Boston Seminar Series

Life Sciences Patents 2016 Year in Review

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Topics to be Covered

- Developments With Biosimilars
  - BPCIA Patent Dance / Notice Requirements
    - *Amgen v. Sandoz*
    - *Amgen v. Apotex*
- Divided Infringement
  - *Eli Lilly & Co. v. Teva Pharms. USA, Inc.*
- Subject Matter Eligibility
  - *Ariosa Diagnostics v. Sequenom*
  - *Rapid Litigation Management Ltd. v. CellzDirect, Inc.*
- Other Developments
  - On-Sale Bar, Patent Agent Privilege, Venue
- Biopharma developments at the Patent Trial and Appeal Board

Developments With Biosimilars

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BPCIA Patent Dance / Notice Requirements

***Amgen Inc. v. Sandoz Inc*., 794 F.3d 1347 (Fed. Cir. 2015), cert. granted (Jan. 2017)**

- Neupogen (Filgrastim)
- Sandoz and Amgen failed to agree on confidentiality provisions attendant to exchange of biosimilar application under BPCIA
  - BPCIA says "shall" disclose application (42 U.S.C. §262(l)(2))
  - Sandoz's 180-day notice of commercial marketing is premature because the notice was not "before" being "licensed" by FDA (42 U.S.C. §262(l)(8))
  - Provide a copy of the application, complete patent exchange process, provide notice of commercial marketing

BPCIA Patent Dance / Notice Requirements

***Amgen v. Sandoz*: A divided Federal Circuit panel ruled:**

- Disclosure of biosimilar application is optional
  - "Shall" does not always mean mandatory particularly where the law provides remedies for failure to comply.
  - The disclosure procedures set forth in subsection (l)(2)(A) of the BPCIA (the "patent dance") are not mandatory.
  - Biosimilar applicant can choose between either disclosing application and manufacturing information or not disclosing such information and instead facing an immediate infringement action from the reference product sponsor.
- 180-day notice cannot be provided before FDA approval
  - Notice of commercial marketing pursuant to subsection (l)(9)(A) of the BPCIA can be given only after FDA approval of the biosimilar product, effectively extending the reference drug's exclusivity by 180 days.

Amgen v. Sandoz: Court Grants Cert.

Sandoz appealed (*Sandoz v. Amgen*)

(1) Whether notice of commercial marketing given before Food and Drug Administration approval can be effective; and

(2) Whether, in any event, it is improper to treat Section 262(l)(8)(A) – the Biologics Price Competition and Innovation Act of 2009's "Notice of commercial marketing" provision which states that a biosimilar applicant shall provide notice to the incumbent seller of the biological product "not later than 180 days before the date of the first commercial marketing of the biological product licensed under" an abbreviated pathway for biosimilars – as a stand-alone requirement and as creating an injunctive remedy that delays all biosimilars by 180 days after approval.

Amgen cross-appealed *(Amgen v. Sandoz)*

(1) Whether a biosimilar applicant is required by 42 U.S.C. § 262(l)(2)(A) to provide the reference product sponsor with a copy of its biologics license application and related manufacturing information, which the statute says the applicant "shall provide;" and

(2) Whether, where an applicant fails to provide that required information, the sponsor's sole recourse is to commence a declaratory judgment under 42 U.S.C. § 262(l)(9)(C) and/or a patent-infringement action under 35 U.S.C. § 271(e)(2)(C)(ii).

BPCIA Patent Dance / Notice Requirements

Implications

- Potential far reaching strategic implications for biosimilar applicants and originators
  - Whether to dance or not
    - What must be exchanged as part of the dance?
  - Whether notice of commercial marketing is necessary and when
    - Before or after approval

BPCIA Patent Dance / Notice Requirements

***Amgen Inc. v. Apotex Inc*., 827 F.3d 1052 (Fed. Cir. 2016)**

***Apotex Inc. v. Amgen Inc*., 85 U.S.L.W. 3287, cert denied (Dec. 2016)**

- Neulasta (pegfilgrastim)
- Amgen and Apotex began BPCIA information exchange
- If biosimilar applicant complies with patent dance, when can 180 day notice be given?

Held:

- BPCIA's 180-day notice of commercial marketing cannot begin until after a biosimilar applicant has received FDA licensure,
- The notice of commercial marketing provision is mandatory and enforceable by injunction, even for an applicant that has engaged in the patent dance.

