Structuring Freedom-to-Operate Opinions: Reducing Risk of Patent Infringement

Combating Troubling FTO Results, Overcoming Potential Roadblocks, Addressing Impact of Post-Grant Process on FTO Opinions

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OUTLINE

I. Value of FTO Opinions
   A. Types of Opinions
   B. Damages
   C. Case Law

II. Drafting FTO opinions
   A. Problem results
   B. Roadblocks
   C. Privilege and confidentiality
   D. Alternative resolutions

III. Impact of the post-grant process on FTO opinions
Two Major Types Of Legal Opinions
In IP Practice

1. Freedom To Operate ("FTO")/Non-infringement
Focus on comparing the claim limitations to the physical or structural characteristics of the product in question. For process claims, every step of the process must have been performed. Consider “Doctrine of Equivalents.”
Two Major Types Of Legal Opinions
In IP Practice (Cont’d)

2. Invalidity/Enforceability
Focus on whether a patent meets the statutory requirements of patentability: 35 U.S.C. §101 (double patenting, subject matter eligibility, utility); 35 U.S.C. §102 (anticipation); 35 U.S.C. §103 (obviousness); and 35 U.S.C. §112 (written description, enablement, indefiniteness). Often includes a “prior art” search to establish whether the patent claims have been previously disclosed and thus are anticipated or obvious and therefore invalid.
Enhanced Damages

Upon finding for the claimant the court shall award the claimant damages adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the infringer, together with interest and costs as fixed by the court.

When the damages are not found by a jury, the court shall assess them. In either event the court may increase the damages up to three times the amount found or assessed. Increased damages under this paragraph shall not apply to provisional rights under section 154(d) of this title.
Early Cases--Affirmative Duty of Care

“[The] affirmative duty includes, inter alia, the duty to seek and obtain competent legal advice from counsel before the initiation of any possible infringing activity.”


(overruled by *Seagate*)
**Seagate Two-Prong Test**

To establish willful infringement, a patentee must

“show by clear and convincing evidence that the infringer acted despite an objectively high likelihood that its actions constituted infringement of a valid patent” [objective recklessness] and

demonstrate that the risk of infringement “was either known or so obvious that it should have been known to the accused infringer.” [subjective knowledge]

*In re Seagate*, 497 F.3d 1360 (Fed. Cir. 2007)
Seagate Practice

Under *Seagate*’s first prong, accused infringers could avoid a finding of willful infringement by showing defenses to infringement or arguments of invalidity.

Thus, after Seagate, it became common practice for companies hoping to avoid infringement to seek opinions of counsel that they either do not infringe, or that the patent in question is invalid, or both.
A Defense to Willful Infringement

Reliance on a competent legal opinion letter provided “a sufficient basis for [the accused infringer] to proceed without engaging in objectively reckless behavior with respect to the [accused] patent.”

Halo Overturns Seagate

New standard for willful patent infringement and enhanced damages in patent cases.

Supreme Court overturns the “objective recklessness” standard of Seagate.

**Supreme Court in Halo**

*Seagate* inconsistent with language of §284, which explicitly states that a court “may” increase the damages and the “word ‘may’ clearly connotes discretion. *Halo*, 597 U.S. at *7-8.

The “objective step” of *Seagate* unduly rigid and places undue burden on judicial discretion.
**Totality of the Circumstances**

There is “no precise rule or formula” for awarding damages under §284, a district court’s discretion should be exercised in light of the considerations” underlying the grant of that discretion. *Octane Fitness LLC v. ICON Health & Fitness, Inc.* 572 U.S. ____, 134 S. Ct. 1749.

[rejecting a two-part test to determine whether a case is “exceptional” for the purposes of awarding attorney’s fees under 35 U.S.C. section 285].
The Supreme Court in *Halo* directs district courts to “take into account the particular circumstances of each case in deciding to award damages and in what amount.”

In other words, the totality of circumstances at the time of the infringing activity are considered in determining whether infringement is willful and calls for enhanced damages.
Value of Legal Opinions after Halo

_Halo_ holds that the defendant’s subjective belief is assessed “at the time of the challenged conduct.” Therefore, a competent legal opinion stating that there is no infringement, which is obtained before or at the commencement of possible infringing activity may be useful in showing that the infringement was not willful and that there should not be enhanced damages. This shows the reasonableness of the decision to continue the challenged conduct, which was not made in bad faith.
The failure of an infringer to obtain the advice of counsel with respect to any allegedly infringed patent, or the failure of the infringer to present such advice to the court or jury, may not be used to prove that the accused infringer willfully infringed the patent or that the infringer intended to induce infringement of the patent.
Section 298 addresses the comments of the Court in *Underwater Devices* to seek an opinion before commencing in potentially infringing activity, which is now no longer required and is a means of enforcement of the Federal Circuit rule that “no adverse inference that an opinion of counsel was or would have been unfavorable flows from an alleged infringer’s failure to obtain or produce an exculpatory opinion of counsel.” *Knorr-Bremse Systeme Fuer Nutzfahrzeuge GmbH v. Dana Corp.*, 383 F.3d 1337, 1341 (Fed. Cir. 2004).
New Burden of Proof

*Halo* overturned the burden of proof required by *Seagate* because the Court found that no special burden of proof was explicitly recited in §284. Thus, the preponderance of evidence standard, which applies generally to patent infringement cases, also applies to enhanced damages.
New Standard of Review for Appeals Too

Now that the rigid formula for awarding enhanced damages was gone, the Court likewise rejected the Federal Circuit’s tripartite appellate review framework. As the inquiry under §284 resides with the district court, appeals should be examined under the “abuse of discretion standard,” and not under the tripartite appellate review of Seagate.
Final Thoughts on Halo

The Supreme Court has made it easier for the patentee to show willful infringement by eliminating the need to establish objective recklessness and by lowering the evidentiary standard to preponderance of the evidence. Now the “totality of the circumstances” test is the new norm.
The Supreme Court held that “induced infringement...requires knowledge of the patent and that the induced acts constitute patent infringement. *Global-Tech Appliances, Inc., v. SEB S.A.*, 563 U.S. 754 (2011).

Under this standard, a company that has a competent non-infringement opinion would have a good faith belief that the acts committed were not infringing and therefore would lack the required scienter, *i.e.*, the intent to bring about the desired result of infringement, under 35 U.S.C. §271.
35 U.S.C. §271(a)

(a) “Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent. [direct infringement]
35 U.S.C. §271(b)

(b) “Whoever actively induces infringement of a patent shall be liable as an infringer.” [induced infringement]
35 U.S.C. §271 (c)

(c) “Whoever offers to sell or sells within the United States or imports into the United States a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer.
Induced infringement requires knowledge of the patent and knowledge of the infringement.


However, if it is ultimately found, through additional litigation or proceedings, that the patent is invalid, there can be no liability because there is no valid patent to infringe.
Induced Infringement

Commil sued Cisco for direct infringement and induced infringement of patent directed to wireless networks (Wi-Fi).

As a defense to induced infringement, Cisco said that it had a good-faith belief that Commil’s patent was invalid.

