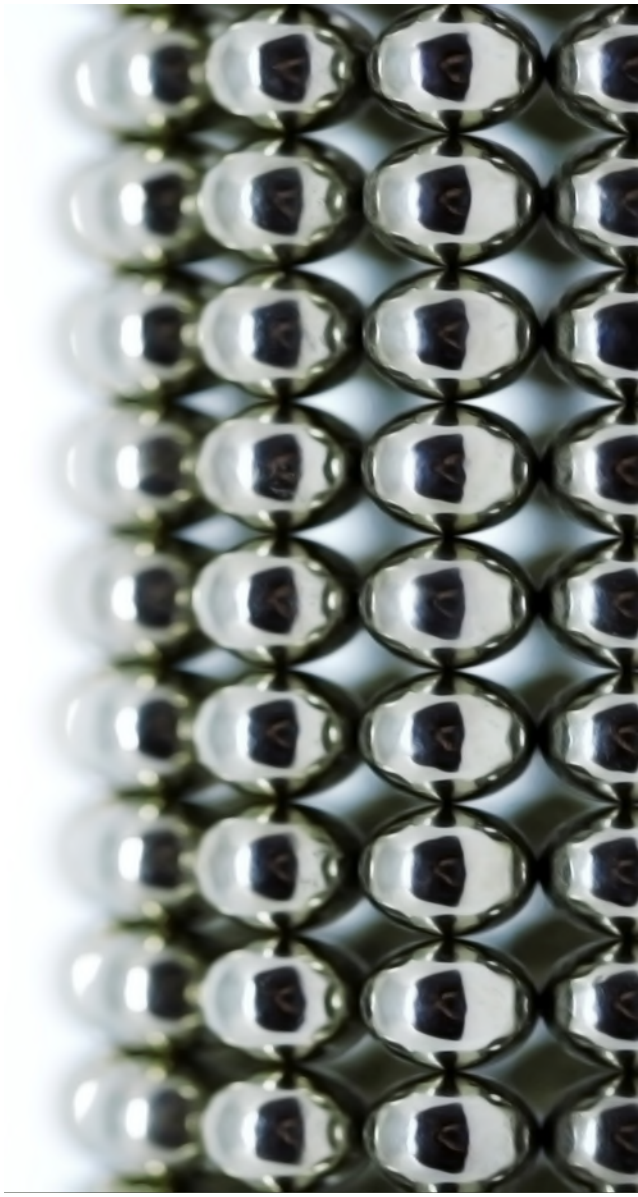
Hot Topics In Patent Law
Looking Back on 2019 and Looking Forward to 2020

Hunter Freeman

Topics Covered

- Patent Law 101
- COVID-19
- Changes To Patent Eligibility
  - Medical Diagnostics
  - Software Inventions
- Pending Legislation
  - Eligibility Standards
  - Pharmaceuticals
  - Patent Enforcement
- Statutory Bars To Patentability
- Inventorship & Artificial Intelligence
- Recent Trends



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Patents 101 - Types of Patents

- Utility Patent
  - Scope of Protection - Structural and Functional Elements
  - Term of Protection - 20 Years from Filing
    - Prior to June 8, 1995 – Longer of 17 yrs. from issuance or 20 yrs. from filing
    - Check with patent attorney (term extension, terminal disclaimer, etc.)
  - Maintenance Fees - Years 3.5, 7.5 and 11.5
- Design Patent
  - Scope of Protection - Appearance of Ornamental Features
    - No protection when appearance is dictated by function
  - Term of Protection - 15 Years from Issuance
- Plant Patent
  - Scope of Protection – New, Asexually Reproduced Plants
  - Term of Protection - 20 Years from Filing

Patents 101 - Eligibility & Rights

- Requirements for Patentability – 35 USC § 101, 102 & 103
  - Useful
  - Novel
  - Non-Obvious
- Non-Patentable Subject Matter - Judicial Exceptions
  - Laws of Nature
  - Natural Phenomenon
  - Abstract Ideas
- Patent Rights (Exclusionary)- 35 USC § 271
  - Making
  - Using
  - Selling / Offering for Sale
  - Importing

Patents 101 – Policy Considerations

- Patents Provide Limited Monopoly
  - Monopolies Are Disfavored – Sherman Anti-Trust Act
- Quid Pro Quo – Government / Society
  - Applicant Must Describe the Invention so that a PHOSITA Would Be "Enabled" Such that S/He Could Make and Use the Invention without Undue Experimentation - 35 U.S.C. § 112
    - Description must be in writing
    - Description must disclose best mode – No invalidity based upon failure to do so.
  - Ensure Inventor only Protects Materials in the Inventor's Possession
- Quid Pro Quo – Inventor
  - Exclusive Right to Prevent Others from Making, Using, Selling, etc. Inventions Falling within Patent Claims

Patents 101 - Novelty & Non-Obviousness

Patents 101 – First To File And Disclosures

- Since March 14, 2016, U.S. Grants Patents on a First To File Basis
- For U.S. Protection, a Patent Application Must be Filed within 1 Year from Public Disclosure
  - This is not the case for foreign protection
- The 1 Year Grace Period is Not Absolute

