Life Sciences IP Due Diligence: Implications of Recent Decisions, Legislation, PTO Guidance on Diligence Analysis

TUESDAY, MARCH 3, 2020

1pm Eastern  |  12pm Central  |  11am Mountain  |  10am Pacific

Today’s faculty features:

Thomas L. Irving, Partner, Finnegan Henderson Farabow Garrett & Dunner, Washington, D.C.

Sherry M. Knowles, Principal, Knowles IP Strategies, Atlanta

Hilary J. Libka, Chief IP Counsel, Dana-Farber Cancer Institute, Boston

Ryan Murphey, Counsel, Ropes & Gray, New York

The audio portion of the conference may be accessed via the telephone or by using your computer’s speakers. Please refer to the instructions emailed to registrants for additional information. If you have any questions, please contact Customer Service at 1-800-926-7926 ext. 1.
Tips for Optimal Quality

**Sound Quality**
If you are listening via your computer speakers, please note that the quality of your sound will vary depending on the speed and quality of your internet connection.

If the sound quality is not satisfactory, you may listen via the phone: dial 1-877-447-0294 and enter your Conference ID and PIN when prompted. Otherwise, please send us a chat or e-mail sound@straffordpub.com immediately so we can address the problem.

If you dialed in and have any difficulties during the call, press *0 for assistance.

**Viewing Quality**
To maximize your screen, press the ‘Full Screen’ symbol located on the bottom right of the slides. To exit full screen, press the Esc button.
Continuing Education Credits

In order for us to process your continuing education credit, you must confirm your participation in this webinar by completing and submitting the Attendance Affirmation/Evaluation after the webinar.

A link to the Attendance Affirmation/Evaluation will be in the thank you email that you will receive immediately following the program.

For additional information about continuing education, call us at 1-800-926-7926 ext. 2.
Program Materials

If you have not printed the conference materials for this program, please complete the following steps:

• Click on the link to the PDF of the slides for today’s program, which is located to the right of the slides, just above the Q&A box.
• The PDF will open a separate tab/window. Print the slides by clicking on the printer icon.
Disclaimer

These materials have been prepared solely for educational and entertainment purposes to contribute to the understanding of U.S. and European intellectual property law. These materials reflect only the personal views of the authors and are not individualized legal advice. It is understood that each case is fact specific, and that the appropriate solution in any case will vary. Therefore, these materials may or may not be relevant to any particular situation. Thus, the authors and Finnegan, Henderson, Farabow, Garrett & Dunner, LLP (including Finnegan Europe LLP, and Fei Han Foreign Legal Affairs Law Firm), ROPES & GRAY, KNOWLES IP STRATEGIES, AND DANA-FARBER CANCER INSTITUTE cannot be bound either philosophically or as representatives of their various present and future clients to the comments expressed in these materials. The presentation of these materials does not establish any form of attorney-client relationship with these authors or firms or companies. While every attempt was made to ensure that these materials are accurate, errors or omissions may be contained therein, for which any liability is disclaimed.
Outline

I. Recent cases

II. Current and pending legislation

III. USPTO guidance

IV. Best practices for life sciences IP due diligence

• What are the best approaches for counsel to identify the IP assets to review during due diligence?

• What implications do recent court decisions have on the IP due diligence process in the life sciences?

• How should counsel address IP ownership questions that arise during due diligence?
Why Is This Important?

• Collaborations and transactions.

• Regularly objectively evaluate own IP and IP strategy; identify and address potential issues and better prepare it for potential partnerships or transactions.

• The result of inadequate IP due diligence is wasted resources! The last thing anyone wants, particularly in deals where the IP plays an important role, is to spend millions of dollars on a deal only to find out when it’s too late that the underlying IP is virtually worthless. Some flaw in the IP was not recognized in time to stop the deal.
Case Law Developments
35 U.S.C. 101
Patent Eligibility - Update

U.S. Constitution:
Congress has the sole power “To promote the progress of science and useful arts, by securing for limited times to inventors the exclusive right to their discoveries.”

Statute:
Whoever invents or discovers a new or useful process, machine, manufacture or composition of matter or improvement thereof.

Case Law (Alice v. CLS Bank):
1. Determine whether claims are directed to a law of nature, natural phenomena, or abstract idea
2. Determine whether there is anything more - transforming the claim into patent eligible subject matter
   - “search for an inventive concept” in the claim elements
   - Is this “significantly more” than the abstract idea alone?
Patent Eligibility – Federal Circuit


- Patent eligibility is an “incoherent body of doctrine” that makes it “near impossible to know with any certainty whether the invention is or is not patent eligible.” *Interval Licensing LLC v. AOL, Inc.*, 896 F.3d 1335, 1348 (Fed. Cir. 2018) (Plager, J. concurring).

- “We now are interpreting what began, when it rarely arose, as a simple § 101 analysis, as a complicated multiple-step consideration of inventiveness (“something more”), with the result that an increasing amount of inventive research is no longer subject to patent.” *Aatrix/Berkheimer*, Lourie and Newman concurring

- “[O]ur § 101 jurisprudence has largely ignored Congress' explicit instruction that a discovery can be the basis for a patentable invention.” *Athena*, Moore, O'Malley, Wallach, Stoll dissenting

- Patent eligibility has become “predominately a question of fact.” *Aatrix/Berkheimer*, Reyna dissenting.
Section 101: 2019 in Review!

- **January** New PTO Guidelines
- **January** Knowles and Prosser “Unconstitutional Application of 35 USC 101 by U.S. Supreme Court” 18 J. Marshall Rev. IPL 144
- **February** CAFC rejects appeal in Athena Diagnostics v. Mayo
- **April** CAFC: Cleveland Clinic v. True Health Diagnostics (comments on PTO Guidelines)
- **May** Senate Judiciary IP Subcommittee releases draft 101 text
- **June** Senate Judiciary IP Subcommittee Hearings
- **July** CAFC Denies en banc review Athena Diagnostics (86-page decision)
  - Dissent: Moore, Newman, O’Malley, Stoll and Wallach
- **Oct-** PTO issues revised Guidelines
- **Dec** U.S. Solicitor General recommends:
  - Against accepting certiorari in Hikma v. Vanda
  - For accepting certiorari in Athena Diagnostics v. Mayo
- **Jan 13, 2020**: SCOTUS denies certiorari in Athena v. Mayo
Patent Eligibility: What’s Left In Life Sciences (Currently)?

A Lot!

- Non-naturally occurring pharmaceutical and biotech compounds
- Pharmaceutical compositions
- Methods to treat disease (*Vanda*)
- Engineered or manipulated cells and vaccines, antibodies
- Clinical pharmacokinetics

Danger Zone:
- Diagnostics
- Personalized Medicines
- Isolated Naturally Occurring Compounds, Genes and gene fragments
35 U.S.C. §102

• Supreme Court test for on-sale bar:

  1) the product must be the subject of a commercial offer for sale; and

  2) the invention must be ready for patenting: either proof of reduction to practice before the critical date or proof that prior to the critical date the inventor prepared drawings or other descriptions of the invention that were sufficiently specific to enable a person skilled in the art to practice the invention.

• No requirement that one step occur before the other.
“Commercial Offer For Sale”

• “on sale” = sale or offer for sale of the claimed invention, or an obvious variant thereof, by the inventor or by a third party in the United States.

• § 102(b) is only triggered by a commercial offer for sale in the United States of the claimed invention more than a year before patent filing.

• “offer for sale” = an offer in the contract law sense.
  ▪ Group One, Ltd. v. Hallmark Cards, Inc., 254 F.3d 1041 (Fed. Cir. 2001)
    – “[N]ormally the on-sale bar does not accrue based on customer contacts made while the product is still being developed or tested.”
    – Such a communication is informational only. The subject matter of the invention was not yet ready or available.
‘Ready For Patenting’

- Fully operational prototype

- Complete conception

- Could satisfy § 112
  - *Space Systems/Loral, Inc. v. Lockheed Martin Corp.*, 271 F.3d 1076 (Fed. Cir. 2001)

- Sufficient grasp of the invention
On-sale Bar of Pre-AIA 35 U.S.C. §102(b)

- The Medicines Co. v. Hospira Inc., 805 F.3d 1357 (Fed. Cir. 2015), reh’g en banc, 827 F.3d 1363 (Fed. Cir. 2016)

- Opinion of July 2, 2015: claims invalid because on-sale bar triggered when TMC hired supplier to prepare three batches of bivalirudin using the eventually patented method more than a year before filing patent applications.

- Vacated, appeal reinstated.

  - (a) Do the circumstances presented here constitute a commercial sale under the on-sale bar of 35 U.S.C. §102(b)?
    - (i) Was there a sale for the purposes of §102(b) despite the absence of a transfer of title?
    - (ii) Was the sale commercial in nature for the purposes of §102(b) or an experimental use?

