



Sweeping Developments in Patent Reform Agenda: The Innovation Act and the PATENT Act - A 2016 Perspective

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Speaker Firms and Organization:

Hanson Bridgett LLP
Robert A. McFarlane
Partner

Fenwick & West LLP
Michael J. Sacksteder
Partner

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Michael Kahn
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Innovation Act**PATENT Act**

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Innovation Act

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Founded in 1958, Hanson Bridgett has more than 150 attorneys located in offices in San Francisco, the North Bay, Sacramento and the East Bay. Our clients range from multinational Fortune 500 corporations to individuals, including a number of public retirement systems and public agencies in California. More information on Hanson Bridgett can be found at www.hansonbridgett.com.

Fenwick & West provides comprehensive legal services to ground-breaking technology and life sciences companies at every stage of their lifecycle. The firm crafts innovative, cost-effective and practical solutions for established and emerging companies on issues ranging from venture capital, public offerings, M&A and strategic relationships, to intellectual property, litigation and dispute resolution, taxation, antitrust, and employment and labor law. For more than four decades, Fenwick has helped some of the world's most recognized companies become and remain market leaders. For information, visit www.fenwick.com.

Akin Gump Strauss Hauer & Feld LLP is a leading global law firm providing innovative legal services and business solutions to individuals and institutions. We were founded in Texas in 1945 by Robert Strauss and Richard Gump, with the guiding vision that commitment, excellence and integrity would drive the success of the firm. We are one of the world's largest law firms, with more than 900 lawyers and professionals in 21 offices. Our lawyers, many of them with years of experience in the boardroom, on the bench and in the halls of government, collaborate across borders and practice areas to provide comprehensive counsel. Our firm's clients range from individuals to corporations and foreign governments.

Brief Speaker Bios:



Robert A. McFarlane

Robert A. McFarlane is a registered patent attorney, litigation partner, and Chair of Hanson Bridgett's Technology Practice. His practice focuses on patent, intellectual property, and technology-related disputes and counseling. Rob is a Stanford-educated engineer who has litigated patent infringement matters involving a wide array of technologies in courts throughout the country. He is experienced in both bench and jury trials and has argued cases in the Federal Circuit and California Courts of Appeals. Rob has been teaching patent law and patent litigation as an adjunct professor at Golden Gate University School of Law since 2008.



Michael J. Sacksteder

Michael Sacksteder is Chair of the Patent Litigation Group at Fenwick & West – a team of more than 50 top-notch litigators with diverse legal and technical backgrounds at one of the foremost technology law firms in the country. Mr. Sacksteder has led patent litigation teams for high-profile clients such as Intuit, Symantec, Supercell, and Ancestry.com. He has successfully served as trial counsel in some of the most active patent litigation courts around the country, including the Eastern District of Texas, the District of Delaware, and the Northern District of California, and he has successfully argued before the United States Court of Appeals for the Federal Circuit. In addition to his work in district courts and the Federal Circuit, Mr. Sacksteder has substantial experience with post-grant proceedings, such as inter partes review proceedings (“IPRs”) before the Patent Trial and Appeal Board. Clients have relied on him in litigation matters in a wide variety of technological fields, including computer hardware, software, networking, and security, semiconductors and semiconductor processing, polymer chemistry, pharmaceuticals, and medical devices.



Michael Kahn

Michael Kahn is an experienced trial lawyer who focuses his practice on litigating patent infringement disputes and related claims such as trade secret misappropriation, unfair competition and breach of contract. Mr. Kahn advises clients concerning intellectual property licensing, planning and strategy – both from a portfolio management perspective and in anticipation of litigation for both patent owners and potential defendants. He also represents clients in connection with Patent Office inter partes review proceedings. Michael is experienced in all aspects of intellectual property litigation, including discovery, Markman, trial and appeal and truly enjoys the fast-paced, oral advocacy components of trial practice.

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Sweeping Developments in Patent Reform Agenda: The Innovation Act and the PATENT Act - A 2016 Perspective

Summary

The patent system has seen dramatic changes over the years with the objective centered on seeking for game-changing patent reforms. Even after the passage of the American Invents Act (AIA) in 2011, certain groups continued to press the Congress for additional reform that addresses patent protection against Patent Assertion Entities (PAEs), most commonly known as patent trolls. In response, the Congress sponsored legislations directed towards patent reform once again. Among these legislations are the Innovation Act and its Senate counterpart, the Protecting American Talent and Entrepreneurship (PATENT) Act.

Re-introduced in February 2015, The Innovation Act includes, among other things, heightened pleading requirements, more limits on early discoveries and greater judicial latitude for awarding fee-shifting. The PATENT Act introduced in April 2015 shares similar provisions as seen in the Innovation Act. Additionally, both the Innovation Act and the PATENT Act include provisions on customer stays and demand letter content.