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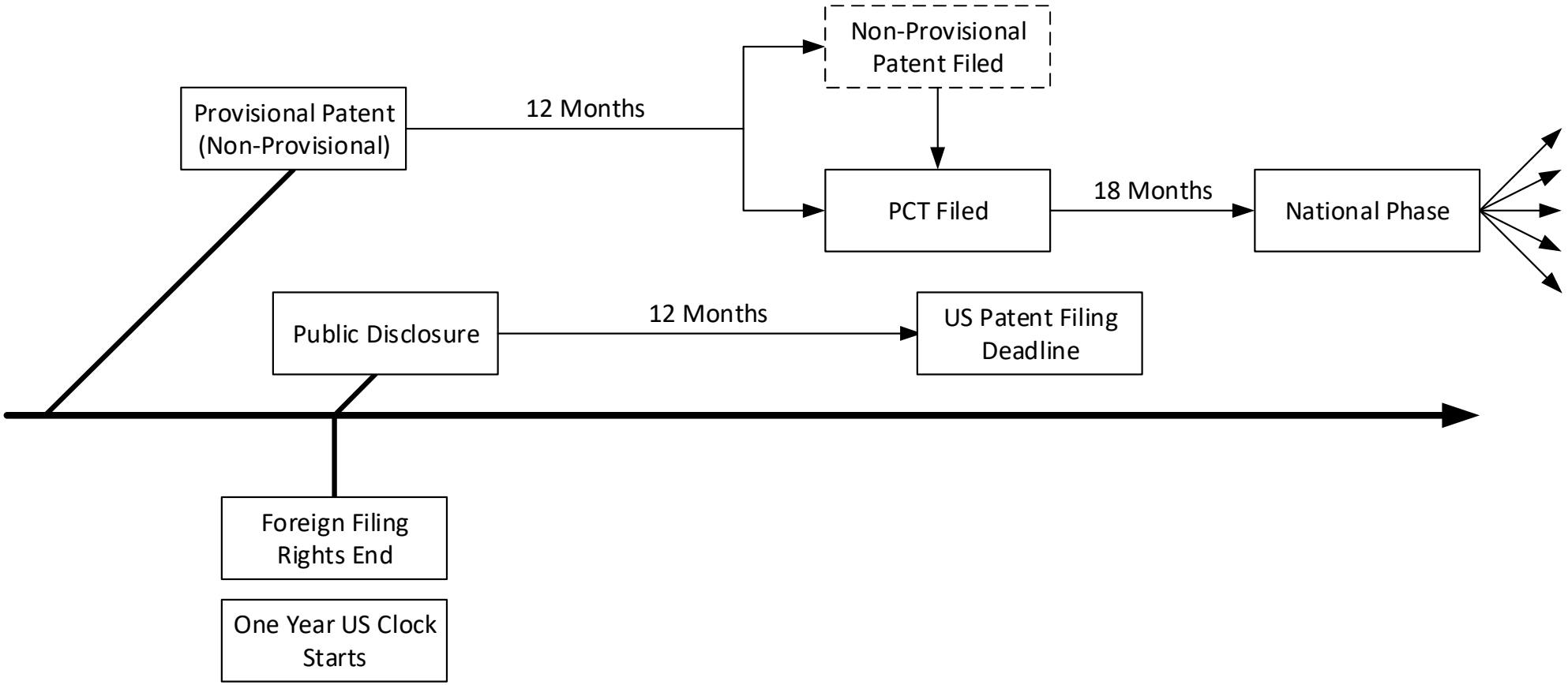
Patents 101 – Possible Protection Timelines



Patent Law 101 – Patent Enforcement

- Test For Infringement
  - Every Element Test
  - Doctrine of Equivalents
- Remedies
  - Reasonable Royalty
  - Lost Profits
  - Injunction
- Defenses
  - Non-Infringement
  - Invalidity
  - Unenforceability

Patents 101 - Value of Patents

- Patents Are Assets
  - They Can Be Bought and Sold
- Patents Are A Source Of Revenue
  - Monopoly
  - Licensing
- Patents Are Marketing Tools
  - Consumer Perception – Pat. No. xxx or Pat. Pending
- Patents Are Capital Raising Tools
  - Investor Protection
  - Proof of Due Diligence

COVID-19: Effects On Patent Ownership

- Default Ownership Rule: Inventor Owns Patent
  - Employer Owns Patent if Employee:
    - Executes assignment or employement agreement with invention assignment clause
    - Was hired specifically to invent
  - Hired To Invent Factors:
    - Employment relationship at time of invention
      - Right to control, equipment, facilities, etc.
    - Scope of duties
- COVID-19's Effect On Ownership Rules
  - Employees Are Telecommuting, Working Remotely and Working Flex Hours
  - How Does Employment Agreement Deal with Inventions Conceived Off Site?
  - How Are the Scope of Employee's Duties Changed?
    - Is employee still using company resources to invent?