Court said induced infringement and validity are separate issues bearing different burdens, different presumptions, and different evidence.
**Belief as to Patent Invalidity ≠ Defense**

The Court decided that a defendant’s belief regarding patent invalidity is not a defense to allegations of induced infringement. Those beliefs cannot negate the scienter required under §271(b), *i.e.*, the “intent to ‘bring about the desired result’ of infringement.”
Nuts and Bolts
**Clearance Opinions**

- “Right to use opinions” or “freedom to operate opinions”
- Analyze whether there are patents that might affect company’s ability to make, use, and sell product
- Search for relevant patents (potentially problematic claims)
- Analyze patents identified in searches
- If necessary, work with client to design around patents, develop invalidity positions, or seek license
Sample Outline Of A FTO Opinion

I. Executive Summary

II. Background
   A. Scope of Opinion
   B. Product/Process at Issue
   C. Procedural History
   D. Patent and File History

III. Legal Framework
   A. Claim Construction
   B. Literal Infringement
   C. Doctrine of Equivalents

IV. Analysis
   A. The Elements/Limitations at Issue Mean X
   B. No Literal Infringement Under This Construction
   C. No Equivalents Infringement Under This Construction

V. Conclusion
FTO Opinions

• Initial audience: Client
  • To provide the foundation for the client's good faith belief that it is not infringing the patent
  • May be offered into evidence and used as a basis for testing that belief

• Should include:
  1. a statement as to why it was prepared;
  2. a description of the scope of the issues to be explored;
  3. a description of the information received from the client;
  4. a description of the nature of the matters studied;
  5. an analysis of the issues that will demonstrate to the client that the opinion is a “thorough analysis of the relevant issues;”
  6. an identification of the judgments to be made on the issues and your opinion as to reasonable conclusions on those judgments; and
  7. a summary the client can point to during a deposition or trial as setting out the essence of the opinion.
FTO Opinions (con’t)

• Potential later audience: judge and jury
  • It will be offered into evidence and will be read by the jurors, perhaps at a time when they have already reported their judgment that, in their opinion, the patent is not invalid and is infringed

• Consequentially, the document should demonstrate it is an opinion to a client on reasonable judgments to be made on a proposed course of action

• Should be:
  – Written in plain English
  – With a structure and headings that are clear
  – Without acronyms or short-hand legal or technical phrases
  – Simple and comprehensive summary
Freedom to Operate and Validity Searches

Freedom-to-Operate

• Purpose
  – Identify patent roadblocks
  – Identify potential competitors
  – Seek out licensing or partnership opportunities

• Coverage
  – Patent documents
    • Focus on claims
  – Countries where company intends to practice (sales or manufacturing)
  – Limited to non-expired patents or pending applications

Validity

• Purpose
  – Evaluate strength of target patents
  – Identify prior art that could be used against target patents in litigation

• Coverage
  – Patent documents
    • Entire disclosure
  – Non-patent publications
    • Scientific articles
    • Theses
    • Conference abstracts
  – Worldwide
  – Documents published or filed before relevant priority date(s) of target patents
  – Acts
**FTO Analysis**

- Analyze results from the FTO search to determine if there are any issues with 3rd party U.S. patents or pending applications
  - For each patent identified during the FTO search, compare claims to proposed product.
  - Consider specifications of the third party patents and, if needed, file histories.

- Assess validity of third-party patent claims reading on target company’s technology

- Identify technical questions.
**FTO Analysis**

- What if the client knows about the third-party patent and has a license under it?
  - Is there a field of use restriction?
    - If so, is the invention within the stated field of use?
  - Is the license limited in time and territory?
  - Is the license transferable and assignable?
    - Share v. asset purchase
    - Notification v. consent
  - Is the “license” merely a covenant not to sue?
**FTO Analysis**

- Check to make sure the patent of concern is still in force, and whether it has been/is being litigated either at PTAB or in the district courts.

- Check to see if the patent has expired, has paid maintenance fees and no statutory disclaimers or has been dedicated to the public.
FTO: Pending Applications

• Source of pending patent applications
  • Directly from search: published patent applications
  • Close calls on issued patents and check for related continuing cases
  • Monitoring competitors’ pending patent applications

• What to do:
  • Pending claims are broad and could cover current or future products
    — Are they patentable?
    — Should a patentability analysis be undertaken?
  • Claims could be in state of flux
    — No enforceable right yet
    — Closely monitor – yes
    — Should you submit art to the PTO or to applicant?
      — PTO: Very risky; not recommended
      — Applicant: risky also, puts burden on applicant to submit
  • Should a license be sought?
  • Should purchase be pursued?
A. Problem results
   • Possible options
     • Design around
     • License
     • Validity analysis

B. Roadblocks
   • Consider post-grant proceeding to knock out troublesome claims.

C. Privilege and confidentiality
   • Will interaction between opinion and trial and/or IPR/PGR counsel waive trial counsel privilege? If so, how much?

D. Alternative resolutions?
What If Opinion Counsel And Trial and/or PTAB Counsel Are From Same Firm?

- Most courts have generally rejected the argument that opinion counsel is a necessary witness

  - Testimony regarding good faith reliance on opinion
    - This “is a question of the party’s state of mind, not the state of mind of counsel.” *Liqui-Box Corp. v. Reid Valve Co.*, 16 USPQ2d 1074, 1075 (W.D. Pa 1989)

  - Testimony regarding competency of the opinion
    - An opinion letter “stands on its own” with regard to competency. *Bristol Myers Squib Co. v. Rhone-Polenc Rorer, Inc.*, No. 95 CIV 8833 (RPP), 2000 WL 1655054, at *6 (S.D.N.Y. Nov. 3, 2000)

- Impact of *Seagate* test being overturned?
Considerations for FTO Opinion

• Consider patent killing issues, such as ODP and *Gilead/TRW* issues.

  • Later-issued, first-expiring is ODP reference against first-issued, later-expiring.
    ― *Gilead Sciences, Inc. v. Natco Pharma Ltd.*, 753 F.3d 1208 (Fed. Cir. 2014), cert. denied (U.S. March 9, 2015)
    ― In same patent family? *Abbvie, Inc. v. Kennedy*, 764 F.3d 1366 (Fed. Cir. 2014)

  • ODP applies where two patents claim same invention and different expiration dates (not issue dates).
Double Patenting Available As Grounds For PGR Petition?

• New 35 U.S.C. §321(b) SCOPE. A petitioner in a post-grant review may request to cancel as unpatentable 1 or more claims of a patent on any ground that could be raised under paragraph (2) or (3) of section 282(b) (relating to invalidity of the patent or any claim).


• Post-grant review effective Sept. 16, 2012
  • for covered business method (CBM) patents; and
  • for any claim with an effective filing date on or after March 16, 2013.

• A number of CBM PGR’s have raised ODP under 101.
    • “Because § 101 is available for invalidating a patent in a CBM review, …so too is ODP, which is predicated on § 101.”

• PTAB said “no” in 2013-00021: ODP is “not statutory” and so cannot be raised at all.
But Double Patenting Does Not Go Away!

• Even if you get through IPR or PGR, you may still face a formidable challenge on ODP, particularly given Gilead and Abbvie and district court TRW.

• Even if the petitioner loses the IPR/PGR, they go into litigation with NO estoppel on ODP!!!
ODP Issues to Look For When Writing FTO Opinion

- Terminal disclaimers filed? Proper?
- Demarcation in chain of divisionals maintained to keep §121 “safe harbor”?
Double Patenting In Litigation

• What if you are the alleged infringer and you are sued for infringement?

• You argue obviousness-type double patenting, but lose on summary judgment.

• File petition for ex parte reexamination in the PTO where there is no presumption of validity, a lower standard of proof, and broadest reasonable claim construction?