  - (b) Should this court overrule or revise the principle in Special Devices, Inc. v. OEA, Inc., 270 F.3d 1353 (Fed. Cir. 2001), that there is no “supplier exception” to the on-sale bar of 35 U.S.C. § 102(b)?
On-sale Bar of Pre-ALA 35 U.S.C. §102(b)

- On rehearing, en banc
  - FC: Unanimously overturned earlier panel decision finding an on-sale bar.

  - “We conclude that, to be ‘on sale’ under § 102(b), a product must be the subject of a commercial sale or offer for sale, and that a commercial sale is one that bears the general hallmarks of a sale pursuant to Section 2-106 of the Uniform Commercial Code. We conclude, moreover, that no such invalidating commercial sale occurred in this case. We, therefore, affirm the district court’s judgment that the transactions at issue did not render the asserted claims ...invalid under § 102(b).”

  - Distinguished Hamilton Beach
On-sale Bar of Pre-AIA 35 U.S.C. §102(b)

- On rehearing, en banc (con’t)
  - FC:
    - No “commercial sale” of patented product under *Pfaff*.
      - “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).”
        - “mere preparations for commercial sales are not themselves ‘commercial sales’ or ‘commercial offers for sale’ under the on-sale bar.”
      - “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.’”
        - “the inventor maintained control of the invention.”
On-sale Bar of Pre-AIA 35 U.S.C. §102(b)

• On rehearing, TMC (con’t)

• FC: Still no “supplier exception.”

  “We still do not recognize a blanket ‘supplier exception’ to what would otherwise constitute a commercial sale as we have characterized it today. While the fact that a transaction is between a supplier and inventor is an important indicator that the transaction is not a commercial sale, understood as such in the commercial marketplace, it is not alone determinative. ...The focus must be on the commercial character of the transaction, not solely on the identity of the participants.”
On-sale Bar of Pre-AIA 35 U.S.C. §102(b)

• On remand
  ▪ DC: no infringement and distribution agreement was not an invalidating “offer for sale.”
    — Distribution agreement was only agreement to be distributor, not an offer to sell the product.

  ▪ FC: Affirm no infringement and remand for determination of on-sale bar.
    — Distribution agreement was agreement to sell and purchase the product.
    — Title changed upon receipt at the distribution center.
    — All the necessary terms and conditions to constitute a commercial offer for sale.
    — No “supplier exception.”
    — Remand to determine if Distribution agreement covered patented product.
“On Sale”

• **Helsinn v. Teva**

  • **Background:**
    - 1995: Phase II Study 2330 Report
    - 1998: Helsinn licenses development program from Syntex/Roche
    - 11/99: Proposed Phase III Protocol
    - 6/6/01: Supply and Purchase Agreement
      - The existence of the sale was public because of SEC (redacted) documents, but the technical details of the invention were not publicly available.
    - 1/30/03: Provisional patent application filed for four asserted patents (1/30/02: Critical Date)
    - 7/03: FDA approves .25 mg dose

  • Teva argued: the AIA on-sale bar applies to Helsinn’s supply and purchase agreement.

  • Helsinn argued: the AIA on-sale bar “does not encompass secret sales and requires that a sale make the claimed invention [the details of the invention] available to the public in order to trigger application of the on-sale bar.”
On Sale (con’t)

  - “the post-AIA on-sale bar also requires that the sale or offer for sale make the claimed invention available to the public. See 35 U.S.C. 102(a)(1).... It is not sufficient that a sale or offer for sale merely occur.”
  - “the Oread and SP Agreements were not ‘public’ sales under the post-AIA standard, because they were entirely subject to and performed under confidentiality restrictions.”
  - “Teva has failed to show how MGI's Form 8-K or Helsinn's press releases on the MGI Agreement made Helsinn's claimed invention, i.e., its palonosetron formulation, available to the public.”

- **Helsinn v. Teva**, 855 F.3d 1356 (Fed. Cir. 2017)(DYK, Mayer, O’Malley)
  - Reversed. On-sale bar applied to invalidate claims.
  - Petition for rehearing en banc denied per curiam Jan. 16, 2018.
“On Sale (con’t)"

- FC:
  - “an invention is made available to the public when there is a commercial offer or contract to sell a product embodying the invention and that sale [fact of sale] is made public. Our cases explicitly rejected a requirement that the details of the invention be disclosed in the terms of sale.”
  - “There are no [Congressional Record] floor statements suggesting that the sale or offer documents must themselves publicly disclose the details of the claimed invention before the critical date. If Congress intended to work such a sweeping change to our on-sale bar jurisprudence and “wished to repeal ... [these prior] cases legislatively, it would do so by clear language.”
  - “We conclude that, 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 sale. ...We do not find that distribution agreements will always be invalidating under § 102(b). We simply find that this particular Supply and Purchase Agreement is.”
On Sale (con’t)

• Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc., 139 S.Ct. 628 (U.S., 2019)

  ▪ Affirmed the Federal Circuit.

  ▪ If fact of sale is public, may be sufficient for on-sale bar, even if details of invention remain confidential.

  ▪ “The new § 102 retained the exact language used in its predecessor statute (‘on sale’) and, as relevant here, added only a new catchall clause (‘or otherwise available to the public’). As amicus United States noted at oral argument, if ‘on sale’ had a settled meaning before the AIA was adopted, then adding the phrase “or otherwise available to the public” to the statute ‘would be a fairly oblique way of attempting to overturn’ that ‘settled body of law.’ Tr. of Oral Arg. 28. The addition of ‘or otherwise available to the public’ is simply not enough of a change for us to conclude that Congress intended to alter the meaning of the reenacted term ‘on sale.’”
Post-FC Helsinn On-Sale PTAB Decision

  - Critical date: Nov. 1, 2015.
  - Petitioner: entered distribution agreement Sept. 8, 2014.
    - Delivery of at least 305 units; no secrecy obligation.
  - Patent Owner: manufacture of products was under confidential obligation.
  - PTAB: On sale under §102(a)(1).
    - No definition of “confidential information” in distribution agreement.
    - Evidence of sales prior to Nov. 1, 2015.
    - Cites Helsinn.
Post-Helsinn On-Sale PTAB Decision

• *Triple Plus* (con’t)
  
  ▪ Critical date: Nov. 1, 2015.
  
  ▪ Petitioner: Patent Owner actively marketing in summer 2014.
    – Email and letters from Aug. 2014 discussing claimed subject matter “establishes an offer for the purchase of, as well as the disclosure of, the Triple+ NWL in August 2014. . . . The products are specified (either the 1/2 inch or 3/4 inch versions), a price quoted (e.g., 890 NIS + VAT for the 3/4 inch), and a method provided for acceptance (calling the telephone number to order).”
  
    – Emails and letters are pre-marketing activity directed to insurance company that in the future would give to agents who would then give to clients.
  
  ▪ PTAB: No “on-sale.”
    – No evidence that alleged offer communicated to intended recipients.
    – No need to reach second prong “ready for patenting.”
Subject Matter of Offer for Sale Must Satisfy Claim Limitations

- *Plumtree Software, Inc. v. Datamize, LLC*, 473 F.3d 1152 (Fed. Cir. 2006)
  - Winter 1994 reduction to practice.
  - January 17, 1995: MA offered to provide its interactive electronic kiosk system during the March 1995 trade show.
    - MA received consideration because “MA was granted a ‘prime location’ and its fee was waived in exchange for the display of MA’s kiosk.”
    - “the agreement with SIA embodied all of the claims of the '040 and '418 patents” because ‘the kiosk at the trade show embodied all of the claims.’”
  - February 27, 1995, critical date.
  - March 3-7, 1995, trade show.
    - Demonstrated system that embodied the claims.
  - DC: granted summary judgment of invalidity for on-sale bar.
Subject Matter of Offer for Sale Must Satisfy Claim Limitations

- Plumtree (con’t)

  ▪ FC: Vacated and remanded.
    - MA received consideration, but invention is method for creating kiosk system, not system itself, so the commercial offer was not for the patented invention.”
    - “the invention that is the subject matter of the offer for sale must satisfy each claim limitation of the patent.”
    - Plumtree did not meet first prong of Pfaff.
    - Plumtree did not show that MA actually performed all of the patented steps before the critical date pursuant to the contract.
      ▪ “Although Kevin Burns began creating SkiPath before the January 17 meeting, the programming and testing of the SkiPath product was not completed until the end of the first day of the trade show. Thus, the record is not clear whether the patented process was used before the critical date.”
Determining Whether Sale Product Meets Claim Limitation(s) Requires Claim Construction First

- *Quest Integrity USA, LLC v. Cokebusters USA Inc.*, 924 F.3d 1220 (Fed. Cir. 2019)
  - June 1, 2004: application filing date.
  - February and March 2003: sale of services using the claimed methods, computer-readable medium, and system; inspection reports generated, services were paid for.
  - Issue: Did the sale satisfy each limitation of the claims?
  - Turns on claim construction.
  - Parties agreed sale inspection reports fit within Ex. 1 of specification.
  - Example 1 within scope of claims as originally drafted.
  - Quest argued claims amended to exclude Ex. 1.
  - DC: No. Ex. 1 within scope of claims as issued.
Determining Whether Sale Product Meets Claim Limitation(s) Requires Claim Construction First

- **Quest (con’t)**
  - DC: Granted summary judgment of invalidity under the on-sale bar.
  - FC: Affirmed with respect to 3 claims, remand for 2 claims where fact issue remained as to whether software used in sale met claim limitations.
    - Record contained expert testimony that extra limitations “commented out” of sale.
**Showing Product on Sale Contained Claim Limitations**


  - Effective filing date July 1, 2016.
  - Petitioner: Pfaff factors satisfied.
    - System for sale at least as early as March 10, 2015; and system was ready for patenting before July 1, 2016.
  - Patent Owner: response did not include claimed adjustment mechanism.
Showing Product on Sale Contained Claim Limitations

• Ely (con’t)

  ▪ PTAB: Instituted.

