Doctrine of Equivalents in Patent Prosecution: DOE Application, Festo Exceptions, Recent Case Law Developments

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Thomas L. Irving, Partner, Finnegan Henderson Farabow Garrett & Dunner, Washington, D.C.
Barbara Clarke McCurdy, Partner, Finnegan Henderson Farabow Garrett & Dunner, Washington, D.C.
Amanda K. Murphy, Ph.D., Partner, Finnegan Henderson Farabow Garrett & Dunner, Washington, D.C.

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**Doctrine Of Equivalents**

Purpose: DOE prevents copying of an invention that would effectively “convert the protection of the patent grant into a hollow and useless thing.”
Approach Of The Federal Circuit

- “The doctrine of equivalents is not a talisman that entitles a patentee to a jury trial on the basis of suspicion; it is a limited remedy available in special circumstances, the evidence for which is the responsibility of the proponent.”  (Schoell v. Regal Marine Indus., Inc., 247 F.3d 1202, 1210 (Fed. Cir. 2001))

- “If our case law on the doctrine of equivalents makes anything clear, it is that all claim limitations are not entitled to an equal scope of equivalents. Whether the result of the All Limitations Rule, ... prosecution history estoppel, ... or the inherent narrowness of the claim language, ... many limitations warrant little, if any, range of equivalents.”  (Moore U.S.A., Inc. v. Standard Register Co., 229 F.3d 1091 (Fed. Cir. 2000))
Federal Circuit Objectives

• Want broad claim scope? Negotiate that scope with the USPTO.

• Do not count on having the doctrine of equivalents available to bail you out.

• Public should be entitled to notice of what is infringing, the claims provide that notice, and it is the patentee, not the public, who should bear cost.
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.
Graver Tank & Mfg. Co. v. Linde Air Products Co.,
339 U.S. 605 (1950)

- Claim: a welding flux containing essentially a combination of alkaline earth metal silicate and calcium fluoride.

- Accused product substituted silicates of manganese, not an alkaline earth metal, for silicates of magnesium, an alkaline earth metal used in the patentee's product.

- USSC: infringement can be found when the accused product “performs substantially the same function in substantially the same way to obtain the same result.”
  - The accused flux containing manganese silicates infringed under the doctrine of equivalents; the manganese silicates performed substantially the same function as the magnesium silicates in substantially the same way to obtain substantially the same result.
‘Purpose, Qualities, and Function’

• *Graver Tank* also articulates the analysis of equivalence as “purpose, qualities, and function” and a POSITA’s knowledge of interchangeability:

  • “Equivalence, in the patent law, is not the prisoner of a formula and is not an absolute to be considered in a vacuum. It does not require complete identity for every purpose and in every respect. .... Consideration must be given to the purpose for which an ingredient is used in a patent, the qualities it has when combined with the other ingredients, and the function which it is intended to perform. An important factor is whether persons reasonably skilled in the art would have known of the interchangeability of an ingredient not contained in the patent with one that was. (emphasis added)
Function-Way-Result Test

Intendis GmbH v. Glenmark Pharms., Inc., USA, 822 F.3d 1355 (Fed. Cir. 2016)

— ANDA litigation over Finacea® Gel.

— Claim 1. 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 triacylglyceride 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.

— DC: DOE infringement, judgment in favor of Intendis.

— FC: Affirmed.
Function-Way-Result Test

Intendis (con’t)

— Proposed generic product substituted isopropyl myristate for the claimed triglyceride and lecithin.

— FC: “To be clear, we 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.”
Function-Way-Result Test

*Intendis* (con’t)

- FC: (con’t)
  - isopropyl myristate “performs substantially the same function as the claimed excipients”
    - Expert testimony;
    - Glenmark’s ANDA included repeated statements that both Glenmark’s excipient and the claimed excipients function as penetration enhancers.
      - “Glenmark ‘should not be permitted to liken their product to the claimed composition to support their bid for FDA approval, yet avoid the consequences of such a comparison for purposes of infringement.’”
  - isopropyl myristate “performed in substantially the same way as the claimed excipients.”
    - Expert testimony; and scientific literature.
  - isopropyl myristate “obtained substantially the same result as the claimed excipients.”
    - Data from the ‘070 patent; Glenmark’s own patent application; a skin penetration study; and a clinical trial.
Function-Way-Result Test

*Intendis* (con’t)

- FC: (con’t)
  - “Glenmark is wrong to the extent that it argues that a determination of the claimed element’s function is limited to a review of the intrinsic record. 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.”

- Glenmark argued that its statements in its ANDA about the claimed excipients (triglyceride and lecithin) functioning as penetration enhancers should be rejected as a “guess” and “wrong.”

- Did not persuade FC of any clear error in the district court’s decision.
**Amgen Inc. v. Sandoz Inc., 923 F.3d 1023 (Fed. Cir. 2019)**

Claimed protein purification using chromatography

1. **applying** the refold solution to a separation matrix under protein binding conditions
2. **washing** the separation matrix
3. **eluting** the protein from the separation matrix.

Accused protein purification using chromatography

1. **applying** the refold solution to the matrix
   - no separate washing step
   - no separate eluting step

RESULT: purified protein
Amgen v. Sandoz (con’t)

- BPCIA litigation
- DC: Granted summary judgment of noninfringement of claim 7 by Sandoz’s filgrastim biosimilar and proposed pegfilgrastim biosimilar.
  - “construed limitations (f) and (g) of claim 7 (the ‘washing’ and ‘eluting’ steps) as separate steps and further clarified that the eluting step ‘must occur after the step of ‘washing the separation matrix.’”
  - Sandoz process had no separate washing or eluting steps.
  - One-step process not equivalent to claimed three-step process.
- FC: Affirmed.
Amgen v. Sandoz (con’t)

- FC:
  - “[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.”
  - On Sept. 3, 2019, CAFC granted petition for panel rehearing only to extent to modify sentence from opinion: “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.’ **London v. Carson Pirie Scott & Co.**, 946 F.2d 1534, 1538 (Fed. Cir. 1991)”
Insubstantial Differences Test

Mylan Institutional LLC v. Aurobindo Pharma Ltd., 857 F.3d 858 (Fed. Cir. 2017)

- Claim: A compound N-[4-[[4-(diethylamino)phenyl] (2,5-disulfophenyl)methylene]-2,5-cyclohexadien-1-ylidene]-N-ethylethanaminium, sodium salt having a purity of at least 99.0% by HPLC.

- Claim: A process of preparing N-[4-[[4-(diethylamino)phenyl] (2,5-disulfophenyl)methylene]-2,5-cyclohexadien-1-ylidene]-N-ethylethanaminium, sodium salt comprising combining a suspension of isoleuco acid of the formula... 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 and then preparatory HPLC to achieve an ISB purity of greater than 99.5%.

- Issue: equivalency of manganese dioxide and silver oxide.

- DC: granted preliminary injunction (used function-way-result test).
  - Mylan was likely to prove infringement under the doctrine of equivalents for both the ISB compound and the process of making claims (3 patents).
Insubstantial Differences Test

Mylan (con’t)

— FC: Upheld for compound claims (1 patent), but not process of making claims (2 patents).

