Current Topics Shaping IP Law

Washington State Patent Law Association March 21, 2018





- Patent Subject Matter Eligibility
- International Patent Harmonization
- PTAB updates
- Selected pending and decided Federal Circuit and Supreme Court cases
- Update on the 115th Congress

Patent Subject Matter Eligibility

Section 101: The turmoil of subject matter eligibility

- Just after the 1952 Act (and for many years)
 - § 101 defined patentable subject with a low threshold requirement
 - Focus was on obtaining and enforcing patents using the patentability requirements set forth:
 - Novelty (102)
 - Non-obviousness (103)
 - Invention disclosure (112)
- Supreme Court precedent
 - Software and biotechnology inventions began growing in patent claims
 - USPTO and Fed. Cir. began to interpret and apply the S. Ct. precedent (confusion and unpredictability)
 - Benson, Flook, Diehr, Chakrabarty, Bilski, Mayo, Myriad, Alice and more

Section 101: The turmoil of subject matter eligibility

- AIPLA's course
 - AIPLA filed amicus briefs in early every § 101 case before the en banc Fed. Cir. and the S. Ct.
 - AIPLA took a step back from the case-by-case approach
 - Established a § 101 Task Force toward end of 2014
 - Reviewed possible judicial and legislative alternatives that could clear up the confusion and bring about more predictability
 - AIPLA Board of Directors adopted a "Legislative Proposal and Report on Patent Eligible Subject Matter"
 - 1952 Act intended Section 101 as an enabling provision, identifying particular categories of subject matter that qualified for patent protection, not as the standard for deciding whether a particular technical advance should receive patent protection

Patent Subject Matter Eligibility

Section 101: Legislation is needed

- Congress must intervene
 - Return the law to the 1952 Patent Act (Objective, evidence-based analysis)
- Present uncertainty has:
 - weakened the US patent system and
 - Discouraged investments in areas ranging from software to life-saving diagnostic tools and therapeutic medicines
- Series of S. Ct. decisions qualified the categories of eligibility with rules of ineligibility directed to natural phenomena, laws of nature and abstract ideas
 - Le Roy v. Tatham, 14 How. 156, 175 (1853) (a patent is available for a general principle in science or law of nature if it is applied by the specification to a special purpose producing a practical result);
 - Corning v. Burden, 15 How. 252, 268 (1854) (no patent is available for the function or abstract effect of a machine, but only for the machine which produces it);
 - Rubber-Tip Pencil Co. v. Howard, 20 Wall. 498, 507 (1874); (An idea of itself is not patentable.)

Patent Subject Matter Eligibility

Section 101: Legislation is needed

- The judiciary used the language from the above series of S. Ct. cases to prevent patentees from preemptively overreaching in broad areas that suppress rather than incentivize innovation:
 - Funk Brothers Seed Co. v. Kalo Inoculant Co., 333 U.S. 127 (1948) (bacteria claimed for discovered inhibiting properties on certain plants are unpatentable products of nature).
 - Brenner v. Manson, 383 U.S. 519 (1966) (a novel process for making a known steroid lacks utility where the process is useful only as an object of scientific research).
- 1952 Patent Act then put in place statutory mechanisms for separately policing patentability and scope, removing the need to apply the judicially created eligibility criteria.

Patent Subject Matter Eligibility

Section 101: Legislation is needed

- Three years later in the *Diamond v. Diehr* decision, the S. Court's decision reflected the analytical discipline intended by the 1952 Act.
- The Diehr decision made it clear that, in a determination of patent elilgibility:
 - (1) the patent claims must be considered as a whole;
 - (2) the claims are not to be dissected into old and new elements;
 - (3) a new combination of process steps may be patentable even if all the constituents were well known before the combination was made; and
 - (4) novelty "is of no relevance" in determining whether the claimed subject matter falls within the Section 101 categories for patent eligibility.
- 2-step analysis in Mayo and Alice set the stage; courts were directed to:
 - (1) consider whether the patent claims are directed to one of the judicially excluded categories – natural phenomena, laws of nature and abstract ideas, and
 - (2) if so, consider whether the claim is otherwise patent eligible because if contains an "inventive step" that is neither routine nor conventional