  — “the question is not whether the “Bid Package ...” ... illustrates the claimed adjustment mechanism, but whether it in fact includes the claimed adjustment mechanism, whether or not that mechanism is expressly shown in the cross-sectional diagram. In our view, as set forth above, on this record, we are persuaded that Petitioner has sufficiently demonstrated that the [Bid Package] includes the adjustment mechanism as claimed.”

  — “the fact that the description is later in time is not dispositive of our determination that Petitioner sufficiently demonstrates that the [Bid Package] includes the claimed adjustment mechanism. An item for sale includes the features it includes for the entire time period of its existence, and not only at the points in time where it is described in a publication.”
Offer to Sell = Bar if All That’s Necessary to Complete Contract is Acceptance

  - Jan. 31, 2017, effective filing date.
  - Petitioner: Nov. 17, 2015 Xiamen Raffel communicated an offer to sell to Man Wah with photo attached.
    - Offer included product description, price, and taxes and note to find more on publicly accessible website, www.raffel.com.
  - Patent Owner: no substantive argument in POPR.
  - PTAB: Instituted.
    - Email “was an offer by Patent Owner to sell the product embodying this design to Petitioner.”
    - Petitioner could have replied to email and received product.
    - Because the email predates the effective filing date by more than a year, the on-sale bar applies.
Sufficient Evidence to Show On-Sale Bar

  
  
  - Petitioner: commercial embodiment sold and in public use based on evidence from investor presentation on March 12, 2012.
  
  - Patent Owner: did not substantively address in POPR though did contest admissibility of Petitioner’s evidence and did assert entitled to earlier filing date of April 18, 2011.
Sufficient Evidence to Show On-Sale Bar

- **C&D Zodiac, Inc. v. B/E Aerospace, Inc., PGR2017-00019**
  
  - **PTAB:** Instituted (not entitled to earlier filing date).
    
    - Sufficient evidence of commercial offer for sale and a sale of claimed design prior to effective filing date.
      
      
      - Images supported “ready for patenting” and within scope of patent claims.

    - Cites *Atlanta Attachment Co. v. Leggett & Platt, Inc.*, 516 F.3d 1361, 1365 (Fed. Cir. 2008) (“[A]n attempt to sell is sufficient if it rises to an offer upon which a contract can be made merely by accepting it.”).

  - **PTAB FWD:** claims unpatentable.
Insufficient Showing to Establish Offer Was Prior Art


  - Petitioner: prior art on sale at least by June 9, 2013.
    - Bare assertion plus expert testimony:
      - “According to www.archive.org, the Air Force Inflator was offered for sale on the Internet at www.conwinonline.com/shop/air-force-4 (“Air Force Inflator Website”) least as early as June 9, 2013. (Id.) Attached as Exhibit 1012 to the petition for post-grant review of the ’749 patent is a true and correct copy of the “Air Force Inflator Website” from June 9, 2013 that I obtained from www.archive.org. My opinions in this declaration are based on the images of the Air Force Inflator that were publicly available on June 9, 2013.”
Insufficient Showing to Establish Offer Was Prior Art

• Telebrands (con’t)

  ▪ PTAB: Insufficient.

    – “No testimony, evidence, or explanation is offered, however, as to what www.archive.org is and why it would establish the date that this web page was available, let alone when this alleged device was on sale. Moreover, Dr. Kamrin does not testify that he has any personal knowledge of the website where the device was allegedly offered, the device, or its sales or offers for sale in June 2013. Thus, given the lack of explanation and lack of personal knowledge, we find this testimony entitled to little weight as to the date that this device was for sale or offered for sale. ... Thus, we determine that Petitioner has failed to show sufficiently that that the Air Force 4 Inflator is prior art.”

  ▪ FWD: Claims not shown unpatentable.
Public Use
Test for Public Use

Did the purported use make the claimed subject matter accessible to the public or was the claimed subject matter commercially exploited?

Experimental Use

There are a number of factors in determining whether a claimed invention was the subject of a commercial offer for sale primarily for purposes of experimentation. "These factors include: (1) the necessity for public testing, (2) the amount of control over the experiment retained by the inventor, (3) the nature of the invention, (4) the length of the test period, (5) whether payment was made, (6) whether there was a secrecy obligation, (7) whether records of the experiment were kept, (8) who conducted the experiment,... (9) the degree of commercial exploitation during testing[,]... (10) whether the invention reasonably requires evaluation under actual conditions of use, (11) whether testing was systematically performed, (12) whether the inventor continually monitored the invention during testing, and (13) the nature of contacts made with potential customers."

_A llen Eng’g Corp. v. Bartell Indus., Inc., 299 F.3d 1336, 1353, 63 USPQ2d 1769, 1780 (Fed. Cir. 2002) (quoting EZ Dock v. Schafer Sys., Inc., 276 F.3d 1347, 1357, 61 USPQ2d 1289, 1296 (Fed. Cir. 2002)) (Linn, J., concurring)._
“Ready For Patenting”

• Barry v. Medtronic, 914 F.3d 1310 (Fed. Cir. 2019)

  ▪ Barry’s patents contained method and system claims.

    – Charged for those surgeries without mentioning to the patients that the device and methods were experimental.

  ▪ Barry filed a U.S. patent application on December 30, 2004, so critical date for 35 U.S.C. §102(b) was December 30, 2003.

  ▪ Issue: Was Dr. Barry's invention in public use or on sale before December 30, 2003? If so, were the public use and sale bars negated by experimental use?
‘Ready For Patenting’

• Barry v. Medtronic (con’t)
  - DC: No public use or sale.
  - FC: Affirmed (2-1).
    - the invention was not ready for patenting prior to the critical date, eliminating both the public use and on sale bars, and up to the critical date, there was only experimental use.
    - “the timing of knowledge that the invention will ‘work for its intended purpose’ is important to both experimental use and readiness for patenting,”
    - “’intended purpose’ need not be stated in claim limitations that define the claim scope.”
    - Majority: substantial evidence supported the conclusion that Barry did not know his invention would work for its intended purpose until January 2004, after completion and follow up of the August and October 2003 surgeries.

Public Use and “Otherwise Available to the Public”

  
  • Critical date: Nov. 1, 2015.
  
  • Petitioner: Aug. 2014 commercial installations for “pilot group of customers” were public use and “otherwise available to the public.”
  
  • Patent Owner: installations were for testing.
    – Details of invention not disclosed, constant supervision.
  
  • PTAB: Public use under § 102(a)(1).
    – *Allen* factors “relatively balanced.”
    – No need to address “otherwise available to the public”
  
• Query: same result after *Barry v. Medtronic*?
Public Use and “Otherwise Available to the Public”

• **Triple Plus (con’t)**
  - Critical date: Nov. 1, 2015.
    - Describe use of the claimed subject matter, shown working for intended purpose, no confidentiality restrictions.
  - Patent Owner: videos are demonstration that does not provide access to details of the invention.
  - PTAB: No public use.
    - Videos clearly show claimed subject matter in use but do not reveal the elements corresponding to the claimed limitations or provide access to the claimed subject matter or provide information to learn details of claimed subject matter.
    - “Similar to *Egbert v. Lippman*, the alleged public use did not reveal the patented features of the device to the public eye. See 104 U.S. 333, 336 (1881)[.]”
    - *Consistent with Helsinn?*
Public Use


  - Effective filing date April 1, 2016.
  - **Petitioner: AvePoint** prior public use rendered claims obvious.
    - May 2014: Press releases, Google analytic report show more than 1200 people downloaded software product.
    - March 2014 live demonstrations at conference.
    - User guide and screen shots show each of claim elements.
    - Declaration of presenter at March 2014 conference.
    - Claim chart mapping each element to user guide and screen shots all dated before Feb. 2015.
  - **OneTrust:** no proof software system actually used to perform each method step.
  - **PTAB:** Instituted and FWD all claims unpatentable (though on s. 101 grounds; s. 103 grounds not reached).
**Commercial Exploitation = Public Use**


  - **Petitioner**: subject matter of claims in public use prior to March 26, 2014, filing date.
    - Supported by claim chart and expert testimony.

  - **Patent Owner**: did not address directly but argued claims entitled to earlier filing date.