— “the law on the doctrine of equivalents as applied to chemical materials is not clear, and its misapplication can lead to unsound results. This appears to be such a case.”

— “the district court conducted an incomplete F-W-R analysis while essentially bypassing the substantial differences test, in a situation where the latter test might seemingly be more appropriate.”

— Full trial on the merits to consider whether the “substantiality of the differences” test is more appropriate for the chemical process claims than the “function, way, result” test.
Especially when evaluating an equivalents dispute dealing with chemical compositions having many components, ... it is often not clear what the ‘function’ or ‘way’ is for each claim limitation. How a particular component of a composition, or substituent of a compound, functions in a human or animal body, or in what way, may not be known or even knowable (although, as technology evolves, that may change). And precedent requires that, for infringement under the doctrine of equivalents, each limitation must satisfy an equivalence test. ... The ‘result’ of using a claimed compound may be more easily evaluated, as the structure and uses of one compound may be directly compared with those of another. But, as indicated above, that is not how infringement under FWR is determined. It must be determined on a limitation-by-limitation basis. See id. Similarly, in the case of a chemical process claim, as in this case, the ‘result’ of a process producing a chemical compound may be clear—why else would a claim for infringement of a process claim be brought if the claimed result is not obtained? But the ‘function’ and ‘way’ of a particular limitation of a chemical process claim may remain vague and often overlap. In some cases, ‘way’ and ‘function’ may be synonymous.”

Aug. 1, 2017, district court order granted joint motion to dismiss with prejudice.
DOE Must Be Proved With Particularized Testimony

- Must provide *particularized testimony and linking argument on a limitation-by-limitation basis*.

- Equivalents is judged on a limitation-by-limitation basis, so that “the application of the doctrine ... is not allowed such broad play as to effectively eliminate that element in its entirety.”

DOE Standard Of Proof:
“Preponderance Of Evidence”

- Siemens Medical Solutions v. Saint-Gobain Ceramics & Plastics Inc., 637 F.3d 1269 (Fed. Cir. 2011)
  - Jury: DOE infringement
  - Siemens’ patent: radiation detectors comprising an LSO scintillator crystal and a photodetector.
  - St Gobain: No DOE infringement because its crystals are separately claimed in the ’420 patent (radiation detectors comprising LYSO scintillator crystals; 0.01% Y to 99.99% Y LYSO).
Siemens (con’t)
  ▪ Fed. Cir.: Affirmed.
    — District court did not err by instructing the jury that equivalents could be proved by a preponderance of the evidence.
    — DOE infringement even though the equivalent was separately patented.
    — “separate patentability may be considered by the jury along with other relevant evidence of noninfringement, [but] this fact does not alter the required burden of proof.”
    — “Patent infringement, whether literal or by equivalence, is an issue of fact, which the patentee must prove by a preponderance of the evidence.”
**DOE May Apply To Numerical Ranges**

- *Adams Respiratory Therapeutics, Inc. v. Perrigo Co.*, 616 F.3d 1283 (Fed. Cir. 2010)
  
  ▪ FC: “The mere existence of a numerical value or range in a claim, absent more limiting language in the intrinsic record, does not preclude application of the doctrine of equivalents.”

  ▪ Issue will be whether the number outside the claimed range is insubstantially different and whether any PHE.

  ▪ Adams argued “at least 3500 hr*ng/mL” infringed by 3494.38 hr*ng/mL.

  ▪ FC: Adams introduced sufficient evidence from which a reasonable fact finder could conclude that 3493.38 hr*ng/mL is insubstantially different from 3500 hr*ng/mL.
    - Vacated grant of summary judgment of noninfringement by DOE.
“About” Makes Equivalents Within Literal Scope Of Claim

- *Cohesive Technologies, Inc. v. Waters Corp.*, 543 F.3d 1351 (Fed. Cir. 2008)
  - DC: Granted SJ of no infringement under the doctrine of equivalents.
  - FC: Affirmed, but for different reason.
    - “‘about 30 μm’ encompasses particle diameters that perform the same function, in the same way, with the same result as the 30 μm particles, as long as those diameters are within the range left open by the specific disclosures of the specification. Thus, by electing to include the broadening word ‘about’ in the claim, the patentee has in this case already captured what would otherwise be equivalents within the literal scope of the claim.”
    - “Where, as here, a patentee has brought what would otherwise be equivalents of a limitation into the literal scope of the claim, the doctrine of equivalents is unavailable to further broaden the scope of the claim.”
Cannot Ignore Statements In Spec


  Federal Circuit: “the specifications expressly recite that ‘the invention’ has a body constructed as a single piece and expressly distinguish the invention from the prior art based on this feature. With these distinguishing statements in the specifications, RTI cannot use the doctrine of equivalents to claim subject matter that the specifications expressly state fall outside the invention. Accordingly, we reverse the district court’s denial of BD’s motion for JMOL and render judgment that the 3mL Integra syringes do not infringe any of the asserted claims as a matter of law.” (emphasis added)
Successful Showing Of DOE Infringement

- **Pozen Inc. v. Par Pharm., Inc.,** 696 F.3d 1151 (Fed. Cir. 2012)

  - Claim 1. 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, separate 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.

  - Claim 2. The tablet of claim 1, wherein said naproxen is in the form of naproxen sodium between 200 and 600 mg.
Successful Showing Of DOE Infringement

- **Pozen** (con’t)
  - DC: Infringement under the doctrine of equivalents
    - Based upon Par's FDA filings (ANDA disclosure) and expert testimony, Par's ANDA product performs the same function in the same way to achieve the same results.
  
- FC: Affirmed.
  - Did not need to show independent dissolution achieved by the ANDA products compared to dissolution rates of the same amount of naproxen or sumatriptan alone.
    - Specification provided % to “substantially all” that allowed application of doctrine of equivalents (otherwise, “substantially all” would bring what otherwise equivalent into literal scope)
Judicial Limitations On DOE

- Prior Art/Ensnarement
- Narrowing Claiming
- All-Limitations Rule
- Unclaimed but disclosed is dedicated to public
- Insubstantial Difference Test
- Prosecution history estoppel/Narrowing Statements in the Specification and Prosecution History

- Claim limitation: “at a pH from approximately 6.0 to 9.0”
  - Upper limitation included to avoid prior art.
  - Parties disagreed why lower limitation added.

- Accused process had pH of 5.0.

- Jury and CAFC found infringement under DOE.

- USSC: Reversed and remanded.
  - “The determination of equivalence should be applied as an objective inquiry on an element-by-element basis. Prosecution history estoppel continues to be available as a defense to infringement, but if the patent holder demonstrates that an amendment required during prosecution had a purpose unrelated to patentability, a court must consider that purpose in order to decide whether an estoppel is precluded. Where the patent holder is unable to establish such a purpose, a court should presume that the purpose behind the required amendment is such that prosecution history estoppel would apply.”
Festo v. SMC, 493 F.3d 1368
(Fed. Cir. 2007)

• DC: No DOE infringement.