  • USPTO and courts do not have to come to same conclusion. See In re Baxter Int’l, Inc., 678 F.3d 1357 (Fed. Cir. 2012); Fresenius USA, Inc. v. Baxter Int’l., Inc., (Fresenius II), 721 F.3d 1330 (Fed. Cir. 2013), cert denied. (U.S. May 19, 2014)
Considerations for FTO Opinion

• Look for *Dayco/McKesson* issues

• Look carefully at any and all declarations.
  
  • A false declaration seems to be per se affirmative egregious misconduct in view of *Therasense*.
  
  • Such declarations can be “bad” on their face.
Considerations for FTO Opinion

• PTAB has found that defective declarations relied on for patentability during prosecution can form an independent basis for instituting an IPR.


    — PTAB reviewed a § 1.131 declaration from the prosecution, found it deficient, and reapplied the prior art the declaration had antedated, instituting the IPR.

    — Case also had live testimony from inventor at oral hearing.

    — If writing opinion for client with patent application still pending, consider getting declarations from the inventor during prosecution that can then by referred to by the Patent Owner in the optional Preliminary Response to try to ward off institution.
What to Look For When Drafting FTO Opinions
Absence Of Definitions And Inconsistently Used Terms

Examples of where failure to define and consistently use terms cost the patentee the desired claim construction.

• **Union Pacific Resources Co. v. Chesapeake Energy Corp.,** 236 F.3d 684 (Fed. Cir. 2001)
  — Patentee's failure to define claim terms “comparing” and “rescaling” resulted in the claims being held invalid.

• **Aqua-Aerobic Systems, Inc. v. Aerators Inc.,** 211 F.3d 1241 (Fed. Cir. 2000)
  — Phrases “prevent flow of air” and “prevent passage of air,” were interpreted differently, even though the patentee argued for them to be construed the same and expert testimony indicated that one of ordinary skill in the art would understand them to be the same.

• **Ortho-McNeil v. Caraco,** 476 F.3d 1321 (Fed. Cir. 2007)
  — Drafter did not use the term “about” every time a range was recited, so the court interpreted ranges with “about” differently than those without.
Case examples where profanity hurt patent owner

- “Very important”

- “Critical,” “Special,” “Peculiar,” “Superior”
  - Bayer AG v. Elan Pharmaceuticals Research Corp., 212 F.3d 1241 (Fed. Cir. 2000)

- “Critical,” “Essential,” “Key”
  - Pharmacia & Upjohn Co. v. Mylan Pharmaceuticals, Inc., 170 F.3d 1373 (Fed. Cir. 1999)

- “Necessary”
  - Atofina v. Great Lakes Chemical Corp., 441 F.3d 991 (Fed. Cir. 2006)
    - “it is necessary to have a catalyst containing solely chromium.”
  - Shows how patentability argument can cause problems later.
Consider Impact of Patent Profanity before PTAB and District Court When Drafting FTO Opinion

- PTAB and PTO ex parte: broadest reasonable claim construction and interpretation (BRI).
  - Profanity could put limits on BRI at PTAB.
Patent Profanity: What Is It?

• Words of characterization
  
  • Chief, Majority  - Vital
  
  • Critical, Essential, Necessary  - Fundamental
  
  • Solely, Only, Is  - Important
  
  • Main  - Principal
  
  • Significant
Words That Make Other Words Profanity

- Surprising
- Unexpected (?)
- All (?)
- Only (?)
- Each (?)
- “The invention is...” or “This invention...”
“Invention Is…”

- **C.R. Bard, Inc. v. U.S. Surgical Corp.,** 388 F.3d 858 (Fed. Cir. 2004)
  - Claimed plug for hernias, but no claim language about plug surface.
  - **Specification “consistently described as having pleats”**
  - **Summary of Invention, Abstract**

- **DC: No infringement.**
  - Claim construed to require pleated plug.

- **FC: Affirmed -> no infringement by plugs without pleats.**
  - “because the patent globally defined the plug as having a pleated surface, the term "pleated" need not be repeated each time a term describing some other aspect of the plug is used.”
  - Statements of general applicability clearly define the claimed plug as "having" or "includ[ing] a pleated surface."
“Invention Is…”

- **C.R. Bard (con’t)**

  - FC: Explicitly relied on statements in the “Summary of the Invention” and the Abstract for its claim construction:
    - “**Statements that describe the invention as a whole,** rather than statements that describe only preferred embodiments, are more likely to support a limiting definition of a claim term. [citation omitted] ...Accordingly, other things being equal, certain sections of the specification [such as the Summary and Abstract] are more likely to contain statements that support a limiting definition of a claim term than other sections.... In this case, the plug claimed by the ’432 patent is defined globally as requiring a pleated surface, which limits claim 20.”
    
    - See also, Edwards Life Sciences v. Cook, Inc., 582 F.3d 1322 (Fed. Cir. 2009)(“specification frequently describes an ‘intraluminal graft’ as ‘the present invention’ or ‘this invention,’ indicating an intent to limit the invention to intraluminal devices.”) ; Regents of University of Minnesota v. AGA Medical Corp., 717 F.3d 929 (Fed. Cir. 2013)
Do The Examples and Drawings Provide §112 Support For Full Range Of Claims?

- Possession and enablement.
  - MSM Investments Co., LLC v. Carolwood Corp., 259 F.3d 1335 (Fed. Cir. 2001): examples helped broad claim construction covering both nutritional and pharmacological uses.

- Drawings and charts.

- Actual and hypothetical examples.
Is There Subject Matter Disclosed but Not Claimed?

Subject matter disclosed but not claimed establishes dedication to the public.

- **PSC Computer Products Inc. v. Foxconn Int’l Inc.,** 355 F.3d 1353 (Fed. Cir. 2004)
  - “If one of ordinary skill in the art can understand the unclaimed disclosed teaching upon reading the written description, the alternative matter disclosed has been dedicated to the public. This ‘disclosure-dedication’ rule does not mean that any generic reference in a written description necessarily dedicates all members of that particular genus to the public. The disclosure must be of such specificity that one of ordinary skill in the art could identify the subject matter that had been disclosed and not claimed.”

- **Toro Co. v. White Consolidated Industries, Inc.,** 383 F.3d 1326 (Fed. Cir. 2004).
- **Pfizer, Inc. v. Teva Pharmaceuticals USA, Inc.,** 429 F.3d 1364, 1378 (Fed. Cir. 2005).
- **Johnson & Johnston Assoc., Inc. v. R.E. Service Co., Inc.,** 285 F.3d 1046 (Fed. Cir. 2002) (en banc).
Is Chain Of Priority Tight?

Medtronic Corevalve, LLC v. Edwards Lifesciences Corp., 741 F.3d 1359 (Fed. Cir. 2014)

FR 99/14462 (1a) filed 11/17/1999

earliest date according to Medtronic

priority claim on face of patent

earliest date according to Edwards

District court granted Edwards’s motion because not every intervening application in the chain claimed priority to FR1b (for § 119) or recited chain properly (for §120 priority). Held claims invalid for anticipation by FR 1b and PCT.
Medtronic v. Edwards (con’t)

- FC: Affirmed.
  - The “specific reference” requirement of §120 means “each [intermediate] application in the chain of priority to refer to the prior applications.”
  - Even though the patent at issue properly recited the priority chain, the intermediate U.S. applications failed to specifically reference the earlier-filed applications in the priority chain.
  - “this application” is not an express, specific reference.
  - “the implementing regulation for § 120, ...requires precise details in priority claims down to the ‘application number (consisting of the series code and serial number),’ 37 C.F.R. § 1.78(a)(2)(i).”
Priority Claim Attack


- Petitioner challenged patent’s priority claim back to the first two provisional applications.