  - **PTAB**: Instituted.
    - “we credit the testimony of Dr. Brown as to prior public use of HFO-1234yf and polyalkylene glycol in an automobile air conditioning system, as Dr. Brown’s testimony is consistent with references of record.”
Commercial Exploitation = Public Use

• Arkema (con’t)

  ▪ FWD: Claims unpatentable as anticipated under §102(a)(1).
    - Patent was PGR_eligible.
    - Subject matter of the claims was in commercial use prior to
      the March 26, 2014, filing date.

    ▪ “Commercial exploitation is a clear indication of public use . . .”
      Invitrogen Corp. v. Biocrest Mfg., L.P., 424 F.3d 1374, 1380 (Fed.
      Cir. 2005).”
Expectation of Confidentiality

  - DC: “summary judgment on a public-use inquiry is inappropriate when the circumstances show a reasonable expectation of confidentiality”
  - DC: Motion for summary judgment denied.
    - Invention ready for patenting prior to critical date but no clear evidence of commercial exploitation prior to critical date.
Potential Consequences of Failure to Disclose Prior Sale(s)
Failure To Disclose Info That Would Implicate On-Sale Bar

  - Critical date Sept. 18, 2008.
  - Before critical date, performed claimed method on at least 61 jobs; were paid.
  - No jobs were disclosed to USPTO even though knew about the on-sale bar.
  - DC: Summary judgment patent unenforceable for inequitable conduct (material information withheld with intent to deceive the PTO).
  - FC: Affirmed.
Supplemental Examination To Insulate Against Inequitable Conduct

- “Information” relating to on-sale bar and/or public use may be submitted in a supplemental examination petition. (35 U.S.C. 257; not limited to patents and printed publications)

- Examples
  - 96/000,037: trade show flyer and item and declarations for date of public use, no SNQ found original claims remain.
  - 96/000,017 and 96/000,018: declaration of a worker re: potential public offer for sale, SNQ found, reexam certificate issued (claims canceled).
  - check 96/000,047: scientific presentation
  - 96/000,079, 96/000,080, 96/000,081: US patents, publications, description of on sale/public use, SNQ found, reexam certificate issued (claims canceled, amended claims).
Effect: Insulate Patent

35 U.S.C. 257  Supplemental examinations to consider, reconsider, or correct information.

• c) EFFECT.—
  • (1) IN GENERAL.—A patent shall not be held unenforceable on the basis of conduct relating to information that had not been considered, was inadequately considered, or was incorrect in a prior examination of the patent if the information was considered, reconsidered, or corrected during a supplemental examination of the patent. The making of a request under subsection (a), or the absence thereof, shall not be relevant to enforceability of the patent under section 282.

“during” the SE
What “Items of Information” Were Submitted?

- **US patents/applications, OA’s**: 201 (37%)
- **Foreign patents/applications, OA’s**: 208 (35%)
- **Publications**: 54 (10%)
- **Declarations**: 26 (5%)
- **Webpages**: 13 (2%)
- **Poster/video/photo/presentation/brochures/manuals/…**: 13 (2%)
- **Case law/statute/rules**: 8 (1%)
- **District court and PTAB litigation documents**: 10 (2%)

2/3 of items of information submitted are patents/patent applications.

Best Practices

- Rule 56 duty applies! Intentional misrepresentation or omission of information relating to sales, offers for sale, or public use may trigger inequitable conduct analysis.
  - Supplemental exam is option for information relating to sales, offers for sale, and public use.

- Coordinate with other departments within company (e.g., sales, finance, research, regulatory) to try and prevent on-sale and public use issues from arising.

- Use your POPR! Don’t let Petitioner allegations go unrebuted.
  - Push back on prior art status of alleged sale or public use.

- “Experimental use” is a negation, not an exception.
35 U.S.C. 103
OSI Pharms., LLC v. Apotex Inc.,
939 F.3d 1375 (Fed. Cir. 2019)

- IPR2016-01284: PTAB held claims 44-46, 53 of OSI’s USPN 6,900,221 to be obvious.
  - Methods of treating certain diseases (e.g., NSCLC) with a therapeutically effective amount of erlotinib
  - Asserted PA: erlotinib inhibits EGFR, EGFRi’s may treat cancers, NSCLC to be studied

- Reversed: PTAB finding of reasonable expectation of success not supported by substantial evidence.
  - “Cancer treatment is highly unpredictable”
    - EGFR is a target in some cancers, but EGFR inhibition is a poor proxy for anticancer effectiveness
    - Most therapies with promising in vitro activity still fail because of poor pharmacokinetics, undesirable drug interactions, and/or off-target toxicity
    - Of 1,631 new drugs for treating NSCLC in Phase II over 15 years, only 7 drugs (including erlotinib) received FDA approval (over a 99.5% failure rate)

  - The “references provide no more than hope—and hope that a potentially promising drug will treat a particular cancer is not enough to create a reasonable expectation of success in a highly unpredictable art such as this. ...It is only with the benefit of hindsight that a person of skill in the art would have had a reasonable expectation of success in view of the asserted references.”

Remember to mind the balance between arguments for nonobviousness and enablement.
• DC: claims of Persion’s USPNs 9,265,760 and 9,339,499 infringed but obvious.
  - Extended-release hydrocodone bitartrate formulations for treating patients with hepatic impairment (at greater risk for opioid overdose)
  - Claims cover Zohydro ER, for which the FDA required a clinical study described in patent Ex. 8
  - Claims also cover identical PA formulation used to treat pain at the same dose
  - POSITA would have been motivated, with reasonable expectation of success, to administer an unadjusted dose of the PA formulation to hepatically impaired patients
  - The “pharmacokinetic limitations...would have been ‘inherent in any obviousness combination that contains the [PA] formulation’ because the recited pharmacokinetic parameters were ‘necessarily present’ in the Zohydro ER formulation described in both [the PA] and the asserted patents.”

• Affirmed: Inherency properly applied and supplied “‘a missing claim limitation in an obviousness analysis’ where the limitation at issue is ‘the natural result of the combination of prior art elements.’”
**Blocking Patent Issues**

- A broad patent that may affect your freedom to operate – deal or no deal?

- Risk assessment: (1) evaluate strength of patent; and (2) broad claims vulnerable to validity attack under § 112

- Strategic considerations:
  - Obtain a license
  - Establish design-around/non-infringement positions
  - Obtain a non-infringement opinion - very useful for avoiding induced infringement of methods of treatment claims
  - File IPR, PGR, DJ action, opposition, etc.
  - Ask partner to pay or share license fees and royalties and litigation costs
35 U.S.C. §112
35 U.S.C. §112

- The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same ...

- Written Description - the patentee invented what is claimed

- Enablement
  - A person of skill in the art, upon reading the disclosure, be able to practice the full scope of the claim without undue experimentation.
  - “Undue Experimentation” test - Wands factors: (1) the quantity of experimentation necessary; (2) the amount of direction or guidance presented, (3) the presence of absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability of unpredictability of the art, and (8) the breadth of the claim. In re Wands, 858 F.2d 737.
**Not Your Grandma’s WD**

  
  - Idenix alleged Gilead’s HCV treatment sofosbuvir would infringe U.S. 7,508,597.
    - Claim 1. A method for the treatment of a hepatitis C virus infection, comprising administering an effective amount of a purine or pyrimidine β-D-2'-methylribofuranosyl nucleoside or a phosphate thereof, or a pharmaceutically acceptable salt or ester thereof.
  
  - Claim construction: require “a methyl group in the 2’ up position and non-hydrogen substituents at the 2’ down and 3’ down positions” and preamble limiting so requires efficacy in treating HCV.
  
  - Jury: valid and awarded damages.
  
  - DC: JMOL patent invalid for failure to meet enablement requirement.
  
  - FC: Affirmed and added invalid for failure to meet WD requirement also.
• **Idenix (con’t)**

  • **Issue:** Would a POSITA know, without undue experimentation, which 2'-methyl-up nucleosides would be effective for treating HCV?

  • **FC majority:** No. “[T] thousands of 2'-methyl-up nucleosides meet the structural limitations of claim 1, not all of which are effective to treat HCV.”

    — Detailed analysis of Wands factors:
      — **Quantity of experimentation to screen thousands of 2'-methyl-up nucleosides for HCV efficacy weighs in favor of non-enablement.**
      — **Nucleotide synthesis routine weighs against non-enablement.**
      — **Lack of meaningful guidance as to which 2'-methyl-up nucleosides effective weigh in favor of non-enablement.**
      — **Working examples narrow relative to claim scope weigh in favor of non-enablement.**
      — **Unpredictable art weigh in favor of non-enablement.**
      — **Breadth of claim weighs in favor of non-enablement.**
Idenix (con’t)

Issue: Does the ’597 patent demonstrate that the inventor was in possession of those 2'-methyl-up nucleosides that fall within the boundaries of the claim (i.e., are effective against HCV), but are not encompassed by the explicit formulas or examples provided in the specification?

– Does the specification demonstrate possession of the 2'-methyl-up 2'-fluoro-down nucleosides that are the basis for Gilead’s accused product?

FC majority: No.

