

Fall Carolina Patent Trademark and Copyright Law Association Meeting

Patent Law Developments

by Tom Irving





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Outline

- Patentable Subject Matter: <u>Bilski</u> and Beyond
- Obviousness
- Joint Infringement
- Written Description
- Claim Construction
 - Preamble
 - □ Product-by-Process Claims

- Inequitable Conduct
- Patent Term Adjustments
- Inducement to Infringe
- Double Patenting
- 271(f) Does Not Apply to Method Claims
- 102(e) and provisional applications
- Patent Marking





What Can Be Patented?



- 35 U.S.C. § 101 authorizes patents for:
 - Machines
 - Compositions of Matter
 - □ Articles of Manufacture
 - Processes



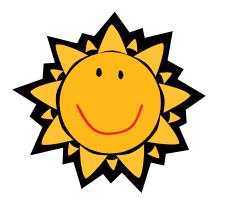






What Can Be Patented?

- Generally very broad
 - □ "[A]nything under the sun that is made by man." <u>Diamond v. Chakrabarty</u>, Supreme Court (1980)



- U.S. Supreme Court has held unpatentable:
 - □ Abstract ideas (e.g., mathematical algorithms)
 - □ Natural phenomena
 - □ Laws of nature
- In <u>Bilski</u>, Supreme Court maintains broad interpretation.





The Bilski Case

- ☐ Bilski's patent application:
 - 1. A method for managing the consumption risk costs of a commodity sold by a commodity provider at a fixed price comprising the steps of:. . .
- US Patent Office rejected.
- Claims are "broad enough to read on performing the steps without any machine or apparatus"
- Appeal to Court of Appeals
- ☐ Heard by full 12-judge court
- Nearly 40 amicus curiae briefs were filed
- Affirmed rejection of Bilski's claims. 545 F.3d 943 (Fed. Cir. 2008) (en banc).





The Federal Circuit's Test

A process is patentable under § 101 only if:

(1) it is tied to a particular machine or apparatus, or

(2) it transforms a particular article into a different state or thing





The Federal Circuit's Test

- Machine-or-Transformation Test
 - □ Transformation prong:
 - Must be central to the purpose of the invention
 - Must transform "physical objects or substances"
 - □ Not: legal obligations, organizational relationships, business risks.
 - Maybe: electronic transformation of data representing physical objects.
 - Machine prong:
 - Open question: whether reciting a computer sufficiently ties a process to a particular machine.





Before the Supreme Court

- Certiorari granted (<u>Bilski v. Doll</u>, 129 S.Ct. 2735 (U.S. Jun 01, 2009), questions briefed:
 - □ 1. Whether the Federal Circuit erred by holding that a "process" must be tied to a particular machine or apparatus, or transform a particular article into a different state or thing ("machine-or-transformation" test), to be eligible for patenting under 35 U.S.C. § 101, despite this Court's precedent declining to limit the broad statutory grant of patent eligibility for "any" new and useful process beyond excluding patents for "laws of nature, physical phenomena, and abstract ideas."
 - □ 2. Whether the "machine-or-transformation" test for patent eligibility adopted by the Federal Circuit, effectively foreclosing meaningful patent protection to a business method involving a series of transactions among a commodity provider, consumers, and market participants, contradicts the clear Congressional intent that patents protect "method[s] of doing or conducting business." 35 U.S.C. § 273.
- Oral Arguments held November 9, 2009.





Bilski Amicus Curiae Briefs Software and Computer Industry

M-or-T test too restrictive, intangibles like software should be patentable

Computerimplemented claims are "technical" and should be patentable

Software is unpatentable

Borland Software

Business Software Alliance

Computer & Communications Industry Association

Dolby Labs.

Entrepreneurial Software Companies

IBM

IEEE-USA

Microsoft, Philips, Symantec

Red Hat

Software & Information Industry Association

> Software Freedom Law Center





Bilski Amicus Curiae Briefs Biotechnology and Medical Technology

M-or-T test
too restrictive,
Chakrabaraty
"anything under the
sun" should apply

M-or-T test should not apply to biotech claims; should not lump biotech/medical methods with business methods

Medical patents raise ethical issues for doctors; scientific principles cannot be patented.

Caris Diagnostics,

Dr. Chakrabarty

Novartis

Univ. of South Florida

Monogram Biosciences

Biotechnology Industry Org.

Medtronic

PhRMA

Prometheus Labs.