• FC: Affirmed – SMC’s aluminum sleeve was a foreseeable equivalent, so PHE applies.
  • “foreseeability does not require the applicant to be aware that a particular equivalent would satisfy the insubstantial differences test or the function/way/result test with respect to the claim as amended.”
  • “foreseeability [is tied] to whether the applicant would have been expected to know of, and thus properly claim, the proposed equivalent at the time of amendment.”
  • “an alternative is foreseeable if it is disclosed in the pertinent prior art in the field of the invention. In other words, an alternative is foreseeable if it is known in the field of the invention as reflected in the claim scope before amendment”
USSC: Criteria For Showing No Surrender Under Festo

“unforeseeable at the time of the amendment and thus beyond a fair interpretation of what was surrendered.”

“the rationale underlying the narrowing amendment [bore] no more than a tangential relation to the equivalent in question.”

“some other reason suggesting that the patentee could not reasonably be expected to have described the insubstantial substitute in question.”
Operation Of W-J and Festo PHE Presumptions

1. Did the amendment narrow the literal scope of the claim?
   - NO → NO PHE
   - YES

2. For a substantial reason relating to patentability?
   - NO → NO PHE
   - YES

3. Scope of subject matter surrendered?
   - NO
   - YES → NO REASON SHOWN

Warner-Jenkinson presumption that reason related to patentability

Rebuttal evidence restricted to prosecution history
Operation Of W-J and Festo PHE Presumptions

3. Scope of subject matter surrendered?

- Festo presumption that patentee surrendered all territory between original claim limitation and amended claim limitation
  - REBUTTED
  - Show no surrender of particular equivalent according to criteria

- No PHE and equivalency of accused element reached on merits

- PHE bars patentee from relying on DOE for accused element
  - NOT REBUTTED
Rewriting Dependent Claim As Independent Claim = Narrowing?

• Ranbaxy Pharms. Ltd. v. Apotex, Inc., 350 F.3d 1235 (Fed. Cir. 2003)

• Original claims:

  1. Process of preparation of amorphous cefuroxime axetil which comprises the steps of:
     a) dissolving crystalline cefuroxime axetil in a highly polar organic solvent and adding the resulting solution to water; or
     b) dissolving crystalline cefuroxime axetil in a highly polar solvent, adding water to the resulting solution and subsequently adding the resulting aqueous-organic solution to water.

  2. The process of claim 1 wherein the dissolution of crystalline cefuroxime axetil is carried out in a volume of solvent only sufficient to dissolve crystalline cefuroxime axetil.

  3. The process of claim 1 or 2 wherein the highly polar solvent is a sulfoxide.

  4. The process of claim 1 or 2 wherein the highly polar solvent is dimethyl sulfoxide.

  5. The process of claim 1 or 2 wherein the highly polar solvent is an amide.

  6. The process of claim 5 wherein the amide is selected from the consisting of dimethyl formamide, dimethyl acetamide, or hexamethyl phosphoramite.

  7. The process of claim 1 or 2 wherein the solvent is formic acid.

  8. The process of claim 1 or 2 wherein the solvent is a homogenous mixture of dimethyl sulfoxide and the amide.

  9. The process of claim 1 or 2 wherein the addition of the resulting solution to water is carried out between 0 to 40ºC.

 10. The process of claim 9 wherein the addition is carried out between 0 to 4ºC.

• In a preliminary amendment, claims 3-9 were amended so as not to be dependent on claim 2.
Rewriting Dependent Claim As Independent Claim = Narrowing?

- Ranbaxy (con’t)

  - Claims 1-10 canceled.

  - New claim 11. Process of preparation of amorphous cefuroxime axetil which comprises the steps of:
    - (a) dissolving crystalline cefuroxime axetil in a volume of a highly polar organic solvent only sufficient to dissolve it, and adding the resulting solution to water; or
    - (b) dissolving crystalline cefuroxime axetil in a volume of highly polar organic solvent, only sufficient to dissolve it, adding water to the resulting solution and subsequently adding the resulting aqueous-organic solution to water,

  - wherein the highly polar organic solvent is selected from the group consisting of a sulfoxide, an amide and formic acid.
Rewriting Dependent Claim As Independent Claim = Narrowing?

• Ranbaxy (con’t)

  • Ranbaxy’s process uses acetic acid rather than any of the specifically claimed solvents (e.g. formic acid).
  • FC: Apotex did not rebut presumption that PHE applied.
    • Addition of an inherent element to a claim “may . . . in some cases” create an estoppel.

  • Cited Deering Precision Instruments v. Vector Distribution Systems, that in deciding whether a narrowing amendment has occurred, “the correct focus is on whether [the] amendment surrendered subject matter that was originally claimed for reasons related to patentability.”

  • Surrender clear.
    • “While Apotex was merely rewriting a dependent claim into independent form, the effect on the subject matter was substantial. The dependent claims that were redrafted into independent form did more than simply add an additional limitation; they further defined and circumscribed an existing limitation for the purpose of putting the claims in condition for allowance. The additional language limited 'highly polar solvent' to a defined group of solvents: sulfoxides, amides, and formic acid. In so doing, the patentee is presumed to have surrendered the equivalents that may have been encompassed by ‘highly polar solvent.’”
Show Narrowing And Then Show Presumption Not Rebutted

**Glaxo '798 patent**
sustained-release tablets of bupropion hydrochloride (sold as Wellbutrin®)

- Original claim: “A controlled sustained release tablet comprising an admixture ... of bupropion hydrochloride.”
- Amended claim 1: “A controlled release tablet comprising 25 to 500 mg of bupropion hydrochloride and hydroxypropyl methylcellulose (HPMC)....”

**Glaxo v. Excel, 356 F.3d 1357 (Fed. Cir. 2004)**
- Excel’s polyvinyl alcohol ("PVA") equivalent to HPMC?
- DC: No.
- FC: Vacated and remanded because of unresolved issue of material fact whether claim was narrowed. Record shows that at the time the amendments were made, no known hydrogels other than HPMC had been tested with bupropion hydrochloride to achieve sustained release.

**Glaxo v. Impax, 356 F.3d 1348 (Fed. Cir. 2004)**
- Impax’s hydroxypropyl cellulose ("HPC") equivalent to HPMC?
- FC: Affirmed SJ of no infringement because amendment narrowed and HPC was foreseeable equivalent (known at time of application).
UCB, Inc. v. Watson Labs. Inc., 927 F.3d 1272 (Fed. Cir. 2019)

• ‘434 patent 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 $\geq 5\%$ (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.

