PATENT LAW

Randy Canis

CLASS 10

Prosecution pt. 2; Infringement pt. 2

Prosecution pt. 2

Inequitable Conduct

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Duty to Disclose Rule

• (a)... Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section. The duty to disclose information exists with respect to each pending claim until the claim is cancelled or withdrawn from consideration, or the application becomes abandoned. Information material to the patentability of a claim that is cancelled or withdrawn from consideration need not be submitted if the information is not material to the patentability of any claim remaining under consideration in the application. There is no duty to submit information which is not material to the patentability of any existing claim. The duty to disclose all information known to be material to patentability is deemed to be satisfied if all information known to be material to patentability of any claim issued in a patent was cited by the Office or submitted to the Office in the manner prescribed by §§ 1.97(b)-(d) and 1.98. However, no patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct.

Duty to Disclose Rule

The Office encourages applicants to carefully examine

- (1) Prior art cited in search reports of a foreign patent office in a counterpart application, and
- (2) The closest information over which individuals associated with the filing or prosecution of a patent application believe any pending claim patentably defines, to make sure that any material information contained therein is disclosed to the Office.
- (b) Under this section, **information is material to patentability when it is not cumulative to information already of record** or being made of record in the application, and
- (1) It establishes, by itself or in combination with other information, a *prima facie* case of unpatentability of a claim; or
 (2) It refutes, or is inconsistent with, a position the applicant takes in:
- (i) Opposing an argument of unpatentability relied on by the Office, or(ii) Asserting an argument of patentability.

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Duty to Disclose Rule

 A prima facie case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.

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Duty to Disclose Rule

- (c) Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:
 - (1) Each **inventor** named in the application;
 - $\ensuremath{(2)}$ Each $\ensuremath{\text{attorney}}$ or agent who prepares or prosecutes the application; and
 - (3) Every other person who is **substantively involved in the preparation or prosecution of the application** and who is associated with the inventor, the applicant, an assignee, or anyone to whom there is an obligation to assign the application.

Duty to Disclose Rule

(d) Individuals other than the attorney, agent or inventor may comply with this section by **disclosing information to the attorney**, agent, or inventor.

(e) In any continuation-in-part application, the duty under this section includes the duty to disclose to the Office all information known to the person to be material to patentability, as defined in paragraph (b) of this section, which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

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Duty of Disclosure

- Types of Materials to be Disclosed:
 - Known Prior Art
 - Prior Art in Related US Matters
 - Prior Art in Related Foreign Matters
 - Advise PTO of related matters

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Current Method of Disclosure

 Submission of one or more information disclosure statements (IDS) during prosecution to make the USPTO aware of any prior art

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Timely IDS Submission

- Before a first office action: may be submitted without certification or fee
- After a first office action: may be submitted with a timeliness certification or a fee
- After allowance: may be submitted with a timeliness certification and a fee
- After payment of issue fee: may be withdrawn from issue, admission of unpatentability of at least one claim, and an amendment with explanation giving reasons why claim(s) patentable

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Failure to Disclose

 Failing to disclosure known prior art may result in a finding of inequitable conduct. An inequitable conduct finding makes a unenforceable even if the patent would otherwise be valid. In addition, an inequitable conduct finding may result in the patent attorney being liable for malpractice.

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Critical points about candor & inequitable conduct

- Inequitable conduct even as to a single claim renders entire patent invalid & unenforceable
- · Fruit of the poisonous tree
- Inequitable conduct can create antitrust liability where patent should have been denied or is invalid from inequitable conduct
- But inequitable conduct can be purged by appropriate handling

Critical points about candor & inequitable conduct

PTO relies on voluntary disclosure of information by an applicant, who has an uncompromising duty to disclose material facts to ensure that a patent issues free from fraud or inequitable conduct.

Critical points about candor & inequitable conduct

· Candor and duty to disclose are at the heart of our U.S. patent system. The applicant has a duty to disclose material information bearing on patentability. All persons substantively involved in the patent application, preparation or prosecution must make such disclosures to the PTO

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McKesson Information Solutions v. Bridge Medical

- The case relates to non-disclosure to the PTO of three items during prosecution of a patent application.
- At the district court, a determination was made the items were material and that the disclosures were made with deceptive intent.

McKesson Information Solutions v. Bridge Medical

- First application Attorney argued "[n]one of the references either singularly or in combination teach or suggest the claimed invention. In addition to numerous other differences, none of the references teach the three node approach to communications as provided in the claimed invention."
- Second application
- Co-pending with the first application Same initial citation of prior art
- The attorney had disclosed the existence of the first application, but did not disclose the rejection of the claims in the office action received in the first case.
- Attorney disclosed and had an interview regarding a new prior art reference for the second application but not the first application.
- Attorney did not make the first Examiner aware of the allowance of the second application.

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McKesson Information Solutions v. Bridge Medical

- · Omissions Deemed Material
- Failure to disclosure a patent considered relevant by PTO in a similar application
- Rejection of claims in a similar application
- Allowance of claims in a similar application

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McKesson Information Solutions v. Bridge Medical

- Unenforceability
- "A patent may be rendered unenforceable for inequitable conduct if an applicant, with intent to mislead or deceive the examiner, fails to disclose material information or submits materially false information to the PTO during prosecution." Digital Control Inc. v. Charles Mach. Works, 437 F.3d 1309, 1313 (Fed. Cir. 2006)

McKesson Information Solutions v. Bridge Medical

- Judgment is based on a reasonable examiner standard
- Would an examiner consider the materials important or cumulative?
- MPEP 2106

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Therasense, Inc. v. Becton, Dickinson & Co.

- · Case History
 - D.C. unenforceable due to inequitable conduct
 - En Banc Federal Circuit vacates and remands
- Invention
 - Disposable blood glucose test strips for diabetes management

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Therasense, Inc. v. Becton, Dickinson & Co.