Since the latter half of 2015, there has been a discussion of possible further amendment to the bills in addition to the mentioned provisions. While these bills promise to strengthen patent rights while simultaneously aiming to discourage patent trolls, there are still criticisms that emerge in response to the bills' proposals. Critics assert that the proposed reforms will undermine the patent system and harm U.S. competitiveness. Nevertheless, companies should stay attentive to the ongoing patent reform issues and should continue to assess the value of their patent portfolio in the present legal environment.

Innovation Act**PATENT Act**

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Summary

In a two-hour LIVE Webcast, a panel of thought leaders and practitioners assembled by The Knowledge Group will discuss the significant and latest issues in Sweeping Developments in Patent Reform Agenda: The Innovation Act and the PATENT Act.

Key issues that will be covered are:

- Overview of the Innovation Act and the PATENT Act
- Significant Provisions:
 - Heightened Pleading Requirements
 - Limited Early Discoveries
 - Fee Shifting
 - Customer Stays
 - Demand Letter Content
 - AIA Amendments
- Recent Legislative Updates

Featured Speakers:

SEGMENT 1:



Robert A. McFarlane
Partner
Hanson Bridgett LLP



HansonBridgett

SEGMENT 2:



Michael J. Sacksteder
Partner
Fenwick & West LLP



SEGMENT 3:



Michael Kahn
Partner
Akin Gump Strauss Hauer & Feld LLP

Akin Gump
STRAUSS HAUER & FELD LLP



SEGMENT 1:

Robert A. McFarlane
Partner
Hanson Bridgett LLP



Introduction

Robert A. McFarlane is a registered patent attorney, litigation partner, and Chair of Hanson Bridgett's Technology Practice. His practice focuses on patent, intellectual property, and technology-related disputes and counseling. Rob is a Stanford-educated engineer who has litigated patent infringement matters involving a wide array of technologies in courts throughout the country. He is experienced in both bench and jury trials and has argued cases in the Federal Circuit and California Courts of Appeals. Rob has been teaching patent law and patent litigation as an adjunct professor at Golden Gate University School of Law since 2008.

Prior to joining Hanson Bridgett in 2011, Rob spent the majority of his career as a litigation partner and patent litigator with Townsend and Townsend and Crew LLP.



SEGMENT 1:
Robert A. McFarlane
Partner
Hanson Bridgett LLP



The American Invents Act of 2011: Is the Reform Agenda Unfinished?



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Robert A. McFarlane
Partner
Hanson Bridgett LLP



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Unprecedented Rate of Change in Patent Law

- *Alice Corp. v. CLS Bank International*, 134 S.Ct. 2347 (2104) (addressing patentability of software and barring patenting of “abstract ideas”)
- *Limelight Networks v. Akamai Technologies*, 134 S.Ct. 2111 (2014) (divided infringement)
- *Octane Fitness, LLC v. ICON Health & Fitness, Inc.*, 134 S. Ct. 1749 (2014) (fee shifting for “exceptional cases under 35 U.S.C. §285)
- *Highmark v. Allcare Health Mgmt.*, 134 S.Ct. 1744 (2014) (fee shifting for “exceptional cases under 35 U.S.C. §285)



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Robert A. McFarlane
Partner
Hanson Bridgett LLP



Unprecedented Rate of Change in Patent Law

- Judicial Decisions Limiting Patent Scope and Damages
 - *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S.Ct. 2107 (2013) (isolated human DNA)
 - *Mayo Collaborative Services v. Prometheus Labs., Inc.* 132 S.Ct. 1289 (2012) (addressing diagnostic procedure found to be law of nature)
 - *Global-Tech Appliances, Inc. v. SEB S.A.*, 131 S.Ct. 2060 (2011)(Indirect Infringement)



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Robert A. McFarlane
Partner
Hanson Bridgett LLP



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Unprecedented Rate of Change in Patent Law

- *eBay Inc. v. MercExchange LLC*, 547 U.S. 388 (2006) (injunctions not automatic in patent infringement cases)
- *KSR International Co. v. Teleflex Inc.*, 548 U.S. 938 (2007) (lowering standard to demonstrate a patent is invalid as obvious)
- *Medimmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007) (lowering threshold for declaratory judgment jurisdiction)
- *Uniloc USA, Inc. v. Microsoft Corp.*, 632 F.3d 1292 (Fed. Cir. 2011); *Lucent Techs., Inc. v. Gateway, Inc.*, 580 Fed. Cir 2009) (exemplary of cases reigning in damages in patent infringement cases)



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Robert A. McFarlane
Partner
Hanson Bridgett LLP



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Unprecedented Rate of Change in Patent Law

- America Invents Act of 2011 (AIA)
 - Most Significant Revision of Patent Law since 1952
 - Creates Proceedings in the USPTO
 - Post Grant Review (35 U.S.C. § 321 *et seq.*)
 - *Inter Partes* Review (35 U.S.C. § 311 *et seq.*)
 - Covered Business Method Review (35 U.S.C. § 324 *et seq.*)
 - Limits Joinder (35 U.S.C. § 299)
 - Must arise out of the same transaction, occurrence or series of transactions relating to the making, using importing, offering for sale or selling the same accused product or process
 - Questions of fact common to all defendants must exist