COVID-19: Effects On Patent Prosecution Deadlines

- USPTO
  - Most Transactions Can Be Completed Remotely
  - Operations Will Continue without Interruption
  - Deadlines Are Not Extended – Revival Petition Fees Waived
    - Only applies to USPTO communications, not statutory filing deadlines
  - Closed to Public
    - In-person Examiner interviews and PTAB hearings are rescheduled or reformatted
- EPO
  - Most Transactions Can Be Completed Remotely
  - March 15 Deadlines Being Pushed to April 17 with Evidence of COVID-19 Delay
    - Includes PCT deadlines (with evidence of COVID-19 delays in home country)
  - All Oral Proceedings Will Proceed but upon Request, They Will Be Remote
  - Persons From High Risk Areas Asked to Abstain From Visiting
- China
  - May Be Able to Extend Deadlines
  - Most Deadlines May, for a Fee, Be Restored within 2 Months of Pandemic's "End"

Recent Eligibility Changes – 35 U.S.C. § 101

- 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…
- Judicial Exceptions To Patentability
  - Laws of Nature
  - Natural Phenomena
  - Abstract Ideas

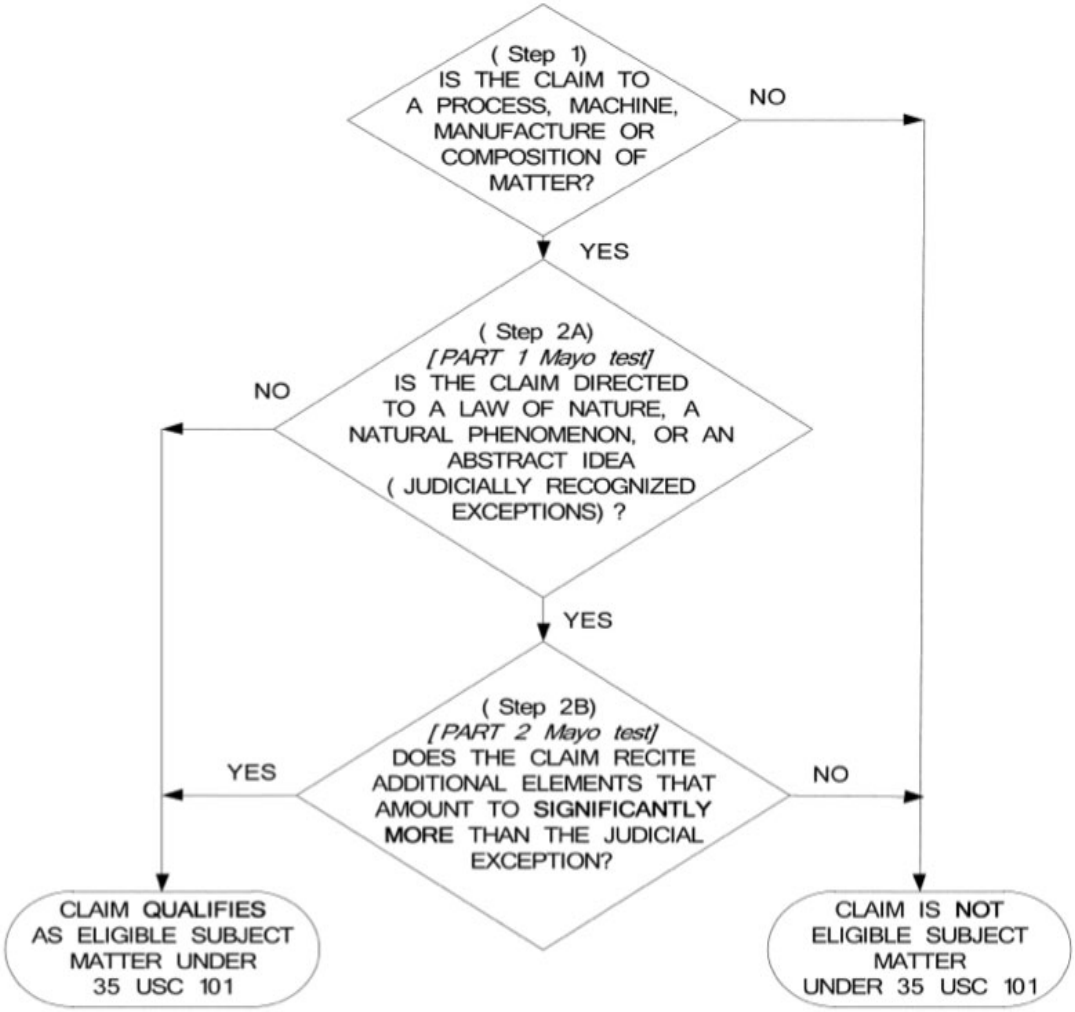
Recent Eligibility Changes – Medical Diagnostics

- *Mayo v. Prometheus*, 566 U.S. 66 (2012)
  - Sup. Ct. Held Medicine Dosing Determination Process Not Patent Eligible.
  - Manner in Which Drug Interacts with Patient Is an Unpatentable Law of Nature.
- Results Of *Mayo*
  - Two Part Test
    - Does invention relate to judicial exception (law of nature, natural phenomena, abstract idea)?
    - If so, does patent restrict others' use of exception?
  - Previously Patentable Material Now Considered Unpatentable.