1. A single use disposable electrode strip for attachment to the signal readout circuitry of a sensor to detect a current representative of the concentration of a compound in a drop of a whole blood sample comprising:

 a) an elongated support having a substantially flat, planar surface, adapted for releasable attachment to said readout circuitry;
 b) a first conductor extending along said surface and comprising a conductive

element for connection to said readout circuitry;
c) an active electrode on said strip in electrical contact with said first conductor

of an active encode of sain stip in electrical contract with sain list conductor and positioned to contact said whole blood sample;

d) a second conductor extending along said surface comprising a conductive

element for connection to said read out circuitry; and e) a reference counterelectrode in electrical contact with said second conductor and positioned to contact said whole blood sample,

wherein said active electrode is configured to be exposed to said whole blood sample without an intervening membrane or other whole blood filtering member

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Therasense, Inc. v. Becton, Dickinson & Co.

- After problems during prosecution, new claims were presented to the Examiner based on a new sensor that did not require a protective membrane for whole blood.
- The Examiner required an affidavit that, at the time of the invention, the prior art required a membrane for whole blood

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Therasense, Inc. v. Becton, Dickinson & Co.

- · US patent counsel
 - "optionally, but preferably" language is patent phraseology and not a technical teaching
- · European counsel
 - "It is submitted that this disclosure is unequivocally clear. The protective membrane is optional, however, it is preferred when used on live blood in order to prevent the larger constituents of the blood, in particular erythrocytes from interfering with the electrode sensor."

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Therasense, Inc. v. Becton, Dickinson & Co.

- D.C. '551 patent unenforceable "for inequitable conduct because Abbott did not disclose to the PTO its briefs to the EPO filed on January 12, 1994 and May 23, 1995."
- DC also found invalidity and nonfringement for the '551 patent and another patent at suit

Therasense, Inc. v. Becton, Dickinson & Co.

- Panel on Fed. Cir upheld with a dissent
- "Recognizing the problems created by the expansion and overuse of the inequitable conduct doctrine, this court granted Abbott's petition for rehearing en banc and vacated the judgment of the panel."

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Therasense, Inc. v. Becton, Dickinson & Co.

- · Effect of Inequitable Conduct
 - Defense to patent infringement
 - Bars enforcement of a patent when found
- · Historical Inequitable Conduct
 - "egregious misconduct, including perjury, the manufacture of false evidence, and the suppression of evidence."
 - "deliberately planned and carefully executed scheme[s] to defraud" not only the PTO but also the courts.

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Therasense, Inc. v. Becton, Dickinson & Co.

- · Evolution of Inequitable Conduct
 - "[E]mbrace[d] a broader scope of misconduct, including not only egregious affirmative acts of misconduct intended to deceive both the PTO and the courts but also the mere nondisclosure of information to the PTO."
 - "[U]nenforceability of the entire patent rather than mere dismissal of the instant suit."

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Therasense, Inc. v. Becton, Dickinson & Co.

- "[I]nequitable conduct came to require a finding of both intent to deceive and materiality."
- "In the past, this court has espoused low standards for meeting the intent requirement, finding it satisfied based on gross negligence or even negligence."
- "This court has also previously adopted a broad view of materiality, using a 'reasonable examiner' standard based on the PTO's 1977 amendment to Rule 56"
- · Sliding scale approach

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Therasense, Inc. v. Becton, Dickinson & Co.

- · Effects
 - Full disclosure
 - "[I]nequitable conduct has become a significant litigation strategy. A charge of inequitable conduct conveniently expands discovery into corporate practices before patent filing and disqualifies the prosecuting attorney from the patentee's litigation team."

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Therasense, Inc. v. Becton, Dickinson & Co.

- "Unlike other deficiencies, inequitable conduct cannot be cured by reissue"
- "[T]he taint of a finding of inequitable conduct can spread from a single patent to render unenforceable other related patents and applications in the same technology family."
- "With [] far-reaching consequences, it is no wonder that charging inequitable conduct has become a common litigation tactic."

Therasense, Inc. v. Becton, Dickinson & Co.

 "With inequitable conduct casting the shadow of a hangman's noose, it is unsurprising that patent prosecutors regularly bury PTO examiners with a deluge of prior art references, most of which have marginal value."

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Therasense, Inc. v. Becton, Dickinson & Co.

 "This court now tightens the standards for finding both intent and materiality in order to redirect a doctrine that has been overused to the detriment of the public."

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Therasense, Inc. v. Becton, Dickinson & Co.

 "To prevail on a claim of inequitable conduct, the accused infringer must prove that the patentee acted with the specific intent to deceive the PTO. ... A finding that the misrepresentation or omission amounts to gross negligence or negligence under a 'should have known' standard does not satisfy this intent requirement."

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Therasense, Inc. v. Becton, Dickinson & Co.

 "[T]he accused infringer must prove by clear and convincing evidence that the applicant knew of the reference, knew that it was material, and made a deliberate decision to withhold it."

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Therasense, Inc. v. Becton, Dickinson & Co.

"[T]he materiality required to establish inequitable conduct is but-for materiality. When an applicant fails to disclose prior art to the PTO, that prior art is but-for material if the PTO would not have allowed a claim had it been aware of the undisclosed prior art. Hence, in assessing the materiality of a withheld reference, the court must determine whether the PTO would have allowed the claim if it had been aware of the undisclosed reference."

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Antitrust Type Claim

- · Fraud on the patent office
- Antitrust liability = treble damages
- "To demonstrate Walker Process fraud, a claimant must make higher threshold showings of both materiality and intent than are required to show inequitable conduct."