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Robert A. McFarlane
Partner
Hanson Bridgett LLP



Post-Grant Review

- Allows any third party to challenge patentability on any basis (e.g., anticipation, obviousness, indefiniteness, written description)
- Must commence within 9 months of grant date
- Any relevant evidence: prior art patents, printed publications, pre-filing “on sale” evidence, declaration evidence, expert declarations
- Preponderance of the evidence, not “clear and convincing” as in litigation
- PTO to establish discovery procedures.
- Estoppel: Party requesting Post-Grant Review cannot raise same issues in later litigation



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Robert A. McFarlane
Partner
Hanson Bridgett LLP



Inter Partes Review

- Allows any third party to challenge validity after 9-month window for Post Grant Review
- More limited basis for review: anticipation and obviousness based on prior art patents and printed publications
- Preponderance of the evidence, not clear and convincing as in litigation
- New standard to institute review: “reasonably likely” that challenger will prevail (former standard a lower “substantial new question of patentability”)
- Estoppel: Requesting party cannot raise same issues in subsequent litigation



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Robert A. McFarlane
Partner
Hanson Bridgett LLP



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Covered Business Method Review

- Applies to patents “that claim a method or corresponding apparatus for performing data processing or other operations used in the practice, administration, or management of a financial product or service, except that the term does not include patents for technological inventions.”
- Permits a party accused of infringement (either through litigation or an infringement assertion that would give rise to standing to file a declaratory judgment action) to challenge the patent in the USPTO
 - On any ground (e.g. 101 and 112, not just 102 or 103 as for *Inter Partes* Review)
 - Standard to commence review: petitioner must show that it is more likely than not that at least one challenged claim is unpatentable
 - No presumption of validity
 - Estoppel: Requesting Party cannot raise same issues in subsequent litigation



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Robert A. McFarlane
Partner
Hanson Bridgett LLP



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Restrictions on Joinder

- Before the AIA: NPEs routinely sued multiple defendants with nothing in common other than alleged infringement of the patents-in-suit
- Now: defendants can be joined in single case only if (a) joint and several liability arising from same accused products or processes, and (b) questions of fact common to all accused infringers
- But: consolidation for claim construction, discovery, and other pretrial still allowed



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Robert A. McFarlane
Partner
Hanson Bridgett LLP



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Legislative Proposals

- Subsequent (and failed) Attempts at Further Legislative Changes:
 - Innovation Act (2013)
 - The Patent Quality Improvement Act (2013)
 - The Patent Abuse Reduction Act (2013)
 - The Patent Litigation Integrity Act (2013)
 - The Patent Transparency and Improvement Act (2013)



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Robert A. McFarlane
Partner
Hanson Bridgett LLP



Primary Themes is 2013 Proposals

- Expansion of covered business method patent review
- Heightened pleading requirements
- Discovery reform
- Transparency
- Customer lawsuits
- Fee shifting



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Robert A. McFarlane
Partner
Hanson Bridgett LLP



Current Proposals

- Innovation Act (HR 9)
- Patent Act (S 1337)
- STRONG Patents Act (S 632)



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Robert A. McFarlane
Partner
Hanson Bridgett LLP



Current Legislative Proposals

- Raising pleading requirements for infringement claims
- Lowering standards for fee shifting



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Robert A. McFarlane
Partner
Hanson Bridgett LLP



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Significant Legislative Proposals

- Compelled identification of Patent Owners
- Restricting Demand Letters
- Restricting “Pay for Delay”
- Delay discovery until after initial motion practice to decrease costs of litigation



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Partner
Hanson Bridgett LLP



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Significant Legislative Proposals

- Venue
 - *E. D. Texas and D. Delaware*
 - *In re TC Heartland LLC*, Case No. 2016-105 (Fed. Cir. April 29, 2016)
 - Legislative Proposals to Change Venue



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Robert A. McFarlane
Partner
Hanson Bridgett LLP



Significant Legislative Proposals

- Reforms to *Inter Partes* and Post-Grant Review Processes
 - Scope of Claim Construction
 - Evidentiary Standard
 - Clear and convincing v. preponderance of the evidence
 - Standing to initiate IPR
 - Changes to initiation process for IPRs
 - Making Amendments Easier
 - Limitations based on Prior Arguments



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Robert A. McFarlane
Partner
Hanson Bridgett LLP



Significant Legislative Proposals

- Willful Infringement
- Divided Infringement
- Restoring the Grace Period



SEGMENT 2:

Michael J. Sacksteder
Partner
Fenwick & West LLP



Introduction

Michael Sacksteder is Chair of the Patent Litigation Group at Fenwick & West – a team of more than 50 top-notch litigators with diverse legal and technical backgrounds at one of the foremost technology law firms in the country. Mr. Sacksteder has led patent litigation teams for high-profile clients such as Intuit, Symantec, Supercell, and Ancestry.com. He has successfully served as trial counsel in some of the most active patent litigation courts around the country, including the Eastern District of Texas, the District of Delaware, and the Northern District of California, and he has successfully argued before the United States Court of Appeals for the Federal Circuit. In addition to his work in district courts and the Federal Circuit, Mr. Sacksteder has substantial experience with post-grant proceedings, such as inter partes review proceedings (“IPRs”) before the Patent Trial and Appeal Board. Clients have relied on him in litigation matters in a wide variety of technological fields, including computer hardware, software, networking, and security, semiconductors and semiconductor processing, polymer chemistry, pharmaceuticals, and medical devices.

Mr. Sacksteder graduated magna cum laude from the Northwestern University School of Law, where he was editor-in-chief of the Northwestern University Law Review. Before going to law school, Mr. Sacksteder worked as a broadcast journalist.



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Michael J. Sacksteder
Partner
Fenwick & West LLP

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2015-16 Patent Reform Bills – Innovation Act

- H.R. 9 – “Innovation Act”
 - Rep. Bob Goodlatte (R.-Va.)
 - Originally introduced in the 113th Congress as H.R. 3309 Passed the House on December 5, 2013 by a vote of 325 to 91 but the Senate never took action on the bill.
 - Reintroduced on February 5, 2015 in the 114th Congress as H.R. 9.
 - “An marked-up version of the bill was approved for debate on the floor of the House on June 14, 2015 by a 24-8 vote of the Judiciary Committee.



SEGMENT 2:

Michael J. Sacksteder
Partner
Fenwick & West LLP

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2015-16 Patent Reform Bills – Innovation Act

The Innovation Act's stated purpose is to institute "a common set of reforms that will address the most serious abuses currently afflicting the patent-enforcement system." Some of these reforms reflect new thinking about ways of addressing the burden and expense of litigation. Others are variants of proposals that were included in preliminary versions of the AIA itself or its various precursors, but which were omitted from the final public law. Still others address problems that have arisen only in the time since the AIA's enactment. Finally, the Innovation Act corrects several important technical problems that have become apparent during the course of the implementation of the AIA."



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Michael J. Sacksteder
Partner
Fenwick & West LLP

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2015-16 Patent Reform Bills – PATENT Act

- S. 1137 – “PATENT Act”
 - “Protecting Talent and Entrepreneurship Act of 2015”
 - Sens. Charles Grassley (R.-Ia.) and Patrick Leahy (D.-Vt.)
 - Introduced on April 29, 2015.
 - Addresses most of the issues proposed in the Innovation Act (but not venue reform).
 - Reported out of committee on September 9, 2016.



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Michael J. Sacksteder
Partner
Fenwick & West LLP



2015-16 Patent Reform Bills

- Innovation Act and PATENT Act
 - Supported by large technology companies (e.g. Apple, Google, Broadcom) and trade groups, small business associations, and consumer protection groups.
 - Opposed by various industry and other interest groups including certain universities, tech startups, venture capitalists, and pharmaceutical companies.
 - Passage by the end of this year (end of the 114th Congress) appears uncertain



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Michael J. Sacksteder
Partner
Fenwick & West LLP

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Other Recently Introduced Patent Reform Bills

- S. 2733
 - “VENUE Act”
 - Sen. Jeff Flake (R.-Az.)
 - This bill contains the venue law reforms proposed in House “Innovation Act”
 - Introduced on March 26, 2016 and referred to the Judiciary Committee
- H.R. 4829
 - “Trade Protection Not Troll Protection Act”
 - Rep. Tony Cárdenas (D.-Ca.)
 - This bill would change the rules for the domestic industry requirement of section 337 of the Tariff Act of 1930 to prevent NPEs from filing complaints (including patent complaints) with the International Trade Commission in most situations.
 - Introduced on March 21, 2016 and referred to the Ways and Means Committee, Subcommittee on Trade



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Michael J. Sacksteder
Partner
Fenwick & West LLP

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Also-Ran Bills

- S. 632 – “STRONG Patent Act” (“Support Technology and Research for Our Nation’s Growth” Patent Act)
- H.R. 2045 – “TROL Act” (“Targeting Rogue and Opaque Letters”)
- H.R. 1896 – Demand Letter Transparency Act
- H.R. 1832 – Innovation Protection Act



SEGMENT 2:

Michael J. Sacksteder
Partner
Fenwick & West LLP

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Major Provisions of the Innovation Act and PATENT Act

- Fee shifting
- Heightened pleading standards
- Discovery reform
- Customer suit stay
- Demand letters
- Venue reform (Innovation Act and VENUE Act)



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Michael J. Sacksteder
Partner
Fenwick & West LLP



Fee Shifting under Current Law

- “The court in exceptional cases may award reasonable attorney fees to the prevailing party.” 35 U.S.C. § 285.
- Under this statute, “an ‘exceptional’ case is simply one that stands out from others with respect to the substantive strength of a party’s litigating position (considering both the governing law and the facts of the case) or the unreasonable manner in which the case was litigated. District courts may determine whether a case is “exceptional” in the case-by-case exercise of their discretion, considering the totality of the circumstances.” *Octane Fitness, LLC v. ICON Health & Fitness, Inc.*, 134 S. Ct. 1749, 1756 (2014).