Divided Infringement

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Eli Lilly & Co. v. Teva Pharms. USA, Inc. et al. (Jan. 12, 2017)

- Split-actor induced infringement case (*Akamai V*)
  - Patients
  - Physicians

- Claim related methods of administering pemetrexed disodium after pretreatment with folic acid and vitamin B12:
    - "A method of administering pemetrexed disodium to a patient in need thereof comprising **administering an effective amount of folic acid** and **an effective amount of a methylmalonic acid lowering agent** [vitamin B12] followed by **administering an effective amount of pemetrexed disodium**…"

- District court held that physicians were direct infringers (patients acting under their direction/control) and that Teva induced infringement (based on ALIMTA product labeling)

Eli Lilly & Co. v. Teva Pharms. USA, Inc. et al. (Jan. 12, 2017)

Under *Akamai V*, direction or control requires:

- Conditioning participation in an activity or receipt of a benefit upon others' performance
  - Benefit: reduction of toxicities vs. treatment with pemetrexed?
  - Product labeling stresses importance of folic acid
  - Expert testimony provides record evidence physicians impose condition and may not treat with pemetrexed otherwise
  - But "conditioning…does not necessarily require double-checking…"
- Establishing the manner and timing of performance
  - Dosage ranges and schedule here overlaps with claims
  - Product labeling is key

Eli Lilly & Co. v. Teva Pharms. USA, Inc. et al. (Jan. 12, 2017)

- Physician is direct infringer, but does Teva induce?
  - Intent must be with respect to the actions underlying the direct infringer
  - Evidence "regarding general prevalence of the induced activity" is not required; it is "irrelevant that some users may ignore the warnings" and not follow instructions
- Vague instructions (e.g., off-label use in *Takeda*) versus specific instruction that track the claims (*AstraZeneca*)
- Still open questions: Scope of patient/physician relationship
  - "We leave to another day what other scenarios might also satisfy the direction of control requirement"

Subject Matter Eligibility

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How the Courts are Viewing Section 101

Ariosa Diagnostics v. Sequenom, 788 F.3d 1371 (Fed. Cir. 2015)

Background

- Claims cover a non-invasive method of prenatal testing for, *inter alia,* Down syndrome (the most common birth defect) that avoided amniocentesis
- Invention was cell-free fetal DNA in maternal blood could be used to test for genetic defects and was not just "medical waste"

District Court - ineligible

Federal Circuit 788 F.3d 1371 (2015) – ineligible

- Court applied the 2-step *Mayo* analysis embodied in PTO Interim Eligibility Guidelines:

  (1) Is claim directed to natural material? If so,
  (2) Do the additional steps add "significantly more" to the invention?

- Cell-free fetal DNA was a natural phenomena or product and the manipulative steps to determine the prenatal condition were routine
- Invention failed the "inventive step" (step 2) test

How the Courts are Viewing Section 101

Ariosa Diagnostics v. Sequenom

- Rehearing *en banc* denied, ___ F.3d ___ (Fed. Cir. December 2, 2015)
  - Numerous judges criticized *Mayo,* raised the lack of preemption, and hoped that the Supreme Court would fix the problem. Judge Newman dissented and explained that patent eligibility could have been found despite *Mayo* and *Myriad*.

- Petition for Cert. – Question Presented:

  Whether a novel method is patent-eligible where:

  (1) a researcher is the first to discover a natural phenomenon;

  (2) that unique knowledge motivates him to apply a new combination of known techniques to that discovery; and

  (3) he thereby achieves a previously impossible result without preempting other uses of the discovery?

- BIG DISAPPOINTMENT – Supreme Court DENIED certiorari on 136 S. Ct. 2511 (June 27, 2016)

How the Courts are Viewing Section 101

***Rapid Litigation Management Ltd. v. Cellzdirect, Inc*. 827 F.3d 1042 (Fed. Cir. 2016)**

- **Background**
  - Claims directed to methods of cryoprotecting liver cells
- **District Court – patent ineligible**
  - Claims challenged under Section 101 and the District Court agreed on summary judgment ("law of nature" that liver cells can survive multiple freeze-thaw cycles)
- **Federal Circuit - vacated and remanded**
  - Method requires an artisan to carry out a number of concrete steps
  - The resulting preparation, and the process for creating it, achieved a notable advance over prior art techniques for preserving hepatocytes
  - "The inventors certainly discovered the cells' ability to survive multiple freeze-thaw cycles, but that is not where they stopped, nor is it what they patented."