• ‘414 patent Claim 1. A polymorphic form of rotigotine characterized by at least one parameter selected from the group consisting of:
  a) a powder X-ray diffraction spectrum comprising [**6] at least one peak at the following $^\circ 2\theta$ angles (± 0.2): 12.04, 13.68, 17.72, and 19.01;
  b) a Raman spectrum comprising at least one peak at the following (±3 cm$^{-1}$): 226.2, 297.0, 363.9, 737.3, 847.3, 1018.7, and 1354.3 cm$^{-1}$
  c) a DSC peak with a Tonset at 97°C. ± 2°C. measured with a heating rate of 10°/min; and
  d) a melting point of 97°C. ± 2°C.
No Narrowing

*UCB* (con’t)

- Actavis argued that UCB’s withdrawal of claims not limited to silicone- and acrylate-based polymer adhesive systems in response to a restriction requirement meant UCB gave up claim scope of adhesives that are not silicates or acrylates.

- **DC:** Infringement under the doctrine of equivalents.
  - Actavis's products use a polyisobutylene adhesive, which was “substantially similar” to the claimed adhesives. (“interchangeable”)

- **FC:** Affirmed; “UCB's claiming of acrylates and silicates does not bar treating polyisobutylene as an equivalent for infringement purposes.”
  - Restriction requirement was not about patentability of polyisobutylene-based adhesive systems.
  - “the restriction requirement here, and UCB’s election in response, do not indicate a surrender of polyisobutylene as an equivalent.”
  - “A restriction requirement does not necessarily invoke prosecution history estoppel.”
  - “Because we conclude that UCB did not make a narrowing amendment in respect to the restriction requirement, we reject Actavis's argument that UCB had the burden to show that a "narrowing amendment" was unrelated to patentability.”
“Tangentially Related” Seems To Be A Very Narrow Exception

- Cross Medical Products Inc. v. Medtronic Sofamor Danek Inc., 480 F.3d 1335 (Fed. Cir. 2007)

  - Original claim: “vertical axis and first threads.”
  - Amendment: threads “to a depth below the diameter of the rod.”
  - Accused screw terminates above the rod diameter.
  - DC: Infringement under the doctrine of equivalents
    - Festo presumption rebutted because the amendment bore no more than a tangential relationship to the equivalent.
  - FC: Reversed
    - Amendments to claims made "to avoid prior art that contains the equivalent in question" could not be tangential.
    - “tangentially related” rebuttal is "very narrow."
Tangential

• Claim: A chair comprising:
  ▪ legs;
  ▪ seat; and
  ▪ back.

  ▪ “Back” is narrowed for reasons relating to patentability either by amendment or argument.

  ▪ DOE available for legs and seat that do not literally fall within the scope of the claim.

  ▪ DOE not available for “backA” that does not literally fall within the scope of the claim unless PHE is rebutted AND unless equivalence is proven between “back” as claimed and “backA.”
Rebutting Festo Presumption With “Tangentially Related” Argument

• *Primos Inc. v. Hunter's Specialties Inc.*, 451 F.3d 841 (Fed. Cir. 2006)
  ▪ “the amendment was merely tangential to the contested element in the accused device, and thus prosecution history estoppel does not apply to prevent the application of the doctrine of equivalents.”

• *Insituform Tech. Inc. v. Cat Contracting Inc.*, 385 F.3d 1360 (Fed. Cir. 2004)
  ▪ “there is no indication in the prosecution history of any relationship between the narrowing amendment and . . . the alleged equivalent in this case.”

• See also, *Regents of the University of California v. Dakocytomation California, Inc.*, 517 F.3d 1364 (Fed. Cir. 2008)
• Claim 2. (Original) A method of reducing the toxicity associated with the administration of an antifolate to a mammal comprising administering to said mammal an effective amount of said antifolate in combination with a methylmalonic acid lowering agent.

• Claim 5. (Original) A method of reducing the toxicity associated with the administration of an antifolate to a mammal comprising administering to said mammal an effective amount of said antifolate in combination with a methylmalonic acid lowering agent and FBP binding agent.

• A dependent claim further limited the antifolate to pemetrexed disodium.

• Issued claim 12. An improved method for administering pemetrexed disodium to a patient in need of chemotherapeutic treatment, wherein the improvement comprises:
  a) administration of between about 350 µg and about 1000 µg of folic acid prior to the first 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.
Lilly (con’t)

- Claims rejected as anticipated (claim 2) and obvious (all other claims).
- In response, Lilly amended both claims to narrow “antifolate” to “pemetrexed disodium” and cancelled the dependent claim limited to pemetrexed disodium.
- Lilly argued that the amendment to claim 2 overcame the anticipation rejection because reference did not disclose pemetrexed disodium.
- Lilly argued that the prior art never suggested vitamin supplementation or “the use of [vitamin B12] to reduce toxicities associated with an antifolate.”
- Claims issued.
Hospira uses pemetrexed ditromethamine.

DC: Infringement under the doctrine of equivalents.
   “the reason for Lilly’s amendment was to distinguish other antifolates and was therefore only tangential to pemetrexed ditromethamine.”

FC: Affirmed.
   The Festo “tangential relation” exception applied.
      “the prosecution history, in view of the [] patent itself, strongly indicates that the reason for the amendment was not to cede other, functional identical, pemetrexed salts... [I]t is implausible that the reason for [patent owner’s] amendment was to surrender other pemetrexed salts. Indeed, such a relinquishment would effectively dedicate the entirety of [patent owner’s] invention to the public and thereby render the [] patent worthless, and it would have been irrelevant for distinguishing the prior art. ... Thus, we conclude on this prosecution record that [patent owner’s] amendment was merely tangential to pemetrexed ditromethamine.”
Ajinomoto Co., Inc. v. ITC, 932 F.3d 1342 (Fed. Cir. 2019)

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

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

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

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

• FC: Affirmed; agreed that Ajinomoto rebutted the \textit{Festo} presumption.
  — Amendment was tangential to the equivalent because “the reason for the narrowing amendment —limiting the amino-acid makeup of the proteins included in one of the alternatives covered by the claim—is unrelated to differences among the several DNA sequences that encode a given protein.”
Foreseeability Seems To Be A High Bar To Overcome

- *Duramed Pharms. Inc. v. Paddock Labs. Inc.*, 644 F.3d 1376 (Fed. Cir. 2011)
  - DC: Summary judgment of noninfringement.
  - FC: A patent owner's ability to overcome prosecution history estoppel when claiming infringement under the doctrine of equivalents is quite limited.
    - Proposed generic would use an alternative coating that was known within the field of invention at the time the patent claim was drafted.
    - Sufficient that the alternative coating was identified only as being “useful,” and no more “precise evidence of suitability” was necessary for a finding of foreseeability.
“unmistakable indication”

- Claim 1, limitation b (amended for patentability)

- Claim 2, limitation b + other limitations not found in claim 1.
  - “other” limitations impart patentability over the prior art

- “unmistakable indication” that PHE does not apply to claim 2 limitation b because claim 2 did not exclusively rely on limitation b for patentability.
Prior Art/Ensnarement


Burden is on patent owner to show that theory of infringement does not ensnare the prior art.
• “prove that if ... the expanded hypothetical claims [were submitted] to the PTO [when the issued claims were filed], the PTO would have found the claims ... patentable[.]