- Using an expert declaration, Petitioner broke priority chain by establishing that the claim limitations contained in challenged claim 1 of the patent did not have written description support all the way back to the earliest two priority applications.

- PTAB Final Written Decision: No priority date.
  - The provisionals did not disclose a representative number of species falling within the scope of the claim, let alone “‘precisely define’ a species falling within the scope of the claimed genus.”
**PTAB Comment on Priority Attack**


- Petitioner attacked priority claimed by patent.
- Patent Owner objected to § 112 issue in an IPR.
- PTAB:
  - We note the difference between compliance with the requirements of 35 U.S. C. § 112 and assessing the earliest priority date for a claim. ...the issue is not whether there is a sufficient written description in the ’894 Patent, but whether the written description in the earlier applications supports Patent Owner’s claim to priority. . . .*A review of the disclosure for purposes of identifying the priority date for the claimed subject matter is appropriate and within the scope of inter partes review.* *Nissan N. Am., Inc. v. Bd. of Regents, Univ. of Tex. Sys.*, IPR2012-00037, Paper 24, at 14-16 (PTAB March 19, 2013).
Any Issues With Adjectives and Adverbs?

Where and how are modifiers used? Defined in specification?
- “lower”
- “substantially” or “essentially”

Karsten Mfg. Corp. v. Cleveland Golf Co., 242 F.3d 1376 (Fed. Cir. 2001)
• “An improved correlated set of iron type golf-clubs, each club...”

ArcelorMittal France v. AK Steel Corp., 700 F.3d 1314 (Fed. Cir. 2012)
• “the steel sheet has a very high mechanical resistance after thermal treatment.”

Aventis Pharmaceuticals Inc. v. Amino Chemicals Ltd., 715 F.3d 1363 (Fed. Cir. 2013)
• “said process comprising: providing a substantially pure regioisomer of the following formula...”
Are Ordinary Words Defined?

- **“or”**
  - *Brown v. 3M*, 265 F.3d 1349 (Fed. Cir. 2001) (“or” = either/or, not one or the other or both)
  - *Schumer v. Laboratory Computer Systems, Inc.*, 308 F.3d 1304 (Fed. Cir. 2002) (construes “or” as designating alternatives)

- **“on” and “onto”**
  - *Inverness Medical Switzerland GmbH v. Warner Lambert Co.*, 309 F.3d 1373 (Fed. Cir. 2002)(cover impregnation within?)
Are Ordinary Words Defined? (con’t)

- “a”
  - KCJ Corp. v. Kinetic Concepts, Inc., 223 F.3d 1351 (Fed. Cir. 2000) (“a” = one or more unless disclaim plural convention)

  - Baldwin Graphic Systems, Inc. v. Siebert, Inc., 512 F.3d 1338 (Fed. Cir. 2008) (“a" or "an" used with “comprising" in claims means “one or more."

  - Harari v. Lee, 656 F.3d 1331 (Fed. Cir. 2011) (While “a” generally means “one or more,” the claim language and specification must support construing the claim according to that convention. In this case, “a” means “one.”).

“At Least One”

• Claim = “at least one of a W, a X, a Y, and a Z”

• Does the phrase mean at least one W and at least one X and at least one Y and at least one Z?

• Maybe
  • “at least one of” modifies each category in the criteria list
  • “and” connotes a conjunctive list
  • see Superguide Corp. v. DirecTV Enterprises, Inc, 358 F.3d 870 (Fed. Cir. 2004)

• What if list ends with “and/or”?
  • “at least one of a W, a X, a Y, and/or a Z”
  • Ambiguous?
“At Least One”

• Biagro Western Sales, Inc. v. Grow More, Inc., 423 F.3d 1296 (Fed. Cir. 2005)
  • Claim: A concentrated phosphorus fertilizer comprising a buffered composition comprising at least one phosphorous-containing acid or salt thereof … and wherein any of said phosphorous-containing acid or salt thereof is present in an amount of about 30 to about 40 weight percent.
  
  • Accused product A is 15% weight percent acid and 25% weight percent salt? “any” – does not infringe; “and/or” – does infringe
  • Accused product B is 60% weight percent acid and 30% weight percent salt? “any” - infringes
  
  • DC: limitation referred to the amount of phosphorous-containing acid or salt actually present in the final fertilizer product
    • fertilizer containing two or more phosphorous-containing salts comes within the literal scope of the claim only if the aggregate amount of such salts is between about 30 and about 40 weight %
At Least One (con’t)

• Biagro (con’t)

• FC: Affirmed
  • written description indicates that total amount of such acids or salts is important

• DC correctly construed the claim to require an aggregate amount of such acids or salts to be between about 30 and about 40 weight %

• -> Affirm SJ of noninfringement
  • 40.3% potassium phosphite present in accused product
  • correct claim construction requires aggregate amount of phosphites to be within the claimed range
  • accused product contains 2 phosphites, resulting in an aggregate phosphate content of at least 59.3%
“At Least One” (con’t)

• **Enzo Biochem Inc. v. Applera Corp., 780 F.3d 1149 (Fed. Cir. 2015)**
  
  • Claim limitation at issue: “wherein A comprises at least three carbon atoms and represents **at least one** component of a signaling moiety capable of producing a detectable signal;”
  
  • **DC:** Infringed.
    • Claim construction - no additional steps required to detect the compound; allowed for both direct and indirect detection of the claimed compound.
  
  • **FC:** Reversed claim construction; vacated infringement.
    • “the plain reading of the disputed claim term requires that a signalling moiety be composed of components, of which at least one is ‘A.’”
    • “claim 1 covers only indirect detection”
“To”

- **Chef America, Inc. v. Lamb-Weston, Inc., 358 F.3d 1371 (Fed. Cir. 2004)**
  - Claim process for baking dough by “heating the . . . dough to a temperature in the range of about 400 degrees F. to 850 degrees F.”
  - If dough were heated to the temperature specified in the claim, “it would be burned to a crisp.”
  - Expert declaration that one skilled in the art reading the claim would believe temperature range referred to temperature of oven, not dough.
  - Patent gives two examples, each stating that the dough product is placed in a multi-layered convection oven and baked “at temperatures” or “at a temperature” of 680° F to 850° F.

- DC: Construed claim to mean temperature of dough -> no infringement.

- FC: Affirmed. “courts may not redraft claims.”
  - Could have chosen “at a temperature”, but didn’t.
“Is”

- **Straight Path v. Sipnet, Inc., 806 F.3d 1356 (Fed. Cir. 2015)**
  - “It depends on what the meaning of the word 'is' is.”
  - Claim language: “transmitting ... a query as to whether the second [unit] is connected to computer network.”
  - Majority: PTAB erred by including second units that are registered as being on-line, whether or not they actually are still on-line.
“Is” (cont.)

• **Straight Path (con’t)**

  • **Majority:**
    
    • Plain meaning of “is” is present tense—“is connected ... at the time the query is sent.”

    • PTAB improperly turned immediately to the specification without directly addressing “the facially clear meaning.”

