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Patent Litigation: Formulating Infringement Positions Within the Scope of the Invention, Avoiding Untenable Positions

WEDNESDAY, APRIL 29, 2020

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

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Outline

I. Patent claims and specifications for the patent litigator

II. Formulating reasonable infringement positions
   - A. Staying within the scope of the claim
   - B. Pitfalls

III. Defending against patent suits

IV. Best practices

- *What guidance can be drawn from court decisions regarding claim construction arguments?*
- *What steps can patent litigators take to avoid untenable positions that exceed the scope of a claim?*
- *How to help litigators understand and recognize untenable positions to avoid formulating positions that attempt to stretch patent claims beyond the breaking point.*
- *What are best practices for defending against patent suits?*

Claim Construction Is Important

- *But be careful not to characterize claim language in such a way as to handicap litigation positions.*

Considerations When Arguing Claim Construction And Level Of Skill In The Art

Level of skill in the art

- Establishing high level of skill in the art may be in the best interest of a patent applicant for overcoming enablement rejection.
- Establishing low level of skill in the art may be in the best interest of a patent applicant for overcoming obviousness rejection.
- Vice versa if you are attacking the patent.

Claim construction

- Broad claim construction may be best for proving infringement and vice versa.
- Narrow claim construction may be best for patent owner for §112 or in an IPR/PGR.

Balance -> if patentee, don't shoot yourself in the foot with estoppels. If alleged infringer, shoot patent owner in the foot!

Broad Claim Construction -> 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 -> 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."
    - *For patent owner, do narrower claims exist and are they enforceable?*

Pre-Litigation

- Review of patent(s) by patent owner/licensee reveals an issue that may lead to an untenable position arguing a word means something nonsensical, e.g., “parallel” = “perpendicular” or needing to rely on disclosure that was left out of the printed patent. Alleged infringer looking for untenable positions.

Possible to correct and/or amend to strengthen patent(s) before enforcing or litigating?

Strategic Considerations

Ready your patent for battle or prepare to defend!

- Keep continuations pending.

- Consider filing a reissue or reexam.
  - Secure stronger claims.
  - Secure more claims for backup positions.
  - Get new claims blessed over new prior art.
    - "The challenger's burden is especially difficult when the prior art was before the PTO examiner during prosecution of the application." Al-Site Corp. v. VSI Intern., 174 F.3d 1308, 1324 (Fed. Cir. 1999)

