Significant Recent Life Sciences Decisions Round Up

Arlene Chow, Hogan Lovells US LLP, New York
LSPN, Boston

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Topics

(1) AIA On-Sale Bar

(2) Patent Term Adjustment

(3) Patent Eligibility of Diagnostic Patents

(4) State Sovereign Immunity

(1) AIA On-Sale Bar

- *Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc. (SCOTUS)*
  - The "on-sale bar" bars patentability when an invention was sold or offered for sale *before* a patent application was filed.
  - Changes made by AIA**:**
    - **Pre-AIA on-sale bar (35 U.S.C. § 102(b)):** 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

AIA On-Sale Bar

- *Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc.*
  - Priority date of patent at issue: January 30, 2003
  - Helsinn entered into agreements with distributor MGI on April 6, 2001
    - Agreements announced in joint press release.
    - MGI's filing with SEC included partially-redacted copies of agreements.
  - ***But price terms and specific dosage formulation were not disclosed.***
  - District court held that AIA changed meaning of on-sale bar.
    - Section 102(a)(1) now requires public sale or offer for sale of the claimed invention.
    - A sale must publicly disclose the details of the invention.
    - Agreements not a public sale because formulation dose was not publicly disclosed.

AIA On-Sale Bar

- *Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc.* (Fed. Cir.)
  - Federal Circuit disagreed with lower court.
    - Rejected argument that AIA on-sale bar does not encompass secret sales and now requires invention to be made available to the public in order to trigger on-sale bar.
    - "[r]equiring such disclosure as a condition of the on-sale bar would work a foundational change in the theory of the statutory on-sale bar."
    - "Prior cases have applied the on-sale bar even when there is no delivery, when delivery is set after the critical date, or, even when, upon delivery, members of the public could not ascertain the claimed invention."
  - **Conclusion: "after the AIA, if the existence of the sale is public, the details of the invention need not be publicly disclosed in the terms of the sale."**

AIA On-Sale Bar

- *Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc. (SCOTUS)*
  - Supreme Court unanimously *affirmed* Federal Circuit's decision.
    - **Commercial sale to a third party who is required to keep invention confidential may place invention "on sale" under § 102(a).**
    - Supreme Court precedent supports view that "secret sales" can invalidate a patent.
    - When Congress reenacted the same language in AIA, it adopted the earlier judicial construction of that phrase.
      - Addition of the catchall phrase "or otherwise available to the public" not enough for Court to conclude that Congress intended to alter the meaning of "on-sale."

(2) Patent Term Adjustment

- *Supernus Pharmaceuticals v. Iancu (Fed. Cir.)*
  - Patent term adjustment statute lengthens patent term to make up for delays during prosecution
    - Statute also states PTO can reduce length of adjustment by deducting # days applicant "failed to engage in reasonable efforts to conclude prosecution"
  - PTO's broad position: once an applicant files a request for continued examination (RCE) after rejection, any subsequent filing is "applicant delay" that reduces patent term adjustment
    - b/c PTO Examiner has to review application again
  - Held: PTO exceeded its statutory authority by reducing Supernus' patent term
    - Because Supernus could not have taken "reasonable efforts to conclude prosecution" of its patent application during a 546 day period, PTO could not treat period as "applicant delay"

Patent Term Adjustment

- *Supernus Pharmaceuticals v. Iancu (Fed. Cir.)*
  - Supernus sought to extend the term of its patent on a drug delivery system used in the hypertension medication Orenitram by 546 days
  - Supernus filed an information disclosure statement several hundred days after filing a request for continued examination (RCE) in order to alert the PTO to a parallel patent examination in Europe
  - Supernus argued: no way of knowing earlier what had happened in the opposition in Europe

(3) Patent Eligibility of Diagnostic Patents

- *Athena Diagnostics Inc. v. Mayo Collaborative Services (Fed. Cir.)*
  - Inventors discovered that 20% of myasthenia gravis (MG) patients (chronic disorder causing waning muscle strength) cannot be diagnosed conventionally
    - instead can be diagnosed by muscle-specific tyrosine kinase (MuSK) autoantibodies
  - Claims directed to:
    - methods for diagnosis by detecting autoantibodies
    - techniques for detecting autoantibodies
    - enzyme-linked immunosorbent assay for detecting autoantibodies and
    - immunoprecipitation assays