Patent Subject Matter Eligibility

Section 101: AIPLA's proposal:

- AIPLA endorsed an approach to return 101 to its intended purpose under the 1951 Act
 - Retain the basic eligibility categories currently contained in § 101
 - Few amendments
 - Additional provisions expressly replacing the current judiciallycreated framework with new statutory test, whether the claimed invention:
 - o Is the result of human effort, or
 - Is capable of being performed solely in the human mind
 - Clean break from the existing framework new framework with clearly defined statutory exceptions
- AIPLA's proposal § 101 revised as § 101(a)
 - Consider if the invention falls into one of the listed categories:
 - Process, machine, manufacture, composition of matter, or any useful improvement thereof

Section 101: AIPLA's proposal:

(a) Eligible Subject Matter.—Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain shall be entitled to a patent therefor, subject only to the conditions and requirements of set forth in this title.

Returns patent eligibility law to the fundamental principle identified in Diehr:

"[t]he 'novelty' of any element or steps in a process, or even of the process itself, **is of no relevance** in determining whether the subject matter of a claim falls within the Section 101 categories of possibly patentable subject matter"

New section 101(b): AIPLA's proposal:

(b) Sole Exceptions to Subject Matter Eligibility.—A claimed invention is ineligible under subsection (a) only if the claimed invention as a whole exists in nature independent of and prior to any human activity, or can be performed solely in the human mind

Section 101(b): AIPLA's proposal:

- "Sole Exceptions" the <u>only conditions</u> under which an invention may be found ineligible for patent protection – conditions exist only where the claimed invention as a whole:
 - (1) Exists in nature independent of and prior to any human activity, or
 - (2) Can be performed solely in the human mind
- "as a whole" eliminates the ability of the USPTO and courts to:
 - Identify the gist or heart of the claimed invention
 - Identify what the invention is "directed to" rather than what the claim language states,
 - Restate the claimed invention in abstract terms rather than using the claim language, and
 - Ignore claim limitations, such as by assuming claim limitations are in the prior art or by ignoring conventional claim limitations

Section 101(b): AIPLA's proposal - Eligibility exceptions:

"exists in nature independent of and prior to any human activity"

- No one is entitled to a patent on something that exists in nature independently of and prior to any human activity - but a claim to anything beyond that ought to be eligible for patenting
- This test is clear and should not be difficult for the USPTO and courts to identify whether the claimed invention as a whole existed in nature independently of and prior to any human activity
- This test has historical roots in the patent system the subject matter categories themselves identify things that are the result of human effort: "process, machine, manufacture, or composition of matter, or any ... improvement..."
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Section 101(b): AIPLA's proposal - Eligibility exceptions:

"can be performed solely in the human mind"

- Responding to S. Ct. law, this exception draws a clear administrable line to exclude claims directed to purely abstract ideas, i.e., claimed steps occurring solely in the human mind
- Excludes only claims describing purely mental calculations or associations
- Unless performed solely in the human mind, the claimed steps would be examined under § § 102, 103 and 112
- Refocuses the analysis on prior art

Section 101(c): AIPLA's proposal - Eligibility exceptions:

- (c) Sole Eligibility Standard.—The eligibility of a claimed invention under subsections (a) and (b) shall be determined without regard to the requirements or conditions of sections 102, 103, and 112 of this title, the manner in which the claimed invention was made or discovered, or whether the claimed invention includes an inventive concept.
- Clarifies that the eligibility standard in subsections (a) and (b) is not to be confused with other standards in the Patent Act

Patent Subject Matter Eligibility

Section 101(c): AIPLA's proposal - Eligibility exceptions:

- Precludes the use of any conditions of patentability to determine patent eligibility
- Ends the confusion created by decision makers who fail to distinguish the patent eligibility inquiry from enablement, written description and definiteness inquiries (112)
- Prohibits the USPTO and courts from determining patent eligibility by considering "the manner in which the claimed invention was made or discovered"
- Clarifies that the "exists in nature" exception does not inquire how the invention was made but instead looks at the invention as claimed
- Prohibits the USPTO and courts from determining patent eligibility by considering "whether the claimed invention includes and invention concept" (overturning the second part of the test articulated in Mayo and Alice)

What's next:

- Congress
- Begin the discussion

International Harmonization

- Substantive Patent Law Harmonization
 - Currently led by the Industry Trilateral (IT3) members include
 - AIPLA
 - Business Europe (BE)
 - Intellectual Property Owners (IPO)
 - Japan Intellectual Property Association (JIPA)
 - Goal is consensus on a single package that includes:
 - Definition of Prior Art
 - Prior User Rights
 - Grace Period
 - Conflicting Applications and
 - 18-month publication
 - Discussions are based on:
 - Balance of Interests
 - Inclusion of Best Practices
 - Motivating behavior consistent with pro-IP policies

International Harmonization

- March 1, 2018, most recent meeting with the Trilateral (USPTO, EPO, JPO)
- Update from IT3 on progress of negotiations
- Fourth Industrial Revolution
- Comparative Study on Software-Related Inventions in JPO and EPO
 - Laws, regulations and guidelines
 - Eligibility, novelty and inventive step
 - Study showed different eligibility criteria and different inventive step standards
 - Next step will the USPTO join the study

- Court decisions issues that have been litigated
 - Claims in AIA trials are to be given the "broadest reasonable interpretation," despite the similarities of the trials to adjudicatory proceedings (Cuozzo);
 - The bar against judicial review of decisions to institute is not confined to interlocutory appeals and applies in appeals of the final written decision as well (Cuozzo);
 - A PTAB decision to institute an IPR need not agree to review every claim raised by the IPR petition (Supreme Court review of this issue is pending in the SAS case);
 - The patentability of amended claims in an IPR is the petitioner's burden to disprove, not the patent owner's burden to prove (Aqua Products).
 - The bar on appealing of PTAB decisions to institute an IPR does not apply where the IPR is time-barred under 35 U.S.C. 315(b) (Wi-Fi).

USPTO decision

- Sovereign immunity of the patent owner Mylan Pharmaceuticals v. Saint Regis Mohawk Tribe
 - Where a state entity is the patent owner, there is little dispute that the Eleventh Amendment presents an immunity that precludes a challenge to patentability before the PTAB as it does before the courts
 - In Saint Regis, an IPR petition was filed against the Native American tribe which acquired a patent and then asserted its own sovereign immunity
 - On February 23, 2018, the PTAB rejected the tribes' motion to terminate the IPR based on its own sovereign immunity. According to a per curiam opinion, the Board held that tribal immunity is limited and does not enjoy the scope of the Eleventh Amendment immunity.

- USPTO released AIA trial statistics through end of 2017
 - 3 interesting points:
- Petition filings remained high
 - o 2017 = 1799
 - o 2016 = 1758
 - o 2015 = 1798
 - Institution rates continued to decline
 - 2017 = 59%
 - 0 2016 = 63%
 - o 2015 = 67%
 - (Institution rate = petitions instituted/petitions instituted + petitions denied)
 - Few PGRs were filed
 - o 86 PGRs
 - o 7311 IPRs
 - 533 CBMs

- USPTO outreach and feedback Specific Recommendations (among other things):
 - Requested the PTAB to:
 - Provide for early briefing and decisions on claim construction,
 - Allow a conference call to request a claim construction briefing and allow the panel to rule on the claim construction to be used for the trial
 - Provide a notice and opportunity to brief particularly important if the claim construction used for the institution decisions should change at trial

- USPTO outreach and feedback Specific Recommendations (among other things):
 - Provide a mechanism for early briefing on claim construction disputes
 - Addresses the complaint that parties to an IPR may go all the way through an entire trial without knowing what claim interpretation will appear in the final written decision
 - Provide a default Sur-reply opportunity for patentees
 - Addresses the shortcomings of the briefing process and specifically seeks a sur-reply opportunity for patentees, explaining that replies sometimes include new evidence which calls for a response.