Improving a Patent Post-Grant is Often a Difficult Path to Navigate

Claims cover competitor activity

Avoid prior art

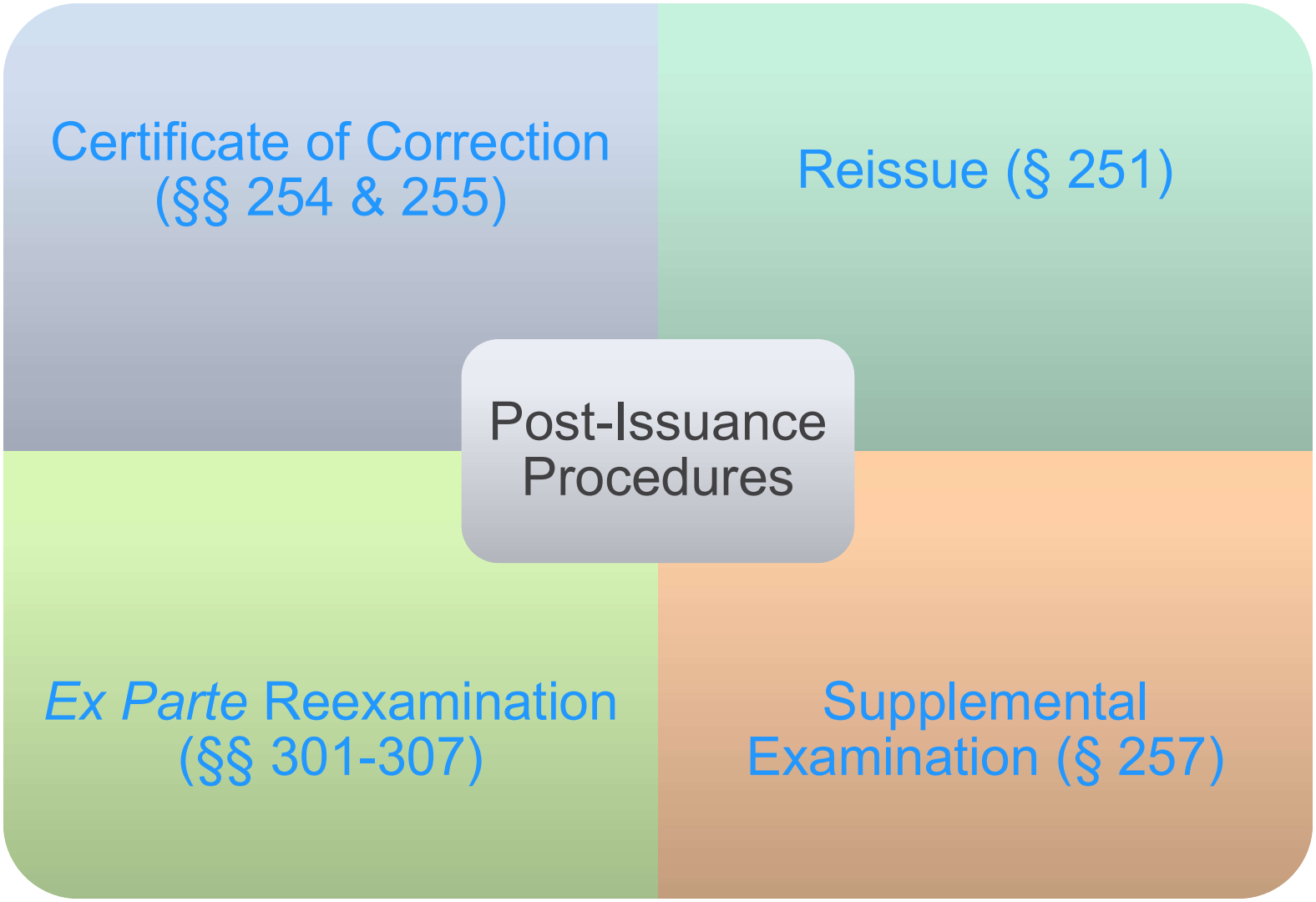
Consistent with original prosecution

Support in original application

Avoid prosecution estoppel and inequitable conduct/unclean hands

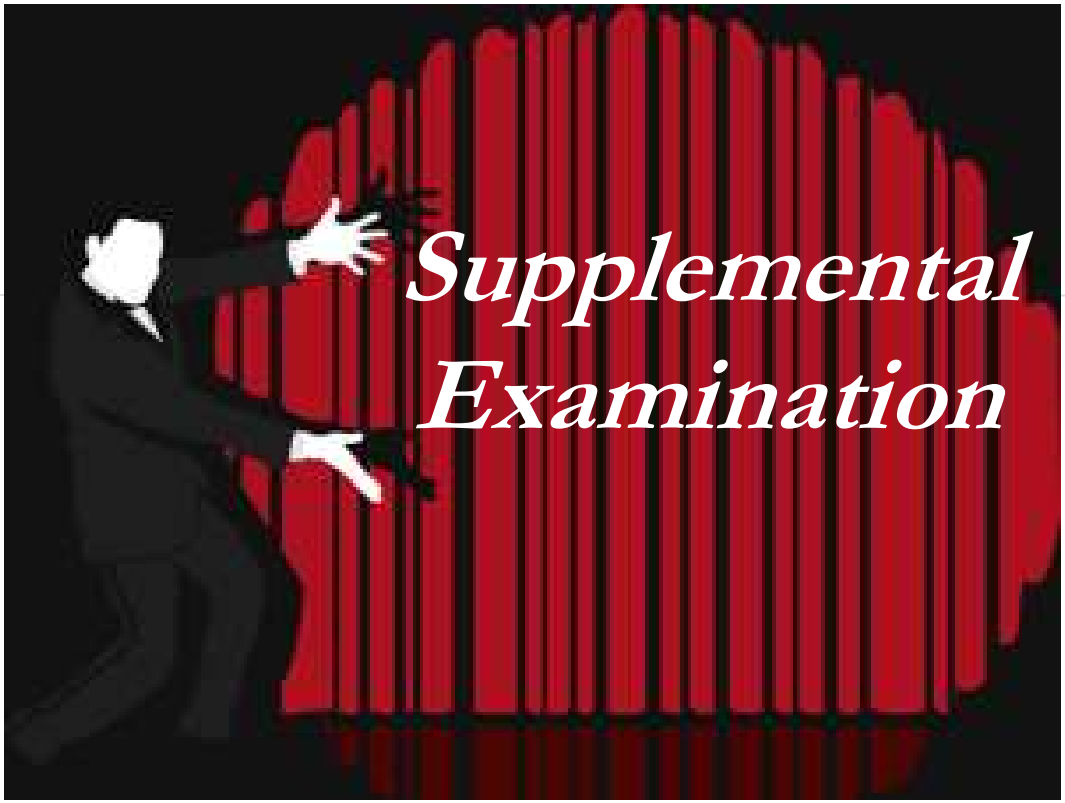
Strong claims under existing case law

Ex Parte Tools Available at USPTO



Comparison of Procedures

	Reissue	***Ex Parte Reexam***	***Supplemental Examination***
Grounds	"Error" in patent	Prior art patents or publications	"information" relevant to patentability (to cleanse of possible inequitable conduct allegation)
Examination	Like a regular application	Only two Office Actions	Only two Office Actions
Examiner	CRU	CRU	CRU
Gov't Fees	$3160	$6000 - $12,000	$4,400 initial fee $12,100 if reexam
Timing	1st Office Action in 5-8 months	1st Office Action in 4-5 months	1st Office Action in 1-2 months



- Introduced by the America Invents Act (AIA), SEC. 12.
- Effective Sept. 16, 2012, applies "to any patent issued before, on, or after that effective date"
- MPEP Ch. 2800
  - May be filed at any time during the period of enforceability of a patent.
  - No third-party participation allowed.

Supplemental Examination

- Grew out of Senator Hatch's efforts to restrict the inequitable-conduct doctrine.

- "If the Office determines that the information [that was submitted to the Office by the patent owner] does not present a substantial new question of patentability or that the patent is still valid, that information cannot later be used to hold the patent unenforceable or invalid on the basis [of] an inequitable-conduct attack in civil litigation." H.R. Rep. No. 112-98, at 50.

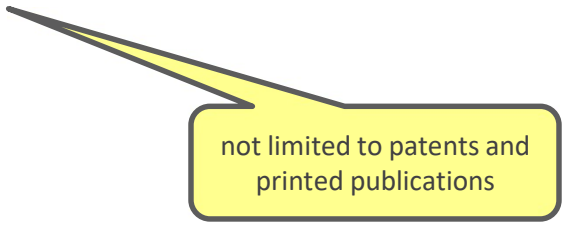
- "New section 257(c)(1) follows the usual practice of referring to inequitable conduct attacks in terms of unenforceability, rather than invalidity, though courts have in the past used the terms interchangeably when describing the effect of fraud or inequitable conduct on a patent. *J.P. Stevens & Co., Inc. v. Lex Tex Ltd.*, Inc., 747 F.2d 1553, 1560, Fed. Cir. 1984…The term should be considered to be used interchangeably with 'invalidity' in this bill as well." S1378 (daily ed. Mar. 8, 2011) (statement of Sen. Kyl).

"Consider, Reconsider, Or Correct"
Relevant Information

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

- (a) REQUEST FOR SUPPLEMENTAL EXAMINATION.—**A patent owner** may request supplemental examination of a patent in the Office to consider, reconsider, or correct information believed to be **relevant** to the patent, in accordance with such requirements as the Director may establish. **Within 3 months** …the Director shall …issu[e] a certificate indicating whether the information presented in the request raises a substantial new question of patentability."

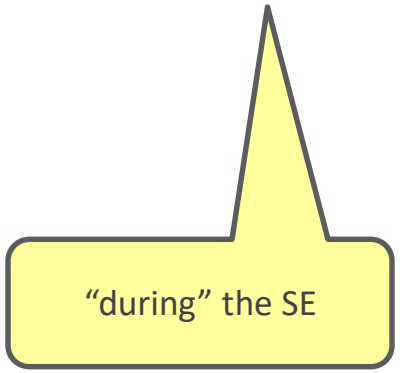
- (b) REEXAMINATION ORDERED.—If the certificate issued under subsection (a) indicates that a substantial new question of patentability is raised by 1 or more items of information in the request, the Director shall order reexamination of the patent. … During the reexamination, the Director shall address each substantial new question of patentability identified during the supplemental examination, notwithstanding the limitations in chapter 30 relating to patents and printed publication or any other provision of such chapter.



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.



Exceptions: Already Pled or in Para. iv Notice

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

- c) EFFECT.—
  - 2) EXCEPTIONS.—
    - (A) PRIOR ALLEGATIONS.—Paragraph (1) shall not apply to an allegation pled with particularity in a civil action, or set forth with particularity in a notice received by the patent owner under section 505(j) (2)(B)(iv)(II) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j) (2)(B)(iv)(II)), before the date of a supplemental examination request under subsection (a) to consider, reconsider, or correct information forming the basis for the allegation.
    - (B) PATENT ENFORCEMENT ACTIONS.—In an action brought under section 337(a) of the Tariff Act of 1930 (19 U.S.C. 1337(a)), or section 281, paragraph (1) shall not apply to any defense raised in the action that is based upon information that was considered, reconsidered, or corrected pursuant to a supplemental examination request under subsection (a), unless the supplemental examination, and any reexamination ordered pursuant to the request, are concluded before the date on which the action is brought.

Burden On Patent Owners For Supplemental Examination

- Steep fee, § 1.20(k) Supplemental Examination
  - $4,400 for request + $12,100 if reexam ordered
  - $180 per nonpatent document 21-50 pages in length + $280 per page above 50 pages

- Patent owner admissions
  - § 1.610(b) A request for supplemental examination **must** include:
    - (5) A separate, detailed explanation of the relevance and manner of applying each item of information to each claim of the patent for which supplemental examination is requested.

- Limit to number of items that a patent owner may raise in a request for supplemental examination.
  - § 1.605 No more than **12** items believed to be relevant to the patent.

- §1.620: (e) No interviews and (f) no amendments (though amendments may be made in subsequent reexam, if ordered).