Walker Process Claim

"In Walker Process, the Supreme Court held that a plaintiff could bring an action under §2 of the Sherman Act based on the alleged maintenance and enforcement of a fraudulently-obtained patent. ... In order to prevail on a Walker Process claim, the antitrust-plaintiff must show two things: first, that the antitrust-defendant obtained the patent by knowing and willful fraud on the patent office and maintained and enforced the patent with knowledge of the fraudulent procurement; and second, all the other elements necessary to establish a Sherman Act monopolization claim. ..."

Walker Process Claim

- "The 'other elements' necessary to establish an attempted monopolization claim are: '(1) that the defendant has engaged in predatory or anticompetitive conduct with (2) a specific intent to monopolize and (3) a dangerous probability of achieving monopoly power.' ... In determining the dangerous probability of achieving monopoly power for element (3), the courts look at 'the relevant market and the defendant's ability to lessen or destroy competition in that market."
- <u>Transweb, LLC v. 3M Innovative Properties (Fed. Cir. 2016)</u>

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Post-Grant Procedures

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Certificate of Correction PTO Mistake

35 U.S.C. 254 Certificate of correction of Patent and Trademark Office mistake.

Trademark Office mistake.
• Whenever a mistake in a patent, incurred through the fault of the Patent and Trademark Office, is clearly disclosed by the records of the Office, the Director may issue a certificate of correction stating the fact and nature of such mistake, under seal, without charge, to be recorded in the records of patents. A printed copy thereof shall be attached to each printed copy of the patent, and such certificate shall be considered as part of the original patent. Every such patent, together with such certificate, shall have the same effect and operation in law on the trial of actions for causes thereafter arising as if the same had been originally issued in such corrected form. The Director may issue a corrected patent without charge in lieu of and with like effect as a certificate of correction.

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Certificate of Correction PTO Mistake

- Who may request that the USPTO issue a certificate of correction?
 - patentee or the patentee's assignee
 - USPTO (sua sponte)
 - Third parties

37 CFR 1.322(a)

Certificate of Correction PTO Mistake

- USPTO has discretion whether to issue the certificate of correction
 - "Office mistakes are of such a nature that the meaning intended is obvious from the context, the Office may decline to issue a certificate and merely place the correspondence in the patented file, where it serves to call attention to the matter in case any question as to it subsequently arises.
 - "[W]here errors are of a minor typographical nature, or are readily apparent to one skilled in the art, a letter making the error(s) of record can be submitted in lieu of a request for a Certificate of Correction. There is no fee for the submission of such a letter."

MPEP 1480

Certificate of Correction Applicant's Mistake

35 U.S.C. 255 Certificate of correction of applicant's mistake.

mistake.

Whenever a mistake of a clerical or typographical nature, or of minor character, which was not the fault of the Patent and Trademark Office, appears in a patent and a showing has been made that such mistake occurred in good faith, the Director may, upon payment of the required fee, issue a certificate of correction, if the correction does not involve such changes in the patent as would constitute new matter or would require reexamination. Such patent, together with the certificate, shall have the same effect and operation in law on the trial of actions for causes thereafter arising as if the same had been originally issued in arising as if the same had been originally issued in such corrected form.

Applicant's Mistake

Certificate of Correction

- · The mistake must be:
 - (1) of a clerical nature,
 - (2) of a typographical nature, or
 - (3) a mistake of minor character.
- · The correction must not involve changes which would:
 - (1) constitute new matter or
 - (2) require reexamination.

M.P.E.P. 1481

Can a Claim be Broadened with a Certificate of Correction?

Superior Fireplace Co. v. Majestic Products Co.

"Sections 251 and 252 evince the clear intent of Congress to protect the public against the unanticipated broadening of a claim after the grant of the patent by the PTO. It would be inconsistent with that objective to interpret §255 to allow a patentee to broaden a claim due to the correction of a clerical or typographical mistake that the public could not discern from the public file and for which the public therefore had no effective notice. Such a broadening correction would leave the public without effective notice without the constraint of a two-year time bar, and without the hope of intervening rights...

Correcting Named Inventor

35 U.S.C. 256 Correction of named inventor.

- (a) CORRECTION.--Whenever through error a person is named in an issued patent as the inventor, or through error an inventor is not named in an issued patent, the Director may, on application of all the parties and assignees, with proof of the facts and such other requirements as may be imposed, issue a certificate correcting
- (b) PATENT VALID IF ERROR CORRECTED.--The error of omitting inventors or naming persons who are not inventors shall not invalidate the patent in which such error occurred if it can be corrected as provided in this section. The court before which such matter is called in question may order correction of the patent on notice and hearing of all parties concerned and the Director shall issue a certificate accordingly.

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Inventorship Correction

- · By the PTO or through a court directing the PTO
- · Inventors may be added or removed
- · Must provide proof of facts

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Ethicon, Inc. v. United States Surgical Corp.

• "35 U.S.C. §256 provides that a co-inventor omitted from an issued patent may be added to the patent by a court 'before which such matter is called in question.' To show co-inventorship, however, the alleged co-inventor or co-inventors must prove their contribution to the conception of the claims by clear and convincing evidence. ... However, 'an inventor's testimony respecting the facts surrounding a claim of derivation or priority of invention cannot, standing alone, rise to the level of clear and convincing proof."

Ethicon, Inc. v. United States Surgical Corp.

• "Thus, an alleged co-inventor must supply evidence to corroborate his testimony. ... Corroborating evidence may take many forms. Often contemporaneous documents prepared by a putative inventor serve to corroborate an inventor's testimony. ... Circumstantial evidence about the inventive process may also corroborate. ... Additionally, oral testimony of someone other than the alleged inventor may corroborate. ..."

