Boston Seminar Series:

2018 Year in Review

January 22, 2019

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Agenda

- Patent Eligibility Under 35 U.S.C. Section 101
- Obviousness
- Obviousness-Type Double Patenting (OTDP)
- Biosimilars
- CRISPR Interference
- Playing With Priority Can Be a Losing Game
- IPRs
- What to Watch For In 2019

Patent Eligibility Under 35 U.S.C. Section 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 therefor, subject to the conditions and requirements of this title.**

- **Supreme Court has defined three exceptions to patent eligibility:**
  - Laws of nature
  - Natural phenomena
  - Abstract ideas

Burdens and Facts Required to Show Patent Eligibility

***Berkheimer v. HP Inc.*, 881 F.3d 1360 (Fed. Cir., February 8, 2018)**

- Patent relates to digital processing and archiving of files.
- Berkheimer sued and HP asked the court to invalidate the patent for lack of patent eligibility under 35 U.S.C. 101; district court held the patent invalid on summary judgment as covering an abstract idea.
- Section 101 is a question of law that can have underlying facts.
- Summary judgment was not appropriate here for claims 4-7, because the patent indicated the invention was not "well-understood, routine, and conventional," so a question of fact remains.
- **IMPORTANT**: Determining what is "conventional" goes beyond whether something is known in the prior art.
- *En banc* was denied, but judges voiced their frustration with Section 101.

Berkheimer Takeaways

- Patent drafters should include assertions or evidence in the application that the invention provides some clear improvement or that some aspect of the invention operates in an unconventional or unique way.
- Important NOT to describe any important aspect of your invention as being well-understood, routine, conventional in your patent application.
- USPTO issued guidance (April 19, 2018) to examiners requiring them to provide better support for rejections under Section 101 with evidence:
  - admissions in the patent application,
  - prior art that demonstrates an aspect of the invention was “widely prevalent or in common use in the relevant field,”
  - a court decision on similar facts, or
  - in limited circumstances, “official notice” by the examiner.

Methods of Treatment Can Be Patent Eligible

***Vanda Pharmaceuticals, Inc. v. West-Ward Pharmaceuticals International Limited,* 887 F.3d 1117 (Fed. Cir., April 13, 2018)**

- Patent relates to methods of treating schizophrenia with iloperidone (Fanapt ®) and the claims require determining whether the patient has a specific genotype related to metabolism of the drug and selecting a lower dosage to avoid side effects in patients who do not metabolize the drug well and a higher dosage in other patients.
- West-Ward filed an ANDA for approval to sell generic with an almost identical label including instructions for a lower dose for poor metabolizers, but argued that the patent covered a natural law.
- District court held claims not invalid under Section 101, because the specific tests and results are not routine or conventional.
- Federal Circuit held that claims are not "directed to" a law of nature, but require a specific drug to be administered to specific patients at specific dosages to provide a safer therapy and thus recite more than a natural relationship.

Vanda Takeaways

- Patent drafters should include a discussion of specific steps of administering specific drugs in specific dosages for medical therapy inventions rather than just describing the natural law or natural phenomena on which an invention may be based.
- Avoid drafting claims that may suggest optimizing a dosage in certain scenarios without including a step of administration.
- Patent applicants should consider adding administration steps to medical therapy or diagnostic claims in appropriate circumstances.
- The key is to include steps in method claims that actually use a natural law or relationship rather than merely describing such a natural law or relationship.

USPTO Revised Patent Subject Matter Eligibility Guidance (January 7, 2019)

- Supersedes all prior versions of USPTO guidance, but does **not** have the force and effect of law, but represents PTO policy.
- Three main changes:
  - First, based on court decisions, the abstract idea exception should be limited (with only rare exceptions) to: mathematical concepts, certain methods of organizing human activity, and mental processes.
  - Second, a two-prong inquiry for whether a claim is "directed to" a judicial exception.
    - Prong One - whether the claim recites a judicial exception and if so, proceed to the second prong.
    - Prong Two – "whether the claim as a whole integrates the recited judicial exception into a practical application" (e.g., does claim apply, rely on, or use the judicial exception to meaningfully limit the exception).