    • “When claim language has as plain a meaning on an issue as the claim language does here, leaving no genuine uncertainties on interpretive questions ..., it is particularly difficult to conclude that the specification ... reasonably supports a different meaning.”
• **Straight Path** (con’t)
  • Dissent:
    • “John is home.”
    • “How do you know?”
    • “I spoke to him five minutes ago.”
    • “[T]he use of the word ‘is’ does not necessarily imply absolute accuracy or absolute currency.”
Is “About” Used? If So, How?

Jeneric/Pentron, Inc. v. Dillon Co., Inc., 205 F.3d 1377 (Fed. Cir. 2000)

- Jeneric used to modify some component ranges in claim, but not others.
- Claim 1. A two-phase porcelain composition comprising a leucite crystallite phase dispersed in a feldspathic glass matrix, \[ \text{“a temperature effective for maturing” or “means for maturing” said feldspathic glass matrix} \] a maturing temperature of from about 750°C to about 1050°C and a coefficient of thermal expansion of from about 12 x 10^{-6}/°C. to about 17.5 x 10^{-6}/°C. (room temperature to 450°C), said porcelain composition comprising:

<table>
<thead>
<tr>
<th>Component</th>
<th>Amount (wt.%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SiO₂</td>
<td>57-66</td>
</tr>
<tr>
<td>Al₂O₃</td>
<td>7-15</td>
</tr>
<tr>
<td>K₂O</td>
<td>7-15</td>
</tr>
<tr>
<td>Na₂O</td>
<td>7-12</td>
</tr>
<tr>
<td>CeO₂</td>
<td>0-1</td>
</tr>
<tr>
<td>Li₂O</td>
<td>0.5-3</td>
</tr>
<tr>
<td>CaO</td>
<td>0-3</td>
</tr>
<tr>
<td>MgO</td>
<td>0-7</td>
</tr>
<tr>
<td>F</td>
<td>0-4</td>
</tr>
</tbody>
</table>

wherein the leucite crystallites possess diameters not exceeding about 10 microns and represent from about 5 to about 65 weight percent of the two-phase porcelain composition.
“About” (con’t)

• Jeneric (con’t)

  • FC: “Without broadening words that ordinarily receive some leeway, the precise weight ranges of claim 1 do not ‘avoid a strict numerical boundary to the specified parameter.’”

  • Other variables in same claim use qualifying language.

  • Claim had to be written narrowly to avoid prior art.

  • Can’t rely on precise ranges to distinguish prior art during prosecution and then have ranges construed broadly in infringement action.
Ortho-McNeil v. Caraco, 476 F.3d 1321 (Fed. Cir. 2007)

- Claim limitation at issue: “about 1:5”

- DC: Granted SJ of noninfringement.
  - Caraco’s ANDA formulation had weight ratio of 1:8.67.

- FC: Affirmed.
  - Some claims recite single weight ratio; other claims recite ranges of weight ratios - “This leads to a conclusion that one of ordinary skill in the art would understand the inventors intended a range when they claimed one and something more precise when they did not.”
  - “they could easily have claimed a ratio range of ‘about 1:1 to about 1:5,’ or even a ratio range of ‘about 1:3 to about 1:5,’ but they did not. Instead, they chose a specific data point for claim 6 of precisely 1:5.”
  - No DOE infringement because “having so distinctly claimed the ‘about 1:5’ ratio, Ortho cannot now argue that the parameter is broad enough to encompass, through the doctrine of equivalents, ratios outside of the confidence intervals expressly identified in the patent.”

“About” (con’t)
“About” (con’t)

Merck & Co., Inc., v. Teva Pharmaceuticals USA, Inc., 395 F.3d 1364 (Fed. Cir. 2005)

• “A method for treating osteoporosis ... comprising orally administering about “70 mg” of alendronate monosodium trihydrate and “about 35 mg”

• DC: Merck redefined the ordinary meaning of "about" in claims from “approximately” to exactly 35 (or 70) mg.
  – Specification: “about 70 mg ... calculated based on 70 mg of alendronic acid.”
  – “about 35 [or 70] mg” means the amount of the derivative compound that gives exactly 35 [or 70] mg of the active compound.

• FC: Reversed. “About” should be given its ordinary meaning.
  – Passage of the specification is ambiguous (because of “For example...” ?).
  – Fails to redefine "about" to mean "exactly" in clear enough terms to justify such a counterintuitive definition of "about."
  – “about 70 [or 35] mg” refers to the amount of the active compound to be administered rather than the amount of the derivative compound.
“About” (con’t)

Cohesive Technologies, Inc. v. Waters Corp., 543 F.3d 1351 (Fed. Cir. 2008)

• Claim limitation: average diameters “greater than about 30 μm.”

• DC: Construed to exclude 29.01 μm.

• FC: District court erred.
  – “When ‘about’ is used as part of a numeric range, ‘the use of the word “about,” avoids a strict numerical boundary to the specified parameter. Its range must be interpreted in its technologic and stylistic context.’”

  – “’about 30 μm’ means a particle of sufficiently large size to assure that a column containing the particles is capable of attaining turbulence. This functional approach is necessary and appropriate, because the deliberate imprecision inherent in the word ‘about’ makes it impossible to “capture the essence” of the claimed invention in strict numeric terms.”
Halliburton Energy Services, Inc. v. M-I LLC, 514 F.3d 1244 (Fed. Cir. 2008)

- Claim: “A method for conducting a drilling operation in a subterranean formation using a fragile gel drilling fluid[.]”

- Specification defined “fragile gel” as:
  - a “gel” that is easily disrupted or thinned, and that liquifies or becomes less gel-like and more liquid-like[.]”

- FC: Halliburton’s claim term “fragile gel” was indefinite - insufficiently defined functionally.
  - “We note that the patent drafter is in the best position to resolve the ambiguity in the patent claims, and it is highly desirable that patent examiners demand that applicants do so in appropriate circumstances so that the patent can be amended during prosecution rather than attempting to resolve the ambiguity in litigation.”
  - “A patent drafter could resolve the ambiguities of a functional limitation in a number of ways. For example, the ambiguity might be resolved by using a quantitative metric (e.g., numeric limitation as to a physical property) rather than a qualitative functional feature. The claim term might also be sufficiently definite if the specification provided a formula for calculating a property along with examples that meet the claim limitation and examples that do not.”
Did Patent Drafter Try to Use A Special Definition? Would a POSITA Understand?

Thorner v. Sony Computer Entertainment America LLC, 669 F.3d 1362 (Fed. Cir. 2012)

- FC:
  - “Our case law is clear, claim terms must be given their plain and ordinary meaning to one of skill in the art. ... We must decide whether the patentee has redefined this term ...[through] either lexicography or disavowal. Both exceptions require a clear and explicit statement by the patentee. ... [T]he “implied” redefinition must be so clear that it equates to an explicit one. In other words, a person of ordinary skill in the art would have to read the specification and conclude that the applicant has clearly disavowed claim scope or has acted as its own lexicographer. Simply referring to two terms as alternatives or disclosing embodiments that all use the term the same way is not sufficient to redefine a claim term.”
Aventis Pharma S.A. v. Hospira, Inc., 675 F.3d 1324 (Fed. Cir. 2012)

- 5. A perfusion, which contains approximately 1 mg/ml or less of compound of formula as defined in claim 1, and which contains less than 35 ml/1 of ethanol and less than 35 ml/1 of polysorbate, wherein said perfusion is capable of being injected without anaphylactic or alcohol intoxication manifestations being associated therewith.