Fraud Reported to AG

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

- (e) FRAUD.—If the Director becomes aware, during the course of a supplemental examination or reexamination proceeding ordered under this section, that a material fraud on the Office may have been committed in connection with the patent that is the subject of the supplemental examination, then in addition to any other actions the Director is authorized to take, including the cancellation of any claims found to be invalid under section 307 as a result of a reexamination ordered under this section, the Director shall also refer the matter to the Attorney General for such further action as the Attorney General may deem appropriate. Any such referral shall be treated as confidential, shall not be included in the file of the patent, and shall not be disclosed to the public unless the United States charges a person with a criminal offense in connection with such referral.

Other Sanctions

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

- (f) RULE OF CONSTRUCTION.—Nothing in this section shall be construed—
  - (1) to preclude the imposition of sanctions based upon criminal or antitrust laws (including section 1001(a) of title 18, the first section of the Clayton Act, and section 5 of the Federal Trade Commission Act to the extent that section relates to unfair methods of competition);
  - (2) to limit the authority of the Director to investigate issues of possible misconduct and impose sanctions for misconduct in connection with matters or proceedings before the Office; or
  - (3) to limit the authority of the Director to issue regulations under chapter 3 relating to sanctions for misconduct by representatives practicing before the Office.

So far, no published accounts of fraud reported to AG or other sanctions.

M.P.E.P.

- Chapter 2800.
- SE requests may only be filed by the patent owner (of the entire right, title, and interest in the patent).
- May be filed at any time during the period of enforceability of a patent.
- No third-party participation allowed.
- Public access to SE requests and accompanying material only available once the request is granted a filing date.
- §2811.01: "The patent owner must explain, for each claim requested to be examined, either (1) what the item of information teaches with respect to that claims, or (2) which teaching contained in the item of information may be considered by an examiner to be important when determining the patentability of that claim.
  - See also, §2816.02 and §2816.03.

What If You Forget A Claim?

In re Tanaka, 640 F.3d 1246 (Fed. Cir. 2011)

- Board held that it is not reissue "error" under 35 U.S.C. §251 to add a subgeneric claim where all existing claims in the patent are maintained, both broader and narrower than the added claim.

- FC: Reversed and remanded.
  - "adding dependent claims as a hedge against possible invalidity of original claims "is a proper reason for asking that a reissue be granted." In re Handel, 50 CCPA 918, 312 F.2d 943, 946 n. 2 (1963)."
  - "the omission of a narrower claim from a patent can render a patent partly inoperative by failing to protect the disclosed invention to the full extent allowed by law."

NOTE: AIA removes "without deceptive intention" as requirement of reissue §251; applies to proceedings commenced on or after Sept. 16, 2012.

Could Also Possibly Do A Narrower Claim Through Supp Exam

- SE 96/000,021
- U.S. Pat. 6,114,313
- Items requested to be considered:
  - WO 94/18216 (the '216 publication)
  - JP 58-74696 ('the 696 publication)

- **USPTO**: A reasonable examiner would consider the teachings of the '216 publication and the '696 publication important in deciding whether claims 1-13 of the '313 patent are patentable."

- Reexamination certificate issued: claims canceled, amended claims, new claims.

- Win, win to extent that patent owner gets amended claims and new claims and those claims should be free of inequitable conduct charges based on the two items submitted for supplemental examination.

Could Also Possibly Do A Narrower Claim Through Supp Exam

- SE 96/000,185
- U.S. Patent 9,428,647 claim 1-8.

- Submitted 9 items of information, which the patent owner said "[t]hrough a clerical oversight, no Information Disclosure Citation was filed during prosecution of the original . . . application."
  - *Note, no explanation of what exactly the clerical oversight was, how it occurred, or when it was discovered, and the USPTO did not request any explanation during the resulting reexamination proceeding.*

- SNQ found based on two of the items of information submitted, and ex parte reexamination ordered.

- Non-final rejection of claims 2, 5, 6, and 7 based on § 112 and claims 1, 2, and 7 under §102(a)(1).

- Patent Owner canceled claim 5 and amended claims 1, 2, 6, and 7 to incorporate limitations of claim 5 into independent claim 1, as clarifications. (*to avoid Festo?*)

- Reexam Certificate issued.

Bolster Reissue Application with Expert Declarations

- Supporting claim construction, written description (possession), enablement, definiteness, nonobviousness.

- Consider *Therasense*
  - Careful thought and planning.
    - False declaration per se “egregious.”

May Also Bolster SE Request with Expert Declarations

- SE 96/000,297
- U.S. Pat. 10,004,708
- Item of information: WO 2017/201200 (Thacher), inventor declaration, consulting agreement.

- Patent owner: Thacher can only qualify as prior art under 35 U.S.C. §102(a)(2), but the exception under 35 U.S.C. §102(b)(2)(A) applies to remove it.
  - "the relevant subject matter disclosed in Thacher was obtained directly from the inventors of the '708 patent."
  - Supported by inventor declaration.

- Patent owner: Alternatively, Thacher is not prior art because the exception under 35 U.S.C. §102(b)(2)(C) applies (relevant subject matter disclosed in Thacher was subject to an obligation of assignment to IO Therapeutics before the effective filing date of the '708 patent.
  - Supported by consulting agreement.

May Also Bolster SE Request with Expert Declarations

- Examiner concluded no SNQ.
- "this reference is not available as prior art against the claims of the '708 patent."
- "The Thacher reference is an inventor-originated disclosure from the two named inventors of the '708 Patent that meets the exception requirements of 35 U.S.C. §102(b)(2)(A).
- Use of declarations allowed and may be persuasive. Note, these declarations were to support position in SE request. They were not separate "items of information."
- The reference was a patent application, but this SE was used to remove the potential prior art status of Thacher – claims now protected from validity challenge based on Thacher.

Make Sure §112 Chain Tight

- §112(a) attacks on priority date of challenged claims.
- Can even be used in IPR, even though IPR grounds are limited to patents and printed publications.

Little Ability to Amend at Court

U.S. courts can correct only errors plainly evident on face of patent

- H-W Tech. v. Overstock.com (Fed. Cir. 2014) (refusing to correct error that was only evident from prosecution history)
- Chef America, Inc. v. Lamb-Weston, Inc., (Fed. Cir. 2004) (refusing to fix a claim reciting heating dough "to" a temperature instead of "at" the temperature)

Court will not consider a Certificate of Correction obtained after patent owner files suit

- The CoC is only effective for causes of action arising after it was issued
  - See H-W Tech. v. Overstock.com (Fed. Cir. 2014) (because did not obtain CoC until after filing lawsuit, CoC was not effective in lawsuit and court found claim indefinite)

Strategic Considerations

What if the competitor files an IPR/PGR petition before you can fix your patent?

If want to amend, consider:

- Pursue claims in reissue/reexam that do not overlap with those challenged and that can be shown to be separately patentable.
- In other words, pursue claim amendments that are patentably distinct from original claims (see 37 CFR § 42.73(d)(3)) but that are also infringed / useful.
- Intervening rights issues

EXAMPLE: Legend3D v. Prime Focus, IPR2016-00806

- Claims in reissue "nearly identical" to claims in IPR Motion to Amend.
- PTAB granted stay of reissue application (No. 15/394,366).
- After IPR complete, Patentee argued for lift of stay:
  - Claims in the reissue application patentably distinct from the original claims at issue in the IPR.
  - No longer a concern about duplicate efforts or inconsistent results.
- PTAB agreed and lifted the stay (Dec. 8, 2017).
- Reissue application pending, last action Aug. 9, 2019.

