristol-Myers Squibb Company where she is responsible for all aspects of patent procurement, contracts, counseling, due diligence, litigation, R&D Law, regulatory law and policy.

Serena focuses on the global protection of the company's innovation and brands. Serena works closely with R&D, manufacturing, and business colleagues to ensure meaningful exclusivity and freedom of operation for BMS products.

Prior to joining BMS, Serena practiced patent law at Sanofi, Schering-Plough and in private practice at Kenyon & Kenyon. Serena has a B.S. in Chemistry from Howard University, Ph.D. in Biological Chemistry from the University of Minnesota and a J.D. from the University of North Carolina.

Serena frequently provides insight and presents on topics in IP and accelerating diversity and inclusion in the legal profession through leadership roles at BMS and on behalf of law associations and industry groups.



GENDER DIVERSITY IN INNOVATION TOOLKIT

DEVELOPED BY
THE IPO WOMEN IN
IP COMMITTEE

Gender Disparity in Innovation Background

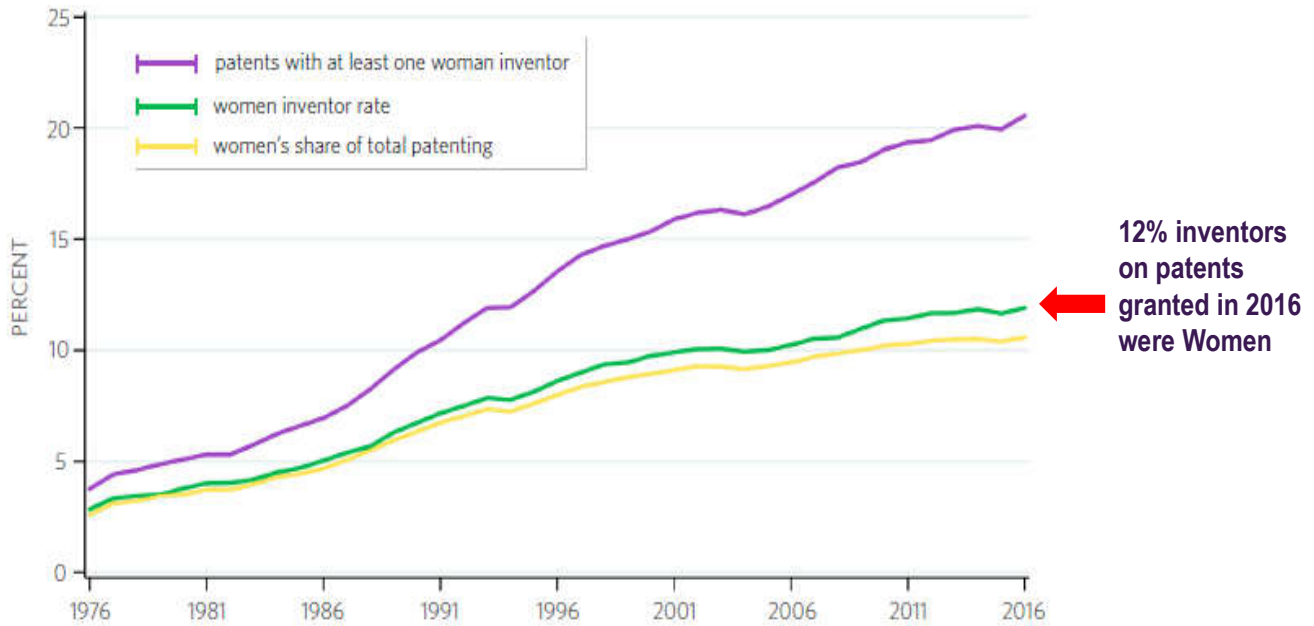
- [WIPO Economic Research Working Paper No. 33](#)

- Identifying the gender of PCT inventors
- November 2016
- Results suggest that there is a gender imbalance in PCT applications, but the proportion of women inventors is improving over time. Also find that the rates of women participation differ substantially across countries, technological fields and sectors.

- [USPTO: Progress and Potential: A profile of women on US Patents Link](#)

- February 2019
- Recent research from Opportunity Insights, a research team based at Harvard shows disparities in opportunity across gender, race, and income.
- ... in 2016 fewer than 12% of all patent inventors were women

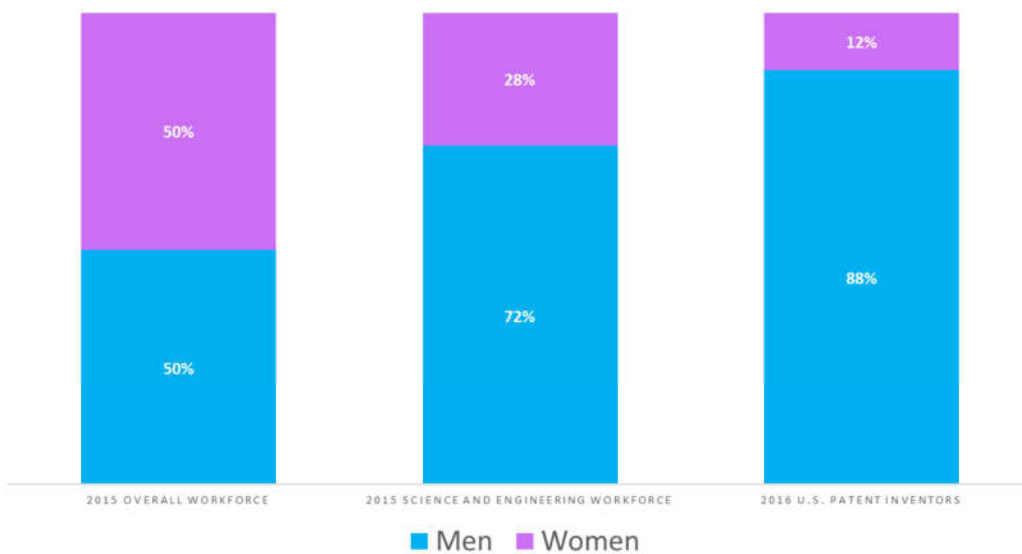
Forty-year trends of women in U.S. patenting



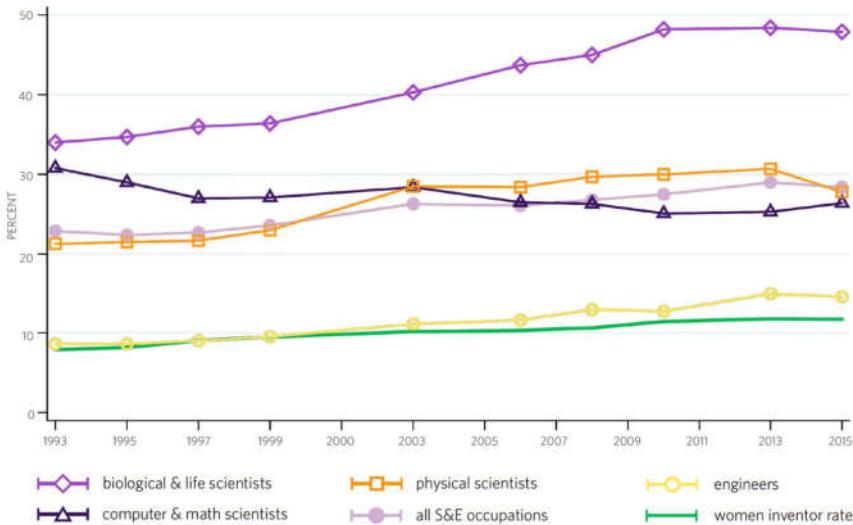
12% inventors on patents granted in 2016 were Women

Source: USPTO Progress and Potential: A profile of women inventors on U.S. patents aims to study U.S. women inventors named on U.S. patents granted 1976-2016

Women inventors in the workforce



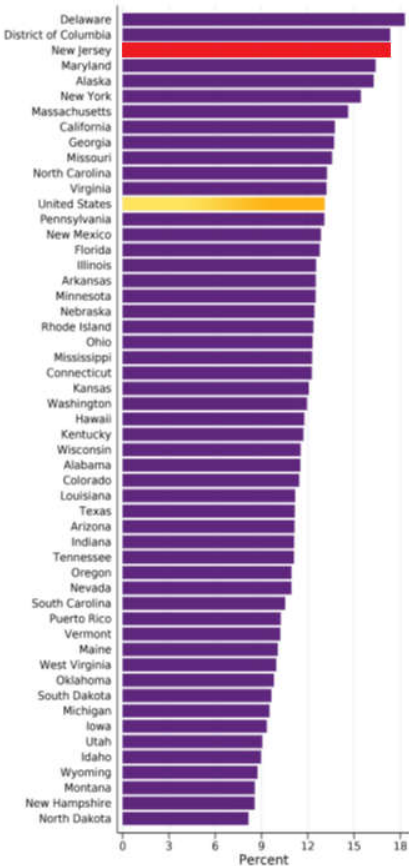
Women Patent Inventors vs. Women in Science and Engineering Occupations



Across nearly all science occupations, women participate at a much higher rate than they invent patented technology.

Source: USPTO Progress and Potential: A profile of women inventors on U.S. patents aims to study U.S. women inventors named on U.S. patents granted 1976-2016

Actual Women Inventor Rate by State, 2012-2016

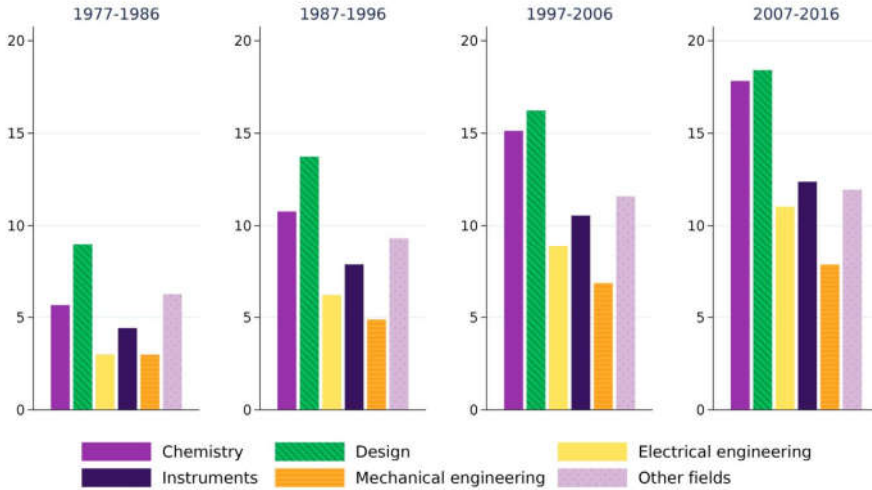


Patenting activity in the United States is heavily concentrated in a few geographical clusters, reflecting both workforce size and technological specialization (Feldman and Francis, 2004). States on both coasts, which host important technology clusters, exhibit higher adjusted and actual women inventor rates.

For 2012–2016 patent grants, women accounted for 17% of inventors residing in New Jersey.

Source: USPTO Progress and Potential: A profile of women inventors on U.S. patents aims to study U.S. women inventors named on U.S. patents granted 1976-2016

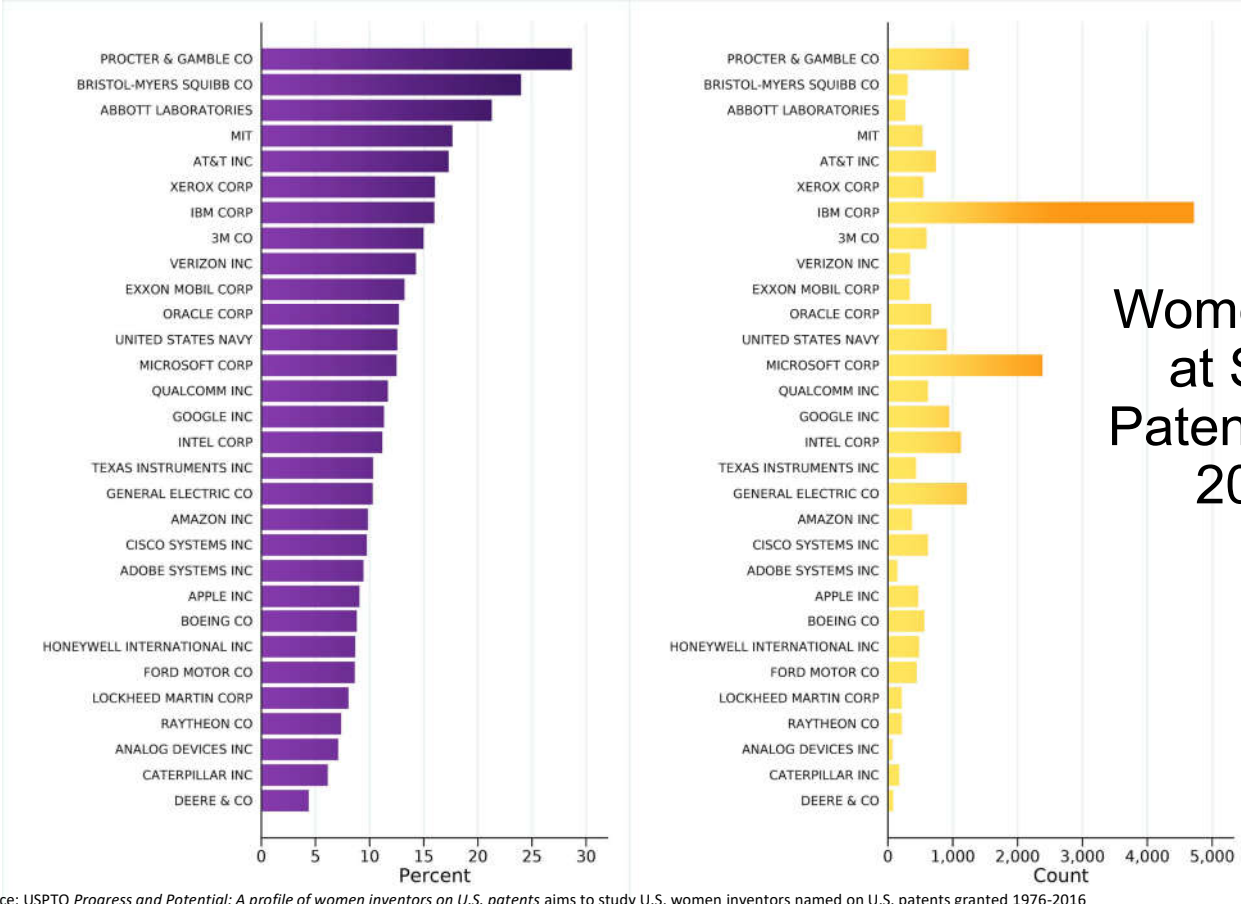
The Women Inventor Rate Across Broad Technology Categories



Although the female share of patent inventors has increased over time in each sector (moving from left to right), there is considerable variation in growth patterns. Women's inventive participation has improved the most in chemistry and design patents. While women accounted for only 6% of inventors on chemistry patents issued 1977–1986, they comprised roughly 18% in the last decade (2007–2016).

In 2016, for example, women accounted for more than one-fifth of inventors granted patents in biotechnology (25% women inventor rate), pharmaceuticals (23%), and organic fine chemistry (21%).

Source: USPTO Progress and Potential: A profile of women inventors on U.S. patents aims to study U.S. women inventors named on U.S. patents granted 1976-2016



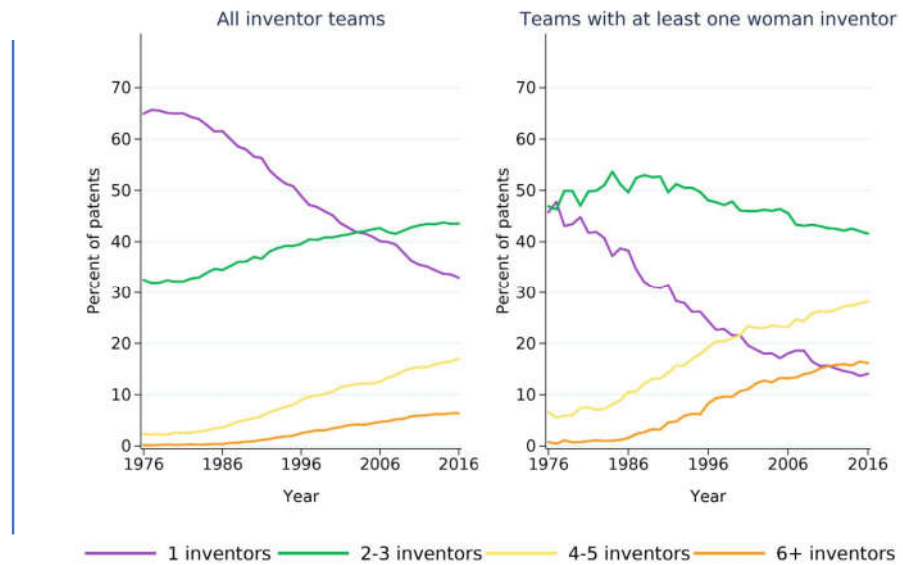
Women Inventors at Select Top Patent Assignees, 2007-2016

Source: USPTO Progress and Potential: A profile of women inventors on U.S. patents aims to study U.S. women inventors named on U.S. patents granted 1976-2016

Share of Patents by Inventor Team Size

Scientific and technological production is increasingly characterized by collaboration among diversely specialized inventors (Jones, 2010; Jones et al., 2008; Wuchty et al., 2007).

Accordingly, patent inventor teams have grown in size. This figure illustrates how the shares of granted patents have changed over time broken out by different team sizes. The panel on the left includes all teams while the panel on the right shows trends for those patent inventor teams with at least one woman.



Source: USPTO Progress and Potential: A profile of women inventors on U.S. patents aims to study U.S. women inventors named on U.S. patents granted 1976-2016

Let's Take a Step Backwards: Diversity and Inclusion

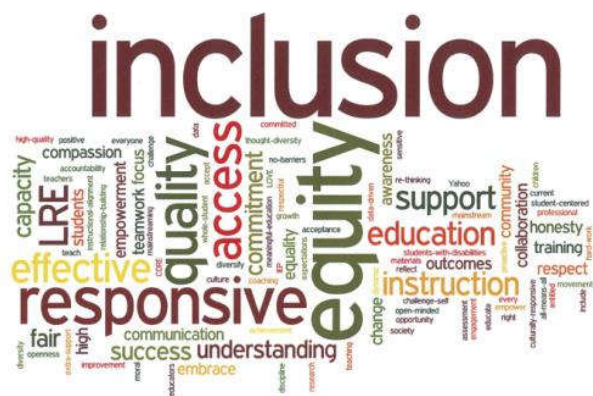


We've seen the data, but let's first take a look at Diversity and Inclusion in general...

- Diversity means different things based on your region or country. Generally speaking, diversity includes gender, age, race, ethnicity, cultures, nationality, physical abilities, sexual orientation, cast, and backgrounds.
- Diversity is any dimension that can be used to differentiate groups and people from one another. In a nutshell, it's about empowering people by respecting and appreciating what makes them different, in terms of age, gender, ethnicity, religion, disability, sexual orientation, education, and national origin.
- Diversity allows for the exploration of these differences in a safe, positive, and nurturing environment. It means understanding one another by surpassing simple tolerance to ensure people truly value their differences. This allows us both to embrace and also to celebrate the rich dimensions of diversity contained within each individual and place positive value on diversity in the community and in the workforce.
- Each individual in an organization brings with them a diverse set of perspectives, work and life experiences, as well as religious and cultural differences.



<https://globaldiversitypractice.com/what-is-diversity-inclusion/>



- Inclusion is an organizational effort and practices in which different groups or individuals having different backgrounds are culturally and socially accepted and welcomed, and equally treated. These differences could be self-evident, such as national origin, age, race and ethnicity, religion/belief, gender, marital status and socioeconomic status or they could be more inherent, such as educational background, training, sector experience, organizational tenure, even personality, such as introverts and extroverts.
- Inclusion is a sense of belonging. Inclusive cultures make people feel respected and valued for who they are as an individual or group. People feel a level of supportive energy and commitment from others so that they can do their best at work.
- The process of inclusion engages each individual and makes people feel valued as being essential to the success of the organization. Evidence shows that when people feel valued, they function at full capacity and feel part of the organization's mission. This culture shift creates higher performing organizations where motivation and morale soar.

<https://globaldiversitypractice.com/what-is-diversity-inclusion/>

Why is D & I Important?



“Diversity fosters creativity. We need to generate the best ideas from our people in all levels of the company and incorporate them into our business practices.”

- Frédéric Rozé, chief executive officer,
L’Oréal USA

- Part of the problem is that “diversity” and “inclusion” are so often lumped together that they’re assumed to be the same thing. But that’s just not the case. In the context of the workplace, diversity equals representation. Without inclusion, however, the crucial connections that attract diverse talent, encourage their participation, foster innovation, and lead to business growth won’t happen.
- Research shows that people with different backgrounds bring new information and alternate viewpoints, that teams with a broader range of experiences and perspectives perform better, and that diverse businesses are more likely to understand the needs of a wider range of customers and clients and are more profitable doing so.
- Research shows a direct link between inclusive decision making and better business performance.
 - Inclusive teams make better business decisions up to 87% of the time.
 - Teams that follow an inclusive process make decisions 2X faster with ½ the meetings.
 - Decisions made and executed by diverse teams delivered 60% better results.

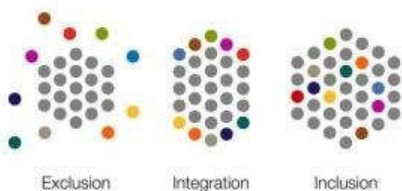
<https://www.forbes.com/sites/eriklarson/2017/09/21/new-research-diversity-inclusion-better-decision-making-at-work/#329f574c4cbf>

“At the end of the day, when you’re creating an environment where people can come together and bring their own views and feel respected, competitively, your company will do so much better,”

- Debbie Storey, senior vice president of talent development and chief diversity officer at AT&T.

D&I: Innovation

- Diversity, inclusion, and innovation are more related than we think, yet organizations often don’t connect these trends.
- A diverse and inclusive workforce is necessary to drive innovation, foster creativity, and guide business strategies.
- Multiple and varied voices have a wide range of experiences, and this can help generate new ideas about products and practices.
- Companies have seen a boost in productivity due to a diverse workforce.