- Parties initially agreed to construe “perfusion” as “a solution suitable for infusion into patients including at least active pharmaceutical ingredient and an aqueous infusion fluid such as physiological saline or glucose.”

- Later, Sanofi asked district court to require that the claimed “perfusion” also be effective for treatment, safe, and stable (i.e., not precipitate) for at least eight hours.
Aventis v. Hospira (con’t)

• DC: Construed “perfusion” to mean “an injectable solution containing the active pharmaceutical ingredient and an aqueous infusion fluid.”

• FC: Affirmed.
  – “Neither the claims, the specification, nor the prosecution history suggest that the claimed perfusion must satisfy certain safety or efficacy standards.”
  – “perfusion,” as that term is normally understood in the art, does not include an eight-hour stability limitation
    – Cited Thorner: “only interpret a claim term more narrowly than its ordinary meaning under two circumstances: 1) when a patentee sets out a definition and acts as [its] own lexicographer, or 2) when the patentee disavows the full scope of a claim term either in the specification or during prosecution.”

  – “Here, because neither exception applies, the district court correctly did not include an eight-hour stability limitation in its construction of ‘perfusion.’”
Does The Patent Describe How Infringement Will Be Proven?

Amgen, Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313 (Fed. Cir. 2003)

• Claim: glycoprotein having “glycosylation which differs from that of human urinary erythropoietin.”

• Specification taught three measurement methods, but failed to limit "glycosylation which differs" to particular method.

• DC: patent failed to identify a single standard by which the “difference” could be measured, so no infringement and patent invalid for failure to satisfy §112.

• FC: Affirmed because claims indefinite. “One cannot logically determine whether an accused product comes within the bounds of a claim of unascertainable scope.”
§112 Issues

Is claim the supported in the specification, self-contained in the body of the claim, and, most importantly, complete?

Allen Engineering Corp. v. Bartell Indus., 299 F.3d 1336 (Fed. Cir. 2002)

• FC: claim ending in the middle of a limitation (“coupled to said gearbox means by rigid...”) is indefinite because it is impossible to discern the scope of such a truncated limitation
Allen (con’t)

• Claims read: "its gear box only in a plane perpendicular to said biaxial plane."

• However specification described structure as "gearbox ... cannot pivot in a plane perpendicular to the biaxial plane."

• Allen argued that one of skill in the art would understand that the term "perpendicular" in the claim should be read to mean "parallel."

• FC: “Allen stretches the law too far.”
§112 Issues (con’t)

- Indefiniteness post-*Nautilus*
  - Inform POSITA with “reasonable certainty” about the scope of the invention?
  - Words of degree definite?

- Means-plus-function claims post-*Williamson*
Assessing Compliance With §112(b) Definiteness Requirement In Opinions

Proper perspective for §112(b) definiteness requirement:

• Compliance should be determined from the perspective of one of ordinary skill in the art at the time the application was filed

• Claim should be considered as a whole
  — In re Larsen, No. 01-1092 (Fed. Cir. May 9, 2001) (unpublished)

• Claim language should be read in light of the specification and in view of prior art
  — Orthokinetics, Inc. v. Safety Travel Chairs, Inc., 806 F.2d 1565 (Fed. Cir. 1986); S3 Inc. v. nVidia Corp., 259 F.3d 1364 (Fed. Cir. 2001).
Teva Pharmaceuticals USA, Inc. v. Sandoz, Inc., 723 F.3d 1363 (Fed. Cir. 2013), on remand from Supreme Court, 789 F.3d 1335 (Fed. Cir. 2015)

• Group I claims
  – Copolymer-1 having a molecular weight of about 5 to 9 kilodaltons, made by a process comprising the steps of:
    – reacting protected copolymer-1 …; and purifying said copolymer-1, to result in copolymer1 having a molecular weight of about 5 to 9 kilodaltons.

• Group II claims
  – Copolymer-1 having over 75% of its mole fraction within the molecular weight range from about 2 kDa to about 20 kDa….”

• “molecular weight” insolubly ambiguous because it could refer to $M_p$, $M_n$, $M_w$, or yet another average molecular weight measure?
Attacking Written Description Support in Opinion

• Written description requirement that the patent applicant “convey clearly to those skilled in the art the information that applicant has invented the specific subject matter later claimed.”

  • Support for every embodiment disclosed?

  • Can one skilled in the art should “reasonably conclude” that patentee had “possession” of the claimed invention and all the recited limitations?

  • Is there disclosure of “sufficiently detailed relevant identifying characteristics”?
Broad Claim Construction (Which is What PTAB Will Apply) -> Not Enabled

Wyeth and Cordis Corp. v. Abbott Labs., 720 F.3d 1380 (Fed. Cir. 2013)

- Invention: use of rapamycin for the treatment and prevention of restenosis (renarrowing of an artery).
- Claim: method of treating or preventing “restenosis in a mammal … which comprises administering an antirestenosis effective amount of rapamycin to said mammal.”
- Specification discloses only one rapamycin species: sirolimus.
- DC: Summary judgment of invalidity for nonenablement and lack of written description.
  - Construed “rapamycin” as “a compound containing a macrocyclic triene ring structure produced by Streptomyces hygroscopicus, having immunosuppressive and anti-restenotic effects.”
**Broad Claim Construction (Which is What PTAB Will Apply) -> Not Enabled**

**Wyeth v. Abbott Labs. (con’t)**

- FC: Affirmed.

- Claims requires excessive—and thus undue—experimentation.
  - Cover any structural analog of sirolimus that exhibits immunosuppressive and antirestenotic effects.
  - Unpredictability of the chemical arts, the complexity of the invention; limited knowledge of treatment of restenosis using sirolimus at the time of the invention.
  - No indication in specification how to structurally modify sirolimus to yield a compound having the recited functional effects.
  - “practicing the full scope of the claims would require synthesizing and screening each of at least tens of thousands of compounds.”
  - Specification “discloses only a starting point for further iterative research in an unpredictable and poorly understood field.”
What About Claim Dependencies?


- Dependent claim 6: "The hemicalcium salt of claim 2."
- Claim 2, however, erroneously recites only an acid and not a salt of the acid.
- Claim 2 depends from claim 1, which recites acids and salts.

- FC: Claim 6 is invalid under §112, ¶4: requires a dependent claim to “contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed.”
  - “A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers.”
  - FN6: “Theoretically, a claimed acid could be liberally construed to include the corresponding salts. See Merck & Co., Inc. v. Teva Pharms. USA, Inc., 347 F.3d 1367, 1372 (Fed. Cir. 2003). But here, given the absence of the ‘pharmaceutically acceptable salts thereof’ language which was used in claim 1, the intrinsic evidence would not have supported such an interpretation of claim 2.”
False declaration filed?

Misrepresentation that was not cured?

• When an applicant files a false declaration, we require that the applicant ‘expressly advise the PTO…’ ...Finally, the applicant must ‘take the necessary action...openly. It does not suffice that one knowing of misrepresentations in an application or in its prosecution merely supplies the examiner with accurate facts without calling his attention to the untrue or misleading assertions sought to be overcome[.]”

— Federal Circuit in Intellect Wireless citing Rohm & Haas Co. v. Crystal Chem. Co., 722 F.2d 1556, 1572 (Fed. Cir. 1983), which was also cited in Therasense, with approval.
Any Attempt to “Cure” Needs To Be Express

Federal Circuit in Intellect Wireless:

- “At best, the revised declaration obfuscated the truth....it never expressly negated the false references to [ARP] in the original declaration.”