How the Courts are Viewing Section 101

***Rapid Litigation Management Ltd. v. Cellzdirect, Inc*. 827 F.3d 1042 (Fed. Cir. 2016)**

- "The '929 patent claims are like thousands of others that recite processes to achieve a desired outcome, e.g., methods of producing things, or methods of treating disease. That one way of describing the process is to describe the natural ability of the subject matter to *undergo* the process does not make the claim "directed to" that natural ability."
- "This type of constructive process, carried out by an artisan to achieve "a new and useful end," is precisely the type of claim that is eligible for patenting."
- "Indeed, to preclude the patenting of an invention simply because it touches on something natural would 'eviscerate patent law.'"
- A new ray of hope in this troubled area of the law?

How the Courts are Viewing Section 101

Oxford Immunotec Ltd. v. Qiagen, Inc. (D. Mass. 2016)

Background

- Patents relate to *in vitro* methods of diagnosing TB
- Eight ESAT-6 peptides are mixed with a test subject's blood and if T cells in the patient's blood produce IFN-γ, indicates that the patient has been exposed to *M. tuberculosis*
- Magistrate Recommends That Defendants' Motion to Dismiss Be Allowed for Kit Claims and Denied for Method Claims

Oxford Immunotec Ltd. v. Qiagen, Inc.

Kit claim:

7. A kit for diagnosing infection in a human host by, or exposure of a human host to, a mycobacterium that expresses ESAT-6, comprising a panel of eight peptides represented by SEQ ID NOS: 1 to 8.

Applying 2-step inquiry:

(1) directed to a judicial exception – YES

(2) amounts to significantly more – NO

"appreciates that isolated peptides perform differently than peptides contained in an intact ESAT-6 strand, the Court does not find this fact significant to its analysis, …"

Oxford Immunotec Ltd. v. Qiagen, Inc.

Method claim:

1. An assay for identifying Mycobacterium tuberculosis-specific immediate effector T cells in a subject, comprising:

(a) providing a sample from said subject containing T cells;

(b) exposing said T cells to an immunogenic amount of a peptide subfragment of ESAT-6 that contains a CD8+ epitope; and

(c) prior to the generation of new immediate effector T cells in the sample, determining whether said T cells are activated by said peptide subfragment by measuring secretion of a cytokine from said T cells;

wherein activation of said T cells identifies the presence of Mycobacterium tuberculosis-specific immediate effector T cells that were present in the original sample, in said subject.

Applying 2-step inquiry:

(1) directed to a judicial exception – YES

(2) amount to significantly more – YES

“the patented invention improves on existing methods for diagnosing TB by making diagnosis more convenient, less dependent on a physician's subjective interpretation of results, and more accurate…"

U.S. Patent & Trademark Office Guidelines

For determining subject matter eligibility

March 2014 – First USPTO Guidance

- Procedure for Subject Matter Eligibility of Claims Reciting or Involving Laws of Nature/Natural Principles, Natural Phenomena, And/Or Natural Products (Myriad/Mayo)

December 2014 – Revised USPTO Guidance

- 2014 Interim Guidance Patent Subject Matter Eligibility (Myriad/Mayo/Alice)

July 2015 Update: Subject Matter Eligibility

- Additional Examples relating to Abstract Idea exception (Myriad/Mayo/Alice) – *no life sciences examples*

May 2016 Update: Subject Matter Eligibility

- Additional Examples relating to Abstract Idea exception (Myriad/Mayo/Alice) – ***Life sciences examples!!***

USPTO website:

http://www.uspto.gov/patents/law/exam/interim_guidance_subject_matter_eligibility.jsp

Other Developments

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On-Sale Bar

"A person shall be entitled to a patent unless … the invention was … on sale in this country, more than one year prior to the date of the application" for the patent. 35 U.S.C. § 102(b) (pre-AIA).

"A person shall be entitled to a patent unless … the claimed invention was … on sale … before the effective filing date of the claimed invention" for the patent. 35 U.S.C. § 102(a)(1) (AIA).

On-Sale Bar

- **Definition of "on sale"**
  - Pfaff v. Wells (Supreme Court 1998) – set out a two prong test:
    - (1) the product must be the subject of a commercial offer for sale, and,
    - (2) the invention must be ready for patenting.

- **Experimental Use Exception**
  - "When an evaluation period is reasonably needed to determine if the invention will serve its intended purpose, the § 102(b) bar does not start to accrue while such determination is being made."