Correctable Pre-Litigation?

- *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.

What If "About" Modifies Some Ranges But Not Others?

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

- Claim 1. A two-phase porcelain composition comprising a leucite crystallite phase dispersed in a feldspathic glass matrix, a maturing temperature of from *about* 750° 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:

Component	Amount (wt.%)	Component	Amount (wt.%)
SiO_2	57-66	Li_2O	0.5-3
Al_2O_3	7-15	CaO	0-3
K_2O	7-15	MgO	0-7
Na_2O	7-12	F	0-4
CeO_2	0-1		

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.

Designing around by alleged infringer

"About"

- *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.

What If the Patent Uses "And/Or"?

- "at least one of a W, a X, a Y, and/or a Z"
  - Creates unnecessary ambiguity? Claim construction; not infringed, as construed?
  - Does disclosure support amending to "at least one ____ (needs to be a noun) chosen from a and b," clearly covers "and/or".

- Another approach is present an independent claim embodiment A and another independent claim to embodiment B.
  - But if on Track I, that spends two independent claims.

Does The Form of the Lists Recited Match the Disclosure?

- 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?

- Likely, yes, so defender fights for broad claim construction

  - "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)

Could Ambiguity In the Limiting Effect of the Preamble Be Fixed?

Butamax Advanced Biofuels LLC v. Gevo, Inc., IPR2014-00250, Paper 29 (P.T.A.B. March 13, 2015)

- Claim 1. A process for preparing a renewable jet fuel comprising: . . . whereby the product of step (g) meets the requirements of ASTM D1655.
- Claim 18. A renewable jet fuel or jet fuel precursor comprising a mixture of aromatic hydrocarbons and C11–C14 aliphatic hydrocarbons.
- PTAB FWD:
  - Preamble in claim 1 not limiting - states an intended use; not relied upon to define subject matter of claimed invention because explicitly recited in body of claim.
  - Preamble in claim 18 is limiting – "recites a specific characteristic of the source component of the invention."

See also Golden Bridge Technology, Inc. v. Apple Inc., 758 F.3d 1362 (Fed. Cir. 2014), for an example of comments about the preamble in an IDS were found to be a disavowal impacting claim construction. Exercise caution when it comes to patentability statements! Capitalize if you are the proposed infringer.

Any Disclosure-Dedication Issue?

Subject matter disclosed but not claimed establishes dedication to the public. Fix if patentee? Attack if alleged infringer?

- *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."

Critical Aspects Of Invention Need To Be Claimed For Objective Evidence To Stick

- *Fox Factory, Inc. v. SRAM, LLC*, 944 F.3d 1366 (Fed. Cir. 2019)
  - PTAB FWD claims not shown to have been obvious; presumed nexus between objective evidence and claims.
    - Presumption of nexus applies when a product is "coextensive" with the claims and "coextensive" means claims must broadly cover the product that is the subject of the objective evidence.
  - FC: Vacate and remand.
    - Specification disclosed features not recited in claims that contributed to "improving chain retention."
    - "SRAM's X-Sync chainrings are not coextensive with the independent claims."
    - "Although we do not require the patentee to prove perfect correspondence to meet the coextensiveness requirement, what we do require is that the patentee demonstrate that the product is essentially the claimed invention."

Beware of Principles In Tension in Claim Construction Arguments

- "[A] court may not read into a claim a limitation from a preferred embodiment, if that limitation is not present in the claim itself." *Bayer AG v. Biovail Corp.*, 279 F.3d 1340, 1348 (Fed. Cir. 2002).
  - Could help a patentee in proving infringement; could help the accused in demonstrating invalidity/unpatentability.

- "When the preferred embodiment is described in the specification as the invention itself, the claims are not necessarily entitled to a scope broader than that embodiment." *SciMed Life Sys. v. Advanced Cardiovascular Sys.,* 242 F.3d 1337 (Fed. Cir. 2001), quoting *Modine Mfg. Co. v. United States Int'l Trade Comm'n*, 75 F.3d 1545, 1551 (Fed. Cir. 1996).
  - Could help the accused for non-infringement; could help the patentee for validity/patentability.

Ensuring Compliance - §112(b) Definiteness Requirement

- Consider including definitions in specification!
- Words of degree can be risky and require special attention.
- Definiteness requirement does not require greater precision than the subject matter permits.
  - *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367 (Fed. Cir. 1986)
    - Claim limitation: "affinity for the antigenic substance of at least about 10^8 liters/mole"
    - FC: Claims are NOT indefinite.
      - "the claims, read in light of the specification, reasonably apprise those skilled in the art and are as precise as the subject matter permits. As a matter of law, no court can demand more."
- If precision is challenged, consider Rule 132 declaration of expert explaining the degree of precision available (for patentee) (or lack thereof for accused) in the relevant art at the relevant time.
- During prosecution, interview – ask what Examiner wants.

Recent Application Of Hybritech Principle

Guangdong Alison Hi-Tech Co. v. ITC, 936 F.3d 1353 (Fed. Cir. 2019)

- Claim: 1. A composite article to serve as a flexible, durable, light-weight insulation product, said article comprising a *lofty* fibrous *batting* sheet and a continuous aerogel through said batting.
- Specification: ""lofty batting" is "a fibrous material that shows the properties of bulk and some resilience (with or without full bulk recovery)."

- Alison argument: "patent fails to disclose precisely how much resilience is enough to satisfy the claim."

- ITC: Term not indefinite.
  - Bulk and resilience further explained in spec.

Recent Recital Of Hybritech Principle

Guangdong (con't)

- FC: Affirmed.
  - Written description (description, functional characteristics, several examples) "informs the meaning of 'lofty…batting' with reasonable certainty."
  - "[t]he degree of precision necessary for adequate claims is a function of the nature of the subject matter."
  - "While we agree that 'lofty . . . batting' is a term of degree, Alison seeks a level of 'mathematical precision' beyond what the law requires."
  - "written description provided sufficient guidance and points of comparison to render claim terms not indefinite."
  - Rejected "multiple ways to measure" argument: "Because 'lofty . . . batting' is expressly defined by the '359 patent based on two properties, bulk and resilience, we find it unremarkable that the specification discloses two methods of measuring loftiness."

§112a Considerations

35 U.S.C. §112(a) IN GENERAL.—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, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.

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

- 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."