Adamas Pharmaceuticals

American Medical Association, Society of Human Genetics, Mayo Clinic





Bilski Amicus Curiae Briefs Services and E-Commerce Industries

Business methods should remain patentable in today's information economy; M-or-T test is too rigid Intangible process may be patentable if not abstract; a tie to a general purpose computer is not enough

Business
methods are not
patentable;
novelty must be
in machine or
technology

Accenture & Pitney Bowes

Double Rock Corp.

Regulatory Data Corp., American Express, SAP, Palm Inc.

On Time Systems
Yahoo!

American Insurance Assoc., The Hartford, Pacific Life

Bank of America, Google, MetLife, Morgan Stanley

Bloomberg

L.L. Beam, Overstock.com, J.C. Penney's, Crutchfield





Bilski Amicus Curiae Briefs Bar Associations

"Anything under the sun" except abstract ideas, laws of nature, natural phenomena

M-or-T test is sufficient but not necessary

Abstract business methods, tax planning methods not patentable but M-or-T is not the only test

Houston IP Law Assoc.

Wash. State Patent Law Assoc.

AIPLA

Austin IP Law Assoc.

Conejo Valley Bar Assoc.

IP Law Assoc. of Chicago

Nevada State Bar IP Section

Boston Patent Law Assoc.

IPO

San Diego IP Law Assoc.

Federal Circuit Bar Assoc.

ABA





Bilski Amicus Curiae Briefs Academia

M-or-T test will harm innovation, application of an abstract idea maybe patented

Constitutional "useful arts" excludes business methods; must show invention in the application/machine

20 Law and Business Professors (Prof. Mark Lemley)

Prof. Kevin Emerson Collins

Franklin Pierce Law Center

Univ. of Washington Law School (CASRIP)

11 Law Professors and AARP (Prof. Joshua Sarnoff)

Profs. Menell and Meurer

Wm. Mitchell College of Law





Oral Argument at the Supreme Court

- Limiting the "useful arts" to machines and technology?
 - ☐ the realm of the physical
- Practical application of a useful result?
- Something more substantive than the mere exchange of information?
 - □ helpful or harmful to the free flow of information?
- Any method, any human activity?
 - surgical methods
 - teaching methods
 - methods to train animals
 - methods to maximize wealth
 - methods of communication Bell versus Carnegie
 - methods of locating other people via the internet versus the Yellow Pages





Oral Argument at the Supreme Court

- Testing the limits of "M-or-T" test
 - □ use of a calculator versus programming a new function
 - □ does novel software transform an old computer into a new machine, or is it the use of an old machine for a new process?
 - □ use of a computer with programmed instructions to perform the steps of the business method does that qualify otherwise unpatentable business methods as patent eligible





Oral Argument at the Supreme Court

- Effect of a bright line rule on other industries
 - □ decide this case and leave the hard questions unresolved?
- Carving out an exception for business methods?
 - □ avoiding a ruling that would affect the computer and biomedical industries
 - □ but would it eliminate patent protection for business methods that are tied to machines – too broad a ruling
- "Any method" is too broad; "M-or T test" is too restrictive





Consideration: Patents May Affect Different Industries Differently

- Innovation in software is different from innovation in shoes -> ?
- Product cycles important immediately or later.





At the Supreme Court: Win for Patentees, Loss for Bilski

- June 28, 2010
- Majority: Justices Kennedy, Roberts, Thomas, Alito, Scalia
- Rejected rigid rule and overturned the Federal Circuit's "machine-or-transformation" test.
- Emphasized that § 101 broadly covers "any" new and useful process and that Congress intended "wide scope" to liberally encourage innovation.
- •Affirmatively recognized that "business methods" are not categorically excluded from the scope of 35 U.S.C. § 101.
- Bilski's claims not patent-eligible because the claims represent an "abstract idea."





At the Supreme Court: Win for Patentees, Loss for Bilski

- 4 statutory categories of patent-eligible subject matter: "processes, machines, manufactures, and compositions of matter".
- 3 judicial exceptions for "laws of nature, physical phenomena, and abstract ideas."
- § 101 analysis is "threshold" before other "conditions and requirements" for patentability found in § 102, § 103, and § 112.





At the Supreme Court: Win for Patentees, Loss for Bilski

- "neither the text of the Patent Act nor Supreme Court precedent supported the 'machine-or-transformation' test as the sole test for deciding which processes are patent-eligible...[but] the 'machine-or-transformation' test remains 'a useful and important clue . . . for determining whether some claimed inventions are processes under § 101."
- no basis for excluding business methods from term "method."
- Concurring opinion (Justices Stevens, Breyer, Ginsburg, and Sotomayor): business methods should not be patentable processes under § 101.
- Classen (immunization method) and Prometheus (treatment method) remanded to Federal Circuit in light of Bilski decision.