On-Sale Bar: The Medicines Company

***The Medicines Co. v. Hospira, Inc*. 791 F.3d 1368 (Fed. Cir. 2015)**

***The Medicines Co. v. Hospira, Inc. 827 F.3d 1357*, (2016) (en banc)**

- **Background**
  - Bivalirudin (Angiomax®) – synthetic peptide anti-coagulant
  - 2005 – several batches contained too much impurity
  - New method discovered for making product with less than 0.6% impurity
  - TMC's Patents - Pharmaceutical batches of Bivalirudin with less than 0.6% impurity
  - More than 1-year before the patents were filed, TMC contracted with supplier for three batches of product to be made by the newly developed process in order to confirm that the process worked as intended
  - The lots were released to TMC for commercial and clinical packaging, and were eventually sold

On-Sale Bar: The Medicines Company

- **District Court – No On-Sale Bar**
  - Ready for patenting – YES
  - Commercial offer for sale – NO
    - Manufacturer sold only services (not products)
    - Experimental use exception applied

- **Federal Circuit Reversed – Sale of Services, Not Product**
  - Unfair to separate sale of services from sale of product
    - "…no principled distinction between the commercial sale of products prepared by the patented method [ ] and the commercial sale of services that result in the patented product-by-process…"
  - Experimental use cannot occur after reduction to practice
    - "This is not a situation in which the inventor was unaware that the invention had been reduced to practice, and was experimenting to determine whether that was the case."

Federal Circuit (en banc) - No On-Sale Bar

- “The mere sale of manufacturing services by a contract manufacturer to an inventor to create embodiments of a patented product for the inventor does not constitute a "commercial sale' of the invention."
- "‘Stockpiling' by the purchaser of manufacturing services is not improper commercialization under § 102(b)."
- “Commercial benefit—even to both parties in a transaction—is not enough to trigger the on-sale bar of § 102(b); the transaction must be one in which the product is 'on sale' in the sense that it is 'commercially marketed.'"

On-Sale Bar: Merck & CIE – Secret Sales

***Merck & Cie v. Watson Laboratories Inc*. 822 F.3d 1347 (Fed. Cir. 2016)**

***Merck & Cie v. Watson Laboratories Inc*. 136 S. Ct. 2441 cert denied (Jan. 9, 2017)**

- **Background**
  - ANDA litigation over "claim 4" directed to a crystalline calcium salt of 5-methyl-(6S)-tetrahydrofolic acid [MTHF]
  - Critical date of claim **April 17, 1999**
  - **1997**: Merck in discussions with Weider to introduce dietary supplements with Merck ingredients – under Confidentiality Agreement
  - **August 1998:** Weider backed out of the arrangement, but inquired with Merck regarding purchase of 2kg of MTHF
  - Merck responded with a set price, delivery, assurance product could be produced (and more if necessary) – Order confirmed **October 1998**
  - Order canceled **January 1999**

On-Sale Bar: Merck & CIE

- Merck & Cie (a Merck subsidiary) brought suit against Watson for infringing “claim 4” for filing an ANDA

- **District Court – No On-Sale Bar**
  - Ready for patenting – YES
  - Commercial offer for sale – NO
    - Merck’s reply to Wieder’ request with price and assurance was "sufficiently definite to qualify as a commercial offer”
    - Confidentiality Agreement between the parties required that there be a "definitive agreement" signed by the parties

On-Sale Bar: Merck & CIE

- **Federal Circuit Reversed – On-Sale Bar**
  - Ready for patenting – YES
  - Commercial offer for sale – YES
    - Applied traditional contract law
    - Confidentiality Agreement does not apply to an offer to sell, which is enough to implicate the on-sale bar
    - "[a]n offer to sell is sufficient to raise the on-sale bar, regardless of whether that sale is ever consummated“ (citing *Hamilton Beach Brands, Inc. v. Sunbeam Prods., Inc.*, 726 F.3d 1370 (2013))

- Federal Circuit held that confidential, non-public discussions between Merck and a third party during preparations to launch a product triggered the on-sale bar.

On-Sale Bar: Merck & CIE

- Cert denied (July 21, 2016)
  - Question Presented

Whether the "on sale" bar found in § 102(b) applies only to sales or offers of sale made available to the public, as Congress, this Court, and the United States have all made clear, or whether it also applies to nonpublic sales or offers of sale, as the Federal Circuit has held.