Statutory Disclaimer

Statutory Disclaimer

35 U.S.C. 253 Disclaimer.

- Whenever, without any deceptive intention, a claim of a patent is invalid the remaining claims shall not thereby be rendered invalid. A patentee, whether of the whole or any sectional interest therein, may, on payment of the fee required by law, make disclaimer of any complete claim, stating therein the extent of his interest in such patent. Such disclaimer shall be in writing, and recorded in the Patent and Trademark Office; and it shall thereafter be considered as part of the original patent to the extent of the interest possessed by the disclaimant and by those claiming under him.
- In like manner any patentee or applicant may disclaim or dedicate to the public the entire term, or any terminal part of the term, of the patent granted or to be granted.

Statutory Disclaimer

- · Patentee may disclaim one or more claims of his/her patent by filing in the Office a disclaimer as provided by the statute.
- · (Maintaining a claim known to be invalid renders a patent unenforceable.)

Reissue/Reexamination

Correction of Substantive Errors

- · Reissue applicants correction of more significant errors affecting the validity and enforceability of an issued patent
- Reexamination allows applicants or third parties to request that the PTO reconsider the validity of the patent

Reissue

- 35 U.S.C. 251 Reissue of defective patents.

 Whenever any patent is, through error, deemed wholly or partly inoperative or invalid, by reason of a defective specification or drawing, or by reason of the patentee claiming more or less than he had a right to claim in the patent, the Director shall, on the surrender of such patent and the payment of the fee required by law, reissue the patent for the invention disclosed in the original patent, and in accordance with a new and amended application, for the unexpired part of the term of the original patent. No new matter shall be introduced into the application for reissue.

 The Director may issue several reissued patents for distinct and separate parts of the thing patented, upon demand of the applicant, and upon payment of the required fee for a reissue for each of such reissued patents.

 The provisions of this title relating to application for patent shall be
- payment of the required net for a resisted or learn of such resisted platents. The provisions of this title relating to applications for patent shall be applicable to applications for reissue of a patent, except that application for reissue may be made and sown to by the assignee of the entire interest if the application does not seek to enlarge the scope of the claims of the original patent or the application for the original patent was filed by the assignee of the entire interest.
- No reissued patent shall be granted enlarging the scope of the claims of the original patent unless applied for within two years from the grant of the original patent.

Reissue

- 1. Applicant must have reasons:
 - Defective specification
 - Defective drawing
 - Claims claimed too much or too little
 - Claim scope can only be expanded during first two years of issuance (i.e., a broadening reissue)
- 2. Applicant must allege that the defective, inoperative, or invalid patent arose through error.

Reissue

How it works

- · Patentee surrenders original patent.
- · Patentee (or assignee with patentee approval) only can file.
- Patentee files oath setting forth error in original patent.
- · Must show error was w/o deceptive intent.
- · Patentee submits marked-up copy of patent with changes/additions/deletions.
- Prosecution starts ab initio.
- · Public is put on notice of reissue proceeding

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Reissue

- Can seek broader claims (only w/in 2 yrs. of issue) or narrower claims
- Cannot be used to correct inequitable conduct in original prosecution
- Cannot recapture claim given up in original prosecution
- Can't defeat "intervening rights" of another who relied upon original claims. Broadened reissue claims can't be enforced against another who designed structure outside original claims
- Reissue petition need not point out any error
- Reissue has risk of involvement in interference

Recapture Rule

- If the patentee opted to narrow its claims to avoid a prior art reference, then he cannot use the reissue proceeding to recapture the abandoned subject matter.
- · Prevents a patentee from acquiring through reissue claims of the same or broader scope than those canceled from the original application.

Recapture Rule

- "If a patentee tries to recapture what he or she previously surrendered in order to obtain allowance of original patent claims, that 'deliberate withdrawal or amendment ... cannot be said to involve the inadvertence or mistake contemplated by 35 U.S.C. §251, and is not an error of the kind which will justify the granting of a reissue patent which includes the matter withdrawn.' ... 'The recapture rule bars the patentee from acquiring, through reissue, claims that are of the same or of broader scope than those claims that were canceled from the original application.' ..."
- Mentor Corp. v. Coloplast Inc.

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Broadening Under the Recapture Rule

- "Reissue claims that are broader in certain respects and narrower in others may avoid the effect of the recapture rule. If a reissue claim is broader in a way that does not attempt to reclaim what was surrendered earlier, the recapture rule may not apply."
- Mentor Corp. v. Coloplast Inc.

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Intervening Rights

 Just because you are able to broaden a patent, does not mean that you will then be able to obtain damages against an infringer that relied on the original claims when acting

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Seattle Box Co. v. Industrial Crating & Packing, Inc.

 "Because of such pre-reissue activity, an infringer might enjoy a 'personal intervening right' to continue what would otherwise be infringing activity after reissue. The underlying rationale for intervening rights is that the public has the right to use what is not specifically claimed in the original patent."

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Seattle Box Co. v. Industrial Crating & Packing, Inc.

 "In these circumstances, the new reissue claims in this case present a compelling case for the application of the doctrine of intervening rights because a person should be able to make business decisions secure in the knowledge that those actions which fall outside the original patent claims are protected."

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Antares Pharma, Inc. v. Medac Pharma Inc.

- Case History
- D.C.DE
 - Reissue claims are invalid for failing to comply with the "original patent" requirement
- 2014 Panel Fed. Cir. of <u>Dyk</u>, Reyna, and Taranto
 - Affirmed

Antares Pharma, Inc. v. Medac Pharma Inc.

- Invention
 - "a system for injecting medicant in which a needle punctures the skin before forcefully expelling the medicant, thereby minimizing some of the downsides of typical jet injectors (in which the medicant itself ruptures the outer layers of skin), while still maintaining some of the advantages of typical jet injectors."

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Antares Pharma, Inc. v. Medac Pharma Inc.

- · What happened during prosecution?
 - "During prosecution, the applicants repeatedly distinguished their invention from the prior art by focusing on the 'jet injector' limitation present in their claims but not the prior art. The originally issued claims all contained the 'jet injection' limitation."

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Antares Pharma, Inc. v. Medac Pharma Inc.