Framework for decision is hypothetical claim analysis:

1) “the patentee must ‘construct a hypothetical claim that literally covers the accused device,’ which involves expanding the claim limitations to encompass the features of the accused product”; and

2) “prior art introduced by the accused infringer is assessed to determine whether the patentee has carried its burden of persuading the court that the hypothetical claim is patentable over the prior art.”
Hypothetical Claim Analysis From Wilson

Claim 1. A golf ball having a spherical surface with a plurality of dimples formed therein and six great circle paths which do not intersect any dimples, the dimples being arranged by dividing the spherical surface into twenty spherical triangles corresponding to the faces of a regular icosahedron, ...

“The accused balls ...have dimples which are arranged in an icosahedral pattern having six great circles, but the six great circles are not dimple-free as the claims literally require.”

“it may be helpful to conceptualize the limitation on the scope of equivalents by visualizing a hypothetical patent claim, sufficient in scope to literally cover the accused product. The pertinent question then becomes whether that hypothetical claim could have been allowed by the PTO over the prior art. If not, then it would be improper to permit the patentee to obtain that coverage in an infringement suit under the doctrine of equivalents. If the hypothetical claim could have been allowed, then prior art is not a bar to infringement under the doctrine of equivalents.”

“to allow the patent to reach Dunlop's balls under the doctrine of equivalents would improperly ensnare the prior art[.]”
Prior Art/Ensnarement


• Janssen product Remicade (infliximab).
• Celltrion biosimilar products Inflectra and Remsima.
• Janssen sued for infringement under the doctrine of equivalents for the process of making the biosimilar products.
  — The accused media contain all 52 ingredients required by claim 1, but several are present in concentrations outside the claimed ranges.
• Celltrion moved for summary judgment of noninfringement because Janssen’s asserted scope of equivalents would ensnare the prior art.
• DC: granted Celltrion’s motion for summary judgment of noninfringement.
  — Janssen’s proposed hypothetical claims would have been obvious (“ensnared by the prior art”).
Prior Art/Ensnarement

Janssen (con’t)

• The hypothetical claims included all ingredients listed in claim 1 with the claimed concentration ranges extended to match the concentrations used in the Celltrion media.

• DC: “it is most appropriate to analyze the obviousness of the hypothetical media under the principles applicable to combinations of known elements[.]”

  — GSK reference “combined 50 of 52 ingredients required by the hypothetical claims, and for those 50 shared ingredients, the concentration ranges disclosed in GSK partially overlap with the concentration ranges in the hypothetical claims.”

  — Life Techs reference “combined 47 of 52 ingredients required by the hypothetical claims, and for those 47 shared ingredients, 46 have partially overlapping concentration ranges.”

  — “As the Supreme Court explained in KSR, ‘[t]he proper question’ is not ‘whether a [POSA] writing on a blank slate’ would necessarily have chosen GSK and Life Techs over another medium for further development, but whether he or she ‘would have seen a benefit’ to modifying the teachings of GSK or Life Techs to achieve the claimed compositions.”
Prior Art/Ensnarement

Janssen (con’t)

– “partially overlapping concentration ranges establish a prima facie case of obviousness.”

– “a POSA would have had a motivation, based on these problems known in the field and the teachings of other references, to produce variations of GSK and Life Techs that supplied the same active ingredients in different salt forms and concentrations.”

– “With respect to the ingredients required by the hypothetical claims that are not disclosed in the GSK and Life Techs media, it is undisputed that the GSK and Life Techs media contain alternative, previously-known ingredients that were known to provide the same active components as the claimed ingredients[.]”

– Objective evidence of copying did not outweigh strong case of obviousness.
Prior Art/Ensnarement

- *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314 (Fed. Cir. 2009)
  - Jury: Infringement under the doctrine of equivalents.
  - Medtronic: asserted scope of equivalency would “ensnare” the prior art.
    - Prior art would have rendered obvious a “hypothetical” version of claim 1 in which alleged equivalent “conically-shaped” is substituted for the actual claim term “spherically-shaped.”
  - DC: Denied Medtronic’s ensnarement defense.
  - FC: Affirmed.
    - Hypothetical claim did not ensnare prior art.
    - Prior art actually taught away from a rigid pedicle screw encompassed by the hypothetical claim.
Ensnarement

Ensnarement

- **Jang (con’t)**

  - BSC: Jang’s doctrine of equivalents theory would ensnare the prior art, referencing three prior art patents.

  - Jang: hypothetical claim—predicated on representative claim 1—is broad enough to literally cover BSC’s Express stent, yet not so broad that it would be unpatentable over the prior art.

  - DC: Jang failed, as a threshold matter, to draft a proper hypothetical claim for the ensnarement analysis.
    - One hypothetical claim impermissibly narrowed claim 1.
    - One hypothetical claim failed to broaden claim 1 at all.

    - “Jang did not meet his burden of persuasion, which includes providing a proper hypothetical claim that does not ensnare the prior art[.]”

    - Vacated the jury verdict of infringement under the doctrine of equivalents and entered judgment of non-infringement in favor of BSC.
**Ensnarement**

- **Jang (con’t)**
  - Jang challenged the district court's vacatur of the jury's finding that the Express stent infringed the asserted claims under the doctrine of equivalents, as well as the entry of judgment of non-infringement in favor of BSC, on the ground that the district court incorrectly held that he failed to provide an acceptable hypothetical claim for an ensnarement analysis.

  - FC: affirmed district court's denial of Dr. Jang's motion for JMOL, its vacatur of the jury verdict of infringement under the doctrine of equivalents, and its entry of judgment of non-infringement.
Ensnarement

• *Jang* (con’t)

  ▪ 2-step process
    — “construct a hypothetical claim that literally covers the accused device.”
    — "determine whether the patentee has carried its burden of persuading the court that the hypothetical claim is patentable over the prior art."

  ▪ “The burden of producing evidence of prior art to challenge a hypothetical claim rests with an accused infringer, but the burden of proving patentability of the hypothetical claim rests with the patentee.”
    — “A patentee, like Dr. Jang, bears the burden of proving that it is entitled to ‘the range of equivalents which it seeks.’…Dr. Jang cannot effectively transfer the responsibility of defining the range of equivalents to which he is entitled to the district court.”

  ▪ Jang's hypothetical claims were flawed, and the district court properly declined to conduct any hypothetical claim analysis as a result.
    — One hypothetical claim added narrowing limitations, which is not allowed.
    — Other hypothetical claim did not change claim scope.
    — “when utilizing the hypothetical claim tool, that burden starts with proposing a proper hypothetical claim that only broadens the issued asserted claims.”
Ensnarement


  - Claim: a discharge valve assembly for a high-pressure fluid jetting system comprising: a discharge valve guide ...
  
  - NLB: PSI’s system infringes under the doctrine of equivalents because guiding with water is the equivalent of guiding with an element of the valve.
  
  - PSI: DOE cannot apply because the equivalent on which NLB relies — guiding with water — would “ensnare” the prior art.
    - Presented evidence that a prior art NLB valve assembly and the valve assembly covered by a prior art patent used water to guide the valve.
    - No DOE unless NLB can show that its theory will not encompass or "ensnare" the cited prior art.
**Ensnarement**

- **NLB Corp. (con’t)**

  - DC: PSI’s motion for summary judgment of no DOE infringement granted.