USPTO Revised Patent Subject Matter Eligibility Guidance (January 7, 2019)

- Second (continued) – for Prong Two, does claim:
  - provide improvement to a technology,
  - apply or use the exception for treatment of disease,
  - implement exception with a particular machine or manufacture that is integral to claim,
  - effect a transformation of an article into a different state or thing,
  - apply/use exception in meaningful way beyond linking exception to a particular environment (does not monopolize the exception).
- Third, if the claim does not integrate the exception into a practical application, then determine whether claim provides "inventive concept" that is not well-understood, routine, and conventional in the field.

- **Bottom line is that the USPTO has now directed examiners to make rejections under Section 101 far less frequently.**

Obviousness

Obviousness – Blocking Patents

- ***Acorda Therapeutics, Inc. v. Roxane Labs., Inc.* 903 F.3d 1310 (Fed. Cir. 2018)**
  - "A patent has been called a 'blocking patent' where the practice of a later invention would infringe the earlier patent."
  - Previously raised (including with regulatory exclusivity) to diminish the weight of commercial success evidence.
    - *Merck v. Teva; Galderma v. Tolmar*
  - But, licensing a blocking patent alone does not justify discounting evidence of commercial success.
    - *Merck v. Hospira*

Obviousness – Blocking Patents

- ***Acorda Therapeutics, Inc. v. Roxane Labs., Inc.*** **903 F.3d 1310 (Fed. Cir. 2018)**
  - As a matter of "common sense," blocking patents "may or may not deter innovation in the blocked space by commercially motivated potential innovators other than the owners or licenses of the blocking patent."
  - Whether blocking patents are such deterrents is a "fact-specific inquiry"
    - Successfully challenged?
    - Costliness of project
    - Risk of failure
    - Nature of improvements and coverage by blocking patent
    - Size of market opportunities for improvements
    - Risk of losing to blocking patent owner
    - Risk blocking-patent owner won't license

Obviousness – Blocking Patents

- ***Acorda Therapeutics, Inc. v. Roxane Labs., Inc.*** **903 F.3d 1310 (Fed. Cir. 2018)**
  - Blocking Patents apply to:
    - **Commercial success**
    - **Long-felt but unmet need**
    - **Failure of others**

Venue

Venue

- ***In re BigCommerce, Inc.*, 890 F.3d 978 (Fed. Cir. 2018)**
  - "[W]e hold that for purposes of determining venue under 1400(B) in a state having multiple judicial districts, a corporate defendant shall be considered to 'reside' only in a single judicial district within that state where it maintains a principal place of business, or, failing that, the judicial district in which its registered office is located."

Obviousness-Type Double Patenting (OTDP)

Double Patenting vs. Uruguay Round Agreements Act

- ***Novartis Pharmaceuticals Corp. v. Breckenridge Pharmaceutical* 909 F.3d 1355 (Fed. Cir., December 7, 2018)**
- Novartis patent relates to everolimus (Zortress®), used in methods for treating certain cancers and to prevent transplant rejection.
- Novartis has two related patents, one filed before June 8, 1995 (date of Uruguay Round Agreements Act), which has a term of 17 years from the issue date, and a second patent filed after June 8, 1995, which claims the same priority date, but has a term of 20 years from the earliest effective priority date because of the URAA.
- Generics argued that the first patent is invalid for OTDP.
- District court applied *Gilead Sciences, Inc. v. Natco Pharma Ltd.*, 753 F.3d 1208,1212 (Fed. Cir. 2014)(the expiration date of a patent is the benchmark of OTDP) and held the first patent invalid for OTDP over the second later-filed, but earlier-expiring patent, because the claims are not patentably distinct.

Double Patenting vs. Uruguay Round Agreements Act

- In *Gilead*, both patents were filed after June 8, 1995, so the Federal Circuit limited the *Gilead* decision to post-URAA patents and thus distinguished the present case from *Gilead*.
- Here, the Federal Circuit looked at the earlier patent's issuance date, and because the second patent had not yet issued, it was not available as a proper reference for an OTDP analysis.
- The Federal Circuit also noted that Novartis had not played any games with its filing strategies.
- The bottom line is that a change in patent term law should not truncate the term statutorily assigned to the pre-URAA patent, and so the Federal Circuit reversed the district court decision.