– The patent does not disclose a 2'-methyl-up 2'-fluoro-down nucleoside.
– Idenix’s “patent fails to provide sufficient blaze marks to direct a POSA to the specific subset of 2'-methyl-up nucleosides that are effective in treating HCV. The patent provides eighteen position-by-position formulas describing ‘principal embodiments’ of compounds that may treat HCV. [But] the specification provides no indication that any nucleosides outside of those disclosed in its formulas could be effective to treat HCV—much less any indication as to which of those undisclosed nucleosides would be effective. ...The specification, however, provides no method of distinguishing effective from ineffective compounds for the compounds reaching beyond the formulas disclosed in the ’597 patent.”
– The lists of effective nucleosides do not explain “what makes them effective, or why.”
**Not Your Grandma’s WD**


  - Amgen markets Repatha, a PCSK9 inhibitor useful for lowering cholesterol. Sanofi/Regeneron sells a rival drug, Praluent.

  - Amgen sued Sanofi for infringing US 8,829,165 and 8,859,741, directed to monoclonal antibodies that bind to PCSK9 and blocks PCSK9 from binding to low-density lipoprotein-receptors.
    
    1. An isolated monoclonal antibody, wherein, when bound to PCSK9, the monoclonal antibody binds to at least one of the following residues: S153, I154, P155, R194, D238, A239, I369, S372, D374, C375, T377, C378, F379, V380, or S381 of SEQ ID NO:3, and wherein the monoclonal antibody blocks binding of PCS9 to LDLR.
    
    19. The isolated monoclonal antibody of claim 1 wherein the isolated monoclonal antibody binds to at least two of the following residues S153, I154, P155, R194, D238, A239, I369, S372, D374, C375, T377, C378, F379, V380, or S381 of PCS9 listed in SEQ ID NO:3.

    29. A pharmaceutical composition comprising an isolated monoclonal antibody, wherein the isolated monoclonal antibody binds to at least two of the following residues S153, I154, P155, R194, D238, A239, I369, S372, D374, C375, T377, C378, F379, V380, or S381 of PCS9 listed in SEQ ID NO:3 and blocks the binding of PCS9 to LDLR by at least 80%.

  - Jury: patents valid and granted a permanent injunction.

  - FC: remanded for a new trial on validity and vacated the permanent injunction.

  - On remand, jury found claims valid for WD and enablement requirements; Sanofi moved for JMOL.
Not Your Grandma’s WD

• **Amgen** (con’t)

  • DC (Judge Andrews): 1) denied motion for JMOL on the issue of WD; 2) granted motion for JMOL on issue of enablement.

  • Undue experimentation would be needed to practice the full scope of the claimed invention
    – Factors: the scope of the claims is broad; the (antibody) art is unpredictable; not enough direction or guidance on how to discover non-disclosed Abs within the scope of the claims; a substantial amount of time and effort would be required to enable the full scope of the claims.

  • Tests for WD: 1) a representative number of species - patents disclosed eight different families of binding and blocking antibodies, there are 80% of similarity between the disclosed Abs and Competitor Abs’ amino acid sequence, and there is functional similarity; 2) common structural features

  • Amgen filed an appeal Oct. 2019 (Fed. Cir. 20-1074).
**Not Your Grandma’s WD**

- *UroPep v. Lilly, 793 F. App’x 643 (Fed. Cir. 2018)*
  - UroPep owns 2 patents directed to the use of PDE selective inhibitors to treat prostatic diseases, in particular, benign prostatic hyperplasia (BPH); the spec. describes both a sufficient number of representative species within the scope of that genus and structural features common to the members of the genus.

- Claim 1. A method for prophylaxis or treatment of benign prostatic hyperplasia comprising administering to a person in need thereof an effective amount of an inhibitor of phosphodiesterase (PDE) V excluding a compound selected from the group consisting of dipyridamole, … … and pharmacologically compatible salts thereof.

- Many known PDE5 inhibitors at time of filing: e.g., sildenafil (Viagra) and tadalafil (Cialis) for erectile dysfunction

- Lilly furthered obtained FDA approval for treating BPH indication with Cialis

- Point of contention - whether the disclosure supports the claim term “an inhibitor of phosphodiesterase (PDE) V,” construed as “a selective inhibitor of PDE5, which is at least 20 times more effective in inhibiting PDE5 as compared to PDE1 through PDE4.”
Not Your Grandma’s WD

• **UroPep (cont’d)**
  
  • UroPep sued Lilly for infringement in E. DC. Tx, 276 F. Supp. 3d 629 (2017)
  
  • Jury found patent claims valid and infringed; Lilly moved for JMOL (lack of WD and enablement); JMOL denied; Fed. Cir. affirmed; Supreme Court denied *Cert* on Oct. 21, 2019
  
  • Holding: Judge Bryson denied JMOL and held that patent claims are adequately described and enabled.
  
  • WD: representative number of selective PDE5 inhibitors – spec. discloses a number of preferred selective inhibitors including 10 discrete compounds and two classes of compounds and identifies them by chemical name and/or structural drawings. These compounds are known selective PDE5 inhibitors.
  
  • Enablement: the field was mature; routine screening of potential selective compounds; common method and standard industry practice to determine compound potency.
  
  • Key takeaway: (1) no “bright-line rule governing the number of species that must be disclosed to describe a genus claim;” (2) when a genus is well understood in the art and not itself the invention (here, hundreds of selective PDE inhibitors are known), background knowledge may provide necessary support.
Not Your Grandma’s WD

- **Nuvo v. Dr. Reddy’s**, 923 F.3d 1368 (Fed. Cir. 2019)
  - Nuvo licensed patents directed to a combination therapy (NSAID and proton pump inhibitors (PPIs); NSAID to control pain and PPIs reduces the acidity in the GI tract to treat side effects associated with NSAIDs such as ulcers, erosions, etc.
  - Dr. Reddy’s submitted an ANDA; Nuvo sued Dr. Reddy’s for infringement
  - Claim 1 of the ‘907 patent recites “[a] pharmaceutical composition in unit dosage form suitable for oral administration to a patient, comprising: ... an acid inhibitor present in an amount effective to raise the gastric pH of said patient to at least 3.5 upon the administration of one or more said unit dosage forms; and wherein “at least a portion of said acid inhibitor is not surrounded by an enteric coating” (emphasis added)
  - Claim 1 of the ‘285 patent recites “[a] pharmaceutical composition in unit dosage form comprising therapeutically effective amounts of (a) esomeprazole, wherein at least a portion of said esomeprazole is not surrounded by an enteric coating” and “wherein said unit dosage form provides for release of said esomeprazole such that upon introduction of said unit dosage form into a medium, at least a portion of said esomeprazole is released regardless of the pH of the medium.”
  - DC: patents valid as nonobvious, enabled, and adequately described
  - FC: reversed
Not Your Grandma’s WD

• Nuvo (cont’d)
  • Issue: whether the claimed effectiveness of uncoated PPI is supported by adequate WD
  • Holding: patent claims are invalid for lack of adequate WD
  • Spec. provides mere claim that uncoated PPI might work; it does not demonstrate that the inventor actually invented what he claimed, i.e., an amount of uncoated PPI that is effective to raise the gastric pH to at least 3.5. Invention does not actually have to be reduced to practice, but, mere wish or hope does not establish possession of the claimed invention
  • WD requirement may be satisfied without an explicit disclosure if the claimed features are necessarily inherent in what is expressly described (doctrine of inherent disclosure), but not in this case, where whether uncoated PPI is inherently effective in raising the gastric pH to at least 3.5 is disputed.
Obviousness-Type Double Patenting
**OTDP – PTE**

- *Ezra v Novartis* - Obviousness-type double patenting does not invalidate a validly obtained Patent Term Extension.
**OTDP – GATT/URAA**

- *Novartis v Breckenridge* - OTDP not apply due to the change in law. Here, the order of expiration of the patents was by operation of statute and not due to patent prosecution gamesmanship as in *Gilead*.
Induced Infringement
Induced Infringement General Principles: The Role Of A Reasonable Belief As A Defense

Commil USA, LLC v. Cisco Systems, Inc.,
135 S.Ct. 1920 (U.S. May 26, 2015)

A reasonable belief of non-infringement is a defense to claims of inducement, but a good faith belief that a patent is invalid is not a defense to a charge of induced or contributory infringement.
Induced Infringement General Principles: Proving Inducement

Global-Tech Appl., Inc. v. SEB S.A.,
563 U.S. 754 (U.S. May 31, 2011)

- “Accordingly, we now hold that induced infringement under §271(b) requires knowledge that the induced acts constitute patent infringement.”
- Patentee must show accused infringer knew of the patent
- Patentee must show accused infringer intended its actions to cause direct infringement
Induced Infringement General Principles: Willful Blindness

Global-Tech Appl., Inc. v. SEB S.A.,
563 U.S. 754 (U.S. May 31, 2011)

- Willful blindness can substitute for actual knowledge: “Given the long history of willful blindness and its wide acceptance in the Federal Judiciary, we can see no reason why the doctrine should not apply in civil lawsuits for induced patent infringement....”