Patent Eligibility of Diagnostic Patents

- *Athena Diagnostics Inc. v. Mayo Collaborative Services (Fed. Cir.)*
  - Affirming lower court's invalidity determination on motion to dismiss based on the pleadings, Fed. Cir. applied two-step *Mayo* test, which "leaves no room for a different outcome":
    - Claims "directed to" natural law
      - correlation between naturally occurring MuSK autoantibodies and MuSK-related neurological diseases like MG
    - Claims lacked "inventive concept"
      - Claims only required standard techniques applied in a standard way
        - Specification stated that immunoassay techniques known/conventional
      - Fed. Cir.: "We cannot hold that performing standard techniques in a standard way to observe a newly discovered natural law provides an inventive concept"
    - Note: outcome likely different if method of treating disease incorporated into claim

Patent Eligibility of Diagnostic Patents

- *Cleveland Clinic Fdtn. v. True Health Diagnostics (Fed. Cir.)*
  - Case law supersedes PTO guidance for patent eligibility; PTO guidance not a safe harbor
  - Upheld EDVA decision invalidating Cleveland Clinic's patents based on *Mayo*
  - Fed. Cir.: Cleveland Clinic's patent claims a natural law ineligible for patenting, the correlation between the presence of a certain protein and an increased risk of heart disease
    - Rejected CC's argument that detecting this relationship requires new techniques and prior tests were too invasive or unreliable
    - "Inadequate measures of detection do not render a natural law any less natural"
  - Fed. Cir.: "while we greatly respect the PTO's expertise on all matters relating to patentability, including patent eligibility, we are not bound by its guidance."

Patent Eligibility of Diagnostic Patents

- *Cleveland Clinic Fdtn. v. True Health Diagnostics (Fed. Cir.)*
  - Illustrative Cleveland Clinic Claim:

    A method for identifying an elevated myeloperioxidase MPO concentration in a plasma sample from a human subject with atherosclerotic cardiovascular disease comprising:

    a) contacting a sample with an anti-MPO antibody, wherein said sample is a plasma sample from a human subject having atherosclerotic cardiovascular disease;

    b) spectrophotometrically detecting MPO levels in said plasma sample;

    c) comparing said MPO levels in said plasma sample to a standard curve generated with known amounts of MPO to determine the MPO concentration in said sample; and

    d) comparing said MPO concentration in said plasma sample from said human subject to a control MPO concentration from apparently healthy human subjects, and identifying said MPO concentration in said plasma sample from said human subject as being elevated compared to said control MPO concentration.

Comparison of PTO Guidance Claim to Ariosa's Claim

Example 29 of Patent Eligible Claim from PTO May 4 , 2016 guidance

A method of detecting JUL-1 in a patient said method comprising:

a. obtaining a plasma sample from a human patient; and

b. detecting whether JUL-1 is present in the plasma sample by contacting the plasma sample with an anti-JUL-1 antibody and detecting binding between JUL-01 and the antibody

Claim 1 of Ariosa's '540 Patent found ineligible by Fed. Cir. in 2015

A method for detecting a paternally inherited nucleic acid of fetal origin

performed on a maternal serum or plasma sample from a pregnant female, which method comprises

amplifying a paternally inherited nucleic acid from the serum or plasma sample and

detecting the presence of a paternally inherited nucleic acid of fetal origin in the sample

Patent Eligibility of Diagnostic Patents

- *Cleveland Clinic Fdtn. v. True Health Diagnostics (Fed. Cir.)*
  - Affirming lower court's invalidity determination, Fed. Cir. applied two-step *Mayo* test:
    - Claims "directed to" natural law: blood MPO levels correlate with atherosclerotic CVD
      - Rejected CC's argument that claims directed to (1) specific immunoassay ID and detection technique for detecting blood MPO levels; (2) correlation between blood MPO and CVD not natural law b/c only detected with certain techniques
      - Claims apply known methods to detect MPO levels in plasma, comparing to standard MPO levels and concluding that patients' blood MPO levels elevated
    - Claims lacked "inventive concept"
      - Rejected CC's argument that applying specific immunoassay ID and detection technique to blood MPO levels supplies an inventive concept
      - Rejected CC's argument that using a known technique in a standard way to observe a natural law can confer an inventive concept

(4) Sovereign Immunity

- *Univ. of Florida Research Foundation v. General Electric (Fed. Cir.)*
  - Fed. Cir.: University waived its immunity by suing GE; patent ineligibility is a defense to infringement
    - Univ. of Florida argued: State of Florida did not consent to try patent eligibility in the district court
      - As an arm of Florida, it enjoys sovereign immunity under the 11th amendment
  - Affirmed lower court's decision that patent covers only an abstract idea of collecting, analyzing, manipulating and displaying data
    - Purported invention improved over manual entry of medical patient data
    - Called "quintessential `do it on a computer' patent"
  - No exception for universities/gov't entities to escape patent eligibility attacks