<https://www.digitalistmag.com/future-of-work/2018/08/22/why-diversity-inclusion-matters-from-innovation-perspective-06183094>
https://images.forbes.com/forbesinsights/StudyPDFs/Innovation_Through_Diversity.pdf

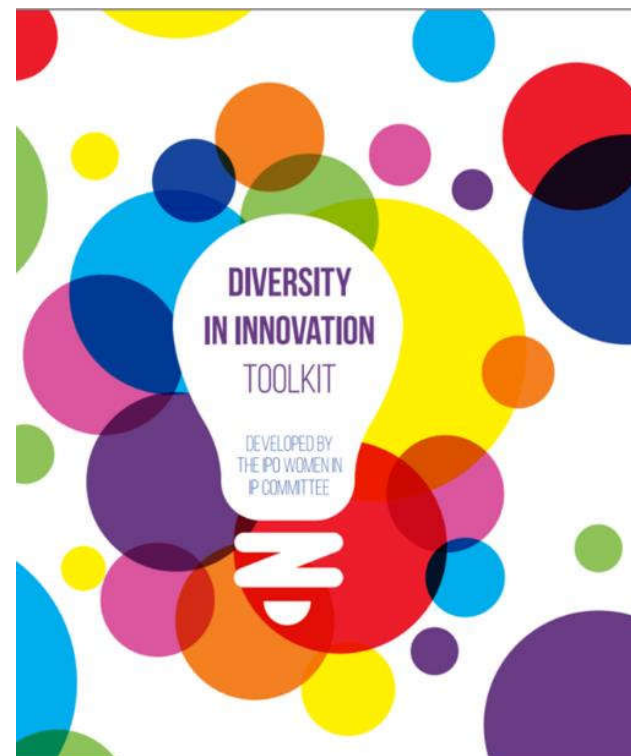
- How do we build and maintain an innovation culture?
 - It is important to look into diversity and inclusion beyond gender and consider more abstract (and difficult to assess) areas such as diversity of thinking. While it's easy to measure gender diversity by counting the proportion of women in the workforce, you can't measure diversity of thinking with numbers and statistics. This makes it even more difficult to generate and maintain diversity of thinking.

<https://www.digitalistmag.com/future-of-work/2018/08/22/why-diversity-inclusion-matters-from-innovation-perspective-06183094>

What Have We Done to Help the Gender Parity in Innovation?

Toolkit Introduction

- The Intellectual Property Owner's Association (IPO) and the Women in IP Committee subcommittee wanted to take action after the World Intellectual Property (WIPO) report showing that slightly less than 30% of PCT applications listed at least one female inventor.
- Created a toolkit to bring awareness to the issue and offer tools to assist people to also bring awareness to the issue, and move toward gender parity in innovation.



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 Not created by the authors for the Intellectual Property
 Association Women in IP Committee to provide background
 facts. It should not be construed as providing legal advice.
 Intans BNA, please CH - click underline text to access.



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- Toolkit available at:

<https://ipo.org/index.php/gender-diversity-in-innovation-toolkit/>

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Gender Parity in Innovation 4-Part Cycle



Gender Parity in Innovation Process

STEP 1 – Increase Awareness & Support	Raising awareness and internal support is an essential first step in making significant change within an organization. Increasing awareness is important in all organizations, but is especially important for those having leaders and/or employees that are largely unaware of gender disparity in innovation and are devoting little effort to addressing this issue. Awareness and support should be an ongoing, regular activity.	Ongoing
STEP 2 – Discover Root Causes	Organizations that are most effective at implementing change are those that spend time up front assessing the key root causes for their current state. As such, organizations that devote time to understanding the causes for their gender disparity will be able to address those specific root causes with targeted programs and thereby be more effective at implementing systemic, long-term change.	
STEP 3 – Develop Short- and Long-Term Programs	Once root causes are identified, organizations should develop a mix of short-term and long-term programs that address the specific root causes identified in step 2. This section is organized by root cause identified and within each root cause chapter suggests short-term and long-term programs that other organizations have found effective at addressing the specific root cause.	
STEP 4 – Launch & Monitor the Programs	This portion of the toolkit focuses on ideas for successful program launch as well as suggested metrics and/or monitoring activities that will enable an organization to measure the success or progress of the gender diversity programs/efforts. This section also provides tips for when and how to go back to steps 1 and 2 routinely to raise awareness and support and to see if new root causes (or unexplored root causes) develop.	

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In the appendix, we have provided sample documents so that your valuable time can be spent working on the issues in your organization rather than creating new documents from scratch. The samples provided are solid drafts for your use in efficiently creating documents that best address your specific organization.

Chapter 1 (Step 1) Increasing Awareness and Support

The goal of this step is to increase awareness and support of the issue of diversity in innovation within your organization.

Chapter Outline:

- Section 1: Initial Executive Level Awareness and Support
 - o Who to Involve
 - o What to Say
 - o What is the “Ask”
- Section 2: Initial Employee Awareness and Support
 - o Target various groupings of employees repeatedly
- Section 3: Ongoing Organization-wide Awareness & Support
 - o Organization-wide spotlights
 - o Social Events / Celebrations
- Section 4: Curated List of Articles on the Topic of Gender Disparity in Innovation and Diversity in Innovation

The first question from many executives is: do we have an issue here at this organization, and what are the statistics for this company/ university?

One way to answer that question is to obtain the [WIPO gender diversity data](#) (or other similar data) for your organization. The WIPO gender diversity data provides the total number of PCT applications filed and the % of these PCT applications with at least 1 female inventor in the previous year. All IPO members can get this information for their organization.

Chapter 2 (Step 2)
Root Cause Assessment

The goal of this step is to identify the key root causes in your organization that contribute to or result in gender disparity in innovation.

Lots of information on commonly used methods to obtain data. Sample surveys and other useful tools.

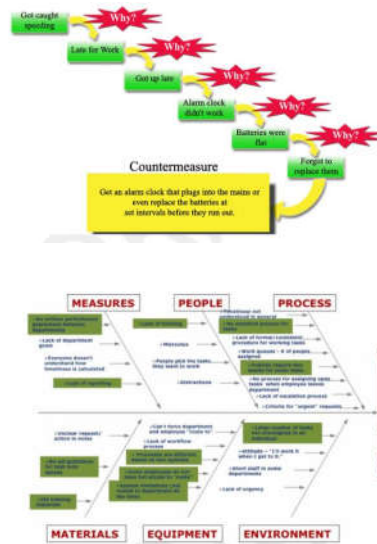
Chapter Outline:

Section 1: 4 Key Steps to Root Cause Assessment

1. Define the Problem
2. Collect Data Relating to the Problem
3. Interpret the Data to Determine What is Causing the Problem
4. Prioritize the Root Causes

Section 2: Collecting and Interpreting the Data

1. Mix-and-Match Data Sources
 - a. Surveys
 - b. Small Group Feedback/Discussion
 - c. 1:1 Conversations
2. Ways to Obtain Data
 - a. The 5 Why Method
 - b. Fishbone or Ishikawa Method
 - c. The Pareto Method
3. Who to Ask



Sample Survey 2
Survey for Underrepresented Inventor Populations¹⁴

Questions are of either (Yes/No) or (Scale 0-1 (disagree completely) to 5 (agree completely))

EXAMPLE: Gender Parity (but could be modified for any type of diversity)

1. Women and men are equally assigned to innovative projects or features at [COMPANY] (1 to 5)
2. Management at [COMPANY] supports improving the representation of women in the patenting program at [COMPANY] (1 to 5)
3. Submitting ideas for patents is an important part of your job at [COMPANY] (1 to 5)
4. Going through the patenting process is a good use of your time (1 to 5)
5. Ideas should be prioritized in order to apply for a patent (1 to 5)
6. I feel confident about or excited about what I can tell company execs if a patent worthy (1 to 5)
7. I know where to go or who to contact in order to submit an idea for patenting at [COMPANY] (1 to 5)
8. The current incentive for submitting a patent application is _____ is this an incentive you'd be interested in? (1 to 5)
9. Most employees are equally likely to be an inventor on a patent application at [COMPANY] (1 to 5)
10. Do you know any women inventors at [COMPANY]? (1 to 5)
11. Have you worked on a project or feature that has been the subject of a patent application? (Yes/No)
 - a. When you filed as an inventor? (1 to 5)
 - b. Being listed as an inventor for the patent application was a positive experience (1 to 5)
12. Have a mentor who has submitted a patent application before (1 to 5)
13. Do you have any other thoughts you'd like to share? (1 to 5)
14. Can we follow-up with you to talk more in a small group or 1:1 about this issue? (1 to 5)

Consider asking, while attempting to maintain anonymity:

- Ask person to self-identify gender, # years at company, what division/tech area you are in, ethnicity, and age range.

¹⁴ Survey prepared by Alison Smith | Perov | H3Mtechnologies.com | Available at alison@h3m.com

Chapter 3 (Step 3)
Develop Short- and Long-Term Programs

People-Related Root Causes

- Inventors or Potential Inventors**
- Lack of awareness of the invention submission process
 - Inventors are too busy
 - Confidence Gap
 - Perfectionist Tendencies
 - Female and Diverse Employees don't self-identify as inventors
- Managers of Inventors or named Inventors**
- Female and Diverse Employees are Not on Programs with High Likelihood of Patent Filing
- IP Professionals (attorneys and agents)**
- Attorneys/Agents Intimidating or Too Busy

Process-Related Root Causes

- Invention Submission / Patenting Process is Biased, Intimidating, or Unclear
- Patenting Process Not Known

Culture/Environment-Related Root Causes

- My Organization Doesn't Support or Is Not Welcoming to Female or Diverse Inventors
- Pipeline / Leaky Pipeline

Exemplary Alignment of Programs to A Root Cause

Female and Diverse Employees Do Not Self-Identify as Inventors

Increasingly, research shows that there is a strong tendency for women or diverse employees to have difficulty self-identifying as an inventor. For example, the most recognized scientists are male (e.g., Einstein, Steve Jobs, etc.) and often the version of a scientist promoted to kids is male (e.g., "Bill Nye the Science Guy"). Outstanding female scientists are not as much a part of mainstream media. On the theory that you can't be it if you can't see it, females and those of under-represented populations interpret this messaging as suggesting that science or being a scientist is not a field or career option open to them. This can propagate through one's career, in that female and diverse employees – even those with technical degrees and verified scientists – do not self-identify as inventors.

Potential Programs:

1. Public Celebration/Recognition of Patenting Activities

Public (internal and/or external to the organization) celebrations of patent activity (patent filing, patent issuance, licensing, etc.) clearly convey the message - through action – that female and diverse employees are inventors. These need not be huge to be impactful. For example, these could be external articles, notices, etc. or internal celebrations company-wide or within a lab. When trying to truly change this perception, volume can be the best weapon – frequent short communications highlighting women and diverse employees as inventors create a new rhetoric that leads to an new implicit message – women and diverse employees across the organization are amazing inventors. Some exemplary recognition communications are provided here and here. Consider using African American, Asian American, Hispanic/Latino

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History, Pride, or Women's History month as a means of touting | specific groups advancing innovation.

2. Affinity Groups for Diverse Technical Employees (Inventors)

Creation of an organization-wide affinity group for diverse and female technical employees/inventors provides these inventors with access to a broad-based, welcoming, and relaxed network of colleagues that can provide support and mentoring as well as frequent reminders that women are amazing inventors.

3. Mentoring and Coaching

Pairing an employee that does not self-identify as being an inventor with a strong and active mentor who is an inventor can help the employee gain comfort with this self-identification. Having a trusted mentor to support an employee increases their confidence and comfort. In many organizations, successful and experienced female inventors mentor less experienced women inventors. Experienced male inventors and/or female inventors from outside the organization also make excellent mentors.

4. IP Professional Engagement

Attorneys and agents write and file the patent applications protecting an organization's valuable inventions. Ensuring that these IP professionals are engaged with the inventive team such that they can identify for themselves who should be rightly deemed an inventor ensures stronger patent protection for the organization and also affords an opportunity for the IP professional to show a female or diverse employee that they are an inventor. Further, truly inclusive IP professionals are skilled at including claims (often dependent claims) in the patent application that permit all members of the team to be included in

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Chapter 4 (Step 4)

Launch & Monitor the Programs

The goal in this step is to effectively launch the programs identified above, monitor and support them, and determine metrics that allow the organization to see progress (or lack thereof). Constant diligence and improvement will allow your organization to flourish.

|

**LAW FIRM COMPLEMENT TO DIVERSITY IN
INNOVATION TOOLKIT²¹**

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**Potential
Next
Steps**



Goals

- **Awareness of the Gender Disparity**
- **Programs to increase innovation gender parity**
 - Awareness of IP Process
 - IDM submission Process (formal and informal submission)
 - Brainstorming Groups
 - Mentorship and Outreach
 - Programs for new inventors, master inventors, and women inventors
 - Managing employees and inspiring future inventors
 - Women resource groups
 - STEM outreach and mentorship
 - Highlight Female Inventors
 - Inventor appreciation banquet

Awareness of the Gender Disparity

- Awareness
 - Shares podcasts, brainstorming sessions, STEM outreach.
 - IPOEF Podcasts:
<https://www.ipoef.org/podcasts/s2-episode-1-lisa-seacat-deluca/>



Programs to Increase Innovation Gender Parity

- Awareness of IP process
- IDM submission process (formal and informal submission)
- Brainstorming Groups
- Mentorship and Outreach
 - Programs for new inventors, master inventors, and women inventors
 - Managing employees and inspiring future inventors
 - Women resource groups
 - STEM outreach
- Highlight Female Inventors
- Other Factors

Awareness of IP process

- Website
- IDM submission process information
- Attorney contact
- Collaborate with women during patent drafting process.



Invention Disclosure Memo Submission Process (Formal and Informal Submission)

- Dropbox
 - Simple submission of an unpolished idea
- Discussion page
 - Potential ideas discussed among coworkers with collaboration across departments
- Invention disclosure memo
 - Formal submission of a complete idea
- IP invention discussion meetings
 - Scientist's presentation in designated IP meeting with technical expert input

Brainstorming Groups

- Pilot Programs
 - Brown Bags (~1 hr) – build awareness
 - Hosted by IP Professional
 - Feature experienced women inventors -> share their story
 - Includes employees in non-technical roles
 - Patent Workshops (~2 hr) – develop disclosure / patent skills
 - Practical skills (~45 min)
 - Active Invent Sessions (~75 min)
 - Seed sourcing
 - Includes OC (focus on including diverse counsel with harvesting/mining experience)
 - What about innovation that doesn't align with your patent strategy?
- Patent Committee Overhaul
 - Ensure adequate diversity on teams involved in IP process
- Additional Ideas from other companies:
 - Metrics for employees. X number of IDM's submitted each quarter.
 - Mentors not only her direct reports but is a mentor for others going through IP process.



What can Patent Attorneys Actually Do?

- Provide key support and information during patent drafting process.
- When determining inventorship, ensure consideration is given to actions and not just how potential inventors talk or sell themselves.
- Advocate for others.

Mentorship and Outreach

- Programs for new inventors, master inventors, and women inventors
 - Women Resource Groups
 - Leadership Groups
 - Development Programs
 - Internal or External Mentorship Opportunities
- Managing employees and inspiring future inventors
- STEM programs
 - Exposure and awareness to high school students regarding future career opportunities
 - Mentorship opportunities with internal and external organizations



Micron Company Initiative

- Great success in increasing number of female inventors.
 - Micron's discovery – only 3 of their ~200 most prolific, active patent inventors were women.
 - Partnered with D&I/Women resource groups, internal business groups, leadership.
 - IP101's and also host sessions where featured experienced women inventors share their story.
 - Hold patent workshops to develop disclosure & patent skills, provide practical skills and hold active invent sessions.

The Program

- **What** – Patent Mentorship Program targeting female inventors.
- **Why** – Increase female participation in Micron's Patent program, further Innovation, promote Collaboration, and aid in female technical retention.
- **Who** –
 - Mentors - Experienced innovators –you do not need to be an "expert."
 - Mentees - Women in a technical role or background that want to become an inventor.
- **When** – Ongoing mentoring program with quarterly networking sessions to connect.
- **How** –
 - Sign up at [WIN/](#) to attend a networking session to connect with other inventors and find a Mentor (sessions held quarterly).
 - Follow the established **Process**.
 - Participate in regular Status Update calls during mentorship session

Micron's Women Innovate (WIN) Program

The Process

Process Steps

1. Mentor/Mentee pairing via Networking Sessions
2. **Register** Mentor, Mentee and Focal Area in the **Mentorship Tracking** list on the [WIN/](#) website, update as progress is made.
3. Add additional members as needed.
4. Hold brainstorming session(s) on the Focal Area chosen and document ideas.
5. Schedule a touch base with Aaron Kraft or Scott Barker to review progress, ask questions, etc.
6. Build out and submit disclosure(s).
7. Review disclosure(s) with patent attorney (may take 1-3 iterations).
8. Review patent application from patent attorney.
9. Sign and Approve patent application.



Female Recognition

- Inventor appreciation banquet
- Patent Awards
- Monetary Compensation
- Employee Recognition

Additional Things to Consider

- Implicit bias
 - Inventorship evaluation
 - Skills training for diversity and inclusion
- Confidence gap
 - Success correlates closely with confidence
 - Perfectionism
 - Awareness
 - Learning to ASK!



Gender Bias in the Workplace Examples

- Women are often expected to do “office housework”: jobs in the office that are not part of their job description, e.g. planning parties, cleaning up after events, taking notes during meetings.
- Women (and other minorities) are disproportionately asked to serve on committees, and expected to contribute to “service” aspects of departmental/workplace life. This puts extra pressure on their time not experienced by many men.
- Women are often expected to do the emotional work in a department, and are less able to “get away” with rude behavior than men. If women are assertive or refuse to agree to the roles expected of them, they are often labeled as “bossy” and seen as less likeable.
- Women are often judged on their appearance - either clothing, weight, attractiveness, or all of the above. Men are rarely judged by appearance, and their appearance is rarely seen as being correlated with competence.
- Women are often talked over or interrupted in meetings by men and other women. Men interrupt people about twice as often as women, and are three times as likely to interrupt women as other men. 87% of the time that women interrupted someone in a conversation, that person was a woman.
- Women making suggestions in meetings can find that no-one responds, and their ideas go unheard. In many cases, a man in the room will later repeat those same ideas and have them acknowledged to general praise. This is often completely unnoticed by people in the room.

Gender Bias in the Workplace Examples

- Women are less likely to get credit during group projects, especially when working alongside men. When women try to claim the credit that is due to them, they are seen as “immodest” and less deserving of success than men who do the same.
- Women tend to get promoted on performance, while men get promoted on potential.
- Women and men are mentored differently – women get mentored, while men get sponsored, and sponsorship leads to more promotions and more extensive networks.
- Women with children are seen as less like “leadership material” and less dedicated to their jobs (the “motherhood penalty”); men with children are seen as better leaders (the “fatherhood bonus”).
- When women express anger in the workplace they are seen as volatile and emotionally unstable. When men express anger they are often seen as strong.
- While men are almost always initially introduced by their full and correct title during conferences/seminars and during kickoff meetings, women often have their titles dropped or misused (e.g. “this is Sarah” or “this is Ms. Field”).
- Women are often “erased” from the room by language that assumes that a whole group is male. E.g. “hey, guys” or “what kind of manpower do we need for that?”



What Else Can be Done?

- Meetings
 - Panels
 - Are they homogeneous in gender, ethnicity, generations?
 - Bring in additional representatives for different views?
 - Staff or Projects
 - Are all attendees drawn into the conversation?
 - Do they all have equal time?
 - Is anyone being talked over or overlooked?
 - If someone is quiet, can the facilitator engage them by name?
 - Speak Up!
 - Wing person!
 - Roles
 - Are the administrative tasks balanced across team members?

What Else Can be Done?

- Assignments/Opportunities
 - Is there a “go to” person consistently chosen?
 - Do you only provide opportunity for people based at your location?
 - As a manager or a delegator, do you make assumptions about a person’s ability based on gender, age, sexual orientation, life/family, or other personal factors?
 - Ex. Employee X does not want to travel because they have small children at home.
 - Ex. Employee Y is not ready for this kind of pressure based on it being a women, LGBTQ, a younger employee, an older employee, an employee with children, former military.

Additional Things to Consider

- We tend to like and relate well to people who remind us of ourselves.
 - This resemblance should not spill over into performance reviews, promotional opportunities, or opportunities in general.
- Research suggests that men and women are assessed very differently at work.
 - Women are more likely to be critiqued for coming on too strong, and their accomplishments are more likely than men's to be seen as the result of team, rather than individual efforts.
 - Women received 2.5 times the amount of feedback men did about aggressive communication styles.
 - Women are described as "supportive," "collaborative" and "helpful" nearly twice as often as men, and women's reviews had more than twice the references to team accomplishments, rather than individual achievements.
 - Women and minorities often evaluated on performance vs. men evaluated on potential.
 - Men were more likely to be given constructive suggestions related to specific skills, while women were more likely to get critical feedback to be quiet and be less aggressive.
 - Avoid attributing women's or minority's contribution to external factors or luck.

New Toolkit Ideas Are Welcome at Anytime

The Toolkit is an evolving documents that needs **YOUR** input

- Share with managers or direct contact / relationships.
 - Involve scientists and IP teams
- Any toolkit can always contain MORE TOOLS. Thus, THE toolkit will evolve through interdustry collaboration (AUTM & IPO) and sharing of best practices from organizations committed to working on this issue.
- To that end, we welcome thoughts, comments, suggestions for things to include in the toolkit, including, for example, root causes, programs or activities, data collection methods or tools, sample awareness documents, etc. Please send any information you are willing to share to Sarah.Hooson@merck.com or to the Women Inventors Subcommittee. All comments are kept strictly anonymous in the toolkit.
- Submit comments via IPO website.





Additional Resources

- [The Gender Patenting Gap](#)
- [Equity in Innovation: Women Inventors and Patents](#)
 - Institute for Women's Policy Research, 2016
 - [Gender in the Global Research Landscape](#)
 - 2017
- [Why Diversity Matters – McKinsey & Co.](#)
 - 2018
- [Gender Differences in Obtaining and Maintaining Patent Rights](#)
 - Nature Biotechnology, April 2018
- [Who Becomes an Inventor in America – The Importance of Exposure to Innovation](#)
 - Harvard – November 2018
- [The Need to Increase Gender Diversity in Innovation and Patenting Testimony Submitted to the Senate Judiciary Subcommittee on Intellectual Property](#)
 - Senate Subcommittee - April 2019



DIVERSITY IN INNOVATION TOOLKIT

DEVELOPED BY
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This paper was created by the authors for the Intellectual Property Owners Association Women in IP Committee to provide background to IPO members. It should not be construed as providing legal advice. Document contains links; please Ctrl + click underlined text to access.