- Two basic requirements: (1) the defendant must subjectively believe that there is a high probability that a fact exists; and (2) the defendant must take deliberate actions to avoid learning of that fact.
Recent Application of Commil and Global-Tech

Omega Patents, LLC v. CalAmp Corp.,
920 F.3d 1337 (Fed. Cir. 2019)

- Jury found induced infringement
- Vacated and remanded:
  - As for whether CalAmp "knowingly induced infringement and possessed specific intent to encourage another's infringement," ..., the district court's erroneous exclusion of [testimony as to CalAmp's state of mind] substantially prejudiced CalAmp’s ability to present its defense for indirect infringement. ...This exclusion deprived CalAmp of the opportunity to support its defense that there was no inducement because it reasonably believed it did not infringe the patents at the time CalAmp launched the products at issue....Of course, CalAmp's state of mind as to the validity of the asserted patents at the time of infringement is irrelevant to the issue of inducement.”
  - “We have repeatedly recognized that advice of counsel is relevant to induced infringement and willfulness....‘The fact and general content of’ a noninfringement opinion from defendant's patent lawyer ‘was relevant and admissible . . . with respect to [defendant's] state of mind and its bearing on [induced] infringement.’”
General Principles: Intent In Hatch-Waxman Cases

• Knowledge of the patent.
  • Easily shown by the patents listed in the Orange Book and the generic manufacturer’s paragraph IV certification.

• Knowledge that accused infringer intended its actions to cause direct infringement.
  • May be established by the instructions and information in a drug label.
General Principles: Carve-outs In Hatch-Waxman Cases

- The “Skinny viii” Option

- An ANDA filer can omit, or “carve out,” a patented indication from its labeling to avoid having to file a paragraph IV certification on the patent(s) that cover that indication.

  - 21 U.S.C. § 355(j)(2)(A)(viii) allows ANDA applicant to submit, in lieu of a paragraph IV certification, a certification that an Orange Book listed patent does not claim an indication for which the ANDA applicant seeks FDA approval.

- Does the labeling still encourage, recommend, or promote the allegedly carved-out use?
Induced Infringement

- *Sanofi v. Watson*, 875 F.3d 636 (Fed. Cir. 2017)

- An example of why patent holders should pursue claim language that mirrors an FDA drug label, particularly regarding clinical trials, provide that clinical trial information in a patent application, set forth that clinical trial information in the label, and reference that clinical trial information in the Indications and Usage Section of the label.

- Multaq® is the brand name version of dronedarone, an antiarrhythmic agent directed towards the treatment of heart rhythm problems in patients with atrial fibrillation.

- However, dronedarone also has the risk of doubling mortality rates in patients who have severe heart failure (NYHA Class IV or Class III with a recent hospitalization for heart failure).
1998 - Sanofi files application that established priority date for the ’800 patent on dronedarone composition.
   ○ Sanofi does not receive FDA approval for Multaq until mid-2009 (leading to the ’167 patent in 2009).

Between 2001-2003, Sanofi conducts two large-scale clinical trials (EURIDIS and ADONIS) to test dronedarone effect on atrial fibrillation or flutter.
   ○ Studies show “potential major clinical benefit” of reduced hospitalization or death in patients with currently normal sinus rhythm but had earlier experienced an episode of atrial fibrillation or flutter.
   ○ Dronedarone further “reduced the incidence of a first recurrence as well as a symptomatic first recurrence within 12 months after randomization, and significantly reduced the ventricular rate during the recurrence of arrhythmia.”
History Of Multaq® Drug Development

- In 2002, Sanofi conducts another trial to investigate safety: ANDROMEDA - designed to test the effects of dronedarone on patients with symptomatic heart failure and severe heart failure symptoms.
  - Dronedarone actually **increased** mortality from heart failure.

- European Medicines Agency, upon review, stated that “the clinical relevance needs further consideration...in particular in the context of the negative effects seen in the ANDROMEDA [trials].”

- 2005-2008: Sanofi conducts the large-scale clinical trial, ATHENA, designed to address the potential for clinical benefits of dronedarone that earlier trials had indicated
  - ATHENA trial found positive results for dronedarone - led to the filing of the ‘167 patent, with four priority documents filed in 2008, two in France and two in the EPO, and also led to FDA approval of Multaq.
Sanofi v. Watson,
875 F.3d 636 (Fed. Cir. 2017)

- Initial ‘167 Application Claim 1 (Filed Apr. 16, 2009):

  1. A method of decreasing the risk of mortality, cardiac hospitalizations, or the combination thereof in a patient, said method comprising administering to said patient an effective amount of dronedarone or a pharmaceutically acceptable salt thereof, with food.

- No reference of clinical trials.
- No indication of any contraindicated symptoms.
- No definition of severe heart failure dangers.
- No description of patient cardiovascular risk factors.

- Such information appeared in issued claims of the ‘167 patent, as seen on the next page, and that information was found in the specification of the ‘167 patent, see, e.g., cols. 3-4, 6, and 14. It was undisputed that issued claims 1 and 8 were entitled to a priority date of February 11, 2009, the second filed French priority application.
Sanofi v. Watson (con’t)

- Final Version of Claim 1 in ’167 Patent: A method of decreasing a risk of cardiovascular hospitalization in a patient, said method comprising administering to said patient an effective amount of dronedarone or a pharmaceutically acceptable salt thereof, twice a day with a morning and an evening meal, wherein said patient does not have severe heart failure, (i) wherein severe heart failure is indicated by: a) NYHA Class IV heart failure or b) hospitalization for heart failure within the last month; and (ii) wherein said patient has a history of, or current, paroxysmal or persistent non-permanent atrial fibrillation or flutter; and (iii) wherein the patient has at least one cardiovascular risk factor selected from the group consisting of:
  1. an age greater than or equal to 75;
  2. hypertension;
  3. diabetes;
  4. a history of cerebral stroke or of systemic embolism;
  5. a left atrial diameter greater than or equal to 50mm; and
  6. a left ventricular ejection fraction less than 40%.
Sanofi v. Watson (con’t)

• As will be seen on the following slides, the original label brilliantly referenced in the Indications and Usages section of the label the Clinical Studies of Section 14 of the label that identifies the patients and that has been carried forward into the most recent label.

• Section 14 provided results from the 2005-2008 large scale, pivotal outcome ATHENA clinical study (referenced above), and also the EURIDIS, ADONIS, and ANDROMEDA clinical studies.

• And importantly, the Clinical Studies results, particularly the ATHENA results, were found in the February 9, 2011, French priority document and were carried into the U.S. filing resulting in the ‘167 patent.
**Sanofi v. Watson (con’t)**

Original Approved Label (07/01/2009):

**1 INDICATIONS AND USAGE**

MULTAQ® is indicated to reduce the risk of cardiovascular hospitalization in patients with paroxysmal or persistent atrial fibrillation (AF) or atrial flutter (AFL), with a recent episode of AF/AFL and associated cardiovascular risk factors (i.e., age >70, hypertension, diabetes, prior cerebrovascular accident, left atrial diameter ≥50 mm or left ventricular ejection fraction [LVEF] <40%), who are in sinus rhythm or who will be cardioverted [see Clinical Studies (14)].

Currently Approved Label (03/31/2014):

**1 INDICATIONS AND USAGE**

MULTAQ® is indicated to reduce the risk of hospitalization for atrial fibrillation in patients in sinus rhythm with a history of paroxysmal or persistent atrial fibrillation (AF) [see Clinical Studies (14)].
Sanofi v. Watson (con’t)

Section 14

14 CLINICAL STUDIES
14.1 ATHENA
14.2 EURIDIS and ADONIS
14.3 ANDROMEDA
14.4 PALLAS

• “The reference to the Clinical Studies section (14) of the label expressly directs the reader to that section for elaboration of the class of patients for whom the drug is indicated to achieve the stated objective, i.e. reduced hospitalization.” Sanofi v. Watson Labs. Inc., 875 F.3d 636, 645 (Fed. Cir. 2017)
  o “Section 14 leads with and features a subsection on the ATHENA study, which sets forth the positive results, relating to reduced hospitalization, for patients having the risk factors written into the ’167 patent. And it is only the ATHENA subsection—not any of the three other brief subsections—that identifies a class of patients as having been shown to achieve reduced hospitalization from use of dronedarone...The label thus directs medical providers to information identifying the desired benefit for only patients with the patent-claimed risk factors.” Id.
Sanofi v. Watson (con’t)

- DC: Patents valid and labels induced infringement.
- FC: Affirmed.
  - “The label thus directs medical providers to information identifying the desired benefit for only patients with the patent-claimed risk factors.”
  - “There was considerable testimony that this label encourages—and would be known by Watson and Sandoz to encourage—administration of the drug to those patients, thereby causing infringement.” The label demonstrate specific intent to encourage physicians to infringe.
  - “The content of the label in this case permits the inference of specific intent to encourage the infringing use.”
  - Can’t avoid infringement by pointing out that there are substantial non-infringing uses.
Sanofi: Why Did It Matter?  
Can You Say 10 More Years?