Personal Jurisdiction: *Acorda Therapeutics*

***Acorda Therapeutics v. Mylan* and**
***AstraZeneca v. Mylan, 817 F.3d 755* (Fed. Cir. 2016)**

- Acorda and AZ sued Mylan in separate Hatch-Waxman cases in D.Del. assigned to different judges (Stark/Sleet)
- Mylan moved to dismiss for lack of personal jurisdiction. Both judges found that Court had specific personal jurisdiction over Mylan but reached different conclusions on general personal jurisdiction
- On appeal, Federal Circuit affirmed finding of specific personal jurisdiction and declined to reach general jurisdiction question
  - Exercise of personal jurisdiction does not offend "traditional notions of fair play and substantial justice" because Mylan has indicated its intent (through ANDA filing) to market and sell product in the jurisdiction in the future
  - Judge O'Malley concurred in the judgment concluding that the filing of the ANDA itself created a present cognizable harm to Delaware plaintiffs; also would have found general jurisdiction extant

Personal Jurisdiction: *Acorda Therapeutics*

***Acorda Therapeutics v. Mylan* and**
***AstraZeneca v. Mylan, 817 F.3d 755* (Fed. Cir. 2016)**

- In concluding that specific personal jurisdiction existed, the Federal Circuit gave a salutary nod to the importance of the venue issue
  - "A finding of minimum contacts does not end the Due Process inquiry.,"—let alone any non-constitutional venue inquiries—into whether a case properly remains in a forum . . . . [A] defendant may still defeat specific personal jurisdiction by sufficiently demonstrating that other considerations render jurisdiction unreasonable"
    - Burden on defendant
    - State interest in adjudicating the dispute
    - Plaintiff's interest in convenient and effective relief
    - Efficient resolution of controversies
- *Certiorari was granted in In re TC Heartland, 821 F.3d 1338 (Fed. Cir. 2016)*

CON Filed on Day Parent Issues Satisfies 35 U.S.C. § 120

***Immersion Corp. v. HTC Corp.* 826 F.3d 1357 (Fed. Cir. 2016)**

- District Court held that Patent No. X was not "filed before the patenting" of Parent Patent No. Y within the meaning of 35 U.S.C. § 120, because the 'X patent application was filed on the same day that the 'Y patent issued.

§ 120:

> An application for patent for an invention [adequately] disclosed . . . in an application previously filed in the United States . . . shall have the same effect, as to such invention, as though filed on the date of the prior application, *if filed before the patenting* or abandonment of or termination of proceedings on the first application or on an application similarly entitled to the benefit of the filing date of the first application . . . [emphasis added].

- The Federal Circuit reversed

A New, Limited Patent Agent-Client Privilege

***In re Queen's University at Kingston* 820 F.3d 1287 (Fed. Cir. 2016)**

- Patent agents are licensed to practice before the USPTO, and perform the same duties as patent attorneys before the USPTO.
- However, patent agents, who are not members of the bar, are not considered attorneys.
- Federal Circuit recognized a "patent-agent privilege," which protects communications between non-attorney patent agents and their clients during the course of the patent agent's authorized practice before the USPTO.
- The court relied in part on the Supreme Court's holding in *Sperry v. State of Fla.*, 373 U.S. 379, 381 (1963), in which the Court ruled that *a patent agent's work* "constitutes the practice of law." *Id.* at 383.
- The privilege is limited to work that is "reasonably necessary and incident" to work done before the USPTO, e.g., not for litigation matters.
- This holding resolved a split in decades of district court decisions.

Looking Forward to 2017

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Multiple IP Cases Up for SC Review

- *Sandoz* (BPCIA patent dance)
- *Life Technologies Corp. v. Promega Corp.* (infringement under 35 U.S.C. § 271(f)(1) for supplying single component)
- *TC Heartland* (Does the general definition of "residence" found in 28 U.S.C. 1391(c) apply to the patent venue statute 1400(b))
- *SCA Hygiene* (whether laches applies in patent cases)
- *Impression Products* (using patents as a personal property servitude)
- **Decisions expected by June 2017**

Developments in Biopharma IPRs

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IPR Activity Related to Biologics

- Avastin (bevacizumab)
  - Pending
- Herceptin (trastuzumab)
  - Pending
- Neulasta (pegfilgrastim)
  - Pending
- Rituxan (rituximab)
  - Pending
- Humira (adalimumab)
  - Trial instituted on RA dosing patents, no FWD
- Tysabri (natalizumab)
  - Denied institution
- Orencia (abatacept)
  - FWD: challenged claims not unpatentable