Intellectual
Property
Owners
Association[®]

Elevator Speech

Over 53% of PhDs are awarded to women.

Yet, only 12% of recognized innovators in the United States are women.¹

Women and diverse employees have technical skill and knowledge, yet their contributions are not patented at the same rate as those of their male counterparts. These statistics suggest that our organizations may not be capturing the full contribution of a large segment of our technical workforce - resulting in significant lost opportunity costs (*e.g.*, unpatented inventions, delayed disclosures, *etc.*). The insights and perspectives of women are necessary to solve the monumental challenges our organizations face. This toolkit can help organizations move the needle on achieving gender parity in innovation.

*Document contains links; please **Ctrl + click** underlined text to access.*

¹ National Science Foundation Statistics

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Introduction

The United States Patent and Trademark Office's recently issued *Progress and Potential Report* finds that in 2016 fewer than 12% of all patent inventors were women.² The Institute for Women's Policy Research predicts that, without a concerted effort to change course, it will take until the end of this century to reach gender parity in innovation.³ That literally means that it will take another lifetime to achieve innovative gender parity.

Why does this matter? In many technical fields, patents are linked to promotion and salary increases, so gender disparity in patent application filings and issuances can correlate to gender disparity in advancement and salary within an organization.

Patent activity is also a key metric for venture capital funding,⁴ so gender disparity in patent application filings may correlate to gender disparity in financial support of entrepreneurial activity. Increasing the number of women filing patent applications may help increase the funding to women's entrepreneurial activity.

From an organization's point of view, leaving innovations unpatented equates to lost economic value. Further, empirical studies have found that even though women patent less than men, the quality and impact of their patents are equal to or exceed those of men.⁵ From a societal view, as the PTO stated in its report, "if women, minorities, and low-income children were to invent patented technology at the

² Office of the Chief Economist, U.S. Patent & Trademark Office, *Progress and Potential: A Profile of Women Inventors on U.S. Patents* (2019), <https://www.uspto.gov/sites/default/files/documents/Progress-and-Potential.pdf>.

³ The Institute for Women's Policy Research, *Briefing Paper: The Gender Patenting Gap*, July, 2016.

⁴ Graham, Stuart, J.H., Robert P. Merges, Pam Samuelson, and Ted Sichelman, *High Technology Entrepreneurs and the Patent System: Results of the 2008 Berkley Patent Survey*, *Berkeley Technology Law Journal*, 24(4) (2009).

⁵ McMillan, G., *Gender Differences in Patenting Activity: An Examination of US Biotechnology Industry*, *Scientometrics*, 80, 683-691 (2009).

same rate as white men from high-income households, the rate of innovation in American would quadruple.”⁶

Data shows that innovative gender parity is better in academic institutions than in the business sector,⁷ but patents generated by universities form a small percentage of granted patents because about 85% of all patents are awarded to for-profit companies.⁸ In order to see meaningful improvements, corporations must play a leading role in effecting cultural change to emphasize and reward diversity in innovation.

Gender disparity is not simply a leaky pipeline issue. Pipeline and leaky pipeline issues are rarely the sole root cause of gender disparity. Increasing the pipeline will help, but it is unlikely to resolve all gender parity issues. Further, it takes time to fill the pipeline and maintain the flow.

The Intellectual Property Owner’s Association (“IPO”) and the Women in IP Committee (“WIP”) got involved after the World Intellectual Property (WIPO) report showing that slightly less than 30% of PCT applications listed at least one female inventor.

The Women Inventors Subcommittee (of the WIP) was formed to address these issues. The goal of IPO and WIP is to bring awareness to the issue of gender disparity in innovation and to offer tools to assist IPO member organizations to bring awareness and move toward gender parity in innovation. In June 2018, the IPO Board of Directors approved an alpha version of the Toolkit, and in July 2018, several companies and organizations agreed to test the Toolkit and provide feedback. During the second half of 2018, additional companies and organizations expressed interest in the Toolkit and agreed to test it and

⁶ Office of the Chief Economist, U.S. Patent & Trademark Office, *Progress and Potential: A Profile of Women Inventors on U.S. Patents* (2019), <https://www.uspto.gov/sites/default/files/documents/Progress-and-Potential.pdf>.

⁷ World Intellectual Property Organization, *Economic Research Working Paper No. 33, Identifying the Gender of PCT Inventors*, November 2016.

⁸ National Science Foundation, *Science and Engineering Indicators 2018*, available at <https://nsf.gov/statistics/2018/nsb20181/report/sections/invention-knowledge-transfer-and-innovation/invention-united-states-and-comparative-global-trends>.

provide feedback. In early 2019, the WIP sought feedback from the companies and worked on a beta version of the Toolkit. In May 2019, the IPO Board of Directors approved the beta version, providing approval for a launch concurrently with the 2019 Annual Meeting.

Using the Toolkit, and ultimately improving gender parity in innovation within an organization, has many benefits. Some of the benefits include: helping to stem the flow of the leaky pipeline (or fill the pipeline with new inventors); helping to create an inclusive culture within the organization where the innovative ideas and contributions of female and diverse employees sought after and valued; and helping to bring greater value to organizations. Simply put, gender parity in innovation is imperative for the nation's innovation policy and global competitiveness.

We hope that you find this toolkit useful and that you are willing to share your input and ideas on how to improve the toolkit with us. We are always looking to improve upon the toolkit, and we are stronger and better when we have more ideas included in the toolkit. So, please contact us to provide input, brainstorm, or find ways we can partner on this important issue.

Sandra Nowak & Michelle Bugbee

Co-chairs of the Women Inventors Subcommittee of IPO Women in IP Committee

Mercedes Meyer

Founding Member of the Women Inventors Subcommittee of IPO Women in IP Committee

Committee Members

Monica Adjemian
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How to Use This Toolkit

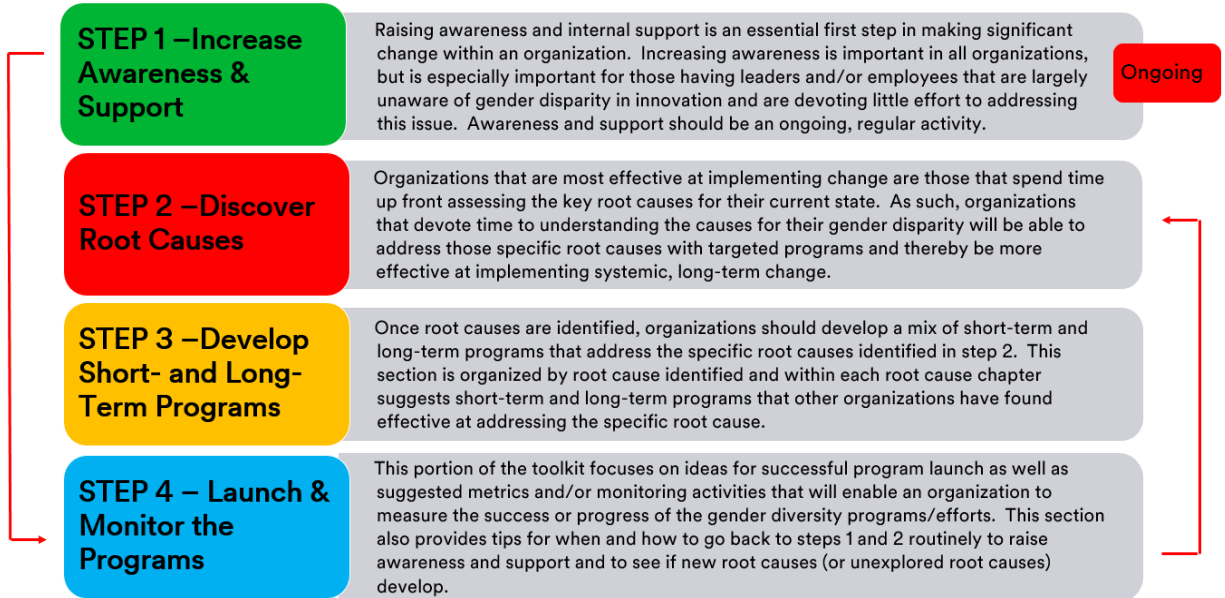
WHO: This toolkit can be used by any organization, including, for example, corporations and universities, to improve their gender parity in innovation. It can be used by Intellectual Property (“IP”) Professionals, Research & Development (“R&D”) leaders, Human Resources (“HR”) professionals, and/or Diversity & Inclusion (“D&I”) professionals.

HOW: The toolkit is best used by understanding the 4-step process highlighted on pages 9 to 11. Then reading through and tackling each of those steps in turn within your organization. We have provided sample communication and other documents so that your valuable time can be spent working on the issues in your organization rather than creating new documents from scratch. The samples provided are solid drafts for your use in efficiently creating documents that best address your specific organization.

WHEN: When you’ve read through or used the toolkit, please send your feedback and any information you are willing to share about your organization. We do not attribute anything to any specific organization unless asked to do so, so any input will remain confidential and will help make the toolkit stronger and better for other organizations also working on this issue.

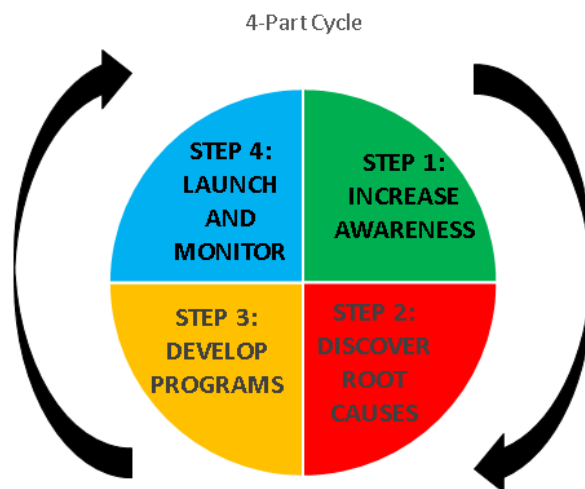
Gender Parity in Innovation 4-Part Cycle

Gender Parity in Innovation Process



4

Importantly, the 4 steps above are not performed only once, but rather are iterative. In other words, the steps are circular rather than linear, as shown in the graphic below:



A description of each of the 4 steps is below:

- **STEP 1 –Increase Awareness & Support**

Raising awareness and internal support of gender disparity in innovation is an essential first step in making significant change within an organization. Increasing awareness is important in all organizations, but is especially important for those having leaders and/or employees that are largely unaware of gender disparity in innovation and are devoting little effort to addressing this issue. Awareness and support should be an ongoing, regular activity.

- **STEP 2 –Discover Root Causes**

Organizations that are most effective at implementing change are those that spend time up front assessing the key root causes for their current state. As such, organizations that devote time to understanding the causes for their gender disparity will be able to address those specific root causes with targeted programs and thereby be more effective at implementing systemic, long-term change.

- **STEP 3 –Develop Short- and Long-Term Programs**

Once root causes are identified, organizations should develop a mix of short-term and long-term programs that address the specific root causes identified in step 2. This section is organized by root cause identified with suggested short-term and long-term programs that other organizations have found effective at addressing each specific root cause.

- **STEP 4 – Launch & Monitor the Programs**

This portion of the toolkit focuses on ideas for successful program launch as well as suggested metrics and/or monitoring activities that will enable an organization to measure the success or progress of the gender diversity programs/efforts. The metrics and monitoring activities will also enable organizations to identify and augment programs that produce superior results, as well as share these results with other organizations through the toolkit. This section also provides tips for when and how to routinely go back to steps 1 and 2 to raise awareness and support and to see if new root causes (or unexplored root causes) develop.

Chapter 1 (Step 1)

Increasing Awareness and Support

The goal of this step is to increase awareness and support of the issue of diversity in innovation within your organization.

Chapter Outline:

- Section 1: Initial Executive Level Awareness and Support
 - Who to Involve
 - What to Say
 - What is the “Ask”

- Section 2: Initial Employee Awareness and Support
 - Target various groupings of employees repeatedly

- Section 3: Ongoing Organization-wide Awareness & Support
 - Organization-wide spotlights
 - Social Events / Celebrations

- Section 4: Curated List of Articles on the Topic of Gender Disparity in Innovation and Diversity in Innovation

Chapter 1. Section 1: Executive Level Awareness and Support

Executive engagement is critical and essential for success. This section of the toolkit provides information on who to initially involve, what to say, and what to ask for to drive executive-level support at the beginning of this initiative.

Who to Involve:

All organizations are different so determine what works best for your organization. Some possibilities to consider include: Chief Diversity and Inclusion Officer, Sustainability Officer, Chief IP Counsel, Chief Technical Officer, Technical Directors, Lab Managers, HR professionals, and Business Executives. In many instances, no more than 5 people (aside from you) may be best to facilitate an open dialogue on the issue. If possible, include at least one person who can drive a cultural change within your organization, either through position or personality (preferably both).

What to Say

You know your team best, so use your best judgment. Some materials to consider include those linked in the box on the right. Organizations vary, so make these pitches your own. Please send any suggestions for modifications or testimonials of what worked for your organization. Additionally, reference the curated articles/publications list at the end of this section to help you generate your discussion outline and presentation materials.

What to Say Sample Materials:

[Elevator Speech](#)

[Sample 1:1 Pitch
Materials](#)

The first question from many executives is: do we have an issue here at this organization, and what are the statistics for this company/ university? One way to answer that question is to obtain the WIPO gender diversity data (or other similar data) for your organization. The WIPO gender diversity data provides the total number of PCT applications filed and the % of these PCT applications with at least 1 female inventor in the previous year. If you are an IPO member, you can get this information by emailing Hannah Denny at IPO.

Another way to answer this question is to run the publicly available WIPO algorithm⁹ that assigns a gender to a name and run that algorithm on your organization's data to determine the gender breakdown of inventors.

Consider whether your organization should additionally or alternatively gather gender disparity data specific to them. To be clear, this is not a required step, as macroscopic data is available for most organizations using the methods identified above. However, some companies do not believe the PTO or WIPO data unless they gather it themselves. Gathering this data for a large, global organization can be both time-consuming and challenging (given varying HR rules globally). Many organizations do not routinely track gender of inventors in docketing databases. For companies/universities who choose to gather their own data, some best practices that have met with successes include the following:

⁹ Please see WIPO algorithm in footnote 4 of Working Paper No. 33.

- Run the publicly available gender-name association algorithms on your organization's data.
- Contact your HR department. Many HR organizations have an employee database in which employees designate their preferred gender. If you provide HR with a list of employees, they can often generate a report summarizing high-level information for use in your diversity in innovation assessment.
- Assign or hire someone in your organization to go through the inventor data for your organization in a given timeframe and identify each inventor's gender (based on knowledge, internet searching, etc.).

Other potential information to consider include

- How many inventors (assess both male and female) are repeat inventors?
- What is the correlation between patent filing and product launch for patents including women versus patents not including women? Data has shown that patents including women are, overall, more commercially successful.
- What is the correlation between patents and associated product sales for patents including women inventors and for patents not including women inventors? Data has shown that patents including women are, overall, more commercially successful.

Self-Assess Your Organization for Gender Parity in Innovation

The following self-assessment can be useful in assessing your organization and turning that assessment into meaningful discussions of needs and next steps.

Gender Parity in Innovation Organizational Self-Assessment

1 - <u>Pre-Aware</u>	• Our leaders and/or employees are largely unaware of gender disparity in innovation and have few or no active programs to create awareness and/or address this issue.
2 - <u>Aware</u>	• Our leaders are aware of gender disparity in innovation and we are bringing awareness to the larger organization as a whole, but we have few or no active programs to address gender disparity in innovation.
3 - <u>Align</u>	• Our leaders and employees are aware of gender disparity in innovation and promote an atmosphere of inclusion and awareness and have a few active programs to address gender disparity in innovation.
4 - <u>Integrate</u>	• Our leaders and employees are aware of gender disparity in innovation and have numerous active programs to address gender disparity in innovation.
5 - <u>Sustain</u>	• Our leaders and employees are aware of gender disparity in innovation and have numerous active programs to address gender disparity in innovation. Further, my organization actively tracks metrics around this issue and/or communicates our commitment to addressing this issue externally. Our organization is a change agent for gender parity.

4

For companies in the “pre-aware” and “aware” categories, their time is best spent initially focusing their efforts on increasing awareness before moving to the next steps.

For companies in the “align” category, their time is best spent assessing root causes and using those assessments to direct programs to these root causes.

For companies in the “integrate” and “sustain” categories, their time is best spent on developing metrics, identifying new or additional programs, celebrating successes, and confirming that no new root causes are arising in the organization (i.e., returning to Step 1).

What is the “Ask”?

Carefully consider your “ask.” Many organizations spend the first portion of their executive meeting creating awareness and walking through the 4 steps of the toolkit at a high level. The second half of the meeting is often spent getting support for a specific request(s). Most organizations ask executives for one of the following two options:

1. A request for (1) support for increasing awareness (and a plan to do so); and (2) support for investigating root causes (and a plan to do so).
2. A request to (1) identify and devote resources to assess the gender diversity statistics for the organization and (2) once this information is obtained, reporting out to the executives and recommending next steps.

Chapter 1. Section 2: Diverse and Female Employee Awareness & Support

Awareness and engagement of employees throughout the organization are both necessary for success. This section recommends ways to initially engage employees at all levels of the organization.

Increasing awareness of the gender disparity issue at various levels in the organization can be effective, even if these groups have overlapping membership. Increasing awareness takes more than a single presentation. Further, awareness presentations should not be limited solely to diverse groups, as success will require awareness and engagement by non-diverse advocates, mentors, and coaches. We have found that women and men alike are unaware of the disparity. Some exemplary groups to bring awareness to include:

- Affinity Groups
 - *e.g.* Women's Leadership, African Americans Network, Hispanic Networks, Latin Americans Networks, Pride Networks, Asian Americans Networks, etc.
 - Consider also soliciting information on root causes for disparity with these groups, as is described in greater detail in Chapter 2.
- Leaders/Managers
 - Update leaders and managers and brainstorm best practices for how to increase and support diversity in innovation in each organization. The presentations can be tailored to each individual group within the larger organization, increasing the chance of overall success.

- Laboratory Groups and/or Technology/R&D Meetings
 - *e.g.* Address the issue during routine management/lab team meetings (such as monthly or quarterly meetings).
 - This can be a great time to identify non-diverse or female employees who are passionate about this issue and can be mentors, advocates, or coaches.
- Small development groups of female or diverse employees:
 - *e.g.* Lean In™ Circles

A sample presentation for use at such events to create initial awareness is attached [here](#).

Chapter 1. Section 3: Ongoing Organization-Wide Awareness

As your organization continues the journey toward gender parity in innovation, it's crucial to routinely update the organization on the efforts and celebrate successes. Providing routine updates at some frequency not only creates positive buzz around these efforts and behaviors but also keeps this topic in the forefront for leaders and employees throughout the organization.

Some quick-hit ways to continue and build organization-wide awareness include the following:

- Organization-Wide or Group-Wide Spotlights
 - These remind people that there are women and diverse inventors and help women and diverse employees self-identify with others.
 - Sample ideas: all organization or group emails, posts on internal websites, presentations, etc. that focus on the research, patents, milestones, personal stories, licensing wins, patent litigation wins, etc. of individuals.
 - Samples available [here](#) and [here](#) and [here](#) and [here](#).
- Social Events and/or Celebrations for Diverse or Female Inventors
 - These events provide networking opportunities and awareness of the work being done.
- Social Medial Spotlights
 - Highlight women and diverse inventor achievements, such as patent or trademark filings or personal stories of achievement.

Chapter 1. Section 4: Curated List of Articles on the Topic of Gender Parity in Innovation

- **WIPO Economic Research Working Paper No. 33**
- **Institute for Women's Policy Research: Gender Patenting Gap**
- **Stanford University: Gender Analysis of Invention Disclosures**
- **Institute for Women's Policy Research: Equity in Innovation - Women Inventors and Patents**
- **PTO Progress & Potential Report**
- **McKinsey & Company: Why Diversity Matters**
- **Josh Bersin: Why Diversity and Inclusion Has Become a Business Priority**
- **Harvard Business Review: How Diversity Can Drive Innovation**
- **Science Magazine: How Scientists are Fighting Against Gender Bias in Conference Speaker Lineups**
- **IPWatchdog on USPTO Report: Only Four Percent of Patents Name Women-Only Inventors Over the Last Decade**
- **NYSBA Journal: Accelerating Talent**
- **MIT White Paper: Who Becomes an Inventor in America**
- **Association of University Technology Managers: Gender in the Global Research Landscape**
- **New York Times: Picture a Leader: Is She a Woman?**

- **Chemical & Engineering News: Coming Out in Chem Class**
- **AUTM: Women Inventor's Toolkit**
- **Yale University: Why Do Women Inventors Win Fewer Patents?**
- **USPTO Inventor Info Chat**

Chapter 2 (Step 2)

Root Cause Assessment

The goal of this step is to identify the key root causes in your organization that contribute to or result in gender disparity in innovation.

Chapter Outline:

Section 1: 4 Key Steps to Root Cause Assessment

Section 2: Collecting and Interpreting the Data

1. Mix-and-Match Data Sources
 - a. Surveys
 - b. Small Group Feedback/Discussion
 - c. 1:1 Conversations
2. Ways to Obtain Data
 - a. The 5 Why Method
 - b. Fishbone or Ishikawa Method
 - c. The Pareto Method
3. Who to Ask

Chapter 2. Section 1: Root Cause Assessment

Often, after identifying that a problem exists, we immediately seek to resolve the problem. For example, if you break your arm, pain medicine will remove the pain (the symptom), but the root cause (the broken bone) must be addressed before you can properly heal. With complex problems, like lack of gender parity in patenting, the long-term results are far superior when adequate time is first spent identifying root causes for the disparity. Initially identifying the root causes allows an organization to tailor efforts to specifically address the root causes for the disparity, thus enabling faster correction and higher levels of success. By eliminating the root causes of the problem, organizations can take measures to eliminate or reduce the recurrence of the problem. The research required to identify the root causes is hard work. But it is essential for long-term success, especially in organizations that are focused on continued improvement.

At the highest level, root cause analysis involves 4 basic steps:

1. Define the problem
2. Collect data relating to the problem
3. Interpret the data to determine what is causing the problem
4. Prioritize the root causes

For purposes of this toolkit, we assume the premise is a lack of diversity in innovation/patenting, as shown from current studies and data. Some ideas for ways to collect data are as follows.

Chapter 2. Section 2: Collecting and Interpreting Data

The most reliable data is gathered by using a variety of collection methods. Specifically, it is preferable to collect data from each of the following (1) large groups; (2) small groups; and (3) individuals. Large groups provide high-level data and facilitate inclusion of many different viewpoints. Smaller groups provide access to more nuanced data and give access to examples that illuminate the larger points derived from the large groups.