    "The Federal Circuit in *Jang* held that the patentee has the burden to propose a hypothetical claim for purposes of an ensnarement defense to infringement under the doctrine of equivalents. NLB has failed to propose a hypothetical claim in this case, and the time to do so has expired. As noted by the Federal Circuit, when the patentee fails to submit a proper hypothetical claim for consideration, the patentee has ‘failed to meet his burden of proving that his doctrine of equivalents theory did not ensnare the prior art.’ *Jang*, 872 F.3d at 1287.”
Narrow Claiming

• “[F]or a patentee who has claimed an invention narrowly, there may not be infringement under the doctrine of equivalents in many cases, even though the patentee might have been able to claim more broadly.”

• “[A]s between the patentee who had a clear opportunity to negotiate broader claims but did not do so, and the public at large, it is the patentee who must bear the cost of its failure to seek protection for [a] foreseeable alteration of its claim structure.”

  — Sage Products, Inc. v. Devon Industries, Inc., 126 F.3d 1420 (Fed. Cir. 1997)
### Claimed Clamp For Garment Hangers

A bifurcated clamp for embracing a plurality of garment hangers comprising... a latching device... for embracing the spaced **shanks** of the spaced garment hangers

### Accused Samsonite Clamp

graps
- the hanger **hooks**
- **not** the hanger **shanks**
**All-Limitations Rule**

- Each and every element of the claimed invention must be met literally or by an equivalent for there to be infringement.

- All-Limitations Rule not vitiated just because two elements of the accused device perform single function.

- “one-to-one correspondence of components is not required.”
All-Limitations Rule

• “If a theory of equivalence would vitiate a claim limitation, however, then there can be no infringement under the doctrine of equivalents as a matter of law.”
  — Tronzo v. Biomet, Inc., 156 F.3d 1154, 1160 (Fed. Cir. 1998)
A parking meter comprising:

- a **housing comprising** an intermediate panel set and **a cover panel**,
  - the **cover panel** being movably attached to the intermediate panel set...
  - the first surface of the **cover panel having** a first window and **a plurality of buttons** that operate the parking meter upon manipulation by a user....

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**Patent Embodiment**

**Accused Meter**

- **cover panel**
- **buttons**
Patentee: Same function way result
• The keypad operates the parking meter, as in the claimed invention, by using buttons to allow the user to purchase time and process credit card transactions.

Federal Circuit: DOE would “vitiage a claim limitation”
• “[W]ould essentially void the claim limitation of a ‘housing [with] a cover panel being movably attached to the intermediate panel set [and with] a plurality of buttons.”
• “[T]he doctrine of equivalents cannot be used to effectively read out a claim limitation . . . because the public has a right to rely on the language of patent claims.”
**All-Limitations Rule**

- **Cook Biotech Inc. v. Acell, Inc., 460 F.3d 1365 (Fed. Cir. 2006)**
  - Claim term: “at least the luminal portion of the tunica mucosa”
  - DC: infringement.
    - Broad enough to include compositions that contained tissues other than submucosa.
  - FC: Reversed.
    - Accused product contains tissue layers expressly excluded by the claim terms as the patentees have defined them.
    - “A claim that specifically excludes an element cannot through a theory of equivalence be used to capture a composition that contains that expressly excluded element without violating the ‘all limitations rule.’ Permitting appellees to assert such a theory of equivalence would effectively remove the requirement that the urinary bladder submucosa be delaminated from ‘the luminal portion of the tunica mucosa.’”
Vitiating Claim Limitation

Akzo Nobel Coatings, Inc. v. Dow Chemical Co., 811 F.3d 1334 (Fed. Cir. 2016)

— Claim: 1. A process for producing a dispersion of a polymer in an aqueous medium ... in an extruder having an outlet ... maintaining the pressure above atmospheric for the extruder at the outlet with a pressurized collection vessel and ... wherein the aqueous dispersion enters the outlet and pressurized collection vessel at a pressure above atmospheric ....

— Dow's process: dispersion exits the extruder, passes through a valve located at the extruder's outlet, and then continuously travels through a series of pipes and heat exchangers.

— Dow’s process infringe under the doctrine of equivalents?
Akzo (con’t)

—DC: Granted summary judgment of no infringement.
  • Construed “pressurized collection vessel” to require accumulation within the vessel.
  • The lack of accumulation in Dow’s process “precluded a finding of infringement under the doctrine of equivalents.”
    • “would vitiate the claim limitation that the ‘pressurized collection vessel’ be a ‘container where the desired material accumulates.’”

—FC: Affirmed.
  • “saying that a claim element would be vitiated is akin to saying that there is no equivalent to the claim element in the accused device …”
  • “Akzo failed to … show that a valve and a series of pipes and heat exchangers, wherein the dispersion flows continuously, generate backpressure in the extruder in substantially the same way to increase the boiling point of the carrier fluid. It did not do so.”
Disclosure-Dedication

- Subject matter disclosed but not claimed establishes dedication 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.”

  - DC: “the Court agrees with Coherus that another reason Amgen’s claim for infringement of the '707 patent must be dismissed is that the patentee dedicated to the public the [Redacted disclosure] ... [Redacted disclosure] was not claimed—and, thus, has been dedicated to the public.”
Claim 1. A component for use in manufacturing articles such as printed circuit boards comprising:

- a laminate constructed of a sheet of copper foil which... constitutes a functional element and a sheet of aluminum which constitutes a discardable element;

- one surface of each of the copper sheet and the aluminum sheet being essentially uncontaminated and engageable with each other at an interface....

While aluminum is currently the preferred material for the substrate, other metals, such as stainless steel or nickel alloys, may be used. In some instances, such as in laminating plastic credit cards, polypropylene can be used.
Disclosure-Dedication

- *Eagle Pharm., Inc. v. Slayback Pharma LLC*, 382 F.Supp.3d 341 (D. Del. May 9, 2019), appeal filed May 24, 2019, Case No. 19-1924, awaiting oral argument date

- Claim A non-aqueous liquid composition comprising: [1] bendamustine, or a pharmaceutically acceptable salt thereof; [2] a pharmaceutically acceptable fluid comprising a mixture of polyethylene glycol and propylene glycol, ... ; and [3] a stabilizing amount of an antioxidant; ...

- Slayback's proposed bendamustine drug contains polyethylene glycol and different solvent.

- Motion to dismiss because disclosure-dedication doctrine bars application of the doctrine of equivalents.
 Disclosure-Dedication

• Eagle Pharm (con’t)

  ▪ Summary of the Invention:
    – “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 glycofurol, and b) a stabilizing amount of a chloride salt.”