Double Patenting vs. Patent Term Extension (PTE)

***Novartis AG v. Ezra Ventures, LLC*, 909 F.3d 1367 (Fed. Cir., December 7, 2018)**

- Novartis patent relates to fingolimod (Gilenya®), which is used in methods for treating multiple sclerosis.
- Ezra filed an ANDA for a generic version; Novartis sued on patent filed before June 8, 1995, and so had 17-year term.
- Novartis patent was extended under 35 USC 156 ("Hatch Waxman Act" of 1984) for PTE of 5 years to make up for time required for FDA approval.
- Novartis had second patent covering method of using drug filed after June 8, 1995, but selected first patent for PTE.
- Ezra argued that first patent should be invalid or at least limited to expire at same time as the second patent under OTDP.

Double Patenting vs. Patent Term Extension (PTE)

- District court found that PTE on first patent was permissible, that OTDP did not apply, that the first patent was valid, and issued injunction until expiration of the extended patent term.
- Ezra argued that Novartis is effectively extending both patents in violation of Sec. 156, which allows only one patent to be extended.
- Federal Circuit held only the first patent was selected and legally extended, and there is no “effectively” extended language in 156.
- Ezra argued that first patent is invalid under OTDP, because the PTE causes first patent to expire after the second patent, which is patentably indistinct from the first.
- Federal Circuit distinguished PTE from patent term adjustment (PTA) under Sec. 154, which cannot overcome a terminal disclaimer.
- Federal Circuit held that OTDP does not invalidate a validly obtained PTE.

Biosimilars

Approval Activity

- 17 approved BLAs
- 7 approved aBLAs
- 3 biosimilars launched

Biosimilar Competition

Antitrust Allegations

- ***Pfizer v. Johnson & Johnson and Janssen* (No. 17-cv-04180, E.D.Pa)**
  - J&J and Janssen maintained their Remicade® (infliximab) market share through a multifaceted scheme of "exclusionary contracts that foreclose Pfizer's access to an overwhelming share of consumers, coupled with anticompetitive bundling and coercive rebate policies designed to block both insurers from reimbursing, and hospitals and clinics from purchasing, Inflectra or other biosimilars of Remicade despite their lower pricing."

Citizen Petition - Pfizer

- "Just as there is a need for policies that support innovation, there is also a need for policies that ensure that patients and physicians have truthful and non-misleading information that encourages appropriate uptake of biosimilars so that biosimilars can reach their full potential for patients."
- Claims that many RPSs have issued misleading communications about biosimilars and asks FDA to issue guidance.

Biosimilar Competition

- **Patient Right to Know Drug Prices Act**
  - Signed into law in October 2018.
  - Amends the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.
  - Requires reference biologic and biosimilar manufacturers to report to the FTC and DOJ settlement agreements relating to the “manufacture, marketing, or sale” of biosimilar products for antitrust scrutiny.
  - Brings biosimilar settlement review procedures more in line with requirements for small molecule drugs.

Litigation – Appeals

- ***Janssen v. Celltrion* (17-1120) and *In re Janssen Biotech, Inc.*, 880 F.3d 1315 (Fed Cir. 2018)**
  - Patent invalidated for obviousness-type double patenting by D. Mass and PTAB (ex parte reexam).
  - Federal Circuit affirms PTAB ruling; moots pending appeal from D. Ct.
  - Rejected Janssen's arguments that OTDP was inapplicable because the safe-harbor provision of 35 U.S.C. § 121 protected the '471 Patent claims.
  - Janssen could not retroactively amend its continuation-in-part application and re-designate it as a divisional application subject to the safe harbor.

Litigation – District Court

- **Likely no declaratory judgment available to biosimilars in the middle of the dance, even if they provide notice of commercial marketing**
  - *Amgen v. Genentech* (C.D. Cal., Jan. 11, 2018 and Feb. 2, 2018):
    - "Allowing an applicant to side-step the BPCIA's exchange and negotiation requirements and bring suit on any patent simply by filing its notice of commercial marketing would effectively vitiate the BPCIA's provisions."
  - *Celltrion v. Genentech* (N.D. Cal., May 9, 2018)
    - Celltrion "fails to state a claim for relief … Because Celltrion did not complete its obligations under Section (l)(5), Celltrion may not file actions for declaratory judgment with respect to the patents at issue."
    - Celltrion may not "satisfy several steps [of the BPCIA dance] at once" by saying it "'wished' to litigate all patents" on the 3(A) list.
    - Celltrion could not pursue a DJ where it gave notice of commercial marketing but did not complete the dance.