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Michael J. Sacksteder
Partner
Fenwick & West LLP

Fenwick
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Fee Shifting under Proposed Legislation

- Innovation Act
 - Court “shall award” reasonable fees and other expenses to prevailing party unless:
 - The position and conduct of the non-prevailing party was reasonably justified in law and fact, or
 - Special circumstances, such as severe economic hardship to a named inventor, make an award unjust.
 - Certification of ability to pay and joinder of another party upon motion
 - Party that unilaterally dismissed and covenants not to sue is treated as non-prevailing party



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Michael J. Sacksteder
Partner
Fenwick & West LLP

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Fee Shifting under Proposed Legislation

- PATENT Act
 - Fees awarded, upon motion, if the position or conduct of the non-prevailing party is shown not to have been objectively reasonable
 - Same provision as House Bill for unilateral dismissal/covenant not to sue
 - Request for certification by NPE of ability to pay/identification of interested parties



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Michael J. Sacksteder
Partner
Fenwick & West LLP



Pleading Standards under Current Law

- Prior to December 2015, FRCP 84 allowed plaintiffs to use Appendix Form 18 (“Complaint for Patent Infringement”) which set out bare allegations and did not require allegations identifying any particular patent claim or accused product.
- In December 2015, FRCP 84 was abrogated and the pleading standard for direct infringement is now governed by FRCP 8 as interpreted by the Supreme Court decisions in *Twombly* and *Iqbal*.
- Thus, FRCP 8 requires that a complaint include facts (as distinct from legal “labels” and “conclusions”) giving rise to a “plausible” (rather than merely “conceivable”) entitlement to relief.



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Michael J. Sacksteder
Partner
Fenwick & West LLP

Fenwick
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Heightened Pleading Standards under Proposed Bills

- Innovation Act
 - Identify claims and accused instrumentality
 - Identify where each element of each claim is found within, and how each limitation of each claim is met by, the accused instrumentality
 - Identify alleged acts of inducement or contributory infringement.

- PATENT Act
 - Same requirements as Innovation Act
 - Motion to dismiss for failure to satisfy



SEGMENT 2:

Michael J. Sacksteder
Partner
Fenwick & West LLP



Discovery under Current Law

- Follows Federal Rules of Civil Procedure, Local Rules (including Local Patent Rules) if any, and the Judge's Scheduling and Standing Orders.
- The December 2015 FRCP amendments reduced the scope of discovery from a "reasonably calculated to lead to the discovery of admissible evidence" standard to a proportionality standard:

"Parties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense and proportional to the needs of the case, considering the importance of the issues at stake in the action, the amount in controversy, the parties' relative access to relevant information, the parties' resources, the importance of the discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit." Fed. R. Civ. P. 26(b)(1).



SEGMENT 2:

Michael J. Sacksteder
Partner
Fenwick & West LLP

Fenwick
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Discovery under Proposed Legislation

- Innovation Act
 - Stay of discovery while motions to dismiss or transfer are pending (except discovery related to motion)
 - Rules changes:
 - Presumptive limit to “core documentary evidence”
 - Bond or showing of ability to pay for additional document discovery
- PATENT Act
 - Similar to House Bill



SEGMENT 2:

Michael J. Sacksteder
Partner
Fenwick & West LLP

Fenwick
FENWICK & WEST LLP

Customer-Suit Stay

- Current law: customer-suit stay generally unavailable
- Proposed bills: Retailer or end user accused of infringement for selling or using accused product “without material modification” may obtain stay, if
 - Manufacturer is party to an infringement action on same patent
 - Covered customer agrees to be bound by result of action against seller
 - Must file early in case
 - May implead manufacturer



SEGMENT 2:

Michael J. Sacksteder
Partner
Fenwick & West LLP

Fenwick
FENWICK & WEST LLP

Demand Letters under Current Law

- Federal law regulating abusive practices limited to the Federal Trade Commissions broad, general authority under the Section 5 of the FTC Act.
- At least 27 states have passed legislation that addresses bad faith assertions of patent infringement in demand letters.