Recent Eligibility Changes – Software

- *Alice v. CLS Bank*, 573 U.S. 208 (2014)
  - Held That Computer Implemented Method of Escrow for Financial Transactions Was Not Patent Eligible.
  - Computer Automation of Known Task Is Nothing More Than an Unpatentable Abstract Idea.
- Results of *Alice*
  - Clarification of *Mayo*
    - Does invention relate to judicial exception?
    - If so, is there an "inventive concept" ensuring that "patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself"?
  - Prohibition Against "Invoking Computer Merely as a Tool"
    - Must enable computers to operate more quickly or efficiently or solve a technological problem - *Customedia Tech v. DISH Network* (Fed. Cir. March. 6, 2020)

Mayo / Alice Test



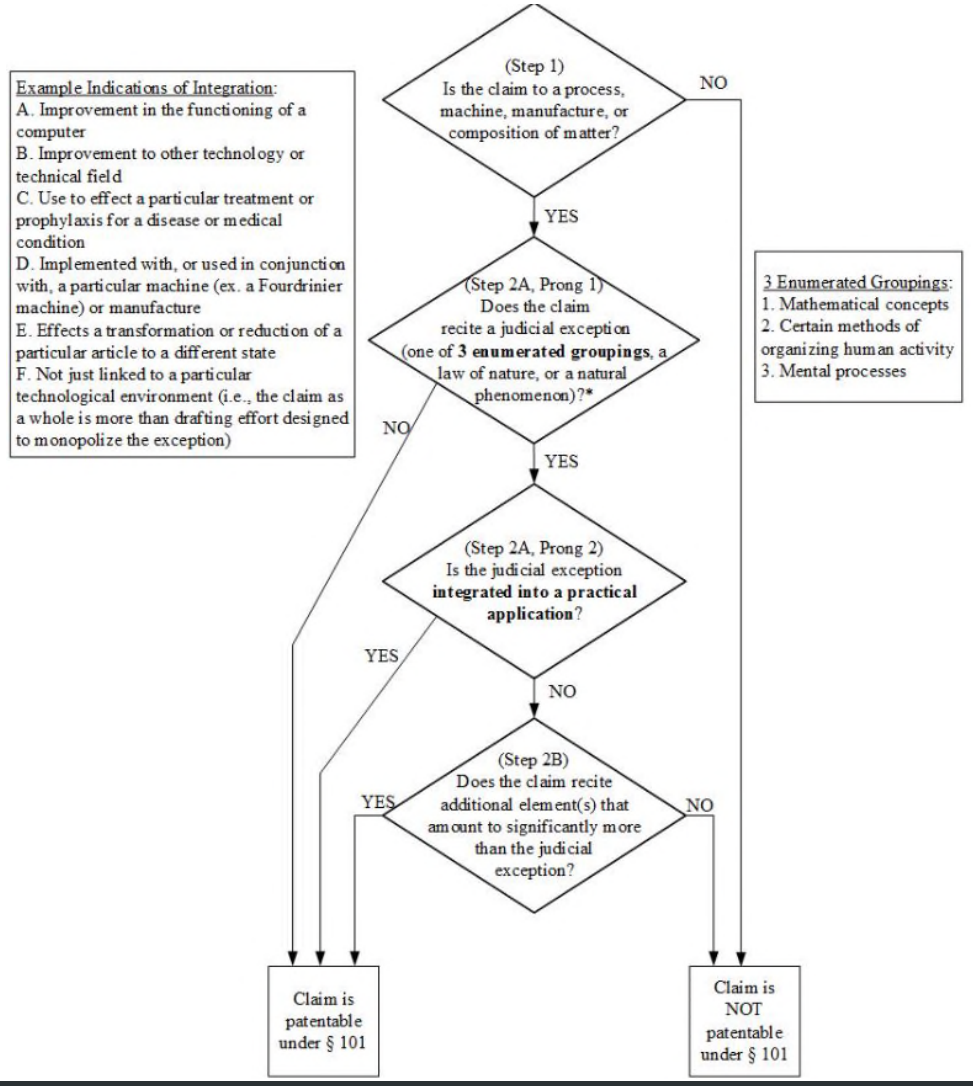
Recent Eligibility Changes – USPTO Patent Eligibility Guidance

- Issued In Jan. 2019 Due To Growing Number Of Cases And Inconsistent Outcomes
- Step 1: Is Claim Directed Toward Process, Machine, Manufacture or Composition of Matter?
- Step 2A, Prong 1: Does Claim Recite A Judicial Exception?
  - Laws of Nature
  - Natural Phenomena
  - Abstract Ideas
    - Mathematical concept
    - Method of organizing human activity
    - Mental process
    - All inclusive list

Recent Eligibility Changes – USPTO Patent Eligibility Guidance

- Step 2A, Prong 2: Is Claim Directed To The Recited Abstract Idea?
  - Is the Exception Integrated into a Practical Application?
    - Improvement in the functioning of a computer
    - Particular treatment for a disease or medical condition
    - Applying exception with or by use of a particular machine
    - Transforming article into different state or thing
    - Application in some other meaningful way beyond generally linking exception to technological environment such that claim does not monopolize the exception
- Step 2B: Is There An Inventive Concept That Provides Significantly More Than Judicial Exception?
- Remember, This Is USPTO's Test For Patentability, Not Court's Test For Validity.