- · Broadening Reissue
 - "Section 251 allows a patent holder to correct an existing, issued patent by broadening or narrowing the originally issued claims. If the claims sought on reissue are broader than the original claims, the patentee must apply for the reissue within two years of the patent issuing."

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Antares Pharma, Inc. v. Medac Pharma Inc.

- Reissue is subject to the recapture rule
 - "The recapture rule generally prohibits applicants from claiming, on reissue, claim scope surrendered during the course of the original prosecution."

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Antares Pharma, Inc. v. Medac Pharma Inc.

Reissue requirements

- 1)Claims cannot violate the recapture rule
- 2)Claims must satisfy the original patent requirement
- 3)Applicant cannot add new matter to the specification

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Antares Pharma, Inc. v. Medac Pharma Inc.

 "Director shall ... reissue the patent for the invention disclosed in the original patent ..." (1952)

Antares Pharma, Inc. v. Medac Pharma Inc.

 "[A] reissue claim is for the 'same invention' if the original patent specification fully describes the claimed inventions, but not if the broader claims 'are [] merely suggested or indicated in the original specification."

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Antares Pharma, Inc. v. Medac Pharma Inc.

"Failing to disclose in the original patent matters claimed in the reissue will not enable the patentee to cover such new matter by the reissue, as least when the matter was within his knowledge when he applied for the original patent[; i]t is not enough that the invention might have been claimed in the original patent or that it was suggested in the specification..."

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Antares Pharma, Inc. v. Medac Pharma Inc.

"The original and reissue patents are for the same invention where the latter fully describes and claims the very invention intended to be secured by the original patent and describes and claims only those things which were embraced in that invention and where it is not merely suggested in the original but constitutes a part or portion of that invention.' [] The court considered that '[i]t is not enough that an invention might have been claimed in the original patent because it was suggested or indicated in the specification,' but must be 'explicitly disclosed and taught' in the specification."

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Antares Pharma, Inc. v. Medac Pharma Inc.

"Whether or not the written description requirement of §112 was satisfied here, Industrial Chemicals made clear that, for §251, 'it is not enough that an invention might have been claimed in the original patent because it was suggested or indicated in the specification.'

Rather, the specification must clearly and unequivocally disclose the newly claimed invention as a separate invention."

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Ex Parte Reexamination

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Reexamination

- Reexamination resulted from legislation intended to restore confidence in the validity of issued U.S. patents.
- The process allows the PTO to reconsider the validity of claims of an issued patent.

The Rexamination Request

- Anyone patentee, third party, or Director of the PTO
- Showing to initiate patents or patent applications raise a substantial new question of patentability
- Timing to initiate 3 months for PTO to decide

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Participation and Claims

- The role of the requestor is limited; only given right to reply to the patentee's opening statement
- Only the patentee may participate in the dialogue with the examiner, and only the patentee may appeal the matter to the Board or to the courts if the PTO reaches an unsatisfactory conclusion.
- Claims may be narrowed, but not broadened

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The Reexamination Process

- PTO first determines if there is a substantial issue of patentability of one or more claims.
- Prosecution is opened ex parte.
 (Patent owner proceeding in PTO)
- If examination proceeds, a certificate setting forth the results of the reexamination proceeding is issued.

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The Result of the Process

 "The reexamination process ends when the Director issues 'a certificate canceling any claim of the patent finally determined to be unpatentable, confirming any claim of the patent determined to be patentable, and incorporating in the patent any proposed amended or new claim determined to be patentable."

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Statutory Presumption?

 The statutory presumption of validity does not apply in a reexamination proceeding.

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Inter Partes Reexamination

- Added in 1999; similar to ex parte reexamination
- Third party requestor may opt to submit written comments to accompany patentee responses to the PTO
- The requestor may appeal a PTO determination that a reexamination patent is not invalid to the Board and the courts
- Third party participants are estopped from raising issues that they raised or could have raised during reexamination during subsequent litigation
- Unsuccessful challengers originally could not appeal to the Federal Circuit, but from new 2002 law can appeal to the Board → Federal Circuit
- Legislated out of existence with AIA

Infringement pt. 2

The Doctrine of Equivalents for Non-Textual Infringement

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Graver Tank & Mfg. Co. v. Linde Air Products Co.

- 1950 Supreme Court
- Issue
 - Test under the doctrine of equivalents (DOE)

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Infringement Under the Doctrine Equivalents

- First Inquiry Does a device or method literally infringe one or more claims of a patent?
- <u>Second Inquiry</u> Does a device or method infringe one or more claims of a patent under the doctrine of equivalents (DOE)?

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Graver Tank & Mfg. Co. v. Linde Air Products Co.

- Determine if literal infringement exists first
- "In determining whether an accused device or composition infringes a valid patent, resort must be had in the first instance to the words of the claim. If accused matter falls clearly within the claim, infringement is made out and that is the end of it."

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Graver Tank & Mfg. Co. v. Linde Air Products Co.

- · What does DOE protect against?
- "Outright and forthright duplication is a dull and very rare type of infringement. To prohibit no other would place the inventor at the mercy of verbalism and would be subordinating substance to form. It would deprive him of the benefit of his invention and would foster concealment rather than disclosure of inventions, which is one of the primary purposes of the patent system."

Graver Tank & Mfg. Co. v. Linde Air Products Co.

 "The essence of the doctrine is that one may not practice a fraud on a patent."

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Graver Tank & Mfg. Co. v. Linde Air Products Co.

- Function-Way Result a/k/a "Triple Identity" Test
- "[A] patentee may invoke this doctrine to proceed against the producer of a device 'if it performs substantially the same function in substantially the same way to obtain the same result." ... The theory on which it is founded is that 'if two devices do the same work in substantially the same way, and accomplish substantially the same result, they are the same, even though they differ in name, form, or shape."