- USPTO outreach and feedback Specific AIPLA Recommendations (among other things):
 - Provide guidance on circumstances warranting extension of the one-year deadline
 - The one-year deadline for a final determination (35 U.S.C. § 316(a)(11)) is a significant constraint for the parties - little is known about the "good cause" standard for an extension
 - Provide guidance on discretion to dismiss IPR petition
 - Guidance in needed on the circumstances in which the Board will exercise its discretion under 35 U.S.C. § 314(a) to dismiss a petition to institute an IPR

- Oil States v. Greene's Energy Group
 - Oil States has contended that the AIA patent review procedure is unconstitutional. Oil States has argued that the power to extinguish patent rights is reserved to the judiciary under Article III, and that a law empowering an Article I administrative tribunal to do so violates the separation of powers doctrine or the Seventh Amendment right to a jury trial.
 - AIPLA argued that Article I of the Constitution authorizes Congress to implement the rights it creates with limited adjudication by the expert agencies charged with administering those rights.
 - AIPLA maintains that PTAB authority neither violates the separation of powers doctrine nor undermines the judiciary's role under Article III of the Constitution because: (1) Congress is the source of the rights adjudicated by the non-Article III tribunal, (2) the adjudication is confined to issues of patentability, and (3) the adjudication is ultimately reviewable by Article III courts.

- SAS Institute, Inc. v. Lee
 - The issue is whether 35 USC 318(a) requires the PTAB to address every patent claim challenged in an IPR review petition.
 - The Federal Circuit panel held that the PTAB is not required to address every patent claim challenged in an IPR petition, relying on Synopsys, Inc. v. Mentor Graphics Corp., 814 F.3d 1309 (Fed. Cir. 2016), a prior panel ruling that read Section 318(a) to require only that the Board address claims as to which review was granted, even though Section 314 on instituting an IPR refers to "claims challenged in the petition."

- WesternGeco LLC v. ION Geophysical Corplanguage of
 - A Federal Circuit decision that a prevailing patent owner in an infringement suit under 35 USC 271 (f) is barred by the extraterritoriality doctrine from recovering lost profits caused by the defendant's foreign conduct.
 - AIPLA's argued that the extraterritoriality doctrine does not apply to Section 271 (f) damages because the focus of the statute is the domestic conduct of supplying components abroad for combination into an infringing product. Any references to foreign conduct in the statute pertain only to the domestic actor's intent that the components be combined abroad. We maintain that Section 284 provides for a damages award to remedy harm proximately cause by all varieties of patent infringement, wherever that harm occurs.

- NantKwest, Inc. v. Matal
 - Pending before the en banc Federal Circuit, this is a challenge to the PTO's position that the requirement in 35 U.S.C. 145 that patent applicants in district court actions over rejected applications must pay "all expenses of the proceeding" includes PTO attorneys' fees.
 - AIPLA disputes the PTO interpretation of the statute, pointing out that "expenses" in this provision, which is over 100 years old, has never been understood to include attorneys' fees until recently. In addition, Congress elsewhere in the statute was explicit about attorneys' fees when it meant to address that subject. More significantly, the PTO's interpretation to require payments of attorneys' fees, win or lose, is a dramatic departure from common law that lacks the clear and explicit mandate from Congress required by the Supreme Court.

- Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc.
 - Are the patent owner's agreements for manufacturing and analytical services exempt from the on-sale provisions of 35 U.S.C Section 102(a)(1) under the AIA because they are not "otherwise available to the public."
 - District Court decision: The on-sale provisions of 35 U.S.C. § 102(a)(1) require that a sale before the critical date must be public in order for it to be given prior art effect, based on the plain language of the statute, USPTO guidelines, the AIA Committee Report, and public policy considerations underlying the passage of the AIA.

- Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc.
 - Panel Ruling: A patent owner's agreement for manufacturing and analytical services before the critical date is not exempt from the on-sale bar under 35 U.S.C. 102(a) as amended by the America Invents Act, even though the agreement did not publicly disclose the claimed invention. The Court rejected the argument that floor remarks when Congress considered the AIA, show that the statutory phrase "otherwise available to the public" requires that the sale disclose the invention to the public for the on-sale bar to apply.
 - En banc review denied

- New Fed. Cir. 101 decisions
 - In AAtrix Software, Inc. v. Green Shades Software, Inc., the court vacated a 12(b)(6) dismissal of an infringement suit.
 - The appellate court pointed out that such a dismissal requires that the allegations of the non-movant be accepted as true, and that the ineligibility issue in this case involved factual allegations which, when accepted as true, preclude the 12(b)(6) dismissal.
 - The allegations state that the claimed data file represents an improvement in importing data which relates to the presence of an inventive concept. "These allegations at a minimum raise factual disputes underlying the § 101 analysis, such as whether the claim term "data file" constitutes an inventive concept, alone or in combination with other elements, sufficient to survive an Alice/Mayo analysis at the Rule 12(b)(6) stage.

- New Fed. Cir. 101 decisions

 Berkheimer v. HP Inc., the court vacated a summary judgment of patent ineligibility after finding a disputed material fact.
 - The mere fact that something is disclosed in a piece of prior art, for example, does not mean it was well-understood, routine, and conventional."
 - Exergen v. Kaz (nonprecedential), a district court rejected a motion for a judgment of ineligibility after a jury found infringement.
 - According to the Fed. Cir., whether a claim element is well-understood, routine, and conventional to a skilled artisan in the relevant field is a question of fact and deference must be given to the determination made by the fact finder on this issue.
 - The role of fact finding in 101 determinations is currently before the Supreme Court in a cert petition for Cleveland Clinic Foundation v. True Health Diagnostics, U.S., No. 17-997.

- Wi-Fi One, LLC v. Broadcom Corp
 - The en banc court held that the Section 314(d) bar against appellate review of PTAB decisions to institute does not apply to the Section 315(b) requirement that PTAB petitions be filed within a year after the petitioner was sued for infringement in district court.
 - The 9-4 decision, which overruled the decision to the contrary in Achates Reference Publishing, Inc. v. Apple Inc., 803 F.3d 652 (Fed. Cir. 2015), recognized the strong presumption in favor of judicial review of agency actions, and found no clear and convincing indication that Congress intended Section 315(b) decisions to be unreviewable.

- In re Aqua Products, Inc
 - A deeply divided en banc court held that the PTAB improperly places the burden on the patent owner in an IPR to show the patentability of a proposed amended claim before a motion to amend the claim will be granted.
 - Judge O'Malley's 68-page opinion, which was joined by four judges (Newman, Lourie, Moore and Wallach), concluded 5-6 that the statute unambiguously prohibited the PTAB practice, relieving the court from applying Chevron deference. However, the opinion picked up two additional votes of Judges Dyk and Reyna, who were not persuaded that deference was avoided but instead believed the PTAB failed to embody the practice in an APAcompliant rulemaking. Thus, this alternative holding prevailed by a 7-4 vote.

One Year Ago.....Issues

- Patent Litigation Legislation
 - Venue
- Copyright Review
- Other Legislation
 - Replacement Parts
- USPTO Director
- IPEC

- Patent Litigation Legislation
 - Three Hearings on Venue
 - S. 2514 Sovereign Immunity)
 - S. 1390, the STONGER Patents Act
 - CBM Hearing
- Copyright Review
 - Register of Copyright bill
 - Various bills: small claims, music licensing, Marrakesh, etc.
- Other Legislation/Issues to Note
 - Replacement Parts No activity
- USPTO Director Iancu Confirmed
- IPEC Amin Confirmed

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- Chris Coons (DE)
- Richard Blumenthal (CT)
- Mazie Hirono (HI)
- Cory Booker (NJ)
- Kamala Harris (CA)

- Still 8 months to go in this Congress
- Great amount of unpredictability
- Elections have consequences
- Majority/Minority
- Corresponding staff also changes
- A long way to go before next year

Thank you!