USPTO 2019 PEG's



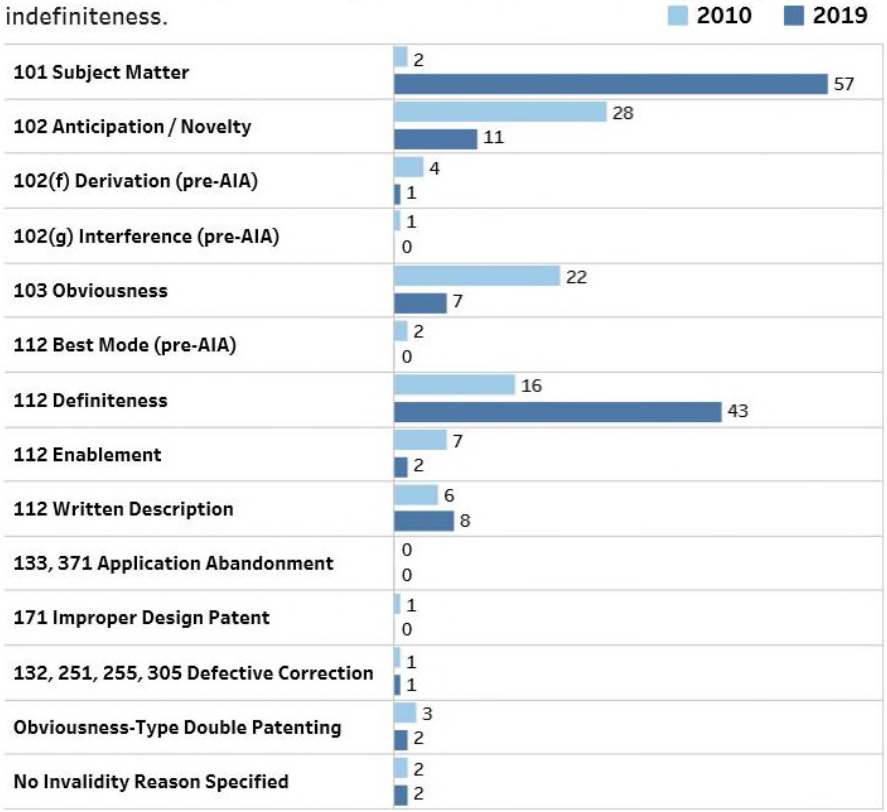
Recent Eligibility Changes – Patent Drafting Tips

- Medical Devices/Diagnostics
  - Focus Diagnostic Claims on Actions Rather Than Correlations
    - Correlation between natural products/laws and disease states are generally not eligible
    - Treatments and other actions typically are under Steps 2A, Prong 2 and 2B
  - Focus Claims on Technology/Systems Rather Than Diagnostic Method
  - Describe Diagnostic Method in Detail
    - Claims that are overly broad or that generically recite detection of natural product or law are ineligible
  - Avoid Statements That a Step Is Conventional or Routine – Step 2B of PEGs
- Software
  - Avoid Claiming Specific Algorithm to Avoid "Mathematical Concept" Exception
  - Include Statements That Method/Process Is too Complex for Humans
  - Emphasize Improvement to Computer Functionality and Use of Systems and Databases to Provide Solution

Mayo/Alice Statistics

Reasons To Be Invalid

Over the past 10 years, the most common reasons why a patent might be found invalid have shifted, from anticipation and obviousness to ineligibility and indefiniteness.



Recent Eligibility Changes – Post *Mayo/Alice* Statistics

- From July 2014 To June 2019 – 781 Patents Invalidated
  - 1056% Increase in Litigation Claims of Ineligibility as Compared to Prior 5 Years
    - Has become the number one defense – for good reason
  - 914% Increase in Patent Invalidation as Compared to Prior 5 Years
    - 58% of all reviewed patents invalidated
    - 62% of all reviewed claims invalidated
- Since *Mayo*, The Federal Circuit Has Invalidated Every Medical Diagnostic Claim It Has Considered
- Issuance Of Software Patents Greatly Reduced
  - As Much as 50% Reduction in Year Following Alice

Recent Eligibility Changes – Is Clarification Coming?

- In its 2019 *Athena v. Mayo* Decision, Federal Circuit Requested Supreme Court Clarification Of Eligibility Test.
  - Fed. Cir. invalidated athena patent on method for diagnosing an autoimmune disease as ineligible natural law
  - All 12 judges agreed that invention should be patentable
  - Judge Dyk -"it is the Supreme Court, not this court, that should reconsider the breadth of *Mayo*."
  - Judge Moore - "The math is simple, you need not be an economist to get it: Without patent protection to recoup the enormous R&D cost, investment in diagnostic medicine will decline. To put it simply, this is bad. It is bad for the health of the American people and the health of the American economy. And it is avoidable depending on our interpretation of the Supreme Court's holding in *Mayo*."
  - U.S. DOJ submits brief asking for Supreme Court to hear *Athena*.
- Despite Requests, Sup. Ct. Refused To Hear All 8 Cases Dealing With Eligibility.