Be Prepared – This Is Not Your Grandma's Enablement or WD

- Nuvo v. Dr. Reddy's, 923 F.3d 1368 (Fed. Cir. 2019): claims invalid for lack of written description support.
  - "the specification provides nothing more than the mere claim that uncoated PPI might work, even though persons of ordinary skill in the art would not have thought it would work, the specification is fatally flawed. It does not demonstrate that the inventor possessed more than a mere wish or hope that uncoated PPI would work, and thus it does not demonstrate that he actually invented what he claimed: an amount of uncoated PPI that is effective to raise the gastric pH to at least 3.5."
  - Ammunition for the accused

- Idenix Pharms. LLC v. Gilead Sciences Inc., 941 F.3d 1149 (Fed. Cir. 2019): claims invalid for lack of enablement and written description support.
  - Thousands of candidates meet the structural limitations of the claims but lack of meaningful guidance as to which will work.
  - Specification failed to provide sufficient "blaze-marks" to direct POSITA to subset of candidates that will work. The lists of effective nucleosides do not explain "what makes them effective, or why."
  - Ammunition for the accused

Examples May Provide §112 Support, But Caution: Verb Tense For Actual Vs. Prophetic Examples

Hoffmann-LaRoche, Inc. v. Promega Corp., 323 F.3d 1354 (Fed. Cir. 2003)

- Example 6 written overwhelmingly in past tense but not performed as written.
  - Originated from Preps 3 and 4; contained all steps but not same order as Example 6.
- Conducting Example 6 as written would give a different result than that obtained with Preps 3 and 4.

- Materiality: threshold level met
  - Response to office action: asserted that claimed product was more pure than prior art product.
  - Reasonable examiner would want to know there were no experimental results to support purity.
- Intent: threshold level met
  - Inventor knew past tense = actual work done.
  - Roche provided no reason why past tense used for an experiment not performed.
  - No evidence of oversight in use of past tense.
  - No clear error in concluding use of past tense was knowingly false.

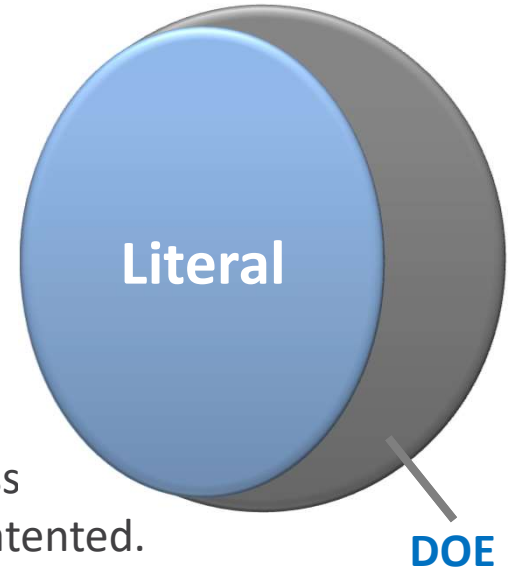
- FC: Remanded to determine if CAFC's findings of inequitable conduct justify sanction of unenforceability.

What If You Want to Argue Infringement Under the Doctrine of Equivalents?

Doctrine of Equivalents (DOE)

- Purpose of DOE:
  - DOE prevents copying of an invention that would effectively "convert the protection of the patent grant into a hollow and useless thing."

- Determining Equivalency:
  - Function-Way-Result (FWR) Test
    - Whether the accused product performs "substantially the same function in substantially the same way to obtain the same result"
  - Insubstantial Difference Test
    - Whether the accused product or process is substantially different from what is patented.



  - *May want to argue one rather than the other depending on facts.*

Amgen v. Sandoz. 923 F.3d 1023 (Fed. Cir. 2019)

- Litigation regarding Sandoz's aBLAs to market biosimilars of Amgen's Neupogen® (filgrastim) and Amgen's Neulasta® (pegligrastim)

- Claim 7 of '878 patent:
  - A method of purifying a protein expressed in a non-native limited solubility form in a non-mammalian expression system comprising:
  - (a) expressing a protein . . . ; (b) lysing a non-mammalian cell ; (c) solubilizing the expressed protein . . . ; (d) forming a refold solution;
  - (e) ***directly applying*** the refold solution to a separation matrix . . . ;
  - (f) ***washing*** the separation matrix; and
  - (g) ***eluting*** the protein from the separation matrix . . . .

- District Court construed claim elements (f) and (g) as separate and consecutive steps.

- Sandoz's process only involves one step—applying the refold solution to the matrix, with no separate washing or eluting steps.

Amgen v. Sandoz (con't)

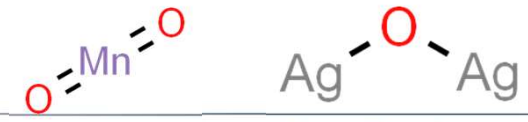
- Amgen argued that Sandoz's one-step, one-solution process is insubstantially different from the claimed three-step, three-solution process because it "achieves the same functions (washing and eluting), in substantially the same way (binding protein preferentially compared to contaminants, and then raising salt concentration to reverse protein binding) to achieve the same result (protein purification)."

- CAFC (Lourie, O'Malley, Reyna): Upheld district court's claim construction and district court's finding of non-infringement under DOE
  - "[T]he claim language logically requires that the process steps, lettered (a) through (g), be performed in sequence."
  - "[W]ashing and eluting are consistently described in the specification as separate steps performed by different solutions."
  - "[O]ur precedent prohibits us from overriding the natural language of claim 7 to extend these limitations to cover nearly any type of adsorbent chromatographic separation."
  - Sandoz's "one-step, one-solution purification process works in a substantially different way from the claimed three-step, three-solution process."
  - **"The doctrine of equivalents applies only in exceptional cases and is not 'simply the second prong of every infringement charge, regularly available to extend protection beyond the scope of the claims.'"**

- *Petition for panel rehearing granted in part to strike out "applies only in exceptional cases."*

Mylan v. Aurobindo, 857 F.3d 858 (Fed. Cir. 2017)

- Litigation regarding Aurobindo's isosulfan blue ("ISB") product that allegedly infringed Mylan's patents.
- Around 1981, Hirsch Industries (later Covidien) developed a 1% injectable solution of ISB, which it commercialized as Lymphazurin®.
- From its inception, Lymphazurin®'s production has been plagued by difficulties in synthesizing and purifying ISB.
- Mylan found a way to synthesize and purify ISB; FDA approved Mylan's ANDA to market a generic Lymphazurin® in 2010.
- Mylan became the sole supplier of the 1% ISB drug product, as Covidien withdrew Lymphazurin® from the market in 2012.
- Claim 1 of '050 patent: A process of preparing [ISB sodium salt] comprising combining a suspension of isoleuco acid in a polar solvent with silver oxide, recovering isosulfan blue acid, and treating the isosulfan blue acid with a sodium solution.
- Aurobindo used manganese dioxide instead of silver oxide:



Mylan v. Aurobindo (con't)

- District Court granted preliminary injunction finding, inter alia, that Aurobindo "more likely than not" infringes the process patents under DOE.
  - Differences in oxidation strength between silver oxide and manganese dioxide is irrelevant under both the FWR test and insubstantial differences test because the claims do not specify a requirement of oxidation strength.
  - Credited Mylan's expert testimony that the silver oxide and manganese dioxide processes produce crude ISB in similar yields.
  - If manganese dioxide was a substantially stronger oxidizing agent than silver oxide, a skilled artisan would expect different results.

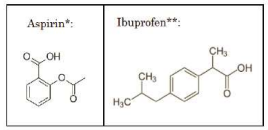
- CAFC (Lourie, Moore, Reyna): The district court's analysis of equivalence in this case was flawed.
  - Each limitation must satisfy an equivalence test.
  - For a chemical process claim, the "result of a process producing a chemical compound may be clear, but the 'function' and 'way' of a particular limitation of a chemical process claim may remain vague and often overlap".
  - Under FWR test, the court failed to address the "way" prong.
  - The district court abused its discretion in rejecting Aurobindo's argument regarding the difference in oxidation strength between manganese dioxide and silver oxide.
  - "Critical facts that might be considered in an equivalents analysis [for the way prong] include the relative oxidation strengths of the two oxidizing agents, as argued by Aurobindo, and the fact that manganese dioxide requires the use of an acid for oxidation, but silver dioxide does not, and results in a different yield."