Data Obtained from Large Groups:

Collection of data from large groups is typically best accomplished through a survey(s). Optimal surveys are short and high-level. They permit organizations to get a pulse on the issue/problem. Sample surveys are available [here](#) and [here](#). These specific surveys were sent to all technical employees and legal staff in large organizations. In such organizations, it is imperative to keep the number of questions to a minimum because the longer the survey, the less likely that people will take the time to respond. Another best practice is to provide an opportunity for survey respondents to write in any specific comments and/or to provide small group or individual discussion(s) or feedback on the topic. Providing an opportunity for small group or individual feedback can be a great way to incentivize passionate people to get involved and further the discussion and collection of data in small groups or 1:1.

Small Group Discussion and 1:1 Discussion(s):

Small group and 1:1 discussion(s) typically provide the richest and most nuanced data, as well as the personal stories that bring the high-level data to life. There are 5 popular methods or tools to use when obtaining this data. Feel free to mix-and-match these:

A. 5 Why Method

At the most basic, 5 Why Method involves asking “why” 5 times (or more) in order to get to the true root cause. A useful graphic that shows how this practice can help get to the “true” root cause is below:

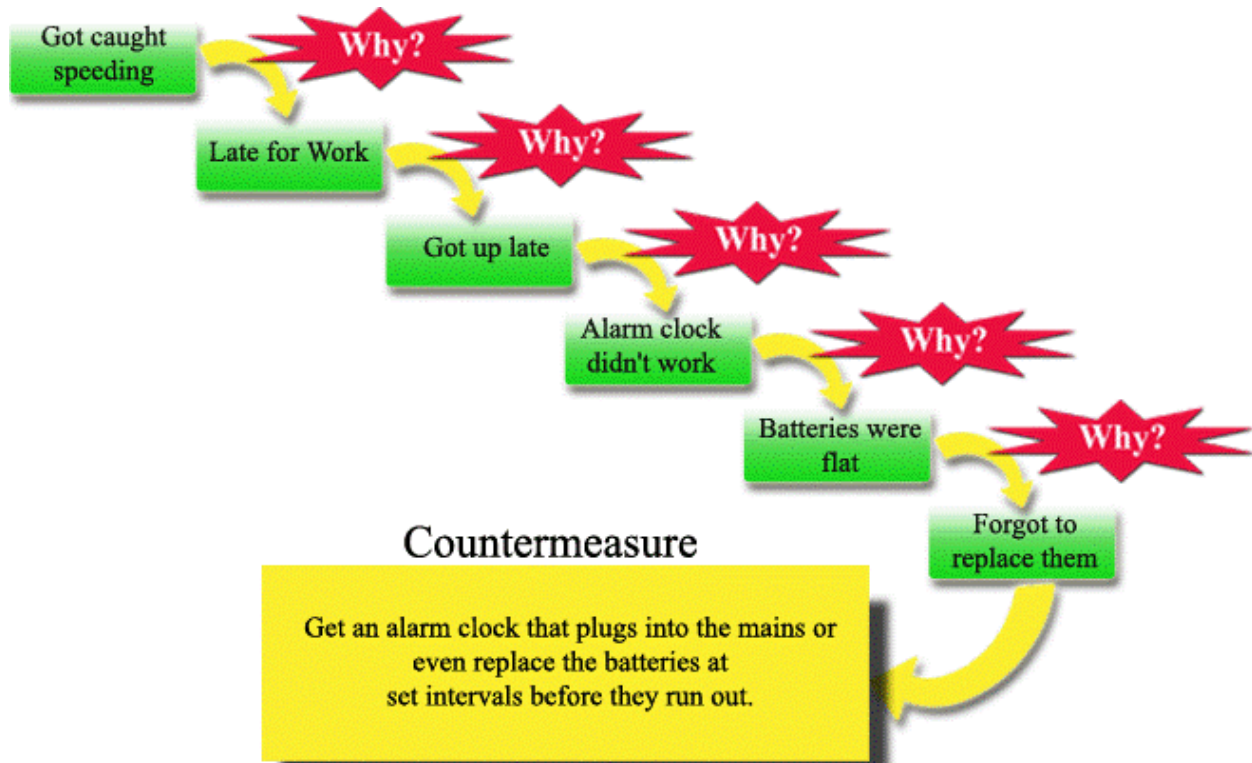


Image source - <http://www.educational-business-articles.com/5-whys/>

The 5 Why Method can be especially effective in brainstorming or 1:1 sessions. The 5 Why Method can be combined with traditional brainstorming (where small groups discuss all possible causes for the problem and possible solutions) or with brain-writing (which focuses on individuals writing their thoughts instead of vocalizing them). Brain-writing can be an excellent way to get the thoughts and opinions of less vocal participants. Once root causes are captured, they can be categorized.

B. Fishbone or Ishikawa Method

Invented by Dr. Ishikawa, the Ishikawa Method involves the following steps:

1. Define the problem
2. Brainstorm with the team on possible root causes of the problem
3. Use the relevant M's while doing so:
 - a. Man (People) – individuals performing the process or involved in it
 - b. Machine (Equipment) – tools used within the process
 - c. Method (Process) – procedures followed
 - d. Materials – inputs to the process
 - e. Measures– data on input
 - f. Mother Nature (Environment) – the environment
4. Prioritize all of the causes under the relevant M's

A sample graphical depiction of the output of this method is as follows:

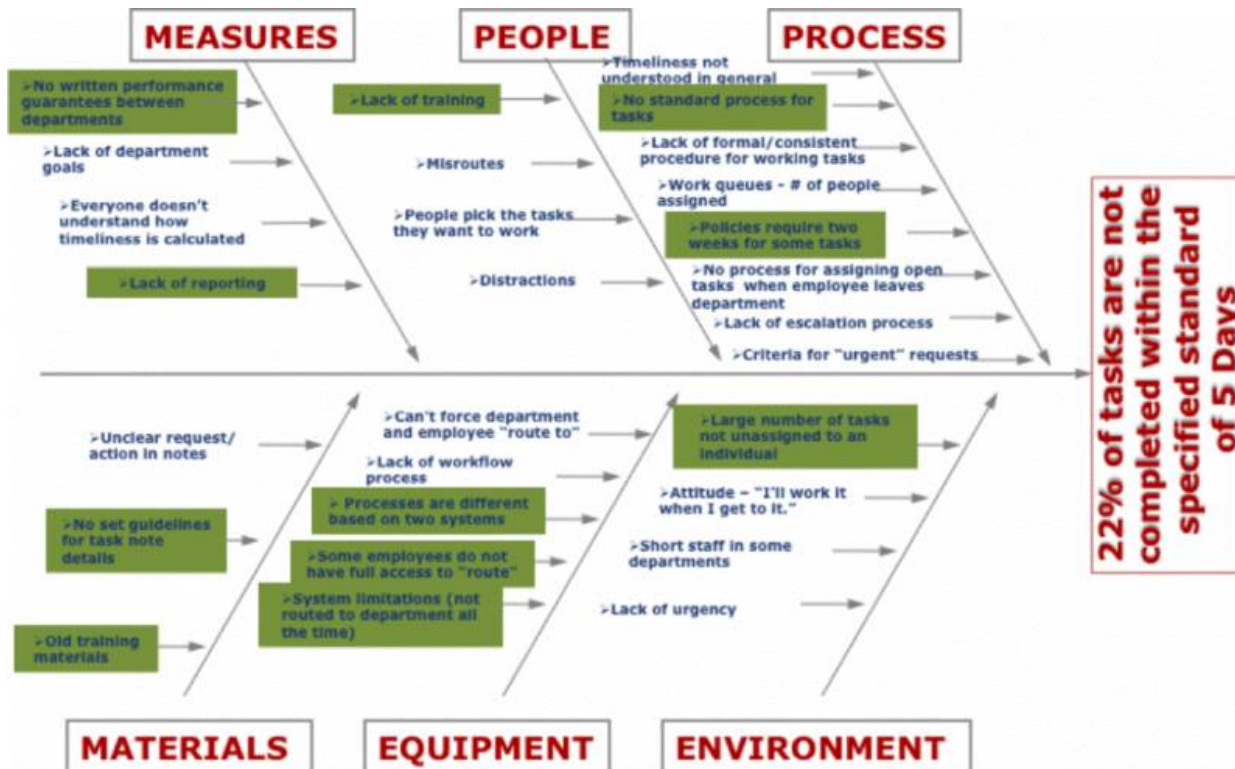


Image source - <https://goleansixsigma.com/achieving-a-19-improvement-in-response-time-using-a-cause-and-effect-diagram/>

Once the root cause brainstorm ideas are prioritized, the major root causes are highlighted. Brainstorming for solutions of the major causes is the next step.

With specific reference to the issues of gender disparity in innovation, many of the M's apply. For example, some of the programs to address root causes discussed in Chapter 3 (Step 3) fit well under the M's as follows:

Man / People

- ❖ Female technical employees typically have strong perfectionist tendencies and often do not submit their inventions for patenting because they are never “perfect”
- ❖ Female technical employees tend to underplay their contributions or the impact of them, which may lead to not submitting their inventions for patenting or not being appropriately listed as an inventor on an invention

Machine

- ❖ The invention submission process may be unknown or not well understood to everyone in the organization, especially diverse employees who have not submitted inventions for patenting

Method

- ❖ The decision-makers for patent filing authorization (i.e., patent review committee) may be all or mostly men, which can be intimidating to female and diverse inventors

Material

- ❖ Inventions are conveyed to an IP professional by word of mouth, and some IP professionals fail to effectively communicate with diverse employees, never realizing that there is a communication issue

- There is a lack of information or consistency (no clear understanding or process) on what is required for an invention to merit patent filing

Mother Nature / Environment

- ❖ The culture of the organization does not put women on key technical programs that lead to patents
- ❖ Women may be in job roles that do not naturally lead to inventions that are typically patented (for example, analytical roles)

Some organizations have found this method and process quite useful in their efforts to improve their gender parity in innovation.

C. Pareto Method

The Pareto Method, also called the 80/20 rule, is based on the principle that 80% of the problems or effects come from 20% of the causes. The Pareto Method aims to determine the 20% in order to resolve 80% of the problem. Using the Pareto Method is a good way to scientifically or mathematically assess all of the data gathered in the steps above to determine which key root causes to prioritize.

Standard Pareto Method steps are as follows:

- Define categories or classifications for the causes (*e.g.*, standard questions that all respondents will answer)
- Collect data (*e.g.* respondent answers)
- Calculate the number of occurrences or observations for each of the categories
- Convert the numbers into percentage of total
- Consider preparing graphs or charts to display the data

D. Who to Ask

Who to ask or obtain data from will vary by organization, but the best organizations obtain information from as many stakeholders and impacted people/groups as possible. Some exemplary groups include:

- Upper level corporate management
- Laboratory management
- Technical employees, including laboratory employees and technicians
- Patent attorneys and agents that work with technical employees on innovation
- Manufacturing and/or process engineering and support staff (where applicable)
- Affinity Groups
- HR representatives who interact with or support technical employees

Chapter 3 (Step 3)

Develop Short- and Long-Term Programs

The goal in this phase is to choose or develop both short- and long-term programs that specifically address the key root causes that were identified during the root cause assessment phase. The chapter is organized by root causes. A tabular Root Cause Summary is included on the next page, and the root causes are hyperlinked to direct the user to a more fulsome discussion of that root cause and the suggested programs to address that specific root cause. (Please press **Ctrl** while clicking the underlined text to be directed to the hyperlink.)

As you are aligning programs with root causes, keep in mind that often more than one root cause may combine to create challenges. For example, a lack of awareness of the process to submit inventions for consideration for patenting is included in the toolkit both Root Causes Stemming from Inventors, as well as Root Causes Stemming from the Process. If the lack of awareness is because inventors do not bother to ask and no training or mentoring is provided, that is largely addressed in the People-Related Root Causes section of the toolkit. If the lack of awareness is because the process is hidden, too complex or biased, that is largely addressed in the Process-related Root Causes section of the toolkit. Therefore, after identifying your key root causes, consider all of the possible areas in which those root causes may arise.

Root Cause Summary

<p><u>People-Related Root Causes</u></p>	<p><u>Inventors or Potential Inventors</u></p> <ul style="list-style-type: none">• <u>Lack of awareness of the invention submission process</u>• <u>Inventors are too busy</u>• <u>Confidence Gap</u>• <u>Perfectionist Tendencies</u>• <u>Female and Diverse Employees do not self-identity as inventors</u> <p><u>Managers of Inventors or named Inventors</u></p> <ul style="list-style-type: none">• <u>Female and Diverse Employees are Not on Programs with High Likelihood of Patent Filing</u> <p><u>IP Professionals (attorneys and agents)</u></p> <ul style="list-style-type: none">• <u>Attorneys/Agents Intimidating or Too Busy</u>
<p><u>Process-Related Root Causes</u></p>	<ul style="list-style-type: none">• <u>Invention Submission / Patenting Process is Biased, Intimidating, or Unclear</u>• <u>Patenting Process Not Known</u>
<p><u>Culture/Environment - Related Root Causes</u></p>	<ul style="list-style-type: none">• <u>My Organization Doesn't Support or Is Not Welcoming to Female or Diverse Inventors</u>• <u>Pipeline / Leaky Pipeline</u>

People-Related Root Causes

“People-related root causes” are causes for which the primary source of the root cause lies in the workforce. Thus, the suggested programs involve affecting the workforce/people in the organization. The term is not meant to suggest that the people are the problem, but instead to suggest that targeting programs to assist the employees will provide the highest impact of change.

For purposes of this toolkit, the “people” of an organization are broken down into 3 groups: (1) inventors or potential inventors; (2) managers of inventors or potential inventors; and (3) IP professionals (including attorneys and agents). Because the root causes differ within each of these employee groups, the programs to target these groups also vary.

Inventor or Potential Inventor-Related Root Causes

Inventor or potential inventor root causes are those for which the primary source of the root cause lies in the inventor or potential inventor community. Because inventors on patent applications are not always technical employees, the term “inventors” includes “potential inventors,” including all employees, any of whom could be inventors on a patent application. This includes non-technical employees, first-time invention submitters, managers, legal professionals, technical service employees, application development employees, etc.

Root Cause: Lack of Awareness of the Invention Submission Process

With this root cause, inventors or potential inventors are simply not aware of or familiar with the process or steps required to submit an invention for consideration for patenting. In our busy lives, the task of figuring out a process can seem daunting enough to deter an inventor from submitting his or her idea. Therefore, it is essential in all organizations that the process is clear and known. In this section, the focus is on making employees aware (1) that there is a process and (2) how to access the process as well as making clear that all employees are encouraged to submit their ideas. The Process root cause section addresses making sure that the invention submission process is straight-forward, unbiased, and accessible to all.

Potential Programs:

1. Organization-Wide Process Awareness Communications

Posting or making available the invention submission process steps (and hyperlinks to any required documents) on an organization-wide system (e.g., an internal website) is a simple step that can generate big results quickly. When paired with training opportunities in small group settings (e.g., for an affinity group or laboratory/business), these communications are especially impactful.

2. Regular Communication to Inventor Populations Re: the Process

Regular reminders – especially by leaders, management and/or IP professionals – of the process and management’s support for the process can be quite impactful. Pairing these reminders with celebrations of people who have filed patent application or

obtained issued patents (such as inventor banquets, plaques, recognition in group meetings, etc.) can be especially meaningful.

3. IP Professional Availability and /or Mentoring

Increase access to IP professionals and/or mentors who can educate and support the less experienced or less confident inventors and increase awareness of the process.

Root Cause: Inventors are Too Busy or Do not View Patenting as an Important Part of their Job

Some inventors report that patenting is not an important part of their job or that they are too busy to bother to patent their inventions. For companies that value this activity but hear this from employees, there is clearly a disconnect that needs to be mended. The following are some programs that may assist in correcting the disconnect.

Potential Programs:

1. Public Celebration/Recognition of Patenting Activities

Public (internal and/or external to the organization) celebrations of patent activity (patent filing, patent issuance, licensing, etc.) clearly convey the message - through action – that this is an activity that the company values and promotes and that will be rewarded in an employee’s career. These celebrations do not need to be extravagant or expensive to be impactful. For example, celebrations could be external articles, notices, etc., or internal celebrations company-wide, within a lab, or even just 1:1 between an employee and their manager. Some exemplary recognition communications are provided [here](#) and [here](#).

2. Patent Activity Remuneration

Some organizations show the value of this activity by monetarily rewarding employees for activities like invention submission, patent filing, and/or patent issuance.

Root Cause: Inventors Experience a Confidence Gap that Deters Them From Submitting their Inventions for Consideration

In their 2012 book *The Confidence Code*, Claire Shipman and Katty Kay state that “there is a particular crisis for women—a vast confidence gap that separates the sexes” and “[w]omen feel confident only when they are perfect. Or practically perfect.”¹⁰ This confidence gap can result in women not submitting their ideas for consideration for patenting because they are “not good enough,” “not ground-breaking enough,” or “they are not yet fully fleshed out.” The confidence gap can also result in women who are part of an inventive team being left off the list of inventors in a patent filing. Because of this confidence gap, organizations may not be capturing the full contribution of a large segment of their technical workforce. As a result, the organization can lose the ability to patent-protect its important ideas and/or its patents could be deemed invalid for improper inventorship. These results can cost millions of dollars. This is one of the most common root causes and is likely present, to some extent, in all organizations.

Potential Programs:

1. Mentoring and Coaching

Pairing an employee who is experiencing the confidence gap with a strong and active mentor or coach shows the organization’s belief in and support of that employee, which can bolster the employee’s confidence. Further, strong mentoring can help the employee learn confidence and develop the comfort and communication skills to convey that confidence through speech and action. Mentoring and coaching can also help diverse and

¹⁰ Kay, Katty and Shipman, Claire. “The Confidence Gap.” *The Atlantic* May 2014, <https://www.theatlantic.com/magazine/archive/2014/05/the-confidence-gap/359815/>. Accessed 12 Aug. 2019.

female employees gain greater comfort with self-promotion. Mentors and coaches of course do not need to be of the same gender, color, or ethnicity as the employee being mentored/coached. In many organizations, successful and experienced female inventors mentor less experienced women inventors. Experienced male inventors and/or female inventors from outside the organization also make excellent mentors.

2. Affinity Groups for Diverse Technical Employees (Inventors)

Creation of an organization-wide affinity group for diverse and female technical employees/inventors provides these inventors with access to a broad-based, welcoming, and relaxed network of colleagues that can provide support and mentoring.

3. Management Training

This training can teach managers how to identify employees experiencing a confidence gap. Effective managers provide support and guidance as well as make their employees aware of the programs or support available to assist them. When paired with inclusion training, this can be especially impactful.

4. Employee Diversity and Inclusion Training

Diversity refers to the traits and characteristics that make each person unique while inclusion is a collaborative, supportive, and respectful environment that increases the participation and contribution of all employees.

Inclusion is a team sport, so training the entire organization on inclusive behavior ensures that non-managers working on inventive teams can identify employees experiencing a confidence gap, alert the manager, and/or personally support the employee

and/or make that employee aware of the programs or support available to assist that employee. It has been shown that there is a strong correlation between diversity in the leadership of large companies and financial outperformance, based on a larger data set of 1000 companies in 12 countries.¹¹ Companies in the top quartile for gender diversity on their executive teams were 21% more likely to have above-average profitability than companies in the 4th quartile.¹²

There are various forms of employee inclusion training and programs that can improve diversity attitudes and behavioral intentions to provide an inclusive, respectful and productive workforce and workplace.

Some examples of inclusion training and programs include:

- Team-building exercises.
- Awareness training such as unconscious bias or discussing the perspective of a minority group and the distinct challenges a minority might face.
- Skills training to help people build skills such as communicating better with people from diverse backgrounds and reducing the level of unconscious bias in their decision-making.¹³
- Creating a company focus and strategy on inclusion.
- Creating a college recruitment program targeting diversity.
- Ensuring well-rounded leadership development programs.

¹¹ Hunt, Vivian et al., “Delivering through Diversity.” *McKinsey & Company* January 2018, https://www.mckinsey.com/~media/McKinsey/Business%20Functions/Organization/Our%20Insights/Delivering%20through%20diversity/Delivering-through-diversity_full-report.ashx. Accessed 10 Sep. 2019.

¹² Refer to 13.

¹³ Lindsey, Alex et al., “Two Types of Diversity Training That Really Work.” *Harvard Business Review* July 2017, <https://hbr.org/2017/07/two-types-of-diversity-training-that-really-work>. Accessed 10 Sep. 2019.

- Reviewing company trainings to ensure they portray an inclusive environment.

5. Regular Communication to Inventor Populations Re: the Process

Regular reminders – especially by laboratory and Research & Development management and leaders and/or IP professionals – of the process and management’s support for the process can be quite impactful. To address this confidence gap root cause, such communications (1) should provide sufficient detail for an inventor to better understand the negative ramifications of not submitting an idea (make clear that it is not an issue of the employee being attention-hogging but instead an issue of lost money for the organization and thus poor performance by the employee), (2) describe what ideas are appropriate for submission, and (3) reinforce that the employee will receive support through the invention submission process. Pairing these reminders with celebrations of people who have filed patent application or obtained issued patents can be especially meaningful because then hesitant or first-time inventors see others who have successfully walked this path and can contact those individuals for advice or mentoring.

6. Public Celebration/Recognition of Patenting Activities

Public (internal and/or external to the organization) celebrations of patent activity (patent filing, patent issuance, licensing, etc.) clearly convey the message - through action – that this is an activity that the company values and promotes and that will be rewarded in an employee’s career. These need not be huge to be impactful. For example, these could be external articles, notices, etc. or internal celebrations company-wide, within a lab, or even

just 1:1 between an employee and their manager. Some exemplary recognition communications are provided [here](#) and [here](#).

7. Group Mentoring Innovation Employees

For example, organize or host Lean In™ circles or a similar group construct. Tools for Lean In™ circles are publicly available. Also publicly available are the tools discussed in Russ Harris' book, *The Confidence Gap: A Guide to Overcoming Fear and Self-Doubt* (2011).