Patent Legislation To Watch - Eligibility

- Senators Tillis (R-NC) & Coons (D-Del) Propose Draft Bill In 2019
  - Would Replace Judicial Exceptions with the Following:
    - Fundamental scientific principles
    - Products that exist solely and exclusively in nature
    - Pure mathematical formulas
    - Economic or commercial principles
    - Mental activities
  - Create a Practical Application Test to Ensure Ineligible Subject Matter Is Construed Narrowly
- Several Hearings Since Introduction In May 2019
  - Promised Formal introduction after July 4 Recess
  - "I don't see a path forward for producing a bill – much less steering it to passage – in this Congress." Sen. Tillis

Patent Legislation To Watch – STRONGER Act

- Support Technology & Research For Our Nation's Growth & Economic Resilience Patent Act - H.R. 3666 (March 2019)
  - Primarily Deals with Patent Office Proceedings Challenging Validity of Patents
  - Makes It More Difficult to Institute Proceeding
  - Limits Number of Proceedings That May Be Brought Against A Patent
  - Eases Standard For Obtaining Preliminary Injunction to Stop Infringement During Litigation

- Initially introduced in 2015
  - Reintroduced in 2017, 2018 and Again in March 2019
  - Has Not Become Law Yet

Patent Legislation To Watch – Inventor Rights Act

- Inventor Rights Act H.R. 5478 – Introduced In December 2019
- Substantial New Rights To "Inventor-Owned-Patents"
  - Patent Must Be Owned by Inventor or Entity Controlled by Inventor
  - Specifically Excludes "Large Corporations, Drug Companies or Typical Nonpracticing Entities"
- Patent Office May Not Review Patent For Validity Without Inventor Consent
  - Such Reviews Must Be Done in Court
- Allows Recovery Of Profits From Infringement
  - Most Recoveries Amount to Reasonable Royalty
- Treble Damages For Willful Infringement Plus Portion Of Attorney's Fees Exceeding 10% Of The Profits Recovered

Patent Legislation to Watch – Inventor Protection Act

- Inventor Protection Act H.R.6557 - Introduced In 2018
- Applies Only To Patents Owned By Original Inventor
- Patent Office May Not Review Patent For Validity Without Inventor Consent
- Allows Inventors To Sue In Their Home State Regardless Of Where Infringement Has Occurred
- Shortens And Simplifies Infringement Lawsuits
- Awards Greater Of Profits Or 25% Of Total Infringing Sales
- Treble Damages And Attorney Fees
- Creates Presumption That Inventor Is Entitled To Injunction

Patent Legislation To Watch – Drug Pricing

- TERM Act H.R. 3199 – Introduced In June 2019
  - Once First Patent on Drug Expires, All Others Are Presumed to Expire
  - Prevents "Evergreening" by Patenting Trivial Changes to Expand Term
  - Drug Company Can Rebut Presumption to Show Patentably Distinct Change
- Prescription Drug Affordability And Access Act – Introduced Nov. 2019
  - Creates Agency to Review and Determine Appropriate Drug Prices
  - If Drug Sold above Set Price, Agency Could Invalidate Patents on the Drug
- Congress Considering At Least 5 Other Bills Relating To Drug Prices
  - These Bills Do Not Involve Patent Law Reform

Patent Legislation To Watch – Design Patents

- Counterfeit Goods Seizure Act of 2019 S.2987 – Introduced in Dec. 2019
- Expands Authority Of Customs & Border Patrol To Seize Goods That Infringe IP, Which Would Now Include Design Patents
  - Previously, Patent Owner First Had to Obtain an Exclusion Order from ITC
  - Now, Patent Owner May Simply Register its Design Patent with CBP
- Broad Support
  - Bi-Partisan Bill
  - Letters of Support from Intellectual Property Owners Association, American Intellectual Property Law Association and International Trademark Association

Patent Legislation To Watch – U.S. Mexico Canada Agreement

- Agreement Recently Approved By Senate And Awaits Enactment
  - Canda and Mexico have both ratified
- IP Provisions Largely Align With Trans-Pacific Partnership Negotiations
- Adopts Strong Patentability Standard In All Fields, Including "New Use Of A Known Product"
- Adopts 1 Year Grace Period Between Disclosure And Application
- Patent Term Extension For Delays Greater Than The Later Of:
  - 5 Years from Filing or
  - 3 Years from Request for Examination
- Creation of Committee On IP Rights
  - Strengthen Border Protection
  - Establish Fairness in Patent Litigation
- Five Year Implementation Period

Patent Legislation To Watch – U.S. China Trade Deal

- Phase One Signed On Jan. 15 – Provides Until April 14 For Chinese Action Plan
- Patent Term Extension For Unreasonable Delays
  - Non-applicant Delays in Patent Examination Process
    - 4 years from filing or 3 years from request for examination, whichever is later
  - Non-applicant Delays in Commercial Approval of Pharmaceuticals
    - No more than 5 year extension but no less than 14 year patent term
- Important Provisions For Pharmaceuticals
  - China Patent Office Will Consider Supplemental Data During Examination
    - Test results to show novelty, non-obviousness and inventive element
  - Early Resolution of Patent Disputes through Early Notification of Generic and Resolution Prior to Release of Generic

Patent Legislation To Watch – U.S. China Trade Deal

- Combating Online Infringement With Takedown Notices
  - Expeditious Response to Notice
  - Eliminate Liability for Erroneous Notices Submitted in Good Faith
  - Liability for Bad Faith Notices
  - Extend Time to File Complaint in Response to a Counter-Notice
- Combating Counterfeit Goods On E-commerce Platforms
  - Revoking Operating License for Repeated Failures to Curb Sale of Counterfeit Goods
- Increases Protection For Trade Secrets
  - Additional Acts Included in Definition (Hacking, Breach of NDA, Disclosure under Circumstances Where Secrecy Should be Maintained)
  - Eases Ability to Bring Civil/Criminal Actions for Trade Secret Misappropriation and to Obtain Preliminary Injunction
  - Steps to Curb Disclosure of Information by Governmental Agencies to Chinese Companies