SEGMENT 2:

Michael J. Sacksteder
Partner
Fenwick & West LLP



Demand Letters under Proposed Legislation

- PATENT Act
 - Notice letters must contain specific allegations, omit monetary demands in order to serve as notice for willful infringement
 - Civil penalties for “bad-faith demand letters”
 - False representations
 - Materially misleading
 - Enforceable by FTC



SEGMENT 2:

Michael J. Sacksteder
Partner
Fenwick & West LLP

Fenwick
FENWICK & WEST LLP

Demand Letters under Proposed Legislation

- Innovation Act
 - “Purposely evasive demand letters to end users” cannot serve as notice for willful infringement
 - PTO director to conduct study of bad-faith demand letters



SEGMENT 2:

Michael J. Sacksteder
Partner
Fenwick & West LLP

Fenwick
FENWICK & WEST LLP

Current Venue Statutes for Patent Infringement Actions

- “Any civil action for patent infringement may be brought in the judicial district where the defendant resides, or where the defendant has committed acts of infringement and has a regular and established place of business.” 28 U.S.C. 1400(b)
- A corporation “shall be deemed to reside, if a defendant, in any judicial district in which such defendant is subject to the court’s personal jurisdiction with respect to the civil action in question.” 28 U.S.C. 1391(c)(2)



SEGMENT 2:

Michael J. Sacksteder
Partner
Fenwick & West LLP



Current Venue Statutory Interpretation – “Resides”

- In *VE Holding Corp. v. Johnson Gas Appliance Co*, 917 F.2d 1574 (Fed. Cir. 1990), the Federal Circuit held that “resides” in the patent venue statute (§ 1400(b)) means the same as “corporate residence” as defined by the general venue statute (§ 1391(c)).
- In *In Re: TC Heartland LLC* (Fed. Cir. Apr. 29, 2016), the Federal Circuit rejected petitioner’s argument that Congress’ 2011 amendments to § 1391 means that that statute’s definition of “corporate residence” is now inapplicable to § 1400(b).
- Rather, the court noted that Congressional reports have repeatedly recognized that *VE Holding* is the prevailing law, including reports for the house bill and S.R. 2733 (VENUE Act).



SEGMENT 2:

Michael J. Sacksteder
Partner
Fenwick & West LLP

Fenwick
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Venue Reform (Innovation Act and VENUE Act)

- Venue proper if defendant:
 - Is incorporated or headquartered in district, or
 - Has regular and established place of business in district that gives rise to claim of infringement, or
 - Has consented to being sued in district



SEGMENT 2:

Michael J. Sacksteder
Partner
Fenwick & West LLP

Fenwick
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Venue Reform (Innovation Act and VENUE Act)

- Venue also proper if:
 - Named inventor conducted research or development in district, or
 - A party has regular and established physical facility and
 - Managed significant R&D for invention, or
 - Manufactured a practicing product, or
 - Implemented manufacturing process for a tangible good where process alleged to practice invention



SEGMENT 3:

Michael Kahn
Partner

Akin Gump Strauss Hauer & Feld LLP

Akin Gump
STRAUSS HAUER & FELD LLP

Introduction

Michael Kahn is an experienced trial lawyer who focuses his practice on litigating patent infringement disputes and related claims such as trade secret misappropriation, unfair competition and breach of contract. Mr. Kahn advises clients concerning intellectual property licensing, planning and strategy – both from a portfolio management perspective and in anticipation of litigation for both patent owners and potential defendants. He also represents clients in connection with Patent Office inter partes review proceedings. Michael is experienced in all aspects of intellectual property litigation, including discovery, Markman, trial and appeal and truly enjoys the fast-paced, oral advocacy components of trial practice.



SEGMENT 3:

Michael Kahn
Partner

Akin Gump Strauss Hauer & Feld LLP

Akin Gump
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**Recent Trends In Intellectual Property Law:
The Narrowing Scope of Patent-Eligible Subject Matter and
New Federal Trade Secret Law**



SEGMENT 3:

Michael Kahn
Partner

Akin Gump Strauss Hauer & Feld LLP

Akin Gump
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Overview

- The Scope of Patentable Subject Matter
 - Section 101
 - Recent Supreme Court Cases
 - *Ariosa Diagnostics* – a case study

- Trade Secrets as an Alternative
 - Patents v. trade secrets
 - *Myriad*, post-*Myriad*
 - The Defend Trade Secrets Act of 2016



SEGMENT 3:

Michael Kahn
Partner

Akin Gump Strauss Hauer & Feld LLP

Akin Gump
STRAUSS HAUER & FELD LLP

Are Patents at Risk?

- “It is said that the whole category of diagnostic claims is at risk. It is also said that a crisis of patent law and medical innovation may be upon us, and there seems to be some truth in that concern.”

–Judge Lourie (Concurring in denial of rehearing *en banc* in *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, December 2, 2015)



SEGMENT 3:

Michael Kahn
Partner

Akin Gump Strauss Hauer & Feld LLP

Akin Gump
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35 U.S.C. § 101

- “Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.”



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Michael Kahn
Partner

Akin Gump Strauss Hauer & Feld LLP

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Exceptions to § 101

- “The [Supreme] Court has long held that this provision contains an important implicit exception. ‘[L]aws of nature, natural phenomena, and abstract ideas’ are not patentable.”