Mylan v. Aurobindo (con't)

- CAFC: The FWR test may be less appropriate for evaluating equivalence in chemical compounds if it cannot capture substantial differences between a claimed and accused compound.
  - "For example, consider the well-known compounds aspirin and ibuprofen, which chemists would not usually consider to be structural equivalents under the insubstantial differences test. . . . [T]he two compounds would seem to be substantial equivalents under the FWR test. They each provide analgesia and anti-inflammatory activity ("function") by inhibiting prostaglandin synthesis ("way") in order to alleviate pain, reduce fevers, and lessen inflammation ("result")."

  - "In this case, the district court conducted an incomplete FWR analysis while essentially bypassing the substantial differences test, in a situation where the latter test might seemingly be more appropriate."
    - "[T]he court failed to consider whether the key reagent in the process, manganese dioxide, was substantially different from the claimed reagent, silver oxide, and hence whether the substitution for, and omission of, silver oxide left the accused infringer outside the bounds of the claims."
    - "Manganese dioxide and silver oxide are substantially different in many respects. For example, manganese and silver are in different groups of the Periodic Table. In oxide form, manganese has an oxidation state of +4, while silver is +1."

APPENDIX



* acetylsalicylic acid
** (*RS*)-2-(4-(2-methylpropyl)phenyl)propionic acid

Pozen v. Par Pharma, 696 F.3d 1151 (Fed. Cir. 2012)

- ANDA litigation regarding Par's proposed generic for Pozen's Treximet® (combination of naproxen and sumatriptan), a drug for treatment of migraines.

- Claim 1 of the '499 patent: A multilayer pharmaceutical tablet comprising naproxen and a triptan and, wherein:
  - a) substantially all of said triptan is in a first layer of said tablet and substantially all of said naproxen is in a second layer; and
  - b) said first layer and said second layer are in a side by side arrangement such that the dissolution of said naproxen occurs independently of said triptan.

- Par's ANDA product included 100% of the tablet's triptan and 15% of the tablet's naproxen in the first layer, with the remaining 85% of the naproxen in the second layer.

- Court construed a) to mean "at least 90%, and preferably greater than 95%, of the total triptan present in the tablet is included within one distinct layer and at least 90%, and preferably greater than 95%, of the naproxen present in the tablet is included within a second distinct layer."
  - "The doctrine of equivalents is not foreclosed with respect to claimed ranges."
  - Same function: Separate, distinct layers of triptan and naproxen.
  - Same way to achieve function: By formulating the triptan and naproxen in different manners to create physical barriers.
  - Same result: Substantially naproxen is separated from the triptan, thereby providing independent dissolution.

Pozen v. Par Pharma (con't)

- Parties agreed that b) means "dissolution of naproxen and triptan from the multilayer tablet occurs in the same amount of time ± 10% as when the same amount of naproxen . . . and triptan are given separately" (described in specification).
- No direct evidence comparing the rate of dissolution of the NDA products to that of the agents individually.
- CAFC affirmed the district court's finding of infringement under DOE based on the evidence below:
  - Par's ANDA stated: "Most of our experiments were targeted to match the in-vitro dissolution profile of the individual brands. Naproxen Sodium, is poorly soluble in lower pH conditions, and tends to form a gel like matrix and thereby retard the release of co-administered drugs. Our primary objective is to develop a formulation having minimal effect of Naproxen Sodium over Sumatriptan Succinate dissolution, thereby having release profiles independent of each other in all the pH conditions. . . ."
  - Par's expert showed that triptan dissolves completely and independently from the naproxen and that the naproxen dissolves completely and independently from the triptan in the ANDA product.

Intendis v. Glenmark, 822 F.3d 1355 (Fed. Cir. 2016)

- ANDA litigation regarding Glenmark's proposed generic for Intendis's Finacea® (azelaic acid) Gel, a topical drug for treatment of inflammatory papules and pustules of mild to moderate rosacea

- Claim 1 of '070 patent: A composition that comprises:
  (i) azelaic acid as a therapeutically active ingredient in a concentration of 5 to 20% by weight,

  (iii) at least one triacylglyceride3Link to the text of the note in a concentration of 0.5 to 5% by weight,

  (iv) propylene glycol, and

  (v) at least one polysorbate, in an aqueous phase that further comprises water and salts, and the composition further comprises

  (ii) at least one polyacrylic acid, and

  (vi) lecithin, wherein the composition is in the form of a hydrogel.

- Glenmark's ANDA product included isopropyl myristate.

Intendis v. Glenmark (con't)

- Glenmark's argument: The patent does not state the function of lecithins or triglycerides

- CAFC (Moore, Prost, Taranto): Glenmark's isopropyl myristate is an equivalent to triglyceride and lecithin.
  - Function = Enhancing azelaic acid's penetration of the skin.
    - Several experts testified that the claimed excipients could act as penetration enhancers.
    - Glenmark's ANDA included repeated statements that both Glenmark's excipient and the claimed excipients function as penetration enhancers.
  - Way = By disrupting the lipids in the skin's outermost layer, known as the stratum corneum.
  - Result = A therapeutically effective azelaic acid composition that is able to penetrate the skin in order to deliver the active ingredient

  - "[W]e are not presented with the issue of the substantiality of the differences between the chemical structures of isopropyl myristate, triglyceride, and lecithin. This appeal is limited to whether the district court clearly erred when it determined that triglyceride and lecithin function as penetration enhancers in the claimed compounds."

  - "[W]e disagree that the lack of disclosure of the claimed excipients as penetration enhancers in the '070 patent is fatal to Appellee's infringement case."
    - "The relevant inquiry is what the claim element's function in the claimed composition is to one of skill in the art, and a fact finder may rely on extrinsic evidence in making this factual determination."
    - "Fatal to Glenmark's argument is its own ANDA submission to the FDA repeatedly referring to the claimed excipients as penetration enhancers."

Which Test?

- Focus on insubstantial differences test to determine equivalency for chemical compounds.
  - Since the Mylan CAFC decision, district courts have used insubstantial differences test for chemical compound cases (e.g., UCB (acrylate-based or silicone-based polymer adhesives vs. polyisobutylene adhesive) and Lilly (pemetrexed disodium vs. pemetrexed ditromethamine)).
  - Still perform Function-Way-Result test in case courts find the FWR test more applicable (see *Intendis*).

- Note, FWR test is still used frequently.
  - *Par v. Pozen* – quantitative elements; "substantially all" and independent dissolution.
  - *Intendis v. Glenmark* – equivalency of penetration enhancers.
  - *Amgen v. Sandoz* – method of purifying protein.

Judicial Limitations on DOE

- Prosecution history estoppel
- Narrow claiming
- All-Limitations Rule
- Dedication-Disclosure
- Narrowing statements in specification or prosecution
- Ensnarement

Ensnarement

- "A patentee may not assert 'a scope of equivalency that would encompass, or ensnare, the prior art.'"
  - *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1322 (Fed. Cir. 2009)

- First step: Construct a hypothetical claim that literally covers the accused product.