### Patent Data

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>001</td>
<td>7323493</td>
<td>06/19/2018</td>
<td></td>
<td>DP</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>001</td>
<td>8318800</td>
<td>06/19/2018</td>
<td></td>
<td>DP</td>
<td></td>
<td></td>
<td>12/18/2012</td>
</tr>
<tr>
<td>001</td>
<td>8410167</td>
<td>04/16/2029</td>
<td></td>
<td></td>
<td>U-1387 U-1388</td>
<td></td>
<td>04/30/2013</td>
</tr>
<tr>
<td>001</td>
<td>8602215</td>
<td>06/30/2031</td>
<td></td>
<td></td>
<td>U-1473</td>
<td></td>
<td>01/08/2014</td>
</tr>
<tr>
<td>001</td>
<td>9107900</td>
<td>04/16/2029</td>
<td></td>
<td></td>
<td>U-1726 U-1728</td>
<td></td>
<td>08/21/2015</td>
</tr>
</tbody>
</table>
Takeaways From Sanofi

- The “see Clinical Studies” language, included in the FDA drug label, was an extremely important factor that helped Sanofi prove induced infringement in both cases.

- Safety/Efficacy of drug led to specific patient population with patent-claimed risk factors.
  - Consider drafting claims based on a specification reporting results of clinical trials that match those set forth in the label.
  - Avoid waiting too long to file application such that the clinical trial results become prior art against the claims (the results of the ATHENA trials post-dated the critical prior art date).

- Method-of-treatment claims that appear to be very narrow can sound the death knell for generic manufacturers where the claim limitations closely correspond with generic label language, relying in the Indications and Usage section of the label on critical clinical trial results that find their way into the patent specification.

- But see Indications and Usage section of “Labeling for Human Prescription Drugs and Biologicals Products - Content and Format, Draft Guidance for Industry, FDA July 2018, For Comment Purposes Only”
A method for treating a patient with iloperidone, wherein the patient is suffering from schizophrenia, the method comprising the steps of: determining whether the patient is a CYP2D6 poor metabolizer by: obtaining or having obtained a biological sample from the patient; and performing or having performed a genotyping assay on the biological sample to determine if the patient has a CYP2D6 poor metabolizer genotype; and if the patient has a CYP2D6 poor metabolizer genotype, then internally administering iloperidone to the patient in an amount of 12 mg/day or less, and if the patient does not have a CYP2D6 poor metabolizer genotype, then internally administering iloperidone to the patient in an amount that is greater than 12 mg/day, up to 24 mg/day, wherein a risk of QTc prolongation for a patient having a CYP2D6 poor metabolizer genotype is lower following the internal administration of 12 mg/day or less than it would be if the iloperidone were administered in an amount of greater than 12 mg/day, up to 24 mg/day.
INDICATIONS AND USAGE

FANAPT is an atypical antipsychotic agent indicated for the acute treatment of schizophrenia in adults (1). In choosing among treatments, prescribers should consider the ability of FANAPT to prolong the QT interval and the use of other drugs first. Prescribers should also consider the need to titrate FANAPT slowly to avoid orthostatic hypotension, which may lead to delayed effectiveness compared to some other drugs that do not require similar titration.
Induced Infringement

• DC: West-Ward’s proposed products induce infringement.

• Federal Circuit: Affirmed.
  
  • “the proposed label ‘recommends’ that physicians perform the claimed steps, ...and its analysis of the proposed label to assess potential direct infringement by physicians was proper under our precedent.”
  
  • “Even if not every practitioner will prescribe an infringing dose, that the target dose range ‘instructs users to perform the patented method’ is sufficient to ‘provide evidence of [West-Ward’s] affirmative intent to induce infringement.’”
  
  • “even if the proposed ANDA product has ‘substantial noninfringing uses,’ West-Ward may still be held liable for induced infringement. “Section 271(b), on inducement, does not contain the ‘substantial noninfringing use’ restriction of section 271(c), on contributory infringement.”
Injunctive Relief

• Granted injunction
  • Pursuant to § 271(e)(4)
Label and Claim


- Horizon method of use patents.
  - Claim 10. A method for applying topical agents to a knee of a patient with pain, said method comprising:
    - applying a first medication consisting of a topical diclofenac preparation ... ;
    - waiting for the treated area to dry;
    - subsequently applying a sunscreen, or an insect repellant to said treated area after said treated area is dry, ....

- Horizon formulation patents.
  - Claim 49. A topical formulation consisting essentially of:
    - 1-2% w/w diclofenac sodium; 40-50% w/w DMSO; 23-29% w/w ethanol; 10-12% w/w propylene glycol; hydroxypropyl cellulose; and water to make 100% w/w, wherein the topical formulation has a viscosity of 500-5000 centipoise.
HZNP (con’t)

• DC induced infringement holding.
  • Horizon’s claimed methods required three steps; to perform Horizon’s claimed methods, all the steps must be conducted.
  • Horizon premised its allegations of induced infringement upon Actavis’s ANDA product label.
  • Horizon’s and Actavis’s labels essentially the same.
    • “[w]ait until the treated area is dry” before applying a second topical agent, such as sunscreen, insect repellant, or covering the area with clothing.
  • Warning insufficient to show induced infringement because Horizon’s claimed method requires application of a second topical agent whereas the label merely permits, without encouraging, post-product application of sunscreen, insect repellant, or a second topical medication.
Federal Circuit: Affirmed No Induced Infringement

• HZNP (con’t)
  
  • Affirmed no induced infringement holding.
    • ANDA label: apply, dispense, “Wait until area is completely dry before covering with clothing or applying sunscreen, insect repellent, cosmetics, topical medications, or other substances.”
    • Only first claimed step is required. Second and third steps recited in claim are only permitted, not ordered or encouraged.
Pre-launch/Post-launch

• *GSK v. Teva*, No. 14-878, (D. Del), appeal argued Sept. 4, 2019

• Reissue Claim 1. A method of decreasing mortality caused by congestive heart failure in a patient in need thereof which comprises administering a therapeutically acceptable amount of carvedilolin conjunction with one or more other therapeautic agents, said agents being selected from the group consisting of ..., wherein the administering comprises administering to said patient daily maintenance dosages for a maintenance period to decrease a risk of mortality caused by congestive heart failure, and said maintenance period is greater than six months.
Pre-launch/Post-launch

• **GSK v. Teva**, No. 14-878, (D. Del), appeal argued Sept. 4, 2019
  
  • GSK approved for hypertension, mild-to-severe CHR and left ventricular dysfunction; use code “decreasing mortality caused by congestive heart failure.

  • GSK de-listed original patent and listed the reissue patent with the same use code.

  • Teva filed ANDA to market generic carvedilol.

  • Teva then filed section viii carve out to market only for uses not covered by patent (hypertension and post-MI LVD).

  • Teva (and others) marketed generic when GSK patent expired.

  • But after de-listing, Teva revised label to be copy of full label.
Pre-launch/Post-launch

- **GSK v. Teva**, No. 14-878, (D. Del), appeal argued Sept. 4, 2019

- No induced infringement.

  - “GSK failed to prove by a preponderance of the evidence that "Teva's alleged inducement, as opposed to other factors, actually caused the physicians [i.e., as a class or even at least one of them] to directly infringe," by prescribing generic carvedilol and to do so for the treatment of mild to severe CHF. ...Without proof of causation, which is an essential element of GSK’s action, a finding of inducement cannot stand.

  - Difference between pre-launch and post-launch infringement.
Inventorship / Ownership
Ownership Analysis

- Is all of the relevant IP owned by the conveying/target entity?
- Can the entity convey clear title?

- Begin with publicly available information
  - USPTO assignment database and other public assignment records
  - State records for security interests/liens
  - Internet search and review of background of inventor(s)

- Determine whether more in-depth analysis is required
  - Agreements documenting assignment obligations of inventor(s)
  - Agreements documenting IP obligations to sources of funding, materials, or other resources
  - Inventor notebooks
  - Inventor interviews
Doctrine of Equivalents
Ajinomoto Co., Inc. v. ITC, 932 F.3d 1342 (Fed. Cir. 2019)

• Claim 9. A recombinant Escherichia coli bacterium, ... and in which said protein consists of the amino acid sequence of SEQ ID NO: 2 ...

• During patent prosecution, AJ submitted a claim amendment narrowing the scope of the protein sequence in apparent response to a prior art rejection.

• ALJ: CJ strain did not infringe “because its non-E. coli YddG protein was not equivalent to the claimed E. coli YddG protein under the doctrine of equivalents.”

• ITC: Both of CJ’s later strains infringed.
  ▪ “the YddG protein encoded by the codon-randomized non-E. coli yddG gene of this strain is an equivalent of SEQ ID NO:2”
Ajinomoto (con’t)

• CJ: Based on a claim amendment, PHE bars Ajinomoto from relying on DOE to meet the protein limitation and the non-\textit{E. coli} YddG protein of CJ’s second later strain cannot reasonably be found to be an equivalent of the claimed \textit{E. coli} YddG protein under the function-way-result test.