The Emergence Of Artificial Intelligence Created Inventions

- Patent Applications Seeking Protection For AI Created Inventions Have Been Filed In EPO, UKIPO and USPTO
- In August 2019 The USPTO Issued "Request For Comments On Patenting Artificial Intelligence Inventions"
  - What Are The Protectable Elements of an AI Invention?
  - How Can a Person Contribute to the Conception of an AI Invention so as to be Named an Inventor?
  - Do Patent Laws Need to be Amended to Account for AI Inventions?
  - Should Entities Other Than Natural Persons be Able to Own an AI Patent?
  - Are There Eligibility Considerations That Are Unique to AI Inventions?
  - Does AI Affect the Level of Skill in the Art for Determining Patentability?
- Additional Requests Regarding Copyright Protection Issued in October
- Response Period Ended January 10, 2020.

The Emergence Of Artificial Intelligence Created Inventions

- EPO Rejects Both Of Its Applications
  - Failure to Comply with Art. 81 of EPC
  - Art. 60 Interpreted as Only Allowing Natural Persons to be Inventors
- Inventor May Appeal To EPO Boards Of Appeal
- UK Similarly Rejected Its Application In A Parallel National Phase Case
- Implications
  - If Ruled Unpatentable, What Protection Is Available for AI Inventions?
  - Can AI Execute the Oath?
  - Does AI Own the Patent?
- No Word On USPTO Applications
  - USPTO is rejecting 90% of AI related applications as "abstract ideas"

Bars To Patentability – Ready For Patenting And Experimental Use

- *Medtronic v. Barry* - Issue Pending Before Sup. Ct. – Must The Invention Work For Intended Purpose To Trigger The On Sale Bar To Patentability
- On Sale Bar (35 U.S.C. § 102(b)) – No Patent For Inventions "In Public Use Or On Sale" More Than A Year Before Filing Date
  - Traditionally, Clock Starts When Invention Is Used Publicly and Is "Ready for Patenting".
  - Experimental Use Exception – Traditionally, Non-commercial Use to Determine Usefulness of Invention. Thirteen Factor Blanacing Test.
  - Must the Invention Work for Its "Intended Purpose"? If So, How Do You Determine the Intended Purpose and Whether it Was Achieved.
- Federal Circuit 2019 Holding - To Trigger The One Year Clock:
  - The Invention Must Work for its Intended Purpose.
  - The Intended Purpose May Be Determined From Extrinsic Evidence.

Bars To Patentability – Ready For Patenting And Experimental Use

- Barry Sued Medtronic For Infringement
- Medtronic Argued Patents Invalid Due To Prior Public Use
  - Late 2002 – Dr. Barry begins working on trying to link certain components of a device.
  - Early 2003 – Dr. Barry begins to revise standard equipment to achieve his goals.
  - July 2003 – Dr. Barry develops a prototype of the tool.
  - Aug. 4, 2003 – Dr. Barry performs first surgery with the tool.
  - Aug. 5, 2003 - Dr. Barry performs second surgery with the tool.
  - Oct. 14, 2003- Dr. Barry performs third surgery with the tool.
  - Aug. 2003 - Jan. 2004 – Dr. Barry follows up with patients to review the surgery results.
  - Dec. 30, 2004 - Dr. Barry files his patent application.

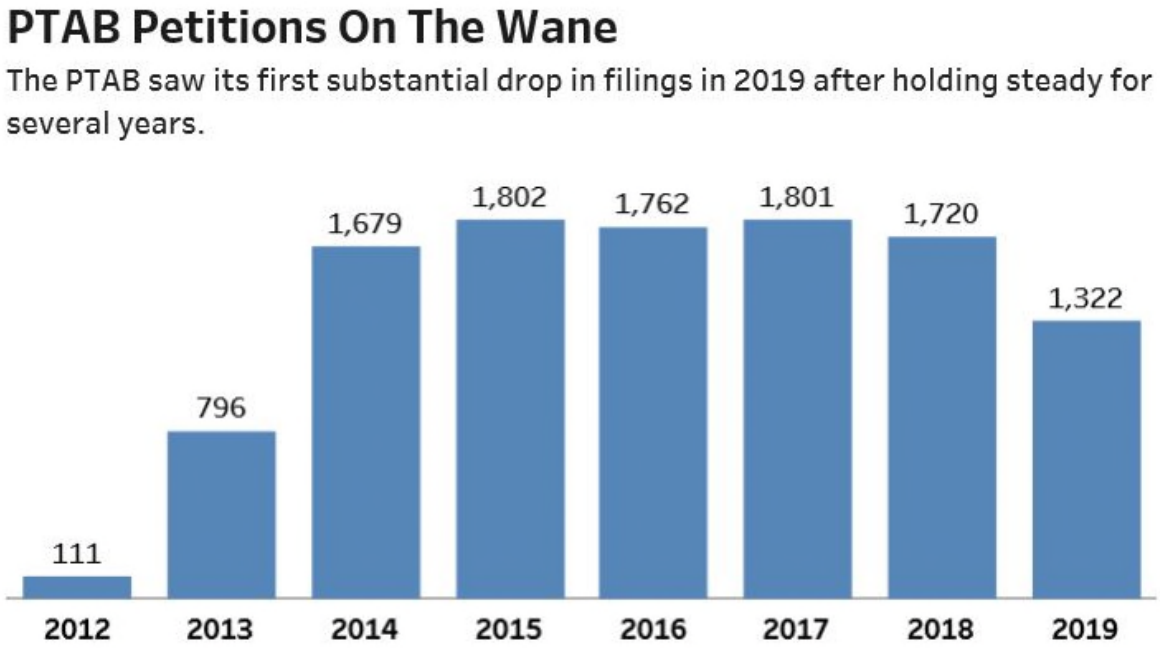
Bars To Patentability – Ready For Patenting And Experimental Use