- Second step: Determine whether the patentee has carried its burden of persuading the court that the hypothetical claim is patentable over the prior art.

Intendis v. Glenmark, 822 F.3d 1355 (Fed. Cir. 2016)

- Glenmark argued that the hypothetical claim must be construed to capture all penetration enhancers.

- Glenmark did not challenge the district court's determination that the hypothetical claim as constructed would have been patentable

- CAFC: No ensnarement.
  - Glenmark's asserted prior art = "Gasco," which disclosed a microemulsion containing azelaic acid and DMSO as a penetration enhancer.
  - Did not disclose isopropyl myristate, lecithin, or triglyceride.
  - District court adopted a proper hypothetical claim, one that includes triglycerides and lecithin or alternatively isopropyl myristate.

Prosecution History Estoppel

- Two types: (1) Amendment-based estoppel; and (2) Argument-based estoppel.

- Presumption of **amendment-based estoppel**: A patentee's decision to narrow his claims through amendment may be presumed to be a general disclaimer of the territory between the original claim and the amended claim.
  - Overcoming presumption:
    - Equivalent may have been unforeseeable at the time of the application;
    - The rationale underlying the amendment may bear no more than a tangential relation to the equivalent in question; or
    - Some other reason suggesting that the patentee could not reasonably be expected to have described the insubstantial substitute in question.

- **Argument-based estoppel**: Only applies when the prosecution history evinces a clear and unmistakable surrender of subject matter.

Intendis v. Glenmark, 822 F.3d 1355 (Fed. Cir. 2016)

- Glenmark argued that Applicants expressly disavowed and disclaimed formulations without lecithin.

- Prosecution history
  - The examiner noted that two dependent claims reciting "concentration of up to 1%" and "concentration of up to 3%" of lecithin could include zero lecithin.
  - Applicants argued that those range limitations clearly did not include zero because they depend from claims that require lecithin.
  - Regardless, Applicants amended the two claims to recite "concentration of from more than 0 to 1%" and "concentration of from more than 0 to 3%".

- CAFC: Amendment-based estoppel does not apply because the amendment was not a narrowing amendment; rather, the amendment was a clarifying amendment.

Eli Lilly v. Hospira
933 F.3d 1320 (Fed. Cir. 2019)

- ANDA litigation regarding Hospira's proposed generic for Lilly's Alimta® (pemetrexed disodium) for treating certain types of non-small cell lung cancer and mesothelioma.

- Claim 12 of '209 patent: An improved method for administering pemetrexed disodium to a patient in need of chemo-therapeutic treatment, wherein the improvement comprises:
  - a) administration of between about 350 µg and about 1000 µg of folic acid prior to the administration of pemetrexed disodium;
  - b) administration of about 500 µg to about 1500 µg of vitamin B12, prior to the first administration of pemetrexed disodium; and
  - c) administration of pemetrexed disodium.

- Hospira's ANDA product included pemetrexed ditromethamine salt, rather than the claimed pemetrexed disodium salt.

- District Court construed "administration of pemetrexed disodium" to mean "liquid administration of pemetrexed disodium".

Eli Lilly v. Hospira (con't)

- Prosecution history
  - Original independent claims recited "an antifolate" instead of "pemetrexed disodium".
  - In order to overcome anticipation and obviousness rejections, Applicant amended "an antifolate" to "pemetrexed disodium" in the independent claims.
    - Applicant argued that the amendment overcame the anticipation rejection because reference 1 does not disclose pemetrexed disodium. Applicant also argued that, while reference 2 discloses hematologic and immunologic toxicities from administration of pemetrexed disodium, it never suggested vitamin supplementation.
  - Examiner withdrew the anticipation and obviousness rejections.

- Lilly conceded that the amendment was both narrowing and made for a substantial reason relating to patentability, but argued that it was "no more than a tangential relation to the equivalent in question".

- The reason for amendment was to distinguish pemetrexed from antifolates generally and that the different salt type is a merely tangential change with no consequence for pemetrexed's administration of mechanism of action within the body.

Eli Lilly v. Hospira (con't)

- CAFC (Lourie, Moore, Taranto): No PHE.
  - "The reason for Lilly's amendment . . . was to narrow original claim 2 to avoid [reference 1], which only discloses treatments using methotrexate, a different antifolate."
  - "[T]he particular salt to which pemetrexed is complexed relates only tenuously to the reason for the narrowing amendment, which was to avoid [reference 1]."

- Appellants argued that where the reason for the amendment and the equivalent in question both relate to the same claim element, the tangential exception should not apply.

- CAFC: No bright line rule; "Whether an amendment was merely tangential to an equivalent must be decided in the context of the invention disclosed in the patent and the prosecution history".
  - Here, "we conclude that this consideration is not dispositive because the rest of the prosecution history, and the '209 patent itself, show that it was implausible that the reason for Lilly's amendment was to surrender other pemetrexed salts."
  - "Indeed, such as relinquishment would effectively dedicate the entirety of Lilly's invention to the public and thereby render the '209 patent worthless, and it would have been irrelevant for distinguishing the prior art."

Amgen v. Coherus, 931 F.3d 1154 (Fed. Cir. 2019)

- Litigation regarding Coherus's aBLA for a biosimilar version of Amgen's pegfilgrastim product Neulasta®

- Claim 1. A process for purifying a protein on a hydrophobic interaction chromatography column such that the dynamic capacity of the column is increased for the protein comprising
  - mixing a preparation containing the protein with a combination of a first salt and a second salt,
  - loading the mixture onto a hydrophobic interaction chromatography column, and eluting the protein,
  - wherein the first and second salts are selected from the group consisting of citrate and sulfate, citrate and acetate, and sulfate and acetate, respectively, and . . . .

- Coherus's proposed ANDA product does not include any of the three recited salt combinations.

- Amgen asserted DOE infringement.

Amgen v. Coherus (con't)

- Coherus filed a Rule 12(c) motion to dismiss the complaint for failure to state a claim, arguing that Amgen is barred from seeking DOE infringement for under prosecution history estoppel.

- Prosecution history:
  - The Examiner rejected the pending claims as obvious in view of "Holtz," which disclosed several salts for improving hydrophobic interactions between a protein and the column matrix.
  - Amgen responded by pointing out that "the pending claims recite a particular combination of salts," and that no combination of salts is taught in Holtz, and no particular combination is taught in Holtz.
    - Amgen submitted a declaration supporting that using the particular combinations of salts resulted in substantial increases in the dynamic capacity of a HIC column and reduced purification costs compared to using a single salt.

- District Court granted Coherus's motion to dismiss finding prosecution history estoppel barring any DOE assertion.

Amgen v. Coherus (con't)

- Amgen argued that it distinguished Holtz on the basis that Holtz failed to disclose increasing dynamic capacity and failed to disclose any salt combinations at all.

- CAFC (Stoll, Reyna, Hughes): Affirmed district court's dismissal.
  - "We hold that argument-based prosecution history estoppel applies here because Amgen clearly and unmistakably surrendered unclaimed salt combinations during prosecution."
  - Prosecution history estoppel applies to the "particular combinations" ground regardless of the other arguments Amgen made.
  - Although Amgen asserted three bases for distinguishing Holtz—(1) no combinations of salts are taught in Holtz; (2) no particular combinations of slats are taught in Holtz; and (3) there is no description in Holtz for the use of any combination of salts to increase the dynamic capacity of a HIC, estoppel can attach to each argument unless the prior art was distinguished based on the combination of the argued grounds.