- “Nowhere did the declaration openly advise the PTO of Mr. Henderson’s misrepresentations, as our precedent clearly requires.”

  — Federal Circuit quotes from Rohm & Haas:
  - “When an applicant files a false declaration, we require that the applicant ‘expressly advise the PTO of [the misrepresentation’s] existence, stating specifically wherein it resides.”
  - “if the misrepresentation is of one or more facts, the PTO [must] be advised what the actual facts are.”
  - “applicant must ‘take the necessary action...openly. it does not suffice that one knowing of misrepresentations in an application or in its prosecution merely supplies the examiner with accurate facts without calling his attention to the untrue or misleading assertions sought to be overcome, leaving him to formulate his own conclusions.”
<table>
<thead>
<tr>
<th>Case</th>
<th>Decision Maker</th>
<th>Outcome</th>
<th>Reason for Inequitable Conduct</th>
<th>Additional Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aventis Pharma S.A. v. Hospira, Inc., 675 F.3d 1324 (Fed. Cir. 2012)</td>
<td>PROST, Linn, Dyk</td>
<td>Affirmed inequitable conduct</td>
<td>Withheld references material</td>
<td>No credible explanation why disclosed to FDA but not PTO.</td>
</tr>
<tr>
<td>Apotex Inc. v. Cephalon, Inc., 2011 WL 6090696 (E.D. Pa. 2011), aff'd without opinion (Fed. Cir. April 8, 2013)</td>
<td>PER CURIAM (Rader, Lourie, O’Malley)</td>
<td>Affirmed inequitable conduct</td>
<td>Concealed supplier’s involvement in claimed invention</td>
<td>No alternative explanation why told PTO it modified Lafon’s modafinil when it did not.</td>
</tr>
<tr>
<td>Intellect Wireless, Inc. v. HTC Corp., 732 F.3d 1339 (Fed. Cir. 2013)</td>
<td>MOORE, Prost, O’Malley</td>
<td>Affirmed inequitable conduct</td>
<td>Submission of false declaration = affirmative egregious misconduct</td>
<td>Pattern of conduct showed intent to deceive: similar false statements in related patents; never notified examiner of error in the declaration or attempted to correct it.</td>
</tr>
<tr>
<td>Ohio Willow Wood Co. v. Alps South, LLC, 813 F.3d 1350 (Fed. Cir. Feb. 19, 2016)</td>
<td>BRYSON, Dyk, and Wallach</td>
<td>Affirmed inequitable conduct</td>
<td>Failure to disclose material information = submitting a false affidavit</td>
<td>“(1) that Mr. Colvin was aware that OWW’s reexamination counsel had represented to the Board that Mr. Comtesse's testimony was entirely uncorroborated; (2) that Mr. Colvin was aware of materials that corroborated Mr. Comtesse's testimony; and (3) that Mr. Colvin failed to correct his counsel's misrepresentations.”</td>
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### FEDERAL CIRCUIT: INEQUITABLE CONDUCT POST-HERASENSE

<table>
<thead>
<tr>
<th>Case</th>
<th>Judges</th>
<th>Affirmation of Inequitable Conduct</th>
<th>Reason for Affirmation</th>
<th>Pattern of Conduct</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Apotex, Inc. v. UCB, Inc.</strong>, 763 F.3d 1354 (Fed. Cir. 2014)</td>
<td>REYNA, Wallach, and Hughes</td>
<td>Affirmed inequitable conduct</td>
<td>Affirmative misrepresentations of prior art and test results</td>
<td>Pattern of conduct showed intent to deceive.</td>
</tr>
<tr>
<td><strong>American Calcar, Inc. v. American Honda Motor Co., Inc.</strong>, 768 F.3d 1185 (Fed. Cir. 2014)</td>
<td>PROST, Wallach Dissent - Newman</td>
<td>Affirmed inequitable conduct</td>
<td>Failure to disclose material information</td>
<td>“Mr. Obradovich deliberately decided to withhold the information from the PTO.”</td>
</tr>
<tr>
<td><strong>Worldwide Home Prods., Inc. v. Time, Inc.</strong>, 626 Fed.Appx. 1009 (Fed. Cir. Dec. 16, 2015)</td>
<td>PER CURIAM (Moore, O’Malley, Taranto)</td>
<td>Case dismissed</td>
<td>Misrepresentation about prior art was basis for overcoming prior art rejection (“but for” materiality)</td>
<td>Attorney jointly and severally liable with client for $800K. “Mr. Sonnabend prosecuted this litigation very aggressively and ignored numerous opportunities to withdraw plaintiff’s claims,” ...“His conduct was vexatious and in bad faith and is a proper predicate for the imposition of sanctions pursuant to 28 U.S.C. section 1927.”</td>
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Summary: What Are You Looking For?

- Gaps in specification.
- Ambiguous terms.
- Improper claim dependencies.
- How the claim terms will be construed by PTAB and district courts.
- Is the “embodiment is in fact the entire invention presented”?
- Can claim be infringed by a single actor?
- Any potential inequitable conduct issues?
Interplay Between AIA Post-Grant Proceedings and Opinions
## Reminder: Different Standards

<table>
<thead>
<tr>
<th>ISSUE</th>
<th>PGR/CBM PGR/IPR</th>
<th>DISTRICT COURT</th>
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<tbody>
<tr>
<td>Burden of proof</td>
<td>Preponderance of the evidence</td>
<td>Clear and convincing evidence</td>
</tr>
<tr>
<td>Presumption of Validity?</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Claim construction</td>
<td>Broadest reasonable Interpretation (BRI)*</td>
<td>Phillips/Markman framework: analyze claims, specification, and prosecution history to determine how claims would be understood by one of ordinary skill in the art</td>
</tr>
<tr>
<td>Decision maker</td>
<td>Patent Trial and Appeal Board (APJs)</td>
<td>District court judge or jury</td>
</tr>
</tbody>
</table>
PTAB Institution Decision Non-Appealable

- 35 U.S.C. § 314(d): NO APPEAL.—The determination by the Director whether to institute an inter partes review under this section shall be final and nonappealable.

  - Federal Circuit decision not allowing attack of the decision to institute affirmed.
  - “The text of the ‘No Appeal’ provision, along with its place in the overall statutory scheme, its role alongside the Administrative Procedure Act, the prior interpretation of similar patent statutes, and Congress’ purpose in crafting inter partes review, all point in favor of precluding review of the Patent Office’s institution decisions.”
  - In this case, §314(d) bars judicial review of whether PTAB wrongly instituted an IPR on grounds not specifically mentioned in a third party’s review request.
Benefits of Using AIA Post-Grant Proceedings for FTO

• If petitioner can knock out broad claims in AIA post grant proceedings, that in and of itself might achieve FTO in that narrower claims may not be infringed.

• Knocking out dependent claims may also achieve FTO of non-infringement.

• No claim finally found to be unpatentable in an AIA post grant proceeding will be infringed in district court/Fed. Cir proceedings.