  ▪ DC: Granted motion.
    – “the disclosure-dedication doctrine applies to bar Eagle's claims for infringement under the doctrine of equivalents.”
    – “The written description of the asserted patents explicitly and repeatedly identifies Slayback's second solvent as an alternative to propylene glycol in embodiments of the patented invention.”
    – “I understand Johnson to hold implicitly that the disclosure-dedication doctrine is not restricted to disclosures of embodiments and that the doctrine applies to claim limitations.”
Prosecution History Estoppel

• “When the patentee has chosen to narrow a claim, courts may presume ... that the territory surrendered is not an equivalent of the territory claimed.”

• “‘[A]mendment is not essential [to find estoppel] when argument is made, and relied on, to distinguish the claimed subject matter from the prior art”
  • *Canton Bio Medical, Inc. v. Integrated Liner Technologies, Inc.*, 216 F.3d 1367 (Fed. Cir. 2000)
Argument-Based PHE

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

- Claims require a salt combination chosen from one of three pairs: citrate and sulfate, citrate and acetate, or sulfate and acetate.

- During prosecution, Amgen argued the “particular combination of salts.”
  - “choosing a working salt combination was a ‘lengthy development path’ and that ‘merely adding a second salt' would not result in the invention’”
  - Supported by expert declaration.

- DC: Dismissed Amgen’s complaint for failure to state a claim.
  - PHE bars Amgen’s claim for DOE infringement.
Argument-Based PHE

Amgen (con’t)

- FC: Affirmed.
  - Coherus used a salt combination, but not one of the specific combinations recited in the claims.
  - “during prosecution of the '707 patent, Amgen clearly and unmistakably surrendered salt combinations other than the particular combinations recited in the claims. Prosecution history estoppel thus bars Amgen from succeeding on its infringement claim under the doctrine of equivalents.”
  - “while Amgen did assert multiple reasons for why Holtz is distinguishable, our precedent instructs that estoppel can attach to each argument. ... Amgen did not rely on the combination of its asserted grounds to distinguish Holtz, so prosecution history estoppel applies to the ‘particular combinations’ ground regardless of the other two arguments Amgen made.”
Argument-Based and Amendment-Based
PHE

Pharma Tech Solutions, Inc. v. Lifescan, Inc., --F.3d-- (Fed. Cir. Nov. 22, 2019)

Issued claim: 1. An apparatus for measuring compounds in a sample fluid, comprising:
   a) a housing having an access opening therethrough;
   b) a sample cell composed of:
      (i) a first electrode …;
      (ii) a second electrode …;
   c) means for applying an electrical potential …;
   d) means for creating an electrical circuit …;
   e) means for measuring a first Cottrell current reading through the sample fluid at a first predetermined time after the electrical potential is applied and for obtaining at least one additional Cottrell current reading through the sample fluid, the at least one additional Cottrell current reading occurring at a second predetermined time following the first predetermined time;
   f) microprocessor means for converting the first Cottrell current reading into a first analyte concentration measurement using a calibration slope and an intercept specific for the first Cottrell current measurement, for converting the at least one additional Cottrell current reading into an additional analyte concentration using a calibration slope and an intercept specific for the at least one additional Cottrell current measurement, and for comparing the first analyte concentration measurement with the at least one additional concentration measurement to confirm that they are within a prescribed percent-age of each other; and
   g) means for visually displaying the results…

Original claim: 1. An apparatus for measuring compounds in a sample fluid, comprising:
   a) a housing having an access opening therethrough;
   b) a sample cell composed of:
      (i) a first electrode …;
      (ii) a second electrode …;
   c) means for applying an electrical potential …;
   d) means for creating an electrical circuit between said first electrode and said second electrode through said sample,
   e) means for measuring Cottrell current through said sample and
   f) means for visually displaying results of said measurement.
Argument-Based and Amendment-Based PHE

• **Pharma Tech (con’t)**

  • Accused product neither convert multiple Cottrell current readings to analyte concentration measurements nor compare multiple analyte concentration measurements.

  • Pharma Tech: “an analyte measurement can be expressed as a current at a given time or as a concentration” and, thus, the accused device infringes under the doctrine of equivalents.
    
    — The relevant equivalent is “the functionality of a system that (a) measures current at two different times, (b) compares the current[s] to ensure they are within a prescribed percentage and (c) converts the current readings into a glucose concentration.”

  • During prosecution, in response to rejection, Pharma Tech amended claim by adding claim language and distinguished the references based on the new language.

  • In response to second and third rejections, again argued “converting” and “comparing” language added in amendment distinguished the invention from the prior art:
    
    — “the present invention is directed to a system which takes two different Cottrell current readings, converts them to two different analyte concentration measurements, and then compares the two analyte concentration measurements to each other to confirm that they are within a prescribed percentage of each other. That operation in the present invention is neither taught nor suggested by Walling et al or White (’516), or any combination thereof.”

• Patent issued.
**Argument-Based and Amendment-Based PHE**

- *Pharma Tech* (con’t)
  
  - LifeScan: argument-based and amendment-based prosecution history estoppel barred Pharma Tech’s doctrine of equivalents infringement theory.
    - “when the inventors amended their claims to require conversion of Cottrell current readings to analyte concentration measurements and subsequent comparison of those analyte concentration measurements, they surrendered any claim scope covering systems and methods that do not compare analyte concentration measurements.”
    - “inventors’ arguments distinguishing the prior art constituted clear and unambiguous disclaimers of meters that do not perform the claimed conversion and comparison steps.”
  
  - Pharma Tech: amendment was narrowing but was “tangential to the real purpose of the amendment, which was to require a linear comparison of multiple measurements.”
Argument-Based and Amendment-Based PHE

- **Pharma Tech** (con’t)
  
  - DC: Granted LifeScan’s motion for summary judgment.
    - LifeScan’s accused system falls within the claim scope surrendered by the inventors during prosecution[.]
      - “tangentiality exception did not apply because the inventors’ remarks during prosecution indicated that ‘comparison of analyte concentration measurements was, at a minimum, a significant aspect of the [October 1997] amendment.’ ...
      - “the inventors ‘consistently relied on the comparison of two analyte concentration measurements as a distinguishing feature of [their] claims.’”
  
  - FC: Affirmed.
    - “amendment-based and argument-based prosecution history estoppel bar Pharma Tech’s infringement claims under the doctrine of equivalents. Pharma Tech’s asserted equivalent is within the territory that the inventors surrendered during prosecution of the ’069 pa-tent. Moreover, the inventors’ arguments accompanying and following the October 1997 amendment clearly and un-mistakably surrendered systems that do not convert Cottrell current readings to analyte concentration measurements and compare those analyte concentration measurements. The inventors’ clear statements not only establish argument-based estoppel, but also negate Pharma Tech’s reliance on the tangential relation exception.”
Argument-Based and Amendment-Based

PHE

- Pharma Tech (con’t)
  - Different than Lilly and Ajinomoto.
    - “In Eli Lilly, for example, the patentee’s amendment ... was merely tangentially related to the equivalent at issue, because the prosecution history “indicate[d] that the reason for the amendment was not to cede other, functionally identical, permetrexed salts.” ... Here, the comparison of analyte concentration measurements was integral to the inventors’ October 1997 amendment. The prosecution history indicates that throughout prosecution, the inventors viewed the “converting” and “comparing” limitations as necessary to overcome the prior art.”