BRI Is the Proper Standard at the PTAB

Cuozzo Speed Technologies, LLC v. Lee, 579 U.S. __ (2016)

- The US Supreme Court considered issues regarding claim construction and 'appealability' of institution decisions
- Is "broadest reasonable interpretation" (BRI) the proper claim construction standard?
  - Supreme Court decided that the PTAB may apply the BRI standard, explaining that the standard was within a "reasonable exercise of its rulemaking authority"
  - The Court, however, did not explain *how* that standard is to be applied
- Are institution decision appealable?
  - PTAB decisions made at institution are, for the most part, unreviewable on appeal
  - However…the Federal Circuit might have review in extreme cases, such as when a constitutional right is implicated

IPR - APA Right to Respond

- ***SAS Institute, Inc. v. ComplementSoft, LLC (Fed. Cir. 2016)***
  - APA – Parties must be afforded an Opportunity to Respond

- ***Genzyme Therapeutic Products Ltd. v. Biomarin Pharmaceutical Inc.*, Nos. 2015-1720 & 1721, slip op. (Fed. Cir. June 14, 2016)**
  - APA Right to Respond – Parties Must Take Action

- ***In re NuVasive, Inc*., 841 F.3d 966 (Fed. Cir. 2016)**
  - APA Right To Respond – New Combinations

SAS Institute, Inc. v. ComplementSoft, LLC

- The Federal Circuit vacated on procedural grounds the PTAB's final written decision confirming the patentability of one claim.
- Term X was construed in the ID, and it was not challenged by the patent owner in its response.
- Term X was otherwise construed by the Board in the FWD, however, in a manner that significantly differed from the institution decision, to the demise of the petitioner's grounds.
- As a consequence of this process, Petitioner was not afforded notice that a different construction was even being considered, and thus could not have imagined the need to address the new construction in its reply.

SAS Institute, Inc. v. ComplementSoft, LLC

- The Federal Circuit held that the PTAB's actions deprived petitioner of its APA right to respond to an agency's change in legal theory:

  "It is difficult to imagine either party anticipating that already-interpreted terms were actually moving targets, and it is thus unreasonable to expect that they would have briefed or argued, in the alternative, hypothetical constructions not asserted by their opponent." slip op. at 17-18.

- On remand, the Federal Circuit instructed the PTAB to re-evaluate the patentability of the claim after hearing from both parties.

Genzyme Therapeutic Products Ltd. v. Biomarin Pharmaceutical Inc.

- Federal Circuit upheld PTAB, despite reliance by the final written decision on references not offered in the petition or earlier relied upon in the institution decision.
- Setup:
  - In its reply, petitioner cited two references (Kikuchi and van der Ploeg ‘91) to show the state of the art at the time of the invention.
  - Neither reference formed the basis of a proposed ground of unpatentability, nor did the PTAB discuss either reference substantively in the institution decision or rely in the grounds on which it granted the petition.
  - During oral argument, the parties disputed what use the PTAB could make of the two references.
  - In its final written decision, the PTAB referred to both references as support for its findings regarding the state of the art. However, the grounds themselves on which the PTAB found the claims unpatentable were the grounds identified in the institution decision.

Genzyme Therapeutic Products Ltd. v. Biomarin Pharmaceutical Inc.

- Patent owner appeal:

  PTAB abridged its procedural rights under the APA by changing its theory of the cases between institution and final written decision when it referred to the Kikuchi and van der Ploeg '91 references.

- The Federal Circuit rejected patent owner's argument:

  "[T]he introduction of new evidence in the course of the trial is to be expected in *inter partes* review trial proceedings and, as long as the opposing party is given notice of the evidence and an opportunity to respond to it, the introduction of such evidence is perfectly permissible under the APA …." slip op. at 9.

- Patent owner had received adequate notice of the two references.
- Patent owner could have sought to exclude the references or could have sought file an additional reply

In re NuVasive, Inc.

- Petition relied on art having many different embodiments, but only argued invalidity based on certain embodiments.
- For the first time in the Reply, the Petitioner proposed relying on a new embodiment.
- The PTAB ultimately invalidated based on the new embodiment.

- The CAFC vacated and remanded, stating that "NuVasive was entitled to an adequate opportunity to respond" to the new arguments.

  "Despite requests from NuVasive, the Board refused to permit NuVasive to file a surreply or even to address the matter during oral argument."

Thank you!

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