CRISPR Interference

CRISPR

- CRISPR-Cas9 is a new technology that can be used to edit parts of the genome by removing, adding, or modifying sections of a specific DNA sequence.
- The CRISPR-Cas9 system includes two key components that introduce a change into the DNA. These are:
  - an enzyme called Cas9 that can cut two strands of DNA at a specific location so that a segment of DNA can then be added or removed; and
  - a piece of RNA called guide RNA (gRNA) that includes a small RNA sequence located within a longer RNA scaffold that is complementary to, and thus binds to, a target DNA and the gRNA "guides" the Cas9 enzyme to cut a specific a target DNA.

CRISPR Interference

- ***Regents of the University of California v. Broad Institute, Inc.*, 903 F.3d 1286 *(Fed. Cir., September 10, 2018)***
- UC filed a patent application claiming the use of a CRISPR Cas9 system for cutting a specific DNA molecule, without referring to a particular cell type or environment.
- The Broad obtained a patent (US 8,697,359) for methods of altering expression of a gene product in a eukaryotic cell using a CRISPR Type-II Cas9 system.
- The USPTO instituted an interference to determine which group first invented the subject matter of the overlapping claims.
- The Broad moved to terminate the interference, because the claims are patentably distinct – one of skill in this field reading the UC claims would not have believed that the CRISPR system would work in eukaryotic cells.
- The PTO determined there was no interference-in-fact.

CRISPR Interference

- The Broad's expert testified as to the significant differences between prokaryotic and eukaryotic cells.
- An article by the UC inventors noted whether their system would work in eukaryotic cells "remains to be seen."
- UC's Jennifer Doudna stated that her paper "was a big success, but there was a problem. We weren't sure if CRISPR/Cas9 would work in eukaryotes" and that she had "many frustrations" getting the system to work in human cells.
- The Federal Circuit affirmed the PTO's judgment of no interference-in-fact, because substantial evidence supported the finding that there was no reasonable expectation of success of using the CRISPR-Cas9 system in eukaryotic cells.
- Thus, both parties are entitled to their own patents.

Playing With Priority Can Be a Losing Game

Playing With Priority Can Be a Losing Game

- ***Natural Alternatives International, Inc. v. Andrei Iancu,* 904 F.3d 1375 (Fed. Cir., October 1, 2018)**
- NAI's competitor requested *inter partes* re-exam of NAI's patent on beta-alanine dietary supplements for increasing athletic endurance.
- NAI's patent was the 8th of a series of applications, each claiming priority back to all prior applications; however NAI amended the 5th application (a Continuation-in-Part) to delete the benefit claim to the earlier applications to get a longer patent term on this patent.
- The 6th through 8th applications again claimed priority to all earlier applications.
- The re-exam request alleged that the 8th patent had a defective priority claim, because applicant had intentionally broken the chain of priority.
- NAI argued that since the 6th application listed the complete priority chain, it was irrelevant what they had done in the 5th application.

Playing With Priority Can Be a Losing Game

- The PTO Board of Appeals disagreed and rejected the 8th patent over prior art including the first patent in the chain.
- NAI appealed and argued that the Board erred in viewing priority as a single growing chain rather than multiple fixed chains.
- The Federal Circuit agreed with the Board and noted a long-standing interpretation of priority as a single chain, growing with each additional continuation.
- The Federal Circuit also held that the 8th application claimed its benefit of priority to the 1st application through the 5th application, which applicant had amended to remove the priority claim.
- When NAI decided to cancel the priority in its 5th CIP application to get a longer patent term, it had to deal with the consequences for the lack of priority in its 6th through 8th patents.
- NAI cannot have it both ways.

IPRs

Supreme Court Activity

- ***Oil States Energy Services, LLC v. Green Energy Group, LLC***
  - IPR did not violate Article III of the Constitution or the Seventh Amendment.

- ***SAS Institute Inc. v. Iancu***
  - No partial institutions.
  - Impact: remanding decisions where the board had partially instituted on only some claims or some invalidity grounds.