Inventors or Potential Inventors Have Perfectionist Tendencies that Deters Them From Submitting their Inventions for Consideration

In their 2012 book *The Confidence Code*, Claire Shipman and Katty Kay found that “[w]omen are more likely than men to be perfectionists, holding themselves back from answering a question, applying for a new job, asking for a raise, until they’re *absolutely 100 percent sure* we can predict the outcome. (Women applied for a promotion only when they met 100 percent of the qualifications. Men applied when they met 50 percent.)”¹⁴ These perfectionist tendencies can result in women not submitting their ideas for consideration for patenting because “more data is needed” or the idea is “not good enough.” Because of this drive for perfectionism, organizations may not be capturing the full contribution of a large segment of their technical workforce.

Potential Programs:

1. Mentoring and Coaching

Pairing an employee who tends toward perfectionist tendencies with a strong and active mentor can help the employee learn and gain comfort with the concept of “good enough” to submit for consideration. Having a trusted mentor to support an employee increases their confidence and comfort. In many organizations, successful and experienced female inventors mentor less experienced women inventors. Experienced male inventors and/or female inventors from outside the organization also make excellent mentors.

¹⁴ Bennett, Jessica. “It’s Not You, It’s Science: How Perfectionism Holds Women Back.” *Time Magazine* 22 Apr. 2014. <https://time.com/70558/its-not-you-its-science-how-perfectionism-holds-women-back/>. Last accessed 12 Aug. 2019.

2. Affinity Groups for Diverse Technical Employees (Inventors)

Creation of an organization-wide affinity group for diverse and female technical employees/inventors provides these inventors with access to a broad-based, welcoming, and relaxed network of colleagues that can provide support and mentoring.

3. Management Training

This training can teach managers how to identify employees whose perfectionist tendencies may be blocking them from submitting their inventions for consideration. Effective managers provide support and guidance, as well as make their employees aware of the programs or support available to assist them. When paired with inclusion training, this can be especially impactful.

4. Employee Diversity and Inclusion Training

Diversity refers to the traits and characteristics that make each person unique while inclusion is a collaborative, supportive, and respectful environment that increases the participation and contribution of all employees.

Inclusion is a team sport, so training the entire organization on inclusive behavior ensures that non-managers working on inventive teams can identify employees experiencing a confidence gap, alert the manager, and/or personally support the employee and/or make that employee aware of the programs or support available to assist that employee. It has been shown that there is a strong correlation between diversity in the leadership of large companies and financial outperformance, based on a larger data set of 1000 companies in 12 countries.¹⁵ Companies in the top

¹⁵ Hunt, Vivian et al., "Delivering through Diversity." *McKinsey & Company* January 2018,

quartile for gender diversity on their executive teams were 21% more likely to have above-average profitability than companies in the 4th quartile.¹⁶

There are various forms of employee inclusion training and programs that can improve diversity attitudes and behavioral intentions to provide an inclusive, respectful and productive workforce and workplace.

Some examples of inclusion training and programs include:

- a. Team-building exercises.
 - b. Awareness training such as unconscious bias or discussing the perspective of a minority group and the distinct challenges a minority might face.
 - c. Skills training to help people build skills such as communicating better with people from diverse backgrounds and reducing the level of unconscious bias in their decision-making.¹⁷
 - d. Creating a company focus and strategy on inclusion.
 - e. Creating a college recruitment program targeting diversity.
 - f. Ensuring well-rounded leadership development programs.
 - g. Reviewing company trainings to ensure they portray an inclusive environment.
 - h.
5. Regular Communication to Inventor Populations Re: the Process
Regular reminders – especially by laboratory management and/or IP professionals – of the process and management’s support for

https://www.mckinsey.com/~media/McKinsey/Business%20Functions/Organization/Our%20Insights/Delivering%20through%20diversity/Delivering-through-diversity_full-report.ashx. Accessed 10 Sep. 2019.

¹⁶ Refer to 13.

¹⁷ Lindsey, Alex et al., “Two Types of Diversity Training That Really Work.” *Harvard Business Review* July 2017, <https://hbr.org/2017/07/two-types-of-diversity-training-that-really-work>. Accessed 10 Sep. 2019.

the process can be quite impactful. To address the perfectionism root cause, such communications should provide sufficient detail for an inventor to better understand when an idea is appropriate for consideration. Pairing these reminders with celebrations of people who have filed patent application or obtained issued patents can be especially meaningful because then hesitant or first-time inventors see others who have successfully walked this path and can contact those individuals for advice or mentoring.

Female and Diverse Employees Do Not Self-Identify as Inventors

Increasingly, research shows that there is a strong tendency for women or diverse employees to have difficulty self-identifying as an inventor. For example, the most recognized scientists are male (*e.g.*, Einstein, Steve Jobs, etc.) and often the version of a scientist promoted to kids is male (*e.g.*, “Bill Nye the Science Guy”). Outstanding female scientists are not as much a part of mainstream media. On the theory that you can’t be it if you can’t see it, females and those of under-represented populations interpret this messaging as suggesting that science or being a scientist is not a field or career option open to them. This can propagate through one’s career, in that female and diverse employees – even those with technical degrees and verified scientists – do not self-identify as inventors.

Potential Programs:

1. Public Celebration/Recognition of Patenting Activities

Public (internal and/or external to the organization) celebrations of patent activity (patent filing, patent issuance, licensing, etc.) clearly convey the message - through action – that female and diverse employees are inventors. These need not be huge to be impactful. For example, these could be external articles, notices, etc. or internal celebrations company-wide or within a lab. When trying to truly change this perception, volume can be the best weapon – frequent short communications highlighting women and diverse employees as inventors create a new rhetoric that leads to an new implicit message – women and diverse employees across the organization are amazing inventors. Some exemplary recognition communications are provided [here](#) and [here](#). Consider using African American, Asian American, Hispanic/Latino

History, Pride, or Women's History month as a means of touting specific groups advancing innovation.

2. Affinity Groups for Diverse Technical Employees (Inventors)

Creation of an organization-wide affinity group for diverse and female technical employees/inventors provides these inventors with access to a broad-based, welcoming, and relaxed network of colleagues that can provide support and mentoring as well as frequent reminders that women are amazing inventors.

3. Mentoring and Coaching

Pairing an employee that does not self-identify as being an inventor with a strong and active mentor who is an inventor can help the employee gain comfort with this self-identification. Having a trusted mentor to support an employee increases their confidence and comfort. In many organizations, successful and experienced female inventors mentor less experienced women inventors. Experienced male inventors and/or female inventors from outside the organization also make excellent mentors.

4. IP Professional Engagement

Attorneys and agents write and file the patent applications protecting an organization's valuable inventions. Ensuring that these IP professionals are engaged with the inventive team such that they can identify for themselves who should be rightly deemed an inventor ensures stronger patent protection for the organization and also affords an opportunity for the IP professional to show a female or diverse employee that they are an inventor. Further, truly inclusive IP professionals are skilled at including claims (often dependent claims) in the patent application that permit all members of the team to be included in the patent (while simultaneously strengthening and broadening the patent coverage).

Manager – Related Root Causes

Manager-related root causes are those for which the primary source of the root cause lies with the managers and/or management team.

Root Cause: Female and Diverse Employees are Not on Programs with High Likelihood of Patent Filing

Certain types of development programs in an organization lead to patent filings while other programs do not. For example, changing the color or raw materials of an existing product can be challenging and important technical work, but often will not result in patent application filings. In contrast, creating a new-to-the-world product or chemical is more likely to lead to patent filings. Many organizations report that women and diverse employees are not put on patent-heavy programs at the same rate as their non-female or non-diverse counterparts. The causes for this disparity are many and varied. Examples range from confidence gap issues keeping female or diverse employee from volunteering for these projects to manager bias against women with young children keeping managers from assigning female employees to these high-profile projects. This version of the toolkit recommends general actions for female and diverse employees not being on programs with high likelihood of patent filing. A best practice is to understand some of the organization-specific sub-causes for this disparity and tailor the programs to address those root causes specifically, and we encourage organizations to dig deeper as they improve their programs.

Potential Programs:

1. Manager Training.

Managers lead organizations so training the managers increases the number of change agents and/or people who can communicate about the issue of disparity in innovation. But managers also need to be able to identify the areas where they can improve. Ensuring that female and diverse employees are placed on programs that lead to invention is something managers can control. Managers can be trained on how to take an honest look at their team and how they have staffed the programs for the laboratory and/or research & development facility. This can create a greater self-awareness of inherent bias and tendencies. Awareness is followed by action to move people onto programs where patents are more likely, where possible, or to put them onto new programs as the programs are getting started.

2. Brainstorming Sessions

For an array of reasons, it is not always possible to move employees onto teams working on programs that are likely to file patent applications. In such instances, managers can sponsor such employees for group brainstorming / inventing sessions. Many companies have company-wide brainstorming/inventing sessions focused on how to solve a specific issue for the company or how to take advantage of a global trend. These brainstorming sessions are typically of limited duration (*e.g.*, 1 day to 2 weeks) and give the employee the opportunity to engage in innovation activities that are likely to result in patent application filings without changing the employee's existing assignment.

3. Address Pipeline and Leaky Pipeline Issues

Managers are typically in charge of hiring for their organization and are often in the best position to ensure a strong pipeline of excellent STEM employees that are female and/or diverse.

Further, studies show that one of the top reasons people do not like their job is their manager. Managers can help set the tone for the organization, including ensuring that the tone is inclusive, where female and diverse employees are valued and recognized and on programs that will further their development and career. Setting this tone will reduce the leak in the pipeline.

4. Managers Should Have Their Own Mentors/Coaches/Network

Make sure that managers have access to mentors, coaches, and colleagues so that they can share suggestions and ideas for creating a supportive environment for their employees. Managers can help set the tone for the organization, including ensuring that the tone is inclusive, where female and diverse employees are valued and recognized and on programs that will further their development and career. Some companies have had manager-only brainstorm sessions on how to move female and diverse employees onto programs where there is a lot of inventive activity and a high likelihood of patent application filings.

IP Professional-Related Root Causes

IP professional-related root causes are those for which the primary source of the root cause lies with the IP professionals, including attorneys, agents, liaisons, outside counsel, etc.

Root Cause: Attorneys/Agents Intimidating or Too Busy

Many first-time or newer inventors struggle with a confidence gap. When such inventors work up their confidence to approach their IP professional and that person is intimidating, dismissive, or too busy to assist, the inventor is not motivated to push back or return. The experience that inventors have with their IP professionals can determine their likelihood of repeating the process.

Potential Programs:

1. Thank Inventors for their Work

A simple thank you goes a long way. One inventor credits her 60+ patents to early experiences in her career with a patent attorney who made her feel valued and heard and routinely thanked her for her work.

2. IP Professional Availability

Increase access to IP professionals who can educate and support the less experienced or less confident inventors and increase awareness of the process. Specific examples include: office hours at the lab or research facility, “ask an IP attorney” email site with fast turn-around for questions, co-locate IP professional at lab or research location on a regular basis, and attend affinity sessions. Consider attending group meetings (i.e., get out of your office and

meet people). Alternatively, create a series of classroom style trainings given by IP staff (preferably including women or diverse employees) about patenting.

3. Inclusion Training

Include the IP professionals in inclusion training so that they understand the unique role that they play in supporting female and diverse inventors in building confidence and expanding their presence in patent filings.

4. Sharing of Best Practices

The best IP attorneys and agents work with the full team and understand the contributions from all members of the team. Inventorship is a legal determination that the patent attorneys or agents make. As such, patent attorneys and agents are uniquely able to add claims (including dependent claims) to ensure that all members of the team are listed as inventors and to get broader, stronger patent coverage. Training other attorneys and agents how to do this and making it an expected practice will change inventor behavior and acceptance. Additionally, patent attorneys and agents who work closely with the inventive team will recognize who is involved and can dig deeper to make sure all participants, not just the most active or loudest, are considered when determining inventorship.

5. Pairing Female / Diverse Potential Inventors with Female / Diverse IP Professionals

Female and diverse employees or potential inventors may feel more comfortable working with an IP attorney or agent who is also either female or diverse. One reason for increased comfort is that having something in common with another person establishes a common ground and therefore certain base level of

comfort. When the employee is more comfortable speaking with the IP professional, the employee may be more forthcoming with potential ideas for new invention disclosures, or may be more likely to speak up about their contributions.

6. Outside IP Counsel

Outside IP counsel can assist as well. A guide for outside counsel who want to assist advance their clients on this issue can be found here and below:



Law Firm
Complement to Tool

Process-Related Root Causes

Process-related root causes are those for which the primary source of the root cause lies in the invention submission / patenting process. Thus, the suggested programs involve affecting the invention submission / patenting process. Since people implement processes, some of these root causes closely align to some of the People-Related Root Causes.

Root Cause: Invention Submission / Patenting Process is Biased, Intimidating, or Unclear

Many diverse or female employees report that the patenting process itself is either too intimidating (*e.g.*, present your idea to the attorney or to a technical director and convince them to support a patent application filing), biased (*e.g.*, no one on the review committee is female or diverse or most of the review committee is non-diverse), lacks feedback or provides vague feedback (*e.g.*, if an invention disclosure is denied, how is the information sent back to the inventor), or unclear (*e.g.*, it seems like each attorney wants something different for an invention submission, so an employee is never sure if the invention is ready and it is the right time for submission).

Potential Programs:

1. **Audit & Change the Organization's Invention Submission / Patenting Process**

Focus the audit on sources of implicit bias and user-friendliness. Follow the root cause guidance in Chapter 2 by getting feedback from organization-wide participants (*e.g.* surveys), in small groups, and 1:1 with employees. Consider things like “Are

decision makers diverse?” and “Can all inventors make submissions?” This audit will identify sources of bias and barriers to submission. Based on the data, revise the invention submission/patenting process to eliminate sources of bias or reduce their impact. Widely publish the revised process – especially to diverse and female groups and affinity groups in the organization. Ensure that the technical managers also spread the word within their groups on the revised process.

Some examples of revisions organizations have made are as follows:

- Create objective criteria (a list) to evaluate invention ideas for patenting. Communicate the list and stress its consistent usage to make patenting decisions more objective. Be a gatekeeper who stresses that decisions not to patent are supported by objective justifications.
- Change decision making committee membership periodically to include women and diverse employees.
- Where possible, include inventors in the decision-making process so they can defend inventions and learn how the decision is made. Invite them to have an ally, advocate, or the full team join them so that quieter and more introverted employees are comfortable in this setting.

2. Inclusion Training

Include the IP professionals in inclusion training so that they understand the unique role that they play in supporting female and diverse inventors in building confidence and expanding their presence in patent filings, as well as to help them understand the diverse needs of the employee population, which require them to be approachable and patient. This is especially impactful when paired with increasing inventor availability to IP professionals so

that the inventors can form a relationship with and feel comfortable approaching IP professionals.

3. Sharing of Best Practices

The best IP attorneys and agents work with the full team and understand the contributions from all members of the team. Inventorship is a legal determination that the patent attorneys or agents make. As such, patent attorneys and agents are uniquely able to add claims (including dependent claims) to ensure that all members of the team are listed as inventors and to get broader, stronger patent coverage. Training other attorneys and agents how to do this and making it an expected practice will change inventor behavior and acceptance. Additionally, patent attorneys and agents who work closely with the inventive team will recognize who is involved and can dig deeper to make sure all participants, not just the most active or loudest, are considered when determining inventorship.

Root Cause: Patenting Process Not Known

With this root cause, inventors or potential inventors are simply not aware of the process or steps to submit an invention for consideration for patenting because the process is not written down, may not be clear, or the inventor has not yet been made aware of or trained on the software necessary for submission. In our busy lives, the task of figuring out a process can seem daunting enough to deter an inventor from submitting their idea. Therefore, it is essential in all organizations that the process is clear and available for everyone in the company in a common sense, known place, and help is available if needed.

Potential Programs:

1. Ensure that the Process is Clearly Written and is Easily Accessible to All Employees

Posting or making available the invention submission process steps (and hyperlinks to any required documents) on an organization-wide system (e.g., an internal website) is a simple step that can generate big results quickly. When paired with training opportunities in small group settings (e.g., for an affinity group or laboratory/business), these communications are especially impactful.

2. Regular Communication to Inventor Populations Re: the Process
Regular reminders – especially by laboratory and/or research facility management and/or IP professionals – of the process and where to go to see the steps/get the documents.

3. IP Professional Availability and /or Mentoring

Increase access to IP professionals and/or mentors who can educate and support the less experienced or less confident inventor and increase awareness of the process.

4. New Employees Are Made Aware of the Process Early and Often

New employees are inundated with new information when they begin a new job. It is important to make them aware of the process and where to find it and to repeatedly remind them of this information. Managers and leaders should periodically check in with new employees to make sure they are aware of the process for invention submission.

Culture/Environment-Related Root Causes

Culture/environment-related root causes are those for which the primary source of the root cause lies in the organization's culture and/or environment. These root causes are common and present in many organizations. For example, pipeline and leaky pipeline issues are included in this section. These are omnipresent in most organizations. However, pipeline and leaky pipeline issues are rarely the sole root cause. As such, it may be a mistake to conclude that increasing the pipeline will resolve all gender parity issues, and it takes time to fill the pipeline. As one corporate executive told us, "We are committed to working on increasing the pipeline. But if we do not simultaneously make the culture and environment into which the new hires will enter inclusive and welcoming, we will lose those new hires quickly or, perhaps even worse, never get the full value of their potential contributions." Because organizational cultures and environments vary so widely, the suggested programs below are high-level. Use these ideas as guidance to be modified to address the specific culture / environment of your organization.

Root Cause: My Organization Doesn't Support or Is Not Welcoming to Female or Diverse Inventors

Some inventors do not feel safe or comfortable sharing their inventive contributions and/or proposing new ideas for fear of not being supported. Other female or diverse inventors report feeling that their co-workers take credit for their ideas, and the female or diverse inventor does not feel comfortable or supported in speaking up and correcting this situation.

Potential Programs:

1. Public Celebration/Recognition of Patenting Activities

Public (internal and/or external to the organization) celebrations of patent activity by diverse or female inventors (patent filing, patent issuance, licensing, etc.) clearly convey the message - through action – that this is an activity that the company values and promotes and that will be rewarded in an employee's career. These need not be huge to be impactful. For example, these could be external articles, notices, etc. or internal celebrations company-wide or within a lab or even just 1:1 between an employee and their manager. Some exemplary recognition communications are provided [here](#) and [here](#). These celebrations and recognitions also remind the organization of the many female and diverse inventors and help women and diverse employees self-identify as inventors.

2. Mentoring and Coaching

Active mentoring and coaching programs for female and diverse employees shows the organization's belief in and support of that employee and of employees who are female or diverse, which can

bolster their confidence. In many organizations, successful and experienced female inventors mentor less experienced women inventors. Experienced male inventors and/or female inventors from outside the organization also make excellent mentors. Where the mentor and mentee have commonalities, this pairing can help women and diverse employees self-identify as inventors.

3. Affinity Groups for Diverse Technical Employees (Inventors)

Creation of an organization-wide affinity group for diverse and female technical employees/inventors provides these inventors with access to a broad-based, welcoming, and relaxed network of colleagues that can provide support and mentoring and that visibly shows the organization's support for female and diverse employees.

4. Management Training

This training can teach managers how to make clear to all employees, including those who are diverse or female, the important role they play and the value of their contributions. Effective managers provide support and guidance, as well as making their employees aware of the programs or support available to assist them. When paired with inclusion training, this can be especially impactful.

5. Employee Inclusion Training

Inclusion is a team sport, so training the entire organization on inclusive behavior ensures that non-managers working on inventive teams convey the value and import that all members of the team, including female and diverse members, bring to the team.

Root Cause: Pipeline / Leaky Pipeline

If your organization concludes that its only issue is pipeline, then you may want to consider revisiting the root cause assessment section. Pipeline and leaky pipeline issues are rarely the sole root cause, so it may be a mistake to conclude that increasing the pipeline alone will resolve all gender parity issues. As one corporate executive told us, “We are committed to working on increasing the pipeline. But if we do not simultaneously make the culture and environment into which the new hires will enter inclusive and welcoming, we will lose those new hires quickly or, perhaps even worse, never get the full value of their potential contributions.”

With specific reference to pipeline issues, most organizations have pipeline issues and have active programs to increase their hiring of female and diverse STEM employees. Find ways to link into those programs and advertise to potential new employees the programs that are in place or being launched to make this an excellent workplace once the prospective employee joins. This can be an excellent new hire sales pitch.

With specific reference to the “leaky pipeline” issue, this refers to the fact that once organizations hire qualified female and diverse STEM employees, these employees leave the technical organization at a faster rate than their non-female or diverse colleagues. Leaky pipelines are also omnipresent, but a leaky pipeline itself is never the sole root cause of gender disparity in innovation. Instead, devote time to understanding the root causes for the leaky pipeline and create programs to address those. These will improve the retention of these key employees and thus their satisfaction and contributions to innovation.

Chapter 4 (Step 4)

Launch & Monitor the Programs

The goal in this step is to effectively launch the programs identified above, monitor and support them, and determine metrics that allow the organization to see progress (or lack thereof). Constant diligence and improvement will allow your organization to flourish.

Launch:

Best practices when launching programs include the following:

- Select a few meaningful and highly impactful programs and launch them really well instead of launching many small programs.
- Ensure that all stakeholders are aware of and support the programs to be launched.
- Have the program details determined and well-articulated, including audience, scope, timing, communication plan, and definition of success.
- Before launching, have a clearly defined and agreed upon definition of success, and determine metrics to measure that success.
- Clear and visible buy-in and support from management.

Exemplary metrics:

- Number or percentage of female or diverse inventors on patent applications, issued patents, or invention submissions and trajectory over a defined time period.
- Number or percentage of female or diverse first-time invention submitters or patent inventors and trajectory over a defined time period.
- Number or percentage of female or diverse repeat invention submitters or patent inventors and trajectory over a defined time period.
- Number or percentage of female or diverse new technical employees submitting inventions for patenting and trajectory over a defined time period.
- Number of affinity groups to whom presentations to increase awareness have been made.
- Number of invention submissions received from each affinity group.
- Number or percentage of women or diverse employees on key inventive programs and trajectory over a defined time period.
- Reduction in pipeline leak of diverse employees and diverse leaders.

Monitor:

Best practices to monitor the launched programs include the following:

- Review the activities / programs / processes on a regular basis and assess whether improvement is possible / needed.
- If possible, make improvements on the fly.
- Share the result(s) within the organization.
- Solicit feedback from the organization about the program and ways to improve upon it.
- On some set basis or timing, reengage in brainstorming and feedback solicitation to ensure that new root causes for gender disparity are not arising.
- Bad habits are like weeds – they grow where there is space. Make sure they are being ferreted out early. Receiving communication from others lets people know this is an ongoing issue and not a once and done issue.
- Best practice or example sharing with other companies or organizations and receiving their ideas for consideration within your organization.
- Communication externally provides more ideas and also helps create an external positive view of your organization for others.
- Learn from others and teach others through mentoring on this topic.