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Graver Tank & Mfg. Co. v. Linde Air Products Co.

"Equivalence ... does not require complete identity for every purpose and in every respect. In determining equivalents, things equal to the same thing may not be equal to each other and, by the same token, things for most purposes different may sometimes be equivalents. 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."

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Warner-Jenkinson Company v. Hilton Davis Chemical Co.

- 1997 Supreme Court
- Issue:
 - How did the '52 Patent Act change the Doctrine of Equivalents? Clarifying the proper scope of the doctrine of equivalents.

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Warner-Jenkinson Company v. Hilton Davis Chemical Co.

- The Doctrine of Equivalents
 - "... [A] product or process that does not literally infringe upon the express terms of a patent claim may nonetheless be found to infringe if there is 'equivalence' between the elements of the accused product or process and the claimed elements of the patented invention."

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Warner-Jenkinson Company v. Hilton Davis Chemical Co.

 "Hilton Davis says it goes too far to describe that the function-way-result test as 'the test' for equivalents. ... Evidence beyond function, way, and result informs application of the doctrine, which focuses on the substantiality of changes from the claims in the accused device. ...

Warner-Jenkinson Company v. Hilton Davis Chemical Co.

· "One of ordinary skill in the relevant art provides the perspective for assessing the substantiality of differences between the claims and the accused device. ... 'The test is objective with proof of the substantiality of the differences resting on objective evidence.' ..."

Warner-Jenkinson Company v. Hilton Davis Chemical Co.

· "Each element contained in a patent claim is deemed material to defining the scope of the patented invention, and thus the doctrine of equivalents must be applied to individual elements of the claim, not to the invention as a whole. It is important to ensure that the application of the doctrine, even as to an individual element, is not allowed such broad play as to effectively eliminate that element in its entirety."

Warner-Jenkinson Company v. Hilton Davis Chemical Co.

- What is "prosecution history estoppel" or "file wrapper estoppel"?
- estoppel*?

 You can't claim that something is covered by the doctrine of equivalents if it was given up during patent prosecution.

 "In our view, holding that certain reasons for a claim amendment may avoid the application of prosecution history estoppel is not tantamount to holding that the absence of a reason for an amendment may similarly avoid such an estoppel. Mindful that claims do indeed serve both a definitional and a notice function, we think the better rule is to place the burden on the patent holder to establish the reason for an amendment required during patent prosecution."

 Does the intent of the potential infringer matter when considering the scope of the doctrine of equivalents?

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Warner-Jenkinson Company v. Hilton Davis Chemical Co.

· "Insofar as the question under the doctrine of equivalents is whether an accused element is equivalent to a claimed element, the proper time for evaluating equivalency—and thus knowledge of interchangeability between elements-is at the time of infringement, not at the time the patent was issued."

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Warner-Jenkinson Company v. Hilton Davis Chemical Co.

 "There seems to be substantial agreement that, while the triple identity test may be suitable for analyzing mechanical devices, it often provides a poor framework for analyzing other products or processes. On the other hand, the insubstantial differences test offers little additional guidance as to what might render any given difference 'insubstantial."

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Warner-Jenkinson Company v. Hilton Davis Chemical Co.

"Does the accused product or process contain elements identical or equivalent to each claimed element of the patented invention? Different linguistic frameworks may be more suitable to different cases, depending on their particular facts. A focus on individual elements and a special vigilance against allowing the concept of equivalence to eliminate completely any such elements should reduce considerably the imprecision of whatever language is used An analysis of the role played by each element in the context of the specific patent claim will thus inform the inquiry as to whether a substitute element matches the function, way, and result of the claimed element, or whether the substitute element plays a role substantially different from the claimed element.

Warner-Jenkinson Company v. Hilton Davis Chemical Co.

- "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.

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Ring & Pinion Service Inc. v. ARB Corp. Ltd.

- · Case History
- W.D.WA
- Summary judgment of noninfringement
- Panel Fed. Cir. of <u>Moore</u>, Clevenger, and Revna
 - Reverse and remand with instructions to enter judgment of infringement

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Ring & Pinion Service Inc. v. ARB Corp. Ltd.

- · Claim 1
- · A locking differential comprising
- a differential carrier . . . ,
- · a locking means . . .
- cylinder means formed in said differential carrier and housing an actuator position[ed] to cause movement of said locking means relative to said carrier

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Ring & Pinion Service Inc. v. ARB Corp. Ltd.

- Issue "whether an equivalent is barred under the doctrine of equivalents because it was foreseeable at the time of the patent application."
- · "All-Limitations Rule"

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Ring & Pinion Service Inc. v. ARB Corp. Ltd.

 "There is not, nor has there ever been, a foreseeability limitation on the application of the doctrine of equivalents. It has long been clear that known interchangeability weighs in favor of finding infringement under the doctrine of equivalents."

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Ring & Pinion Service Inc. v. ARB Corp. Ltd.

 "Excluding equivalents that were foreseeable at the time of patenting would directly conflict with these holdings that 'known interchangeability' supports infringement under the doctrine of equivalents. We conclude that the foreseeability of an equivalent at the time of patenting is not a bar to a finding of infringement under the doctrine of equivalents."

Ring & Pinion Service Inc. v. ARB Corp. Ltd.

"Equivalence under section 112(f) is evaluated at the time of issuance. ... Equivalence under the doctrine of equivalents, in contrast, is evaluated at the time of infringement. [] Hence, an after-arising technology, a technology that did not exist at the time of patenting, can be found to be an equivalent under the doctrine of equivalents even though it cannot be an equivalent under the literal infringement analysis of §112(f)."

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Ring & Pinion Service Inc. v. ARB Corp. Ltd.

 "For literal infringement, the accused structures must perform the function recited in the claim (identical function). ... The doctrine of equivalents thus covers structures with equivalent, but not identical, functions."