Mayo quoting *Diamond v. Diehr*, 450 U.S. 175 (1981).



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Michael Kahn
Partner

Akin Gump Strauss Hauer & Feld LLP

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Recent Supreme Court Cases

- ***Bilski v. Kappos***, 561 U.S. 593 (2010) (Abstract Ideas)
- ***Mayo Collaborative Services v. Prometheus Laboratories, Inc.***, 132 S. Ct. 1289 (2012) (Laws of Nature)
- ***Association for Molecular Pathology v. Myriad Genetics, Inc.*** 133 S. Ct. 2107 (2013) (Laws of Nature)
- ***Alice Corp. v. CLS Bank International***, 134 S. Ct. 2347 (2014) (Abstract Idea)



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Michael Kahn
Partner

Akin Gump Strauss Hauer & Feld LLP

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The Two-Part Test

(1) Determine whether the claims at issue are directed to a patent ineligible concept.

If they are,

(2) Consider the elements of each claim both individually and as an ordered combination to determine whether additional elements transform the nature of the claim into a patent-eligible application.



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Michael Kahn
Partner

Akin Gump Strauss Hauer & Feld LLP

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Growing Challenges

- Application of the two-part test:
 - Computer-implemented systems/methods
 - Diagnostic methods
 - Genetic material



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Michael Kahn
Partner

Akin Gump Strauss Hauer & Feld LLP

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A Case Study

■ *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*,

788 F.3d 1371 (Fed. Cir. 2015); *en banc petition denied at*
2015 U.S. App. LEXIS 20842 (Fed. Cir. 2015)

- Discovered paternally-inherited cffDNA in maternal plasma and serum
- Patented a method of isolating, amplifying and testing the cffDNA to determine fetal characteristics
- Used a combination of known techniques



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Michael Kahn
Partner

Akin Gump Strauss Hauer & Feld LLP

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A Case Study

- District court granted summary judgment of invalidity under § 101
- Ariosa appealed
- Parties agreed that the patent does not claim cffDNA or even paternally-inherited cffDNA



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Michael Kahn
Partner

Akin Gump Strauss Hauer & Feld LLP

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A Case Study

■ Comments from the original panel:

- “[T]he method reflects a significant human contribution in that [Drs.] Lo and Wainscoat combined and utilized man-made tools of biotechnology in a new way that revolutionized prenatal care”
- The invention “avoids the risks of widely-used techniques that took samples from the fetus or placenta”
- “A groundbreaking invention.”
- “The new use of the previously discarded maternal plasma to achieve such an advantageous result is deserving of patent protection.”



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Michael Kahn
Partner

Akin Gump Strauss Hauer & Feld LLP

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A Case Study

■ But... the panel *affirmed*:

- “The method therefore begins and ends with a natural phenomenon. Thus the claims are directed to matter that is naturally occurring.”
- “For process claims that encompass natural phenomenon, the process steps are the additional features that must be new and useful.”
- “Because the method steps were well-understood, conventional and routine, the method of detecting paternally inherited cffDNA is not new and useful”



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Michael Kahn
Partner

Akin Gump Strauss Hauer & Feld LLP

Akin Gump
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Amici Curiae Supporting Review

- The invention must be considered as a whole, and not “dissected into its individual steps”
- Whether the claims target the natural phenomenon or a patentable application of a natural phenomenon

(Brief of IPO, as amicus curiae, at 2, 7-8)



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Michael Kahn
Partner

Akin Gump Strauss Hauer & Feld LLP

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Amici Curiae Supporting Review

- The court should consider whether claims are narrowly drawn to “not unduly preempt ineligible subject matter”
(IPO Br. at 8-9)
- “[T]he principle of preemption is the basis for the judicial exceptions to patentability.”
(788 F.3d at 1379)
- Is a lack of undue preemption evidence that there is an inventive concept that transforms the claim under Mayo’s Step 2?
(IPO Br. at 10)



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Michael Kahn
Partner

Akin Gump Strauss Hauer & Feld LLP

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Amici Curiae Supporting Review

- The panel's application of the two-part Mayo test renders the preemption inquiry moot
(Brief of NYIPLA as amicus curiae in favor of en banc rehearing)
- "The failure to consider preemption has resulted in courts and the PTO over-using § 101 as a gatekeeper."
(NYIPLA Br. at 7)



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Michael Kahn
Partner

Akin Gump Strauss Hauer & Feld LLP

Akin Gump
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Rehearing Denied

- December 2, 2015 - Concurrences by Judges Lourie and Dyk; Dissent by Judge Newman

- Judge Lourie's concurrence
 - "I find no principled basis to distinguish this case from *Mayo*, by which we are bound. I write separately to express some thoughts concerning laws of nature and abstract ideas, which seem to be at the heart of patent-eligibility issues in the medical sciences."

 - "In my view, neither of the traditional preclusions of laws of nature or of abstract ideas ought to prohibit patenting of the subject matter in this case."