    - “In Ajinomoto, this court held that the rationale underlying the patentee’s amendment narrowing the scope of the claimed DNA sequences to avoid the YfiK prior art protein was unrelated to the asserted equivalent—selecting from the codon-randomized sequences that correspond to the YddG protein. .... Here, by contrast, the rationale for the October 1997 amendment—avoiding prior art that does not convert a plurality of current readings or compare a plurality of analyte concentration measurements—directly relates to the accused equivalent, a system which also does not convert a plurality of current readings or compare a plurality of analyte concentration measurements.”
Narrowing Statements

• “[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)
SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc., 242 F.3d 1337 (Fed. Cir. 2001)

- Claims construed as limited to coaxial lumens
- Specification:
  - “specifically identified, criticized, and disclaimed the dual lumen configuration....”
  - “made clear that the patentee regarded the dual lumen configuration as significantly inferior to the coaxial lumen configuration used in the invention.”
- “[T]he patentee cannot now invoke the doctrine of equivalents to embrace a structure that was specifically excluded from the claims.”
Acts Giving Rise To Prosecution History Estoppel

- Remarks made after allowance.
  - *Hormone Research Found. v. Genentech, Inc.*, 904 F.2d at 1564 n.9 (Fed. Cir. 1990)

- Multiple arguments to overcome prior art may or may not create separate estoppels.

- Representations to foreign patent offices.
  - *Tanabe Seiyaku Co., Ltd. v. USITC*, 109 F.3d 726 (Fed. Cir. 1997)

- Failure to continue prosecution.
  - *Merck & Co. v. Mylan Pharmaceuticals, Inc.*, 190 F.3d 1335 (Fed. Cir. 1999) (by limiting claims to single species without pursuing broader polymer claims, patentee surrendered other subject matter disclosed)
Acts Giving Rise To PHE

• Criticizing the prior art in the specification.
  
  - Retractable Technologies, Inc. v. Becton, Dickinson and Co., 653 F.3d 1296 (Fed. Cir. 2011)
    
    - RTI argued DOE infringement by BD’s 3 mL syringes.
    
    - FC: RTI precluded from asserting DOE infringement because the specifications expressly criticized prior art syringes similar to BD’s:
      
      “It is well settled that when a specification excludes certain prior art alternatives from the literal scope of the claims and criticizes those prior art alternatives, the patentee cannot then use the doctrine of equivalents to capture those alternatives.” [citation omitted].
**Estoppel Applies To**

- Claims in same patent.

- Claims in related patent(s).
  - *Southwall Technologies, Inc. v. Cardinal IG Co.*, 54 F.3d 1570 (Fed. Cir. 1995)
  - *Biovail Corp. Int'l v. Andrx Pharmas., Inc.*, 239 F.3d 1297 (Fed. Cir. 2001)

- On same claims prosecuted by different counsel?
Estoppel Also Applies To Priority Claim

- Also, arguments made during prosecution estopped patentee from claiming priority to earlier application under 35 USC § 120.

  - Established in *Bradford Co. v. Conteyor North America, Inc.*, 603 F.3d 1262 (Fed. Cir. 2010)

    "The applicants' statement to the examiner is a compelling disclaimer of scope such that the ’096 patent is not entitled to an earlier priority date. ... That is because arguments made to persuade an examiner to allow an application trump an ambiguous disclosure that otherwise might have sufficed to obtain an earlier priority date. ... We therefore affirm the court's decision limiting the priority date of the ’096 patent to its own filing date."
Drafting And Prosecution:
Keep Enforcement In Mind When Drafting Claims

Consider who will infringe the claims and how infringement will be proven.

Goal: claims that will be directly and literally infringed by competitors.
Why is the goal to draft claims that will be directly and literally infringed by competitors?

• Avoid difficulties of proving infringement under doctrine of equivalents.

• Deny your competitor the additional defenses to induced and contributory infringement (knowledge, intent, etc.).

• Avoid having to take extensive third-party discovery, especially of your own customers or prospective customers.
Tips to Avoid Limitations on DOE

Claim drafting: aim for “Goldilocks” claims from the start.
- Too broad: narrowing amendments limit DOE (*Festo*).
- Too narrow: construed as limited to narrow scope (*Duncan Parking*).
- Claim all disclosed alternatives (*Johnson & Johnston*).

Specification drafting.
- Avoid narrowing characterizations of the “invention.”
- Focus on “embodiments” and include lots of them.
- Focus on objective of literal infringement (by single actor).

Prosecution.
- Attack *prima facie* case without characterizing claims.
- Avoid “kitchen sink” approach to arguments.
- Coordinate consistent approach US and OUS.
**Tips**

- Try to cover variations and permutations of each claim element (e.g., reverse order).

- **Draft claim with separate elements.**
  - Separate elements with semicolons and paragraphs.
  - Increase the number of elements in a claim.
  - If have to amend, can make it clear relates to only one element.
    - Can focus comments.
    - Can limit prosecution history estoppel to a single element.
**Post-Festo Prosecution Suggestions**

- If amend, state if for reason not related to patentability or clarify what is surrendered.
- Be aware of potential estoppel in every statement.
- Unmistakable assertion made in support of patentability.
- Estoppel effect even though statement not necessary to secure allowance of claim.
- **DOE:** paragraph included in U.S. Pat. No. 6,781,030 (cloning patent issued August 24, 2004) under a subheading entitled “Equivalents”:
  - While this invention has been particularly shown and described with references to preferred embodiments thereof, it will be understood by those skilled in the art that various changes in form and details may be made therein without departing from the scope of the invention encompassed by the appended claims.
More Prosecution Suggestions

• Being prevented by the "new matter" doctrine from adding a known equivalent to a claim at the time of the amendment is no excuse.
  ▪ If an equivalent is unknown at the time of filing, but known at the time of the amendment, the patentee should file a CIP to cover the known equivalent.

• EXAMINER ESTOPPEL!!!: "If the patentee does not rebut an examiner’s comment or acquiesces to an examiner’s request, the patentee’s unambiguous acts or omissions can create an estoppel.”

• Infectious estoppel: if a claim is narrowed to a certain limitation, infectious estoppel applies to all other claims containing that limitation UNLESS “unmistakable indication to the contrary.” See Glaxo v. Impax (Fed. Cir. 2004).
Thank you

J. Michael Jakes
Finnegan, Henderson, Farabow, Garrett & Dunner, LLP
901 New York Avenue, NW
Washington, DC 20001-4413
202.408.4045
mike.jakes@finnegan.com

Barbara C. McCurdy
Finnegan, Henderson, Farabow, Garrett & Dunner, LLP
901 New York Avenue, NW
Washington, DC 20001-4413
202.408.4047
barbara.mccurdy@finnegan.com

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

Amanda K. Murphy, Ph.D.
Finnegan, Henderson, Farabow, Garrett & Dunner, LLP
901 New York Avenue, NW
Washington, DC 20001-4413
202.408.4114
amanda.murphy@finnegan.com