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Ring & Pinion Service Inc. v. ARB Corp. Ltd.

 "Where a finding of non-infringement under §112(f) is based solely on the lack of identical function, it does not preclude a finding of equivalence under the doctrine of equivalents."

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Limitations on the Doctrine of Equivalents

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Limitations on DOE

- In what ways might the Doctrine of Equivalents be limited?
 - "All Elements" rule
 - Prosecution History Estoppel
 - Scope of Prior Art

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"All Elements" Rule

- "[T]he doctrine of equivalents can only apply to an accused product or process that contains each limitation of a claim, either literally or equivalently."
- How is the "all elements" rule applied?

Pennwalt Corp v. Durand-Wayland

"[I]n applying the doctrine of equivalents, each limitation must be viewed in the context of the entire claim... 'It is ... well settled that each element of a claim is material and essential, and that in order for a court to find infringement, the plaintiff must show the presence of every element or its substantial equivalent in accused device.' Lemelson v. United States, 752 F.2d 1538..."

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Corning Glass Works v. Sumitomo Electric USA, Inc.

 "Although each claim limitation may not literally be found in the accused structure, the 'substantially the same way' prong of the Graver Tank test is met if an equivalent of a recited limitation has been substituted in the accused device."

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Corning Glass Works v. Sumitomo Electric USA, Inc.

"Element' may be used to mean a single limitation, but it has also been used to mean a series of limitations which, taken together, make up a component of the claimed invention. In the All Elements rule, 'element' is used in the sense of a limitation of a claim....
 An equivalent must be found for every limitation of the claim somewhere in an accused device, but not necessarily in a corresponding component, although that is generally the case."

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Corning Glass Works v. Sumitomo Electric USA, Inc.

 "Although each claim limitation may not literally be found in the accused structure, the "substantially the same way" prong of the Graver Tank test is met if an equivalent of a recited limitation has been substituted in the accused device."

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Prosecution History Estoppel

- What range of equivalents are you entitled to when you amend claims during prosecution?
- Hilton Davis decision added a stronger prosecution history estoppel rule. Under the new rule, where the record does not reveal the reason for a claim amendment made during prosecution, a rebuttable presumption arises that the amendment was made "for reasons of patentability."

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Festo Corp. v. Shoketsu Kinzoku

 Federal Circuit C.A. in Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co. considered charges that Festo's patents on "magnetically coupled rodless cylinders" were infringed under the doctrine of equivalents.

Festo Corp. v. Shoketsu Kinzoku

 Court considered whether to apply prosecution history estoppel under its previous "flexible bar," even if such charges were barred for the preamended claims (that is, before making the amendment during prosecution).

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Festo Corp. v. Shoketsu Kinzoku

 In an 8-4 ruling, the en banc Federal Circuit abandoned its flexible bar and adopted a <u>complete bar</u> against equivalents infringement for the amended claims in the issued patent.

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Festo Corp. v. Shoketsu Kinzoku

 The Federal Circuit court in also held 11-1 that prosecution history estoppel applies to any amendment that narrows the scope of a claim for any reason related to patentability, not just to avoid prior art.

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Festo Corp. v. Shoketsu Kinzoku

 In June 2001, the Supreme Court granted Festo's petition for certiorari, which presented the following questions:

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Festo Corp. v. Shoketsu Kinzoku

Issue #1 on Appeal at Supreme Court

 Whether every claim-narrowing amendment designed to comply with any provision of the Patent Act-including those provisions not related to prior art--automatically creates prosecution history estoppel regardless of the reason for the amendment; and

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Festo Corp. v. Shoketsu Kinzoku

Issue #2 on Appeal at Supreme Court

 Whether the finding of prosecution history estoppel completely bars the application of the doctrine of equivalents.

Festo Corp. v. Shoketsu Kinzoku

"Prosecution history estoppel requires that the claims of a patent be interpreted in light of the proceedings in the PTO during the application process. Estoppel is a 'rule of patent construction' that ensures that claims are interpreted by a reference to those 'that have been cancelled or rejected.' ... The doctrine of equivalents allows the patentee to claim those in substantial alterations that were not captured in drafting the original patent claim but which could be created through trivial changes."

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Festo Corp. v. Shoketsu Kinzoku

 "When, however, the patentee originally claimed the subject matter alleged to infringe but then narrowed the claim in response to a rejection, he may not argue that the surrendered territory comprised unforeseen subject matter that should be deemed equivalent to the literal claims of the issued patent..."

1

Festo Corp. v. Shoketsu Kinzoku

 "A rejection indicates that the patent examiner does not believe the original claim could be patented. While the patentee has the right to appeal, his decision to forgo an appeal and submit an amended claim is taken as a concession that the invention as patented does not reach as far as the original claim."

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Festo Corp. v. Shoketsu Kinzoku

Holding on Issue #1

- "... [A] narrowing amendment made to satisfy any requirement of the Patent Act may give rise to an estoppel."
- A patentee who narrows a claim as a condition for obtaining a patent disavows his claim to the broader subject matter, whether the amendment was made to avoid the prior art (not for other reasons tangential to patentability). In either event ... estoppel can apply as to elements narrowed by amendment.

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Festo Corp. v. Shoketsu Kinzoku

Holding on Issue #2

 Prosecution history estoppel is not a complete bar to assertion of the doctrine of equivalents. ... "Warner-Jenkinson held that the patentee bears the burden of proving that an amendment was not made for a reasons that would give rise to estoppel, we hold here that the patentee should bear the burden of showing that the amendment does not surrender the particular equivalent in question."

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Festo remanded to Federal Circuit - what happened there?

Sept. 26, 2003, Fed. Cir. concluded that a patentee failed in part to overcome prosecution history estoppel, and sent the case back to the trial court for further fact findings on whether the accused equivalent was foreseeable at the time of the claim amendment.