• Remember, amendment for patent owner at this point is a very, very, very long shot.
Granted Motions to Amend Substituting Claims Are Still Rare

“The process however, is not as unfair as Cuozzo suggests. The patent holder may, at least once in the process, make a motion to do just what he would do in the examination process, namely, amend or narrow the claim. §316(d) (2012 ed.). This opportunity to amend, together with the fact that the original application process may have presented several additional opportunities to amend the patent, means that use of the broadest reasonable construction standard is, as a general matter, not unfair to the patent holder in any obvious way.” (p. 18-19)
In Opinion, Analyze the Relative Strength Based On The Softer “PTAB” Standards Vs. The Harder District Court Standards

- Priority
- Claim construction
- Indefiniteness
- Lack of written description
- Lack of enablement
- §102
- §103, including objective evidence
Claim Construction

• Claim construction fundamental.
  • First step when addressing validity/patentability, infringement, support in the specification, as well as often a preliminary step in determining patent-eligible subject matter and inventorship.
  • Arise during post-grant proceedings in the USPTO, and patent infringement litigation in U.S. courts.

• In litigation, claim construction is, at present, a task for the judge (not the jury).

• USPTO and the US courts use different standards for claim construction, and the meaning in litigation *may* be narrower than that accorded the claims in the USPTO.
  • USPTO post-grant proceedings, claims are construed according to their “broadest reasonable interpretation.”
  • In U.S. courts, claim construction is based on interpreting the claims, specification and prosecution history, generally according to the ordinary meaning, from the perspective of one of ordinary skill in the art at the time of filing to arrive at the “correct” claim construction.
Claim Construction

• Because of the different standards of claim construction, as well as different burdens of proof and presumptions concerning validity of the underlying patent, it is possible that a patent claim upheld in litigation as “not proved to be invalid,” may be later found unpatentable and canceled by the USPTO.
  • No estoppel from district court litigation to prevent the alleged infringer who loses in court litigation to return to the USPTO and contest those same claims in an appropriate post-grant proceeding.

• Further complication: when a claim construction issue is heard by the Court of Appeals for the Federal Circuit (“CAFC”).
  • Claim construction reviewed de novo on appeal.
§ 42.100 Procedure; pendency.
(a) An inter partes review is a trial subject to the procedures set forth in subpart A of this part.
(b) A claim in an unexpired patent shall be given its broadest reasonable construction in light of the specification of the patent in which it appears.

§ 42.200 Procedure; pendency.
(a) A post-grant review is a trial subject to the procedures set forth in subpart A of this part.
(b) A claim in an unexpired patent shall be given its broadest reasonable construction in light of the specification of the patent in which it appears.

• Held:
  – Federal Circuit decision not allowing attack of the decision to institute affirmed. (Part II)
    – In this case, §314(d) bars judicial review of whether PTAB wrongly instituted an IPR on grounds not specifically mentioned in a third party’s review request.

  – Federal Circuit decision affirmed (unanimous, 8-0), as to the BRI standard (Part III).
    – USPTO has authority under §316(a)(4) to enact 37 CFR §42.100(b) (BRI is the claim construction standard in IPRs).
Consider Obtaining Opinion on “Non-Estopped” Issues BEFORE Petitioning for IPR

• IPR petition may be filed anytime up to 12 months after being sued for infringement.

• IPR involves ONLY patents and printed publications under 35 U.S.C. §§102/103.
  • Except for assertion that 35 U.S.C. §112 is not met in a priority chain, thereby restricting a patent to its own filing date.

• So IPR can ONLY have estoppel on the issues of patents and printed publications under 35 U.S.C. §§102/103.
  • No petitioner estoppel in subsequent litigation against §§102/103 attacks grounded on public use, on sale, or sale.
  • No petitioner estoppel in subsequent litigation against patentable subject matter eligibility, indefiniteness, ODP, or inequitable conduct.
Consider Obtaining Opinion on “Non-Estopped” Issues BEFORE Petitioning for PGR

• PGR is a bit more tricky
  • 9-months post-issuance deadline;
  • More issues are involved, including substantive 35 U.S.C. §112 attacks.

• But again issues such as ODP or inequitable conduct will never be petitioner estoppel issues in subsequent litigation.
  – Judicially-created doctrines, not statutory.

• In opinion work, may need to choose between IPR and PGR, based on what “non-estopped” issues you want to preserve for litigation.
**ESTOPPEL**

- IPR and PGR estoppel only runs one way - issues raised by the petitioner in litigation or that could have been raised by the petitioner in litigation can still be relied on for PGR, IPR, or ex parte reexam.
Under Cuozzo as seen by USSC, Different Results Remain Very Real Possibility

- *In re Baxter Int’l*, 678 F.3d 1357 (Fed. Cir. 2012)

- Board’s decision of unpatentability affirmed despite earlier no invalidity finding in district court and affirmance by Federal Circuit.

- Federal Circuit considered Federal Circuit’s earlier affirmance of validity, but nevertheless upheld rejections.
  - PTO and courts “take different approaches in determining validity and on the same evidence could quite correctly come to different conclusions”
  - Different claim construction standards;
  - Different burdens of proof; and
  - Different records.

- “Because the two proceedings necessarily applied different burdens of proof and relied on different records,” PTO did not err in reaching different conclusion than district court.
Cuozzo at p. 19:

“Cuozzo says that the use of the broadest reasonable construction standard in inter partes review, together with use of an ordinary meaning standard in district court, may produce inconsistent results and cause added confusion. A district court may find a patent claim to be valid, and the agency may later cancel that claim in its own review. We recognize that that is so. This possibility, however, has long been present in our patent system, which provides different tracks—one in the Patent Office and one in the courts—for the review and adjudication of patent claims. As we have explained above, inter partes review imposes a different burden of proof on the challenger. These different evidentiary burdens mean that the possibility of inconsistent results is inherent to Congress’ regulatory design.”
Consistent with Cuozzo USSC: End Of Litigation May Not Be the End (Fresenius II)

- *Fresenius USA, Inc. v. Baxter Int’l., Inc.,* *(Fresenius II)*, 721 F.3d 1330 (Fed. Cir. 2013)
  - Pending infringement suit must be dismissed as moot after PTO finding of unpatentability during reexamination; wipes out $24 M damage award.
    - USPTO’s cancellation of the claims as unpatentable divested Baxter of a cause of action for infringement.

- Patentee argued that earlier final judgment by district court on damages operated as *res judicata*, precluding challenging district court’s underlying holding of validity (upheld in *Fresenius I*)
  - BRI lead to unpatentability (aff’d PTO’s determination that the rejected claims unpatentable).
  - Phillips led to no invalidity
      - Jury claims invalid, but JMOL of no invalidity and infringement.
Litigation May Not Be the End (Fresenius II) (con’t)

- **Fresenius II (con’t)**

  - Majority disagreed, distinguishing between final judgments for the purposes of appeal and final judgments for the purposes of preclusion.

  - Since scope of relief remained to be determined, there was no final judgment binding on the parties or the court.
**Competent Opinions**

- Provide the recipient with a good faith belief in its contents and conclusions.

- Make clear that all the materials necessary to support and reach the conclusion were actually considered.
  - Thorough evaluation and description of the product or process at issue
  - Patent, prosecution history, prior art

- Reflect a proper understanding and application of the current legal principles.
  - Claim construction, infringement analysis (literal and DOE)
  - Apply the law to the facts
In All Opinions: Provide the Bottom Line

- Detailed analysis of the relevant issues, including separate analysis of claims
- Accurate legal conclusions
- Indicate problem areas (shortcomings)
- Recommend solutions
  . . . AND most important, what is the bottom line?
- Give your opinion!
- State the legal and business conclusions you reach
Thank you.

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