• FC: Affirmed; agreed that Ajinomoto rebutted the Festo presumption.
  - Amendment was tangential to the equivalent because “the reason for the narrowing amendment —limiting the amino-acid makeup of the proteins included in one of the alternatives covered by the claim—is unrelated to differences among the several DNA sequences that encode a given protein.”
Eli Lilly & Co. v. Hospira, Inc.,
933 F.3d 1320 (Fed. Cir. 2019)

- Lilly’s claims recited particular methods of treatment by administering pemetrexed disodium.

- Hospira used a different pemetrexed salt, pemetrexed ditromethamine.

- During patent prosecution, Lilly submitted a claim amendment changing “an antifolate” to “pemetrexed disodium” in apparent response to a prior art rejection.

- FC: DOE infringement; no PHE; tangential exception applied.
  - Reason for the amendment was to narrow the drug not the salt.
  - The court refused to adopt a bright-line rule that the tangential exception does not apply where the reason for the amendment and the equivalent in question both related to the same claim element.
Safe Harbor
Amgen Inc. v. Hospira, 944 F.3d 1327 (Fed. Cir. 2019)

- DC: denied the parties’ motions for JMOL or alternative motions for new trial, regarding infringement, invalidity, §271(e)(1) Safe Harbor, and damages.

- Regarding Safe Harbor, Hospira challenged the jury instructions, which indicated that manufacturing a batch of a particular drug was protected by the Safe Harbor provision if it was “reasonably related” to submitting information to the FDA to obtain approval.

- FC: Affirmed.
  - Because the accused activity is Hospira’s use of Amgen’s claimed methods of manufacture, the relevant inquiry is not how Hospira used each batch it manufactured, but whether each act of manufacture was for uses reasonably related to submitting information to the FDA.
Legislative Developments
Government Funding Compliance

- Bayh-Dole, P.L. 96-517 (as amended), codified at 35 U.S.C. § 200 et seq., and EO 12591

- 37 C.F.R. § 401 et seq., most recently amended by NIST on April 13, 2018
  1. Grants awarded or amended on or after May 14, 2018?
  2. Agreements in place to presently assign entire title and interest?
  3. Obligations of collaborators?
  4. Misleading disclosures of federal funding in other forums?
  5. Any deadlines missed? For example:
     - 2 months to notify agency of disclosure or 1 month to request extension;
     - 2 years (or no more than 60 days before a statutory bar) to elect title after notice or request justified 2-year extension;
     - 1 year to file a U.S. patent application and a confirmatory license after electing title or request justified 1-year extension;
     - 10 months (down from 12 months) to convert provisional or 8 months to request “automatic” 1-year extension;
     - 60 days (up from 30 days) to notify agency before allowing to go abandoned or taking action in a USPTO proceeding/submission;
     - 120 days to submit final invention statement and certification after project period.
Government Funding Compliance

• *Campbell Plastics v. Brownlee*, 389 F.3d 1243 (Fed. Cir. 2004)

• *KEI v. NIH et al.*, 8 F. Cas. 18 (D. Md. 2019) (No. 1130)

• Affordable Pricing for Taxpayer-Funded Prescription Drugs Act of 2019, H.R. 4640

• We Protect American Investment in Drugs (PAID) Act, S. 2387

• #BreakThePatent.org

• Foreign countries with similar legislation: BR CN DE FI DE IT JP MY MX NO PH RU SG ZA KR GB
Drug Pricing Bills in the 116th Congress

• “Obviousness” and “double patenting”
  ▪ S. ---- No Combination Drug Patents Act: Rebuttable presumption of obviousness for patent claims directed to dosing regimens, delivery/treatment methods, formulations of existing drugs/biologics
  ▪ S. 0659 Biologic Patent Transparency Act: Limited enforceability of late-filed biologic patents once biosimilar application filed
  ▪ H.R. 3199 TERM Act: Rebuttable presumption of patent term disclaimer after first patent related to drug/biologic expires

• Other exclusivity penalties
  ▪ H.R. 0465 / S. 0102: HHS audit of brand name drug prices – if deemed excessive based on international and other criteria, authority to void any government-granted exclusivity, issue nonexclusive licenses, and expedite review of generics/biosimilars
  ▪ H.R. 0938: Earlier FDA approval of subsequent generic under certain conditions
  ▪ H.R. 1188 / S. 366: Reduced regulatory exclusivity for certain price increases
  ▪ S. 0377: HHS authority to negotiate drug prices or offer competitive licenses for patent or regulatory exclusivity
Drug Pricing Bills in the 116th Congress (con’t)

• Patent transparency
  ▪ H.R. 1503: More OB reporting requirements (passed House)
  ▪ H.R. 1520: Purple Book codification
  ▪ H.R. 3812 / S. 1209: OB updating requirement to reflect patent invalidation
  ▪ S. 1617 Second Look at Drug Patents Act of 2019: USPTO requirement to reexamine validity of patents before listing in OB
  ▪ S. 1895: Purple Book requirements and no new exclusivity for products transitioning from drugs to biologics in March 2020

• Enforcement against “anticompetitive behaviors” (e.g., “product hopping,” “patent thicketing,” pay-to-delay)

• Price transparency, justification, and caps (e.g., launch prices and spikes, referenced to international price indices and inflation)
Tillis-Coons Senate Bill – Patent Eligibility
Off the Table for 2020!

• Notable features of Subcommittee draft:
  ▪ Abrogate judicial exceptions to eligibility; Require consideration of claim as a whole (Diehr approach).
  ▪ Remove “new” from 101, forcing all considerations of novelty to go through section 102 or 103.
  ▪ Added new draft 112(f).
    – Elements in claim expressed in functional language w/o structure covers examples in specification and equivalents only.

• Stakeholders at a standstill over draft 112(f).
  ▪ Techies: Focus on means plus function
  ▪ Biotechies: Focus on Lilly v. Ariad Standard

• Unsupervised Stakeholder meetings not making progress.
Patent Eligibility – Private Stakeholders

“...The Court’s decisions have created significant uncertainty about what is eligible for patenting in the United States. This has reduced investment in new technologies, produced inconsistency and uncertainty about patent rights and their enforceability, cast a cloud over licensing and other intellectual property transactions, and driven industry to foreign jurisdictions that are more welcoming to their innovations.” (AIPLA)

“The Supreme Court’s test has caused confusion and uncertainty for applicants seeking to obtain patents from the U.S. Patent and Trademark Office ... [and] as patent owners seek to enforce their rights in court... putting at risk the significant investment companies make in developing and commercializing advanced technologies.” (IPOA)

“Recent Supreme Court opinions on section 101, however, have injected ambiguity and unpredictability into the eligibility determination ... discourag[ing] investment in new technologies, thereby risking U.S. leadership in many inventions previously subject to patent protection.” (ABA)
USPTO Guidance
Patent Eligibility – Where are we today?

• USPTO issued guidance on patent eligibility and updated that guidance in Oct 2019.

• Ultimately, the authority is in the courts; the USPTO cannot guarantee patentability.

• No examples and limited guidance specific to life science claims or composition claims.
  - The previous guidance treated nature-based product claims differently, under the Myriad rule of “markedly different characteristics” instead of the Mayo framework - so the new guidance may not have any change for product claims
  - IPO comment: “IPO is concerned that the application of the 2019 Guidance to claims directed to certain types of inventions in the life sciences might be inconsistent with the Federal Circuit’s jurisprudence.”
Additional Updates


- Patent term adjustment applicant delay only for period failed to act - *Supernus Pharm., Inc. v. Iancu*, 913 F.3d 1351 (Fed. Cir. 2019).

- No state sovereign immunity for IPRs - *Regents of the Univ. of Minnesota v. LSI Corp.*, 926 F.3d 1327 (Fed. Cir. 2019).


- Appointments Clause challenge to PTAB APJs limited to those cases where final written decisions were issued and where litigants present an Appointments Clause challenge on appeal - *Arthrex Inc. v. Smith & Nephew, Inc.*, --F.3d-- (Fed. Cir. Oct. 31, 2019).

- Don’t forget, must remain alert to whether pre-AIA law or AIA applies to the claims in the patents under investigation.
Best Practices For Life Sciences IP Due Diligence
Thank you.

Tom Irving
Finnegan, Henderson, Farabow, Garrett & Dunner, LLP
901 New York Avenue, NW
Washington, DC 20001-4413
202.408.4082
tom.irving@finnegan.com

Hilary J. Libka
Dana-Farber Cancer Institute
450 Brookline Ave.
Boston, MA 02215
617.632.3000
Hilary_Libka@dfci.Harvard.edu

Sherry M. Knowles, Principal, Knowles IP Strategies
400 Perimeter Center Terrace NE
Suite 200
Atlanta, GA 30346
678-694-1262
sknowles@kipsllc.com

Ryan Murphey
Ropes & Gray
1211 Avenue of the Americas
New York, NY 10036-8704
212.596.9737
Ryan.Murphey@ropesgray.com