APPENDIX

Sample 1:1 or Small Group Pitch Materials

The following is a sample “script” to give you an idea of what has worked for others when talking with the key stakeholders/decision makers 1:1 or in small groups. You will need to go into more detail than the elevator pitch but still keep the conversation at a high level. Your “ask” is really to partner with them to address gender disparity in innovation in the organization/company. Make this script your own – these are just ideas.

Women are significantly underrepresented in the innovation process. Recent studies show that “although women have more than quintupled their representation among patent holders since 1977, only 18.8 percent of all patents had at least one women inventor in 2010.” “At the current rate of progress in recent years (2000-2010), women are not expected to reach parity in patenting until 2091.” Research also shows that increasing diversity in patenting results in higher return on investment and stronger patent protection. As such, it is becoming an imperative to bring awareness of and attention to the gender disparity gap in innovation.

I’m involved with IPO, a global organization including various multinational companies and universities, to look at the issue of gender disparity in innovation. We have teamed with the World IP Organization (WIPO) to have access to statistics for each company. Our general goals are to (1) Bring Awareness to the Gender Disparity in Innovation and the Business Case for Expediting Gender Parity in Innovation; (2) Discuss Factors that Contribute to

the Gender Disparity and (3) Create and Share Various Corporate and University Efforts to Address and Remedy the Gender Disparity.

To aid in all of these, the organization has put a toolkit for companies to use to get ideas for different ways to address these issues within their corporations/ universities/organizations. This toolkit will give us some ideas for how to assess where our company is on this issue, how to identify the key drivers for our current behavior, and ideas for how other companies have moved the needle on increasing their gender parity in innovation.

I'd like to partner with you to look into this issue for our company/organization and to improve our innovative gender disparity. Doing so is in line with our company/organization's diversity and inclusion goals / sustainability goals / HR goals. Further, I want to make sure that the excellent work being done by our female scientists is patented at the same rate as their male colleagues and to make sure that our company/organization is getting the full value of their contributions.

Sample Presentation

Diversity in Innovation



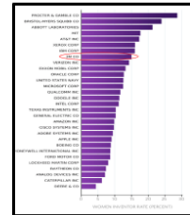
DIVERSITY IN INNOVATION

SAMPLE PRESENTATION

Introduction

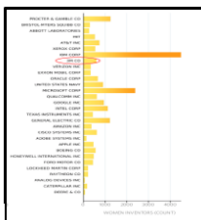
- Awareness and engagement of ALL employees throughout the organization are both necessary for success.
- Women and diverse employees have technical skill and knowledge, yet their contributions are not patented at the same rate as those of their male counterparts.

Over 53% of PhDs are awarded to women.
Yet, only 12% of registered innovators in the United States are women.



Women Inventors at Select Top Patent Assignees, 2007-2016

15% of 3M's US Patent Assignees From 2007-2016 were Female



Women Inventors at Select Top Patent Assignees, 2007-2016

Between 2007-2016, 3M had around 600 different female inventors.

Call to Action

These statistics suggest that we may not be capturing the full contribution of a large segment of our technical workforce – resulting in significant lost opportunity costs (e.g., unpatented inventions, delayed disclosures, etc.).

What to Do

Gender Parity in Innovation Process

- STEP 1 - Assess Current Status**
- STEP 2 - Develop Short and Long-Term Programs**
- STEP 3 - Launch & Monitor the Programs**

Increase Awareness and Support

Presentations unique to affinity groups, small or large groups, leaders and managers, department groups - laboratory and technology groups, or technical groups – business and R&D groups.

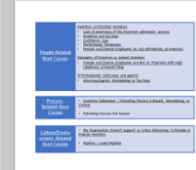
Best practices information for TDs and lab managers.

Determine inventorship numbers globally, by business unit or technology area.

Discover Root Causes for Gender Disparity

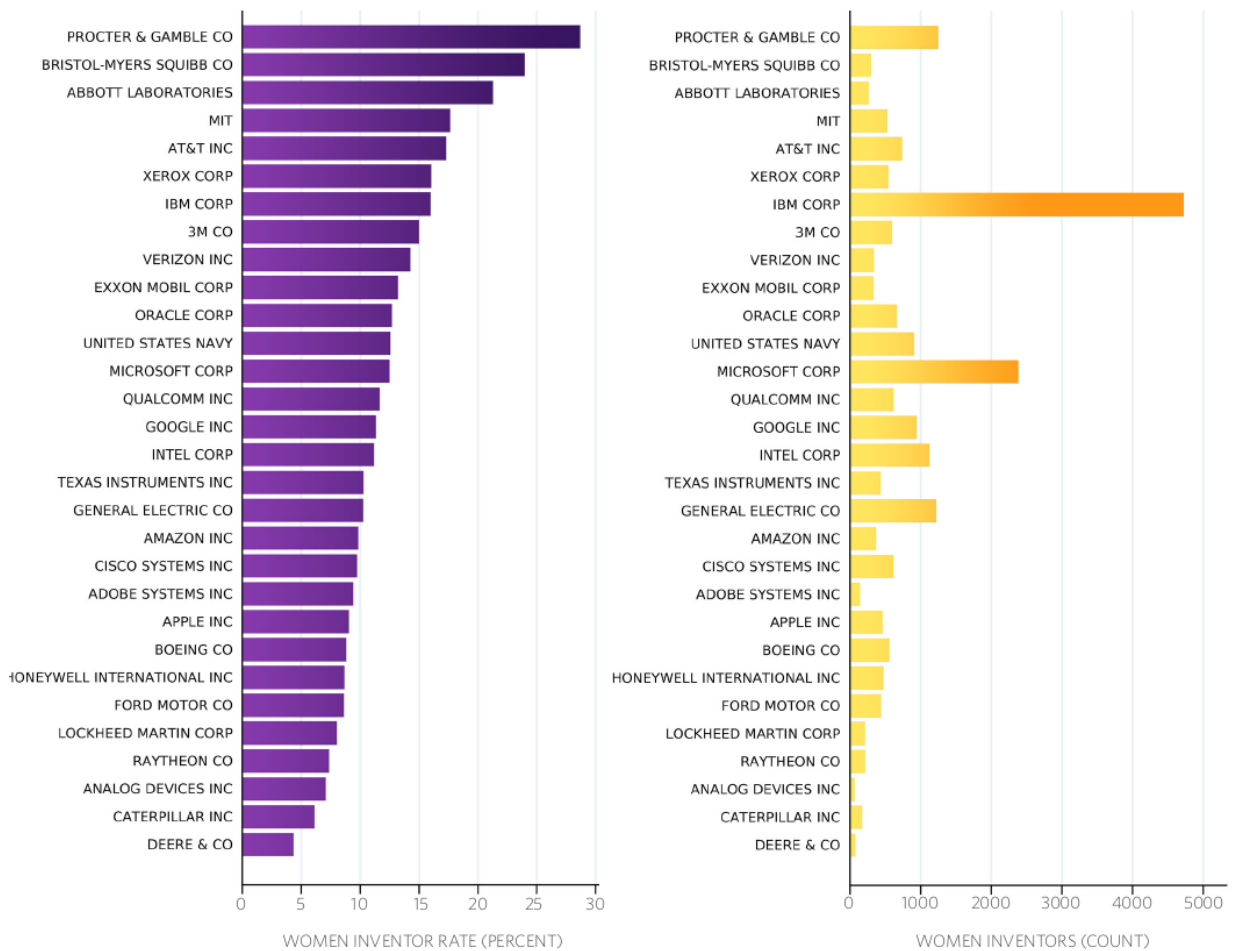
Survey the T-WLF and/or technical community & follow up with a small group and 1:1 sessions.

External Benchmarking




Sample Statistics¹⁸

Figure 7. Women Inventors at Select Top Patent Assignees, 2007-2016



¹⁸ USPTO Progress and Potential

Sample Survey
Gender Diversity in Innovation Survey¹⁹

Scale of 1 (disagree completely) to 5 (agree completely)

1. Women and men are equally likely to be inventors on patent applications
In the company

In my specific business/laboratory
2. Women and men are equally assigned to innovative projects that lead to patenting:
at the company

in my specific business/laboratory
3. Submitting ideas for patents is an important part of my job.
If I am a manager, submitting ideas for patents is an important part of my employees' time.
4. Going through the patenting process is a good use of my time.
If I am a manager, going through the patenting process is a good use of my employees' time.
5. I will submit an idea for patenting even if I am not completely sure if it is patent worthy (meaning that I'm not sure if it's ground-breaking enough and/or I'm not sure if I have enough data to support a filing).
6. I know the process to submit an idea for patenting.
Rate your satisfaction with the process.

Rate whether the process is fair and unbiased/inclusive.
7. I have access to at least 1 person who I can talk to about whether an idea should be submitted for patenting.
I contact that person when I have an idea.

¹⁹ Survey prepared by: Ahsan Shaikh | Partner at [McDermott Will & Emery](#) | available at ashaikh@mwe.com

8. Women and men who have submitted inventions for consideration for patenting are positively and publicly recognized for having done so.
9. Women and men who have been listed on inventors of patent applications are positively and publicly recognized for having done so.
10. Women and men who have issued patents are positively and publicly recognized for having done so.
11. I have worked on a project on which patent applications were filed. If no, skip question.
Rate your satisfaction with being included/not included on the patent application.
Rate your satisfaction with being included by the attorney/agent.
Rate your satisfaction with being recognized by your immediate boss.
Rate your satisfaction with being recognized by the lab.
13. Do you have any other thoughts you'd like to share? [[Fill in box.]]
14. Can we follow-up with you to talk more in a small group or 1:1 about this issue? Yes/No

Sample Survey 2

Survey for Underrepresented Inventor Populations²⁰

Questions are of either [Yes-No] or [Scale Of 1 (disagree completely) to 5 (agree completely)]

EXAMPLE: Gender Parity (but could be modified for any type of diversity)

1. Women and men are equally assigned to innovative projects or features at [COMPANY]
2. Management at [COMPANY] supports improving the representation of women in the patenting program at [COMPANY]. (1 to 5)
3. Submitting ideas for patents is an important part of your job at [COMPANY] (1 to 5)
4. Going through the patenting process is a good use of your time (1 to 5)
5. Ideas should be groundbreaking in order to apply for a patent (1 to 5)
6. I will submit an idea for patenting even if I am not completely sure if it is patent worthy (1 to 5)
7. I know where to go or who to contact in order to submit an idea for patenting at [COMPANY] (Y/N)
8. The current incentive for submitting a patent application is _____. Is this an incentive you'd be interested in?
9. Men and women are equally likely to be an inventor on a patent application at [COMPANY] (1 to 5)
10. Do you know any women inventors at [COMPANY]?
11. Have you worked on a project or feature that has been the subject of a patent application?
 - a. If YES:
 - i. were you listed as an inventor?
 - ii. Your experience with the patent attorney/agent was positive (1 to 5)
 - iii. Being listed as an inventor for the patent application was a positive experience (1 to 5)
12. I have a mentor who has submitted a patent application before.
13. Do you have any other thoughts you'd like to share?
14. Can we follow-up with you to talk more in a small group or 1:1 about this issue?

Consider asking, while attempting to maintain anonymity:

- Ask person to self-identify gender, # years at company, what division/tech area you are in, ethnicity, and age range.

²⁰ Survey prepared by: Ahsan Shaikh | Partner at [McDermott Will & Emery](#) | available at ashaikh@mwe.com

LAW FIRM COMPLEMENT TO DIVERSITY IN INNOVATION TOOLKIT²¹

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Introduction

The Intellectual Property Owners Association (IPO) Women Inventors subcommittee of the Women in IP Committee developed the Diversity in Innovation Toolkit for corporations, universities, and others to help improve the number of women patent holders at their organizations. This Law Firm Complement is a tool for outside lawyers to help their clients become familiar with and use the Toolkit. In the process of helping clients to use the Toolkit, law firms will likely improve their client relationships, develop deeper relationships with their clients, have a better understanding of their clients and their clients' cultures, be part of the client transitioning process, and help younger lawyers have speaking opportunities.

Like with the full Toolkit, as you have ideas and examples, it would be appreciated if you would please share them so that they can be added to this component of the Toolkit. Neither document is static and complete or perfect, and both documents can benefit from everyone's thoughts, creativity, and contribution.

Section 1

Raise Awareness

The goal of this section is to raise your client's awareness of the gender disparity in innovation.

Provide the Data

- Explain that the 3:1 ratio of men to women inventors does not change regardless of how many women are in the industry; therefore, while this may be part of the problem, it is not simply because there are “not enough women” in the pipeline.
- Explain that there are anecdotal examples of delayed inventions because one woman inventor felt that the idea “was not good enough.” Such a mindset means that the company has delayed or lost innovation and thus an opportunity cost that hits the bottom line.
- Make your client aware that corporations can suffer and have suffered from over analyzing. Suggest that they look at their internal numbers to determine the numbers and genders of inventors while simultaneously implementing new steps.

Section 2

Use the Toolkit

The goal of this section is to use the Toolkit to engage with your client.

Understand Your Client

- Use the Toolkit as a method to engage with your client, without of course, asking for work. This helps for relationship building, understanding how the client works, understanding their demographics, and understanding what their issues are. The more you understand the client (*e.g.*, their problems, hurdles, systems), the better your overall relationship will be.
- Using this approach to better understand your client may inherently also teach you about, or expose you to, leadership, strategic planning, and industry hierarchy. Such skills will make any attorney more successful and cannot be obtained while sitting in your office.

Assess Your Client's Invention Submission Process

- Questions to ASK:
 - Is their invention submission process / system known to all the employees? This may be a bigger issue for universities and for employee groups not traditionally considered to be focused on innovation or traditional "inventors." The invention submission process is one that may not be reviewed frequently for

accessibility, friendliness, and relevancy (e.g., if it is up to date), especially if your client(s) has been in the same role for a long time.

- Is their process / system easily accessible? Do employees know where / how to enter an invention disclosure form or idea?
- Is their process / system a tremendous time drain? Do employees not submit ideas because the process or system is tedious or too time consuming?
- Is their process / system user friendly? Does the process / system require extensive training, or are employees able to easily learn how to use it?

- How You Can Help:

- Assist your client by improving their invention submission system. For example, introduce your client to another client who is successfully moving forward on gender parity, or share ideas about how other clients have made improvements. Taking these steps helps you collaborate with industry, while also learning more about your client.
- Help your client explain the disclosure submission process, application preparation and filing process, and prosecution process to the inventor community. For example, help your client explain the steps involved and costs associated with each stage of the process. Also help your client explain how inventors can assist the invention process during application drafting and

prosecution. Sometimes, inventors feel like the patenting system is a “black box,” which includes a flurry of activity prior to application filing, and then silence post-filing. Explain to your client that the inventors may not feel valued by the silence that often occurs post-application filing. Have them listen to the Podcast “Stroke of Genius”²² episode of Lisa Seacat Deluca, who has over 400 patents, but did not feel that she was a patent expert until she shepherded one of her ideas through the patenting process *pro se*.

²² Information on the podcast available on the IPO Education Foundation page at <https://www.ipofef.org/podcasts/s2-episode-1-lisa-seacat-deluca/>.

Section 3

Tailor Approach Based on Type of Client

The goal in this section is to fine tune your approach based on the type (e.g., technology, government, public corporation, private company, university, nonprofit organization (NGO)) and size of your client.

University Clients

- University clients have limited financial and human resources. You can greatly assist them by taking the time to speak to and educate staff and students involved in innovation. Technology Transfer Offices (TTOs) are great starting points for offering this type of service.
- The Association of University Technology Matters (AUTM) has developed a toolkit to provide TTOs with tools for supporting women in (STEM) and entrepreneurship. The Toolkit can be downloaded [here](#).
- Questions to ASK: Review their invention disclosure or submission process and access and ask (or determine the answers to) the following:
 - Are there problems with knowing how and where to access the invention disclosure submission system / process?
 - Do inventors know where the TTO is or who to contact?
 - Do inventors know the intellectual property professionals?

- Have you (as an intellectual property professional) tried to access the system?
- When a new scientist starts at the University, is the technology transfer system (or invention submission system) explained? How often is it explained and reinforced? (Note the Rule of 7 – it takes a person 7 to 10 times to hear something before they remember it.)
- How you can HELP: Based on the answers above, help your client by:
 - Improving the process. For example, provide a “how to do it” manual, or review the steps in the process and suggest ways to improve or streamline it and make it more accessible and understandable.
 - Giving an informational talk to the community of potential inventors and possibly doing so regularly. Explaining the patenting process and being a resource for questions.
- Questions to ASK: Ask or determine how the University’s TTO reviews the technology.
 - Do they rotate diverse professors, professionals, or students through the system so they learn the system by reviewing invention disclosures, assessing patent portfolios, etc.?
- How you can HELP: Based on answers above, help your client by:

- Doing a presentation for the TTO members and engaging with them about their frustrations and concerns with the process and system(s).
- Work with the TTO to develop teaching tools for use with staff and students having various roles.

Corporate Clients (depends on size, see below)

- Questions to ASK: Discuss gender disparity in innovation (as discussed above), and ask your client if they would like to discuss how you can help. If the answer is yes, then move forward with the following steps.
- How you can HELP: Give an overview of the toolkit and its 4-step process to your client. Ask if they would like help in raising awareness and /or data collection on gender disparity at their corporation.
- Questions to ASK: Ask your client about their invention disclosure submission process.
 - How are invention disclosures submitted, and by whom?
 - Who reviews and approves the disclosures?
 - How is the reviewing team composed (*i.e.*, is it diverse, what are the roles of the reviewers)?
 - Do people rotate on and off the review team?

- How are people selected for the invention disclosure review team or committee?
- Is there a program to make sure women are included? How are new members of the team educated on the process?
- How often are refresher presentations on the invention disclosure process provided to the employees?
- How do the scientists and engineers know to seek out the in-house IP professional for IP-related questions?
- Is the in-house IP professional one person, two people, or more? Offer to co-present IP training or help IP professional with an IP question / answer day.
- If there is more than one in-house IP professional, are they the same gender? Having diverse members can make it more comfortable for individuals to choose with whom to speak.
- Is feedback given to inventors after invention disclosures are submitted but not approved (*i.e.*, are inventors told why something is not filed, or that it is on hold, or that more information is needed)?
- Is feedback given to inventors after invention disclosures are approved as to what made the disclosure successful so that the inventor can apply that information to the next invention disclosure.

- How you can HELP: Based on the answers above, help your client by:
 - Helping your client's in-house IP professional prepare and execute a presentation for executive level awareness and support.
 - Helping your client's in-house IP professional with data collection tools (*e.g.*, surveys, small group discussions) and root cause analysis.
 - Going with your client's in-house IP professional (if there is one, or someone in research or technology) to visit the scientists and engineers.
 - Giving a presentation to the scientists and engineers (inventor community) on the invention disclosure submission process, and how you become an inventor. Discuss that the listing of inventors is a legal determination.
 - Having an open discussion with scientists and engineers and others who might be inventors about what frustrates them about the process.
 - Discussing what is important for a good invention disclosure submission (*i.e.*, data, including comparative data, description of the problem solved, unexpected results, *etc.*).
- Listen-Learn-Re-Assess-Re-Teach: To truly help your client, you will need to continuously listen to your client, learn their processes, re-assess your advice and their circumstances, and re-teach based on the foregoing. Some examples of this process include:

- Going back and revising your presentation based on what they taught you (be present to listen and learn when teaching – you don't know everything about your client or their process and you never will). Repeat annually or biannually.
- Based on discussions with scientists and engineers, determining what the potential innovators prefer in terms of process.
- Determining why scientists and engineers get frustrated with the process or decide not to file invention disclosures or follow through on ideas.

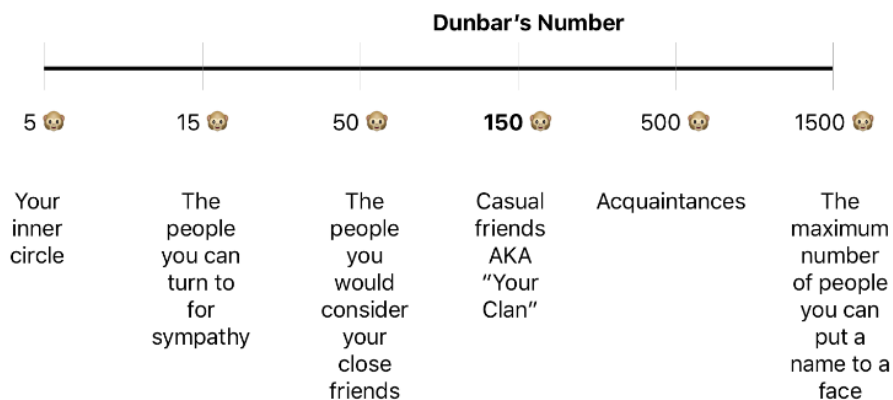
Client Size

- The size of your client can play a role in how you approach your client, as well as what their constituencies' needs are. The level of sophistication often depends on the size of the client. Generally, large entities tend to be more sophisticated. By contrast, however, large entities also can have significant communication problems created by numerous systems and the number of people involved. These issues can result in a lack of familiarity with the patenting process and IP professionals, and thus even a lack of trust.
- Small: Less than 50
 - Usually, at this size, everyone has a good one-on-one relationship.
 - There may be interpersonal / political hierarchy issues, but information is disseminated.

➤ The bigger problem is one of IP savviness.

- Large: More than 150

➤ Dunbar's Number: As shown below, Dunbar's number indicates a cognitive limit to the number of people with whom one can maintain stable social relationships, or relationships in which an individual knows who each person is and how each person relates to every other person.



➤ When your client is large, the relationships are at the upper limit for being casual friends. Consider breaking up the talks into smaller groups so that there is a core of people and a common affinity.

Section 4

Create a Teaching Model

The goal in this section is to identify a successful invention disclosure for your client and create a teaching model around it, if the client does not have a teaching model. This can form a beneficial teaching tool that can help demystify the process inventors. Demystifying the process can improve gender parity in inventorship, as it helps overcome the relative lack of confidence of female inventors.

Make a Sample Invention Disclosure

- Explain the Details of the Invention Disclosure:
 - Break the disclosure into parts and explain each part, its purpose in the process, and the inventor's role in completing the part.
 - Explain how to fill out the disclosure.
 - Explain how to submit the disclosure.
 - Explain how the disclosure is helpful to the IP professional.
 - In a university setting, explain how the disclosure is helpful to the licensing agent.