SEGMENT 3:

Michael Kahn
Partner

Akin Gump Strauss Hauer & Feld LLP

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Rehearing Denied

■ Judge Dyk's concurrence:

- “[A]s I see it, there is a problem with *Mayo* insofar as it concludes that inventive concept cannot come from discovering something new in nature . . .”
- “*Mayo* did not fully take into account the fact that an inventive concept can come . . . from the creativity and novelty of the discovery of the law itself.
- “This is especially true in the life sciences, where development of useful new diagnostic and therapeutic methods is driven by investigation of complex biological systems.
- “I worry that method claims that apply newly discovered natural laws and phenomena in somewhat conventional ways are screened out by the *Mayo* test.”



SEGMENT 3:

Michael Kahn
Partner

Akin Gump Strauss Hauer & Feld LLP

Akin Gump
STRAUSS HAUER & FELD LLP

The Path Forward

- Further clarification of *Mayo*?

- Legislative action?

- Claim drafting solutions?

- Alternatives to patent protection?



SEGMENT 3:

Michael Kahn
Partner

Akin Gump Strauss Hauer & Feld LLP

Akin Gump
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Abolition of Section 101?

- Dave Kappos, former director of the USPTO called for the abolition of Section 101

- Argued that *Mayo*, *Myriad*, and *Alice*, coupled with lower court interpretation, created unacceptable barriers to securing patents in biotechnology and software



SEGMENT 3:

Michael Kahn
Partner

Akin Gump Strauss Hauer & Feld LLP

Akin Gump
STRAUSS HAUER & FELD LLP

**An Alternative to the § 101 Gauntlet:
Trade Secrets**



SEGMENT 3:

Michael Kahn
Partner

Akin Gump Strauss Hauer & Feld LLP

Akin Gump
STRAUSS HAUER & FELD LLP

Patents v. Trade Secrets

- Patent protection
 - Public benefit of disclosure and follow-on innovation
 - Defined market monopoly
 - Maintains the incentive to innovate

- Trade secret protection
 - Individual benefit
 - Restricted access
 - Less-certain route to recoup investment



SEGMENT 3:

Michael Kahn
Partner

Akin Gump Strauss Hauer & Feld LLP

Akin Gump
STRAUSS HAUER & FELD LLP

Trade Secrets

- Information must not be generally known or readily ascertainable
- It must be secret
- The owner must make reasonable efforts to preserve its secrecy
- Must have sufficient value



SEGMENT 3:

Michael Kahn
Partner

Akin Gump Strauss Hauer & Feld LLP

Akin Gump
STRAUSS HAUER & FELD LLP

Myriad, Post-Myriad

- Patents invalidated under § 101
 - Myriad had identified key genetic sequences indicating higher risk of developing breast and ovarian cancer
 - Patents invalidated as “products of nature”

- Myriad is keeping its mutation data as a trade secret, which has made Myriad’s BRCA testing statistically more meaningful than others’



SEGMENT 3:

Michael Kahn
Partner

Akin Gump Strauss Hauer & Feld LLP

Akin Gump
STRAUSS HAUER & FELD LLP

Trade Secrets

■ Defend Trade Secrets Act of 2016 (DTSA)

- Passed Senate (4/4/16) and House(4/27/16); President is expected to sign into law soon
- Federal private civil cause of action for misappropriation
- *Ex parte seizure*
- Injunctions
- Monetary damages
 - Actual loss + unjust enrichment
 - (or) Reasonable royalty
 - Enhanced damages for willful infringement
 - Attorney fees for bad faith litigation



SEGMENT 3:

Michael Kahn
Partner

Akin Gump Strauss Hauer & Feld LLP

Akin Gump
STRAUSS HAUER & FELD LLP

Trade Secrets

- Procedure for requesting a civil seizure of property
 - TRO or injunction would be inadequate
 - Irreparable harm
 - Balance of the hardships
 - Likelihood of success
 - Identifies the property to be seized with reasonable particularity
 - Risk of flight or property destruction
 - Applicant has not publicized the requested seizure
- Proposed only in “extraordinary circumstances”

Contact Info:



Robert A. McFarlane
Partner
Hanson Bridgett LLP

E: RMcFarlane@hansonbridgett.com
T: (415) 995-5072



Michael J. Sacksteder
Partner
Fenwick & West LLP

E: msacksteder@fenwick.com
T: (415) 875-2450



Michael Kahn
Partner
Akin Gump Strauss Hauer & Feld LLP

E: mkahn@akingump.com
T: (212) 872-1082

Q&A:

SEGMENT 1:



Robert A. McFarlane
Partner
Hanson Bridgett LLP



HansonBridgett

SEGMENT 2:



Michael J. Sacksteder
Partner
Fenwick & West LLP



SEGMENT 3:



Michael Kahn
Partner
Akin Gump Strauss Hauer & Feld LLP



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