Federal Circuit decision in Festo

The en banc court elaborated the procedure for rebutting the presumption that a narrowing amendment surrendered subject matter for purposes of prosecution history. Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd., Fed. Cir., No. 95-1066, 9/26/03.

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Federal Circuit decision in Festo

Court spelled out three circumstances in which presumption could be rebutted:

- (1) where the accused equivalent was unforeseeable at the time of amdt.
- (2) where amdt. bore no more than a "tangential relation" to accused equiv.,or
- (3) where "some other reason" prevented patentee from describing accused equivalent in the patent appl.

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Federal Circuit decision in Festo

- The court also held that, despite factual issues relating to the skill in the art, the rebuttal of the presumption is a question of law to be determined by the court (I.e. the judge), not by a jury
 - and the Fed. Cir. Sent case back to trial court to determine if the amendments in question were foreseeable.

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"Foreseeability" in Festo

Whether presumption against finding of infringement under doctrine of equivalents can be rebutted depends on the forseeability of the narrowing patent amendment at the time of the amendment, not at the time of the application. Amgen Inc. v. Hoechst Marion Roussel Inc., D. Mass., No. 97-10814-WGY, 10/30/03, (Young, C.J.)

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The Effects of Festo ...

- Patent owners may breathe an audible sigh of relief that a doctrine of equivalents exists and it has some flexibility BUT . . .
- It is now much more important to develop and clearly understand prior art BEFORE filing of application by careful searching.
- · WHY?

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The Effects of Festo ...

PREPARATION OF SPECIFICATION

- Application must be prepared with even greater care to be sure to describe every conceivable variation and alternative and substitute for the preferred.
- Inventors must help make that true by suggesting alternatives, substitutes, modification, conceivable improvements and different routes to achieve inventive results and advantages.

The Effects of Festo ...

PREPARATION OF CLAIMS

- Care should be taken to avoid presenting claim errors that will require amendments.
- Draft claims in paragraph form to separate elements as much as possible.
- Claims of various scope, form and type can be advantageous, and claim in various different ways, so as to be able to avoid amendments which may destroy doctrine of equivalents.

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The Effects of Festo ...

PREPARATION OF CLAIMS

- Different types of claims: apparatus & method; means plus function
- If claims of different scope in application they can be allowed or rejected without requiring they be amended.

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The Effects of Festo ...

PROSECUTION

- Avoid narrowing amendments, as by substituting new claims.
- Conduct examiner interview(s) to consider with examiner what may be acceptable.
- Consider filing continuation or CIP appl.
- Explain purpose of amending, such as for clarity or purpose other than avoiding prior art, to reduce chances that amendment will be seen as overcoming prior art.

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Another Effect of Festo?

Although Supreme Court lifted complete bar to use of doct. of equivalents imposed by Fed. Cir., where an amdt. relating to patent-ability is made, Fed. Cir. has not make it easy for patent owners to avoid prosecution history estoppel. Because foreseeability is test at the time claims are narrowed by amendment, concern that inft. defendant will produce "hypothetical claims" literally covering accused device, drafted to make difficult for the patentee to explain why they were not included in the issued patent?

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Other problems after Festo?

Dedication Rule: A judicially created doctrine that limits scope of equivalents. How? Where subject matter <u>disclosed</u> in specification of application, but is <u>outside</u> literal scope of claims (left unclaimed), it is deemed dedicated to the public. Even doctrine of equivalents may not capture. See PSC Computer Prod., Inc. v. Foxconn International, Inc., 355 F.3d 1353 [Fed. Cir. 2004].

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The Dedication Doctrine

 ""[S]ubject matter disclosed but not claimed in a patent application is dedicated to the public,' " this court held that [a potential infringer] could not, as a matter of law, infringe under the doctrine of equivalents by using the disclosed [subject matter]."

Prior Art Limitations

Wilson Sporting Goods Co. v. David Geoffrey & Associates

- 1990 Federal Circuit Decision
- Invention
 - Configuration of Dimples on a Golf Ball

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Wilson Sporting Goods Co. v. David Geoffrey & Associates

 "[A] patentee should not be able to obtain, under the doctrine of equivalents, coverage which he could not lawfully have obtained from the PTO by literal claims."

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Wilson Sporting Goods Co. v. David Geoffrey & Associates

 "[S]ince prior art always limits what an inventor could have claimed, it limits the range of permissible equivalents of a claim."

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Tate Access Floors v. Interface Architectural Resources

- Federal Circuit 2002
- Issue
 - If literal infringement is found, will a DOE be considered to determine if the claims are invalid because they are covered by the prior art?

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Tate Access Floors v. Interface Architectural Resources

- · A floor panel for elevated floors comprising
- a rectangular base structure adapted to be supported at its corners and providing a load surface operable to support loads thereon,
- a floor covering mounted on said load surface providing a decorative exposed surface layer on the side thereof opposite said load surface,
- said floor covering providing an inner body portion having an appearance contrasting with the appearance of said decorative surface layer
- said floor covering providing a border along the edges of said panels along which said decorative surface layer is removed to expose said inner body portion and thereby provide an integral contrasting border around said decorative surface layer.

Tate Access Floors v. Interface Architectural Resources

"The doctrine of equivalents expands the reach of claims beyond their literal language. That this expansion is guided and constrained by the prior art is no surprise, for the doctrine of equivalents is an equitable doctrine and it would not be equitable to allow a patentee to claim a scope of equivalents encompassing material that had been previously disclosed by someone else, or that would have been obvious in light of others' earlier disclosures. But this limit on the equitable extension of literal language provides no warrant for constricting literal language when it is clearly claimed."

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Tate Access Floors v. Interface Architectural Resources

 "Moreover, just as the doctrine of equivalents cannot extend so broadly as to ensnare prior art, claim language should generally be construed to preserve validity, if possible."

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Program Completed

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