- Explain Inventorship:

- Explain how one claim or even one limitation of a claim can make someone an inventor.
 - Explain why naming each inventor is important. For example, explain that naming each inventor is important for better understanding of the prior art and future patent enforceability. Explain the problems with not naming all or the correct inventors (*i.e.*, invalidity, unenforceability).
 - Explain why it is important to divide the claims out for attribution. For example, explain why it is important to know which inventors contributed to which claims when claims are canceled and / or filed in divisional applications.
- Explain the Timeline:
- Explain the invention timeline, *e.g.*, from idea, to disclosure, to patent application, to license (optional), to patent, to product, to patent expiry, *etc.*
 - Explain the amount of time it takes to go from invention disclosure to review and then to feedback.
 - In this process, also determine if your client provides any feedback to inventors, and explain how “no feedback” can potentially dissuade inventors, particularly new inventors, from moving forward or filing additional disclosures. Feedback can be educational on teaching for valuation, industry direction shift, *etc.* No feedback can cause a person perhaps to gaslight themselves if they suffer from any imposter syndrome.

- Explain the rationale behind geographic filing strategies.
 - Explain what it means to not be “perfect” and improve over time (if possible).
 - Explain how the scientists and engineers can help identify licensees (if appropriate).
- Questions to ASK: What makes an inventor submit an invention disclosure?
- Do they need to be (or feel they need to be) asked to submit? Is there a metric or job requirement for submitting a certain number of invention disclosures?
 - Do they need to have someone do a first review of their idea and / or invention disclosure before feeling they can submit, *e.g.*, that it is perfect enough such that no one will laugh at them?
 - Would the person reviewing be another IP professional, another inventor, or their boss?
 - Would it help them to talk with someone else (*e.g.*, a mentor) about their idea and/or invention disclosure to make them more comfortable?
 - Ask if your in-house IP professional offers “office hours,” coffee meetings, or meet-and-greets with their “clients.” You could offer to be with them and help them, or facilitate a brainstorming or idea capturing session on a particular technology.

- Does the inventor require another person's authorization before they can submit an invention disclosure? If so, is that a bottleneck in the system?
- Suggest Implementing Incentive Programs
 - Organization-Wide or Group-Wide Spotlights
 - These remind people that there are women and diverse inventors, and help women and diverse employees self-identify with others.
 - Sample ideas: all organization or group emails, posts on internal websites, presentations, *etc.* that focus on the research, patents, milestones, personal stories, licensing wins, patent litigation wins, *etc.* of individuals.
 - Samples available [here](#) and [here](#) and [here](#) and [here](#).

Section 5

Identify Inventor Mentors

The goal in this section is to identify a diverse range of inventor mentors, obtain feedback from them on the invention process, and prepare stories based on their experiences, which can be highlighted by the corporation / university.

- Make a list of inventor mentors, and have them speak with other scientists about their experience in various groups, such as affinity groups, journal clubs, or group meetings. Think about whether mentoring groups can be created having members from the list of inventors as part of the group.
- Determine if the inventor mentors communicate well and get along with other inventors; raise any flags of jealousy / competition / envy.
- Work with the inventor mentors to identify what they find frustrating with their invention process and help the organization identify ways to improve their process.
- Have the inventor mentors write their story for use in the process, as well as to possibly to provide as a spotlight for the corporation / university.

Section 6

Feedback

The goal in this section is to help your client understand the gender differences in how feedback is communicated to, and received by, inventors, and the importance of the feedback system in moving inventions forward.

Gender Differences

- Gender differences are present in language. For example, women use certain words more frequently than men. Such differences can play a tremendous role in what the person actually hears (or understands) when receiving feedback, which effectively complicates how feedback is given and received.
- Despite these differences, feedback should not be vague. Rather, feedback should provide specific and concrete (factual) ways of improving the invention disclosure submission.

The Feedback System

- For many reasons, the feedback system can be a significant barrier to moving potential inventions forward. Ask your client to consider the following:
 - How do you speak to your audience of inventors? Consider the diversity of the inventor spectrum. Understand the realm of assumptions. Know your audience.

- If an inventor receives vague feedback or no feedback, the inventor may be unlikely to file a subsequent invention disclosure. Vague feedback or no feedback can cause an increase in the individual's "confidence gap."
 - Use the invention disclosure process (whether or not it results in a patent application being filed) to explain the basis of the decision, what was helpful in the invention disclosure, and what could be improved.
- Talk to inventors about the feedback system.
 - Is there is something in the feedback system that is turning people off or that could be improved?
 - Are there barriers to the system?
- Talk to the Diversity & Inclusion (D&I) officer to see if the system has been reviewed with a D&I filter to assess other issues. What conscious or unconscious biases might be present?

Section 7

Inventor Recognition

The goal in this section is to help your client understand the importance of inventor recognition. Some exemplary recognition communications are provided [here](#) and [here](#).

- Describe what others in the industry are doing to recognize inventors using the Toolkit. You may want to connect your client with other clients using the Toolkit to help them learn more.
- Explain how inventor “bragging,” especially around your diverse inventors, can improve the company’s / university’s rank as a female or diversity friendly institution. Showing pictures of your successful diverse inventors can attract new inventors who can relate and ‘look’ like those inventors and create a feeling of comfort.
- Explain to the client that these are ways you can help their inventors feel valued and appreciated.
- *Examples:* Some examples of inventor recognition include monthly newsletters highlighting the inventor(s), recognition ceremonies, discussion about new application filings at department meetings, industry spotlights, LinkedIn posts, and Facebook posts.
- Bring the inventors being recognized to meetings if possible when explaining the process to other potential innovators so they can ask questions.

Priya Prasad

Priya Prasad is Counsel at ExxonMobil Research and Engineering Co. based in Clinton, NJ where she manages the IP portfolio for several downstream R&D business units and handles technology transactional work. Priya has also worked at ExxonMobil's Chemical division in Baytown, TX. She has a B.S. Chemical Engineering from Rice University and J.D. from the University of Houston Law Center.



Peter Tu is currently General Counsel and Chief Legal Officer for Signum Biosciences, a private biotechnology company focusing on the development of novel, small-molecule therapeutics to modulate signal transduction imbalances. In that capacity, Mr. Tu heads up the legal function for Signum and its subsidiaries, and is a member of Signum's executive management team.

Prior to joining Signum, Mr. Tu was Vice President, Legal, for moksha8 Pharmaceuticals, Inc., a specialty pharmaceutical company focusing on commercialization of pharmaceutical products in emerging markets, where Mr. Tu led the global legal function and was a member of moksha8's executive management team. Prior to joining moksha8, Mr. Tu was Senior Director of Intellectual Property for Vitae Pharmaceuticals, Inc., where he was responsible for managing Vitae's patent and intellectual property portfolio, licensing and counseling senior management on a wide variety of intellectual property and other strategic issues. Prior to joining Vitae, Mr. Tu was Associate General Counsel and Senior Director of Intellectual Property for Savient Pharmaceuticals, Inc., where he was responsible for patent and trademark prosecution, patent and trademark litigation, licensing and intellectual property law counseling. Prior to joining Savient, Mr. Tu was Senior Counsel and Global Licensing Attorney for Hoffmann-La Roche Inc., where he was responsible for pharmaceutical licensing, patent prosecution and counseling management on patent and intellectual property issues. Prior to joining Roche, Mr. Tu was in-house patent counsel and Director of Intellectual Property for Physiome Sciences, Inc., a privately held biotechnology company, where he was responsible for managing Physiome's patent portfolio and for counseling management on patent and intellectual property issues.

Prior to joining Physiome, Mr. Tu was a senior associate in the Patent Litigation and Counseling Group in the New York office of Weil, Gotshal & Manges. While at Weil, Gotshal & Manges, Mr. Tu specialized in patent litigation and prosecution, intellectual property licensing, antitrust and false advertising law. Prior to Weil, Gotshal & Manges, Mr. Tu served as a law clerk for Justice Stewart G. Pollock (NJ Supreme Court) and later for Judge Leonard I. Garth (Court of Appeals for the Third Circuit).

Mr. Tu graduated *magna cum laude* from Seton Hall Law School, where he served as the Symposium Editor for the Seton Hall Law Review. Mr. Tu also received an MBA in Finance from Seton Hall University and bachelor's degrees in chemical engineering and biology from MIT.

Mr. Tu is active in various bar associations and civic organizations. Mr. Tu has served as a trustee for the New Jersey State Bar Association (NJSBA), the Middlesex County Bar Foundation and for the Middlesex County Bar Association; he has also served as Chair of the NJSBA Minorities in the Profession Section, Chair of the NJSBA Ad Hoc Committee on Racial Profiling and Chair of the NJSBA On-Line Legal Research Committee, and is a member of several NJSBA sections and committees, including the Legislative Committee, Internet and Computer-Related Law Committee, the Intellectual Property Committee, and the Diversity Committee. Mr. Tu served for three years as the NJSBA's representative on the Board of the Institute of Continuing Legal Education (ICLE).

Mr. Tu is also a member of the Asian Pacific American Lawyers Association, the National Asian Pacific American Bar Association, the American Civil Liberties Union (where he served for seven years on the Board of the New Jersey affiliate), Chinese Alumni of MIT (where he served as General Counsel), and the MIT Educational Council. Mr. Tu has served on the NJ Supreme Court Working Group on Judicial Participation in Fundraisers, the NJ Supreme Court Ad Hoc Committee on Bar Admissions (the "Wallace Committee"), the NJ Supreme Court Committee on Model Civil Jury Charges, the District Fee Arbitration Committee for District VIII (Middlesex County) (where he served as Committee Chair during the final year of his tenure) and the District Ethics Committee for District VIII (Middlesex County).

In 2002, Mr. Tu was selected by the National Asian Pacific American Bar Association as one of the Best Lawyers Under 40 in the United States. Only twenty-five attorneys throughout the country were selected to receive this prestigious designation and award.

**AVOIDING THE ON SALE BAR SINS THAT COULD LAND YOUR CLIENT IN PATENT HELL:
LESSONS FROM THE *HELSINN* CASE**

November 20, 2019

Presented by

Priya G. Prasad, Counsel, Exxon Mobil Corp.

Peter Tu, Chief Legal Officer, Signum Biosciences, Inc.

Overview

- What is the On Sale Bar?
- Statutory History of the On Sale Bar
- Elements Needed to Trigger On Sale Bar
 - Sale or Offer for Sale
 - Level of Completion of Invention – “Ready for Patenting” Standard
- The *Helsinn* Case
- Post-*Helsinn* Case Law
- Key Lessons from *Helsinn*
 - Chemical Practice Perspective
 - Pharmaceutical Practice Perspective

What is the On Sale Bar?

- Statutory bar that prevents an inventor from obtaining a patent if the invention was “on sale” in the United States more than one year before the effective US filing date
- 35 U.S.C. § 102(a)(1) provides in relevant part:
 - “A person shall be entitled to a patent unless ... the claimed invention was patented, described in a printed publication, or in public use, **on sale**, or otherwise available to the public before the effective filing date of the claimed invention ...” (emphasis added)
- Sale or offer for sale need not be public to constitute barring activity. The on sale bar rule (like the public use bar) creates a form of “secret” prior art (which is unique to US patent law).
- Affirmative defense of on sale bar must be proven by clear and convincing evidence.
- A sale or offer for sale is deemed to be made in the United States if “substantial activity” preceding such sale or offer takes place in the U.S. *Robbins Co. v. Lawrence Mfg. Co.*, 482 F.2d 426, 434 (9th Cir. 1973); *In re Caveney*, 761 F.2d 671 (Fed. Cir. 1985) (sale is “in this country” where British manufacturer directed an offer to its U.S. distributor, who then placed the order)

Public Policies Underlying the On Sale Bar

- Avoiding detrimental reliance on prolonged sales activity as demonstrating that invention is in the public domain
- Promoting prompt disclosure of new inventions to the public
- Providing the inventor a reasonable amount of time (i.e., one year) to determine whether it is financially worthwhile to file a patent application
 - **Query:** Should the time period be longer in certain industries where it takes longer to determine commercial feasibility of a product because of regulatory hurdles (e.g., pharma/biotech)?
- Preventing the inventor from commercially exploiting exclusivity beyond the statutorily authorized time period (20 years)
 - **Query:** Is this factor relevant since the US has converted from a “first to invent” systems to a “first to file” system?

Statutory History of the On Sale Bar

- First patent statute (enacted in 1790) did not mention the on sale bar
- On sale bar doctrine judicially created in 1829. See *Pennock & Sellers v. Dialogue*, 27 U.S. (2 Pet.) 1, 23-24 (1829) (Justice Story).
- The Patent Act of 1836 codified the rule announced in *Pennock*, barring an inventor from applying for a patent if “at the time of his application for a patent, [the invention was] in public use or on sale, with his consent or allowance”
- The Patent Act of 1839 added a two-year grace period to file and eliminated the requirement that the sale have occurred with the applicant’s consent.
- The Patent Act of 1897 limited the application of the on sale bar to sales occurring in the United States.
- The Patent Act of 1939 shortened the grace period to one year.
- The Patent Act of 1952 made no changes to the on sale bar rule.
- The Leahy-Smith America Invents Act (AIA) was signed into law on September 16, 2011, and made sweeping changes to the US patent system. The legislation also amended the patent statute to move the “on sale bar” language from pre-AIA 102(b) to new 101(a)(1), and adding the phrase “**or otherwise available to the public.**”

Elements Needed to Establish Invention Was “On Sale”

- A definite sale or offer for sale
 - within the United States
 - more than one year before the **effective U.S. filing date**
- Invention has attained a certain level of completion
 - Courts apply the “ready for patenting” standard articulated by the Supreme Court in *Pfaff v. Wells Electronics, Inc.*, 525 U.S. 55 (1998).
 - Supreme Court’s “ready for patenting” test replaced the Federal Circuit’s “totality of the circumstances” test set forth in *UMC Electronics Co. v. United States*, 816 F.2d 647 (Fed. Cir. 1987), *cert. denied*, 484 U.S. 1025 (1988). The *UMC Electronics* test replaced the widely followed three-part test articulated in *Timely Products Corp. v. Arron*, 523 F.2d 288 (2d Cir. 1975) and the also popular but more restrictive “on hand” standard set forth in *McCreery Eng’g Co. v. Massachusetts Fan Co.*, 195 F. 498 (1st Cir 1912) (invention must have been constructed and ready for sale).
 - The “ready for patenting” standard can be satisfied in at least two ways: (1) proof that the invention was reduced to practice; and (2) evidence that “the inventor had prepared drawings or other descriptions of the invention that were sufficiently specific to enable a person skilled in the art to practice the invention.” *Pfaff*, 525 U.S. at 67-68.
- The subject matter of the sale or offer for sale must anticipate or render obvious the claimed invention.

What is the Effective Filing Date?

- Effective filing date can be extended back to date of original parent application for continuations, CIP's and divisional applications.
- Effective filing date can also be extended back to filing date of a provisional application filed under 35 U.S.C. § 111(b).
- The AIA defines “effective filing date” as the earliest of: (1) the actual filing date; or (2) the filing date of the earliest application for which the patent or application is entitled, as to such invention, to a right of priority or the benefit of an earlier filing date under 35 U.S.C. §§ 119, 120, 121, 365, or 386. *See* 35 U.S.C. § 100(i)(1).
- Thus, the one-year grace period (see MPEP § 2151) in AIA 35 U.S.C. § 102(b)(1) is measured from the filing date of any U.S. or foreign patent application to which the patent or application is entitled to benefit or priority as to such invention,
- Note: the one-year grace period in pre-AIA 35 U.S.C. 102(b) was measured from only the filing date of the earliest application filed in the United States (directly or through the PCT). Priority dates claimed under 35 U.S.C. § 119 do not count.

What Constitutes a Definite Sale or Offer for Sale?

- N.B. Sale need not be consummated to trigger the on sale bar. A rejected offer for sale may be sufficient.
- Courts look to federal law – and not state law – to determine whether activity constitutes an “offer for sale” within the meaning of the on sale bar rule.
- A single offer for sale is sufficient to bar patentability. *In re Caveney*, 761 F.2d 671, 676 (Fed. Cir. 1985).
- An offer for sale sufficient to trigger an on sale bar need not rise to the level of a formal offer under contract law principles:
 - Advertisements can constitute “offers.” *See Reactive Metals & Alloys v. FSM, Inc.*, 769 F.2d 1578, 1580 (Fed. Cir. 1985) (two ads in national magazine).
 - Brochures distributed at an exhibition can constitute an offer. *See In re Brigance*, 792 F.2d 1103, 1107 (Fed Cir. 1986).
 - Price quotes can constitute an “offer” even where the claimed invention is not described. *See Sonoscan v. Sonotek*, 936 F.2d 1261, 1263 (Fed. Cir. 1991). Even if the price quote specifically disclaims being an offer, it can nevertheless trigger the on sale bar. *See State Indus., Inc. v. Mar-Flo Indus., Inc.*, 639 F. Supp. 937 (E.D. Tenn. 1986), *aff'd*, 818 F.2d 875 (Fed. Cir.), *cert. denied*, 484 U.S. 845 (1987).
 - Sending a prototype in order to solicit an offer from a customer constitutes an “offer” within the meaning of the on sale bar rule. *See Intel Corp. v. ITC*, 946 F.2d 821 (Fed. Cir. 1991); *Stearns v. Beckmann Instruments*, 737 F.2d 1565 (Fed. Cir. 1984). However, confidential demonstrations of a prototype do not put the invention “on sale” where there was “no evidence that commercial exploitation was present at or a part of the demonstration.” *Pooler v. Massinghoff*, 214 U.S.P.Q., 506, 509 (D.D.C. 1982).

Not All Commercially Oriented Activity Triggers On Sale Bar

- Assignment of a patent or patent application does not trigger the on sale bar. *See Moleculon Research Corp. v. CBS, Inc.*, 229 U.S.P.Q. 805 (Fed. Cir. 1986); *Federal Sign & Signal Corp. v. Bangor Punta Operations, Inc.*, 357 F. Supp. 1222 (S.D.N.Y. 1973).
- Licensing activity also does not implicate the on sale bar. *See Mas-Hamilton Group v. La Gard, Inc.*, 48 U.S.P.Q.2d 1010, 1019 (Fed. Cir. 1998).
- Intracompany transactions do not trigger the on sale bar. *See Union Carbide Corp. v. Filtrrol Corp.*, 170 U.S.P.Q. 482 (C.D. Cal. 1974) (shipment of product from one corporate division to another does not put invention “on sale”).
- However, a subsidiary (at least one that is not wholly owned) may constitute a separate entity from its parents. Hence, transactions between such subsidiaries and their parent companies may trigger the on sale bar. *See Ferag AG v. Quipp Inc.*, 45 F.3d 1562, 1567 (Fed. Cir. 1995) (parent’s 50% ownership interest in subsidiary insufficient to characterize them as a single entity because parent did not completely control subsidiary’s marketing of invention).

Helsinn -- Facts

- Helsinn makes Aloxi® (palonosetron) – a treatment for nausea/vomiting caused by chemotherapy.
- While developing palonosetron, Helsinn entered into two agreements (license and supply/purchase agreement)
 - Third party received right to distribute/promote/market/sell a 0.25 mg dose of palonosetron in the US
 - Required the third party to keep information received under the agreement confidential
 - A joint press release described the agreements, as did a redacted 8K filing by the third party (neither included the dosage formulation as described in the agreement)
- 2 years later, Helsinn filed a US Provisional Patent Application covering 0.25 mg dose of palonestron and subsequently filed other applications, claiming priority to this provisional (one of which was filed in 2013 and is therefore subject to the AIA)
- Several years later, Teva Pharmaceuticals sought approval to market a generic 0.25 mg palonosetron product.
- Helsinn brought suit against Teva for patent infringement. Teva countered that the patent at issue was invalid under the on-sale bar.

Helsinn – Procedural History

- District Court: AIA's on-sale bar did not apply because the press release and 8K filings did not disclose the 0.25 mg dose
- Fed Circuit: Reversed. Sale was publicly disclosed in the press release and 8K filings, regardless of whether the details of the invention were publicly disclosed in the terms of the agreements.
- Cert granted.
 - Issue – Under the AIA, does an inventor's sale of an invention to a third party who is obligated to keep the invention confidential qualify as prior art for purposes of determining patentability of the invention?

Helsinn – Supreme Court Decision

- In an unanimous opinion, delivered by Justice Thomas, the Court held:

“[T]he sale of an invention to a third party who is contractually obligated to keep the invention confidential *may* place the invention ‘on sale.’” (emphasis added)
- Reasoning:
 - “This Court’s precedent ... supports the view that a sale or offer of sale need not make an invention available to the public to constitute invalidating prior art”
 - “[T]he catchall phrase ‘or otherwise available to the public’ is not enough of a change for the Court to conclude that Congress intended to alter the meaning of ‘on sale.’”

Comparison of Pre-AIA § 102(b) to Post-AIA § 101(a)(1)

A person shall be entitled to a patent unless ... the invention was ...

on sale, in this country, more than one year prior to the date of application in the United States

A person shall be entitled to a patent unless ... the claimed invention was patented, described in a printed publication, or in public use, on sale, *or otherwise available to the public* before the effective filing date of the claimed invention

Post-*Helsinn* Case Law

- *Schlumberger Tech. Corp. v. BICO Drilling Tools, Inc.*, 2009 WL 2450948 (S.D. Tex June 12, 2019) – *Helsinn* not applicable to sales of product that discloses the invention by a third party; public use prong, not on-sale bar, relevant.
- *Corus Realty Holdings, Inc. v. Zillow Group Inc.*, 2019 WL 2766508 (W.D. Wash, July 2, 2019) – *relied on Helsinn's* statutory interpretation of catchall phrase “or otherwise available to the public” in Markman hearing.
 - *Also cited outside of patent context* -
 - *Rehaif v. United States*, 139 S. Ct. 2191 (June 21, 2019) – Criminal Justice; “when particular statutory language has received a settled judicial construction, and Congress subsequently reenacts that ‘same language’, courts should presume that Congress intended to ratify the judicial consensus.”
 - *Kleber v. CareFusion Corp.*, 914 F.3d 480 (7th Cir. 2019) – Labor & Employment

On Sale Bar: Considerations

Craft the purpose of the agreement

- Does the agreement mention a desire to sell/purchase/distribute a widget
- Is the purpose of the agreement for commercial sale or for testing/internal evaluation?