- Fed. Cir. Found That Barry's Use Was Experimental
  - Not Ready for Patenting until (A) Surgery and (B) Follow Ups Completed
  - Experimental Use Found Despite Presence of Third Parties, Compensation and Failure to Inform Patients of Experimental Procedure
  - Relied Exclusively on Dr. Barry's After-the-fact Testimony as to Intended Purpose
- Prediction – Sup. Ct. Likely To Deny Cert.
  - Very Fact Specific
  - Denied All Other Patent Cases
- Take Aways
  - Avoid Unnecessary Risk – File Before Use
  - Explain in Application Why Experimentation Is/Was Necessary
  - Use Non-disclosure Agreement / Inform Customers of Experiment
  - Don't Accept Compensation

Patent Agreements – Merger Clauses

- *Molon Motor v. Nidec Motor*: 2004 Infringement Suit Of 3 Patents
  - In Response to Invalidity Counterclaims, Molon Covenanted Not to Sue Nidec over the 2 Allegedly Invalid Patents
  - This Left Only 1 Patent in Suit
- 2007 Settlement Agreement – Exclusive License To Use All 3 Patents In Limited Territory
- 2016 Infringement Lawsuit – Use Of Invention Outside Of Territory
  - Includes Merger Clause – All Prior Agreements "Concerning the Subject Matter Hereof, Are Merged Herein and Shall be of No Further Force or Effect."
  - Fed. Cir. Holds Merger Does Not Apply to Covenant Not to Sue
    - One para. unilateral vs. lengthy bilateral
    - Non-exclusive license vs. exclusive license
    - Limited to 2 patents vs. involves all patents
- Take Away - Specifically Reference Prior Agreements To Be Nullified

Trends – Patent Trial And Appeal Board Proceedings



- Number Of Total Filings Dropped 23% From 2018 To 2019
  - 87% of All 2013 Patent Challenges Were PTAB Proceedings
  - 63% of All 2019 Patent Challenges Were PTAB Proceedings

Trends – District Court Cases

- 2014-2018 – 40% Of All Invalidity/Eligibility Motions Granted
- 2019 – 33% Of All Eligibility Motions Granted – Due To Artful Pleading

Trends – District Court Litigation & Venue

- 28 USC § 1400(b) – Patent Cases 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."
  - "A Domestic Corporation 'Resides' Only in its State of Incorporation for Purposes of the Patent Venue Statute." *TC Heartland V. Kraft Foods (S.Ct. 2017)*
  - Regular & Established Place of Business Requires – (1) a Physical Place in District; (2) That Is s Regular and Established Place of Business; (3)That Is the Placeof the Defendant. - *In Re Cray* (Fed. Cir. 2017)
- *In re Google* (Fed. Cir. Feb. 23, 2020)
  - A Physical Place Does Not Require Ownership or Leasehold Interest
  - A Place of Business Requires Place Where Employee or Agent Conducts Defendant's Business
  - Agent's Activities Must Constitute the Defendant's Business

Trends – Recent Developments At PTAB

- Inter-Parties Review Proceedings
  - Method of Challenging Patent under Section 102 & 103
  - Must Be Filed within 1 Year of Infringement Action
- Post Grant Review Proceedings
  - Method of Challenging Patent Under Sections 101, 102, 103, 112 and Double Patenting
  - Must Be Filed within 9 Months of Grant or Reissue
- One-Year Time Bar In IPRs – *Facebook v. Windy City (Fed. Cir. 3/18/20)*
  - *Parties May No Longer Join Later Filed Proceedings with Those Filed within 1 year deadline*
  - Appealability of PTAB's 1 Year Rulings Is Before Sp. Crt. - *Thryv, Inc. v. Click-To-Call Technologies, LP*
- *Constitutionality of APJs - Arthrex, Inc. v. Smith & Nephew, Inc (Fed. Cir. 3/23/20).*
  - Fed. Cir. Refuses to Rehear Decision Finding Appointment of APJ Unconstitutional
  - For now, no redos for those who have lost at the PTAB

Questions? We Are Here To Help.

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Through his Intellectual Property (IP) and Litigation practices, Hunter creates barriers to entry that can keep competitors at bay and help clients maintain and grow their market share. Hunter helps his clients identify, patent and leverage their inventions to strengthen their competitive advantage. By providing freedom to operate, clearance, non-infringement and invalidity opinions, Hunter also helps his clients avoid competitors' patents. When necessary, Hunter navigates his clients through disputes involving IP infringement claims to obtain business minded solutions both inside and outside of the courtroom.

Hunter serves clients in a wide variety of industries, including medical device, software and gaming, automotive, wireless and telecommunications, consumer goods, sporting goods, cooking appliance, power tool, construction equipment and hospitality.