Amgen v. Coherus (con't)

- Amgen also argued that prosecution history estoppel should not apply here because the response prior to allowance did not contain the "particular combinations" argument.

- CAFC: There is no requirement that argument-based estoppel apply only to arguments made in the most recent submission before allowance.

Narrow Claiming

- "[I]f a patent states that the claimed device must be 'non-metallic,' the patentee cannot assert the patent against a metallic device on the ground that a metallic device is equivalent to a non-metallic device."

- "The unavailability of the doctrine of equivalents could be explained… as the product of a clear and binding statement to the public that metallic structures are excluded from the protection of the patent."

- "[T]he foreclosure of reliance on the doctrine of equivalents in such a case depends on whether the patent clearly excludes the asserted equivalent structure, either implicitly or explicitly."
  - *SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337 (Fed. Cir. 2001)

UCB v. Watson Labs., 927 F.3d 1272 (Fed. Cir. 2019)

- Claims of the ’434 patent cover a transdermal patch to administer rotigotine for treatment of Parkinson’s disease

- Claim 1: A transdermal therapeutic system comprising a self-adhesive matrix layer containing the free base [rotigotine] in an amount effective for the treatment of the symptoms of Parkinson’s syndrome, wherein *the matrix is based on [] an acrylate-based or silicone-based polymer adhesive system having a solubility of ≥5% (w/w) for the free base [rotigotine]*, all of said free base being present in the matrix in the absence of water; a backing layer inert to the components of the matrix layer; and a protective foil or sheet covering the matrix layer to be removed prior to use.

- Actavis’s ANDA products used a **polyisobutylene adhesive**, rather than the claimed acrylate-based or silicone-based polymer adhesives.

- Actavis argued that UCB was barred from asserting DOE because of prosecution history estoppel, intentional narrow claiming, vitiation or ensnarement.

- District Court: Polyisobutylene adhesive is substantially similar to the claimed acrylate-based or silicone-based polymer adhesives.

- CAFC (Chen, Taranto, Schall): Upheld district court’s finding of infringement under DOE.

UCB v. Watson Labs. (con't)

- Actavis argued that UCB had chosen to draft narrow claims and should not be permitted to expand the scope of the claims through DOE.
- Specifically, Actavis argued that the inventor of the patent knew that polyisobutylene was a polymer that could be used in transdermal patches but chose not to prosecute.
- CAFC: Not barred for narrow claiming.
  - Foreseeability at the time of claim drafting is not a per se bar to the application of DOE.
  - Actavis did not argue that '434 patent's specification relies on any unique characteristics of acrylate or silicone-based polymer adhesive systems that would not be present in a polyisobutylene-based system.
  - "[T]he fact that specification repeatedly recites acrylate- and silicone-based polymers is irrelevant to the issue of whether it describes those polymers in a manner that would suggest a skilled artisan that polyisobutylene is not an equivalent."
  - "[T]here is not enough indication from the patent specification, claims, or the record evidence of the inventor's knowledge here to conclude that UCB surrendered polyisobutylene as a possible equivalent."

Dedication-Disclosure

- "[W]hen a patent drafter discloses but declines to claim subject matter, as in this case, this action dedicates that unclaimed subject matter to the public. Application of the doctrine of equivalents to recapture subject matter deliberately left unclaimed would 'conflict with the primacy of the claims in defining the scope of the patentee's exclusive right.'"
  - *Johnson & Johnston Assocs. Inc. v. R.E. Serv. Co.*, 285 F.3d 1046 (Fed. Cir. 2002)

Eagle v. Slayback (D. Del. May 2019)

- ANDA litigation regarding Slayback's proposed generic to Eagle's BALRAPZO® (bendamustine).

- Claim 1 of '796 patent: A non-aqueous liquid composition comprising:
  - bendamustine, or a pharmaceutically acceptable salt thereof;
  - a pharmaceutically acceptable fluid comprising a mixture of polyethylene glycol and propylene glycol, wherein the ratio of polyethylene glycol to propylene glycol in the pharmaceutically acceptable fluid is from about 95:5 to about 50:50; and
  - a stabilizing amount of an antioxidant . . . .

- Slayback's proposed ANDA product includes polyethylene glycol and a second solvent instead of propylene glycol.

Eagle v. Slayback (D. Del. May 2019)

- The second solvent in Slayback's ANDA product was identified in the specification as an alternative to propylene glycol.
  - "In other aspects of the invention, the bendamustine-containing compositions include a) a pharmaceutically acceptable fluid which contains one or more of propylene glycol, ethanol, polyethylene glycol, benzyl alcohol and glycofural, and b) a stabilizing amount of chloride salt."

- Slayback filed a motion for judgment on the pleadings pursuant to Fed. R. Civ. P. 12(c).
  - Argued that there could be no DOE infringement, as disclosure-dedication doctrine bars any DOE argument.

- Eagle argued that disclosure-dedication doctrine applies only when the entire embodiment as claimed is disclosed.
  - "the specification does not specifically disclose the formulation proposed by Slayback, bendamustine, polyethylene glycol, Slayback's second solvent, and an antioxidant"

- Court: Granted Slayback's motion, finding that disclosure-dedication doctrine barred any assertion of DOE infringement.
  - "[L]ike the prosecution history estoppel issue addressed by Judge Stark [in another case], the disclosure-dedication doctrine is a legal question appropriate for resolution at the 12(c) stage of the proceedings."
  - The disclosure-dedication doctrine is not restricted to disclosures of embodiments and that the doctrine applies to **claim limitations.**
    - "Under Federal Circuit law, the disclosure-dedication doctrine applies to unclaimed subject matter that is 'identified by the patentee as an alternative to a *claim limitation.*" (citing *Pfizer v. Teva*, 429 F.36 1364 (Fed. Cir. 2005))

Tips to Avoid Setting Up Limitations on DOE

- Claim drafting
  - Too broad: narrowing amendments limit DOE.
  - Too narrow: construed as limited to narrow scope (*UCB*).
  - Claim all disclosed alternatives (*Eagle*).
- Specification drafting
  - Avoid narrowing characterizations of the "invention".
  - Focus on "embodiments" and include lots of them.
- Prosecution
  - Attack *prima facie* case without characterizing claims.
  - Avoid "kitchen sink" approach to arguments (*Amgen v. Coherus*).

Litigation Strategies for Defendants

- Consider filing IPR or PGR petition.
- Consider filing a Request for Reexamination.
- If the defendant has patents, consider filing a counterclaim or countersuit.
- File summary judgment motion.

Litigation Strategies for Defendants

- Develop invalidity/unenforceability defenses.
  - Many potential defenses exist in addition to prior art and infringement defenses.
  - Other defenses include: lack of enablement, lack of written description, indefiniteness, laches and estoppel, incorrect inventors, double patenting, and inequitable conduct.

- Seek a narrow claim construction.
  - Often infringement can be avoided by a narrow claim construction.
  - Claim language is often ambiguous, creating an opportunity for a narrowing construction.
  - The prosecution history may also provide a basis for a narrowing construction.
  - But narrow construction could bolster a patent owner's patentability/validity positions.

Thank you.

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