Limit discussing price, transfer of title in the agreement

- Does the agreement include any of the following: sales price, tangentially-related prices (e.g., cost to manufacture), or no price
- Do not transfer of title from one party to the other

Do not rely on confidentiality obligations

- Good practice to include confidentiality obligations, but mere inclusion will not protect against the application of the on-sale bar
- Review public announcements
 - Legal Department should review any press release/public filings regarding potential agreements or recently-entered into agreements

Lessons from Helsinn – Practice Pointers

- In theory, best practices should not change, as *Helsinn* merely reiterated existing (pre-AIA) law regarding the on sale bar.
- Primarily a problem for smaller pharma/biotech companies that do not have manufacturing, marketing and distribution capabilities.
 - Big Pharma will generally handle manufacturing of clinical batches internally; if a CMO is used for commercial manufacture, will only enter into a contract in late Phase III.
 - Unlike Big Pharma, smaller companies typically do not have internal patent groups, and outside counsel may not be up to speed on changes to dosage, formulation, etc. during development.
- Make sure that client is well educated about on sale bar and other patent issues.
 - **Query:** For the non-patent savvy client, is it better to encourage early filing of inventions prior to any sale?
- Structure manufacturing agreements as fee for service rather than sale of product (i.e., ownership of product always remains with patentee). Structure other agreements as license agreements or service agreements rather than product sales agreements.
- Patent prosecution tips:
 - File early, file often. Utilize provisional patent applications.
 - Include numerous blaze marks and other support for changes in dosing or formulation.
 - For pipeline products, have regular assessments of commercial embodiment (i.e., IND filing, after dose ranging studies mid-Phase III, NDA filing), and consider filing CIPs or new applications at each stage.
 - For chemical product launches, get input from both commercial clients and technology clients about the timeline for engaging third parties (under agreement or otherwise), including pre-commercial marketing efforts.
 - Include clinical development and commercial team members in Patent Review Committee.

**AVOIDING THE ON SALE BAR SINS THAT COULD LAND YOUR CLIENT IN PATENT HELL:
LESSONS FROM THE *HELSINN* CASE**



Questions?

Presented by

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Peter Tu, Chief Legal Officer, Signum Biosciences, Inc.

Sara Wexler Koblitz

Sara Wexler Koblitz advises FDA-regulated clients on a range of issues with a particular focus on Hatch-Waxman patent and exclusivity, biosimilars, and the Orange Book. She helps drug and device manufacturers in various stages of product development and guides clients through the applicable regulatory requirements with respect to applications and submissions, device classification, potential exclusivities, promotional issues, and post-marketing requirements.

Ms. Koblitz also counsels cosmetics, food, and dietary supplement clients, with experience regarding genetically-modified foods, medical foods, food labeling, and dietary supplement claims and substantiation. Ms. Koblitz has worked with companies of all sizes, from start-ups to fortune 500 companies. Ms. Koblitz also has experience in export control and other areas of regulatory law.

Prior to joining Hyman Phelps & McNamara, Ms. Koblitz practiced at a major intellectual property firm, where she counseled clients on the Hatch-Waxman Act and other areas of FDA regulation. Prior to that she worked on general FDA regulatory matters at an AmLaw 100 firm. While in law school, Ms. Koblitz clerked at the FDA Office of Policy and the Humane Society of the United States.

To Exclusivity and Beyond

November 20, 2019



HP Hyman, Phelps
& McNamara^{PC}

Brief Background

Hatch-Waxman Compromise

- Created modern-day generic drug industry
- Benefits for generic industry
 - Abbreviated approval mechanism for all drugs
 - Reversal of *Roche v. Bolar* to allow testing prior to patent expiration
 - 180-day exclusivity as a reward for patent challenges
- Benefits for innovator industry
 - Patent term restoration
 - Process for resolving patent disputes prior to generic approval
 - Protection for innovative drugs even in absence of patents

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& McNamara^{PC}

Brief Background

Types of Exclusivity

- Non-patent exclusivity
 - NCE exclusivity – 5 years
 - New clinical study – 3 years
- Patent exclusivity
 - 30-month stay
 - Delayed approval until patent expiration
- Generic drug exclusivity – 180 days (ANDA only)
- Orphan drug exclusivity – 7 years
- Pediatric exclusivity – 6 months (add-on only)
- QIDP – 5 years



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Brief Background

Overview of Drug Applications

- “Full” New Drug Application (NDA) – 505(b)(1)
 - Includes “full reports” of studies to prove safety and effectiveness
- 505(b)(2) Application – 505(b)(2)
 - NDA where applicant does not have rights to some of the “full reports” necessary for approval
- Abbreviated New Drug Application (ANDA) – 505(j)
 - No requirement for “full reports”
 - Approval based on showing of similarity to previously approved drug product, including bioequivalence



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Exclusivity Incentives

- Exclusivity Protections for Full NDAs and for 505(b)(2)s
 - Non-Patent Exclusivity (5 and 3 years)
 - Patent Listing and Certification (30-month stay)
 - Pediatric Exclusivity (6 months)
 - Orphan Drug Exclusivity (7 years)
 - QIDP Exclusivity (5 years)
- Full NDAs are not blocked by any exclusivity period other than Orphan Drug Exclusivity
- 505(b)(2) applications are blocked by all types of exclusivity protecting the listed drug, including patent certification
- 505(b)(2) applications are not eligible for, or subject to, 180-day exclusivity



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Exclusivity Incentives

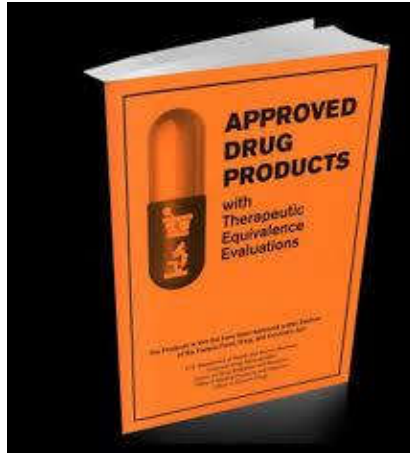
- Exclusivity Protections for ANDAs
 - 180-day
 - Competitive Generic Therapy
- Timing of ANDA approval depends upon patent and non-patent exclusivity of listed drug



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Exclusivity Incentives

- Exclusivities and patents are listed in FDA publication Approved Drug Products With Therapeutic Equivalence Evaluations, commonly referred to as **the Orange Book**
 - Therapeutic Equivalence evaluations (i.e., which products are substitutable also listed in OB)



Exclusivity Incentives

Orange Book

- FDA's Orange Book
 - Only patents listed in the Orange Book are eligible for patent certifications and the related 30-month stay of FDA approval
 - Without Orange Book listing, patent holder can still sue for infringement, but infringer is not required to provide notice to patent holder and no automatic right to enjoin FDA approval
 - Patent holder must monitor market
 - Available recourse is treble damages through patent litigation *AFTER* infringing product has come to market

NCE Exclusivity

Basics

- Granted to drug products containing an active drug molecule that has never been approved before, i.e., a “new chemical entity” (NCE)
- Blocks submission of 505(b)(2) applications and ANDAs for **5 years**
 - 4 years if subsequent application contains a “paragraph IV” certification
 - Effectively provides 6-7 years of exclusive marketing because of 30-month stay
- Umbrella Policy: exclusivity protects all versions of the drug containing the same active moiety



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NCE Exclusivity

New Chemical Entity

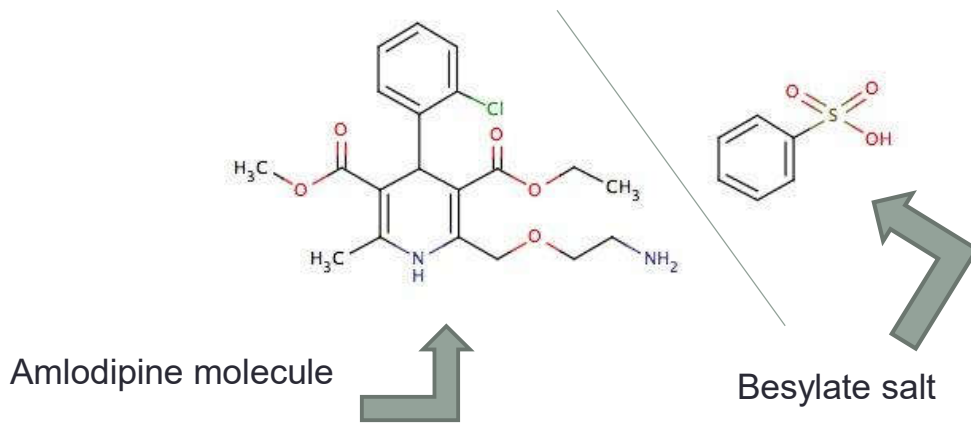
- NCE defined as “a drug that contains no active moiety that has been approved by FDA in any other [application] submitted under section 505(b) of the act” (21 C.F.R. § 314.108(a))
- “Active moiety” defined as “the molecule or ion, excluding those appended portions of the molecule that cause the drug to be an ester, salt . . . or other noncovalent derivative (such as a complex, chelate, or clathrate) of the molecule, responsible for the physiological or pharmacological action of the drug substance” (21 C.F.R. § 314.3(b))
- E.g., Amlodipine maleate versus amlodipine besylate



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NCE Exclusivity

Amlodipine Besylate Example



After removing the besylate salt, the active moiety is the amlodipine molecule

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NCE Exclusivity

Recent Controversies

- *Amarin Pharmaceuticals Case*
 - NCE exclusivity for complex mixtures (fish oil products)
 - Can a single active ingredient (mixture) have multiple active moieties? The DC District Court said no!
- Fixed-Dose Combinations
 - Do all active ingredients in a combination have to be NCEs for the product to be eligible for NCE exclusivity?
 - FDA's historical position was yes.
 - FDA changed this position after submission of 3 petitions – now, NCE exclusivity is available even if only one active ingredient is new
 - FDA, however, refused to apply its new policy retrospectively

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New Clinical Study Exclusivity

Basics

- Granted for changes to previously approved drugs requiring the submission of new clinical studies
- Blocks approval of 505(b)(2) applications and ANDAs for **3 years**
- Protects only the change supported by the new studies, e.g., extended release dosage form
 - Carve-outs may be possible



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New Clinical Study Exclusivity

Requirements

- Studies must be conducted or sponsored by the applicant
- Studies must be “new”
 - “New” does not mean newly conducted
 - It means that the results have not been relied on by FDA to demonstrate effectiveness of a previously approved drug
- Studies must be “essential to approval”
 - No other data could support approval
 - FDA will not make this determination prior to approval
 - Bioequivalence or bioavailability studies not eligible



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New Clinical Study Exclusivity

Recent Controversies

- *Braeburn case*
 - BRIXADI™ (buprenorphine) received tentative approval from FDA in December 2018, but final approval blocked by 3-year exclusivity for Sublocade
 - Court determined that FDA's limit of 3-year exclusivity to the innovation supported by clinical investigations was arbitrary and capricious because no scientific or legal principle guided "innovation" interpretation
 - On remand, FDA posed the critical question: *what unique clinical question(s) about the safety and/or efficacy of the active moiety for the relevant use do the new clinical investigations essential to approval answer for the first time?*



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Orphan Drug Exclusivity

Overview

- Provides incentives for developing drugs to treat rare diseases or conditions
- Development incentives
 - Tax credit
 - Grants/contracts
 - Assistance in product development
- 7-year exclusive marketing



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Orphan Drug Exclusivity

Requirements

- Designation as orphan drug prior to submission of a marketing application
- Rare disease or condition
 - Affects less than 200,000 in U.S.; or
 - No reasonable expectation of recovering costs from U.S. sales
- First approval



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Orphan Drug Exclusivity

Scope

- 7-year exclusivity period
- Blocks approval of NDAs, 505(b)(2) applications, ANDAs, and Biologics License Applications (BLAs), *even if supported by full clinical trials*
- Limited to “same drug” for same indication
 - “Same drug” applies unless “clinically superior” to drug with ODE
 - “Same drug” and “clinically superior” defined by regulation, and after 2017, by statute



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Orphan Drug Exclusivity

Recent Controversies

- *Depomed* and *Eagle*
 - ODD granted based on “plausible hypothesis” of clinical superiority to drugs with ODE, but FDA refused to grant ODE after approval
 - FDA wanted ***proof*** that drug was clinically superior at time of approval
 - D.D.C. in 2014 held that plain language of Orphan Drug Act requires FDA to recognize ODE for ***any*** designated and approved drug
 - FDA didn’t appeal, but applied decision only to *Depomed*, so *Eagle* filed a similar suit
 - D.D.C. found in favor of *Eagle*, but FDA appealed – pending
- Cost-Recovery Provisions
 - In an unprecedented decision, FDA withdrew *Indivior’s* buprenorphine ODD after Citizen Petition
 - FDA concluded that its cost-recovery analysis 25 years earlier should have included an analysis of every possible scenario that could lead to cost recovery, including changes in law and addict behavior



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Pediatric Exclusivity

Overview

- Intended to provide an incentive for companies to conduct pediatric studies and generate pediatric labeling
- Granted to innovators who successfully complete FDA-requested clinical trials in pediatric populations



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Pediatric Exclusivity

Scope

- Adds 6 months to unexpired exclusivity periods, including:
 - Non-patent exclusivity (both 3- and 5-year exclusivity)
 - Orphan drug exclusivity (7 year)
 - Paragraph II, III, and IV certifications (if innovator wins)
- Pediatric exclusivity does not:
 - Extend the patent itself; or
 - Extend a 30-month stay
- Umbrella Policy: pediatric exclusivity applies to any drug product that contains the same active moiety as the drug studied



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Pediatric Exclusivity

Requirements

- Written Request (WR) from FDA for pediatric studies
 - May require development of pediatric formulation
- NDA holder completes studies within timeframes and submits acceptable reports (usually via NDA supplement)
- Acceptable Reports:
 - Do not need to result in pediatric labeling, but
 - Must fairly respond to the written request and be conducted by accepted scientific principles and reported properly



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Pediatric Exclusivity

Recent Controversies

- *Amgen*
 - Sued after FDA refused to grant it pediatric exclusivity for cinacalcet
 - FDA determined that Amgen failed to complete one of the studies in the WR and that the studies conducted did not “fairly respond” to the WR
 - D.D.C. deferred to FDA’s interpretation of “fairly respond” standard

QIDP Exclusivity

Overview

- New exclusivity provision enacted in 2012 for Qualified Infectious Disease Products (QIDP)
- Intended to provide incentives for the research and development of new antibiotic and antifungal drug products
- Adds 5 years of exclusivity for qualifying products to existing exclusivity periods

QIDP Exclusivity

Scope

- Adds 5 years of exclusivity to:
 - NCE exclusivity
 - 3-year exclusivity
 - Orphan drug exclusivity
 - In addition to pediatric exclusivity
- Limitations: QIDP exclusivity does not apply to:
 - Supplements for which QIDP exclusivity already granted
 - Subsequent application for certain changes (new use, dosage form, strength, etc.)
 - Products that fail to meet definition of QIDP



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QIDP Exclusivity

Requirements

- Designation as QIDP before NDA submission
- Approval of NDA (not BLA) on or after July 9, 2012
- QIDP Defined (FDC Act § 505E(g)):
 - Antibacterial or antifungal drug for human use intended to treat serious of life-threatening infections, including those caused by resistant, novel, or emerging pathogens.
 - FDA is required to maintain a list of qualifying pathogens



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Applicability to Combination Products

- All the same exclusivities for NDAs are available for combination products that include a drug approved under the 505(b) pathway
 - Device patents may be listed in Orange Book, but only for combination products
 - To list a device patent in the Orange Book, it is important that the drug labeling has contemplated use of the relevant device
 - Patent must claim a feature of the device that was integral to FDA approval or to the overall safety and efficacy of the drug
- AND**
- It must be reasonable to believe that the device patent would be infringed if an ANDA for the drug is approved



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Labeling Implications of Exclusivity

- Avoid carve-outs and design-arounds
 - Better to integrate exclusivity-protected indications, safety information, or MOUs into a single indication
 - Labeling language should track carefully the exclusivity obtained
 - Including as much relevant trial or patent-protected safety information as possible can help
 - Not an issue for NCE, QIDP
 - The more integral the exclusivity-protection is to the safe-use of the product, the more difficult it is to design-around



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Tactics Used to Extend Monopolies

- Citizen Petitions
- Product Hopping/Evergreening/Forced Switching
- Pay for Delay
- Sample Restrictions
- Authorized Generics

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180-Day Exclusivity

- As an incentive for generic companies to further the statutory purpose of helping the public gain access to lower-cost drug products more expeditiously, the Hatch-Waxman Amendments grant a 180-day period of generic drug market exclusivity to the first ANDA applicant that submits a substantially complete application containing a Paragraph IV patent certification.
- 180-day exclusivity prevents FDA from approving subsequently submitted ANDAs containing a Paragraph IV certification.

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180-Day Exclusivity

- Under amendments made to the FDC Act by the Medicare Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066, the first ANDA applicant that submits a substantially complete application containing a Paragraph IV patent certification can forfeit 180-day exclusivity eligibility for various reasons.
- 180-day exclusivity begins on the date of commercial marketing.

180-Day Exclusivity Forfeiture Event

- Failure to Market
- Withdrawal of application
- Amendment of certification
- Failure to obtain tentative approval
- Agreement with another ANDA applicant, RLD holder, or patent owner
- Expiration of all patents

Competitive Generic Therapy Exclusivity

- Expedited development and approval pathway for generic versions of drugs for which there is *inadequate generic competition*
 - Inadequate Generic Competition: not more than one approved drug in the active section of the Orange Book
- Provides 180-day exclusivity for first approved CGT-designated ANDA applicant referencing an RLD with no unexpired patents or exclusivities



Patent Term Extensions

- PTE available to compensate patent holders for loss of term while product is in development and review
- PTE calculation:
 - Regulatory Review Period (RPP) – Pre-Patent Grant Regulatory Review Period (Pre-Patent) – Time applicant did not act with due diligence (DD) – 1/2 (Testing phase – Pre-Patent) = PTE
 - “Testing phase” begins on the effective date of an IND, and ends on the date a New Drug Application (“NDA”) is submitted to FDA
 - The “review phase” is the period from NDA submission to the date of FDA’s approval of an NDA
- Maximum of 5 years can be restored to the patent
- Total patent life for the product with extension cannot exceed 14 years (from approval)



Patent Term Extensions

- Eligibility Requirements:
 - Patent must claim the product, method of using product, or method of manufacturing product
 - Patent is not expired
 - Patent term has not previously been extended
 - PTE Application must be submitted within **60 days** of FDA approval
 - Product must have been subject to a regulatory review period prior to commercial marketing or use
 - Product must be first permitted commercial marketing of product after regulatory review period:
 - Active ingredient or salt/ester of active ingredient must not have been previously approved

Biologics Price Competition and Innovation Act Exclusivity

- “Data exclusivity”: the period when FDA cannot rely on its prior finding of safety, purity, and potency of the reference product based on BLA holder’s clinical data to support approval of a biosimilar
- Under BPCIA, biosimilar applicant may not **submit** application for 4 years after date when reference product first licensed
- Also, FDA may not **approve** application until 12 years after date when reference product first licensed

BPCIA Exclusivity

Data Exclusivity Period: Evergreening

BPCIA specifies no new 12-year exclusivity period for:

- Supplemental BLA
- Subsequent application with change that results in:
 - New indication
 - New route of administration
 - New dosing schedule
 - New dosing form delivery system
 - New delivery device or strength
 - **Structural modification to molecule that does not change safety, purity, or potency**



BPCIA Patent Dance

Patent Enforcement Overview

- Unlike Hatch-Waxman, no Orange Book
 - Instead, requires private exchange of information to identify relevant patents
- Timing of BPCIA patent litigation
 - Unlike Hatch-Waxman, no automatic 30-month stay of approval upon filing of patent litigation
 - Two waves of pre-launch litigation under statute
 - Complicated procedure to select patents for earliest litigation
 - Potential for at-risk biosimilar product launch
- Notification to third-party patent owners and standing requirements
 - Practical issues raised by necessary participation of third-party patent owners, such as university licensors
 - Effect on rights of third-party patent owners



BPCIA Patent Dance

Amgen v. Sandoz:

Supreme Court interprets BPCIA

- Amgen holds BLA for Neupogen® (filgrastim) for preventing neutropenia
- In 2014, Sandoz filed aBLA for biosimilar filgrastim
- After FDA accepted for review, Sandoz told Amgen it was “opting out” of the BPCIA patent challenge procedures and invited an infringement suit
- Thereafter, the parties did not engage in patent information exchanges, and Amgen sued to enforce BPCIA
- On March 6, 2015, FDA approved Zarxio®, Sandoz’s biosimilar filgrastim
- Issue: can the applicant “opt out” of BPCIA procedures?



BPCIA Patent Dance

BPCIA § (l)(2)(A) and § (l)(9)(C)

- Not later than 20 days after FDA gives notice of acceptance of aBLA, applicant “**shall provide** to the [RPS] a copy of the **application** . . . and such other information that describes the **process or processes used to manufacture** the biological product that is the subject of such application”
- BPCIA also specifies consequences of applicant’s failing to provide application and manufacturing information:
 - If not provided, RPS (but not applicant) can sue for DJ of infringement, validity, or enforceability of patents that claim the biological product or use of the product



BPCIA Patent Dance

Supreme Court Decision

- Holding: when applicant fails its BPCIA disclosure requirements, the **only remedy under federal law** available to the RPS is the right to bring immediate action for declaratory judgment of infringement
 - BPCIA's requirement that applicant provide aBLA and manufacturing information is not enforceable by injunction under federal law, because in granting DJ right, BPCIA excludes all other federal remedies
 - Court remanded to Federal Circuit to decide whether injunction available under applicable state law, and if so, whether state law is preempted. Currently pending.
- At least for the time being, the result of *Amgen v. Sandoz* is that an applicant can opt-out of the BPCIA patent dance and simply accept the consequences prescribed by the BPCIA



BPCIA Patent Dance

180-Day Notice of Commercial Marketing

“The subsection (k) applicant shall provide notice to the reference product sponsor not later than 180 days before **the date of the first commercial marketing of the biological product licensed under subsection (k).**”

BPCIA § (l)(8)(A)



BPCIA Patent Dance

Amgen v. Sandoz

- Federal Circuit: statutory language compels the conclusion that an applicant “may only give effective notice of commercial marketing after the FDA has licensed its product”
- Sandoz argues effect is to give the RPS an extra 6 months of data exclusivity, for a total of 12.5 years
- Supreme Court reverses
- Held: as matter of statutory interpretation, applicant may provide notice “either before or after receiving FDA approval”

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& McNamara_{PC}



THANK YOU!!
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