Time Bar

- ***Wi-Fi One, LLC v. Broadcom Corp.*, 878 F.3d 1364 (Fed. Cir. Jan. 8, 2018) (en banc)**
  - Federal Circuit can review PTAB's decisions on whether IPR petition was filed within a year of Petitioner being sued
  - Overruled *Achates Reference Publishing v. Apple Inc.*

- ***Click-to-Call Techs., LLP v. Ingenio, Inc.*, 899 F.3d 1321 (Fed. Cir. Aug. 16, 2018) (en banc)**
  - The Section 315(b) one-year bar from "service" of a complaint applies even if the suit was subsequently dismissed without prejudice.
  - Plain meaning of "service" controls—no Chevron/Mead deference to the agency.

Standing

- ***Altaire Pharms., Inc. v. Paragon Bioteck, Inc.*, 889 F.3d 1274 (Fed. Cir. 2018)**
  - Injury In Fact Requirement
    - Imminent injury/harm (not hypothetical);
    - Concrete and particularized
  - Supporting Declaration from General Counsel:
    - **Paragon attempting to terminate license via DJ litigation;**
    - **Paragon won't agree not to sue**
    - **Altaire plans to market formulation; file an ANDA;**
    - **Altaire believes Paragon will inevitably sue upon ANDA filing**
  - Estoppel considerations

Standing & Obviousness

- ***E.I. du Pont de Nemours & Co. v. Synvina C.V.*, 904 F.3d 996 (Fed. Cir. 2018)**

- **Standing to Appeal**
  - Injury-in-fact where DuPont built a plant to manufacture the chemical using the claimed reagents;
  - Synvina refused to give CNS and argued copying.
  - No specific threat of litigation is required to establish standing.

- **Obviousness of Overlapping Ranges**
  - "[W]here there is a range disclosed in the prior art, and the claimed invention falls within that range, the burden of production falls upon the patentee to come forward with evidence" of teaching away, unexpected results, or other pertinent evidence of nonobviousness.

Hatch-Waxman Integrity Act

- **Proposed legislation to modify the IPR process for pharmaceuticals under Hatch-Waxman and the BPCIA.**
  - "[T]o restore the careful balance the Hatch-Waxman Act struck to incentivize generic drug development."
- **Would apply to both generic and biosimilar drug applicants, requiring anyone wishing to challenge a pharmaceutical patent to choose between Hatch-Waxman/BPCIA litigation and an AIA challenge (IPR).**
- **The legislation was proposed to House and Senate in December.**

What To Watch For In 2019

On-Sale Bar

Pre-AIA on-sale bar

35 U.S.C. § 102(b) (pre-AIA)

the invention was patented or described in a printed publication in this or a foreign country or in public use or ***on sale in this country***, more than one year prior to the date of the application for patent in the United States

AIA on-sale bar

35 U.S.C. § 102(a)(1)

the claimed invention was patented, described in a printed publication, or in public use, ***on sale, or otherwise available to the public*** before the effective filing date of the claimed invention

On-Sale Bar

- **Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA Inc. (17-1229)**

- **Issue:**
  - Whether, under the Leahy-Smith America Invents Act, an inventor's sale of an invention to a third party that is obligated to keep the invention confidential qualifies as prior art for purposes of determining the patentability of the invention.

- **Argued on December 4**

On-Sale Bar

- **Helsinn's Arguments:**
  - "otherwise available to the public" is a catch-all provision that applies to each exception to patentability;
  - Thus, a sale must be "available to the public" to qualify as prior art

- **Teva's Arguments:**
  - "on sale" is a term of art simply means sold or offered for sale, even to a single buyer
  - Congress didn't change what "on sale" means, but rather, added new category of prior art – "otherwise available to the public"
  - Even if Helsinn was right, it sold the invention to a member of the interested public one would expect to purchase it

Thank you!

Betsy Flanagan
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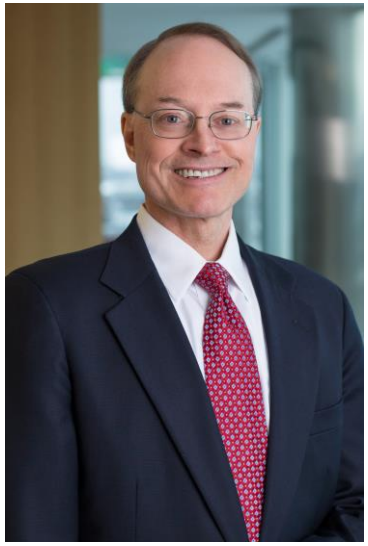

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