USPTO Instruction to Examiners June 28, 2010

- First, apply the "machine-or-transformation" test.
- If the claimed method does not meet the machine-ortransformation test, assess whether claims embody an abstract idea.
- Reject claims embodying an abstract idea.
- Applicant has chance to explain why claimed method does not embody an abstract idea.





Summary

- Generally a "win" for patentees, even though a loss for Bilski.
- Business methods are not per se unpatentable in the U.S.
- Supreme Court rejects Federal Circuit's attempt at bright-line rule.





Post-Bilski

- Vraston Trading, Inc. v. [multiple defendants] in SDNY (separate suits filed against Nasdaq OMX Group Inc., State Street Corp., NYSE Euronext, The Depository Trust and Clearing Corp.)
 - □ Judge Stein dismissed actions alleging infringement of claims covering the trading of exchange-traded funds because claims not enforceable based on USSC decision in <u>Bilski v. Kappos</u>.
 - □ Although business methods not excluded from patent protection, inventions may be "too abstract" to be patent eligible.
 - □ Vraston conceded that its patent titled "Apparatus and process for calculating an option," was the same kind of invention as that "at the heart" of the Bilski patent, and that if the USSC affirmed the Federal Circuit decision, Vraston's patent was invalid.





USPTO Post-KSR Guidelines

- "Examination Guidelines Update: Developments in the Obviousness Inquiry After KSR v.Teleflex," 75 Fed. Reg. 53,643
- Effective Sept. 1, 2010
- Detailed reviews of 24 Federal Circuit cases and the lessons examiners and practitioners should learn from each.



New Guidelines: Combining Prior Art Elements

post-KSR cases have held such combinations to be nonobvious "when the combination requires a greater expenditure of time, effort, or resources than the prior art teachings."

Case	Cite	Notes
In re Omeprazole Patent Litigation	536 F.3d 1361 (Fed. Cir. 2008)	Obviousness is not appropriate when "an extra process step that added an additional component to a known successfully marketed formulation amounted to extra work and greater expense for no apparent reason."
Crocs Inc. v. International Trade Commission	598 F.3d 1294 (Fed. Cir. 2010)	"[M]erely pointing to the presence of all claim elements in the prior art is not a complete statement of a rejection for obviousness."
Sundance Inc. v. DeMonte Fabricating Ltd.	550 F.3d 1356 (Fed. Cir. 2008)	Obviousness was found when "one of ordinary skill in the art would reasonably have expected the elements to maintain their respective properties or functions after they have been combined."
Ecolab Inc. v. FMC Corp.	569 F.3d 1335 (Fed Cir. 2009)	"Office personnel should keep in mind the capabilities of a person of ordinary skill."
Wyers v. Master Lock Co.	No. 2009-1412—F.3d (Fed. Cir. July 22, 2010)	"Common sense may be used to support a legal conclusion of obviousness so long as it is explained with sufficient reasoning."); an
DePuy Spine Inc. v. Medtronic Sofamor Danek Inc.	567 F.3d 1314 (Fed. Cir. 2009)	"An inference that a claimed combination would not have been obvious is especially strong where the prior art's teachings undermine the very reason being proffered as to why a person of ordinary skill would have combined the known elements."





New Guidelines: Substituting One Known Element for Another

"applies when the claimed invention can be viewed as resulting from substituting a known element for an element of a prior art invention"

Case	Cite	Notes
In re ICON Health & Fitness Inc.,	496 F.3d 1374 (Fed. Cir. 2007)	"When determining whether a reference may properly be applied to an invention in a different field of endeavor, it is necessary to consider the problem to be solved."
Agrizap Inc. v. Woodstream Corp.,	520 F.3d 1337 (Fed. Cir. 2008)	("[A]nalogous [prior] art is not limited to the field of applicant's endeavor.");
Muniauction Inc. v. Thomson Corp.	532 F.3d 1318 (Fed. Cir. 2008)	It is "obvious to adapt existing processes to incorporate [Internet and Web browser technologies] for those functions.");
Aventis Pharma Deutschland v. Lupin Ltd.	499 F.3d 1293 (Fed. Cir. 2007)	"In the chemical arts, the cases involving so-called 'lead compounds" form an important subgroup of the obviousness cases that are based on substitution."
Eisai Co. Ltd. v. Dr. Reddy's Laboratories Ltd.	533 F.3d 1353 (Fed. Cir. 2008)	"Any known compound may serve as a lead compound when there is some reason for starting with that lead compound and modifying it to obtain the claimed compound."
Procter & Gamble Co. v. Teva Pharmaceuticals USA Inc.	566 F.3d 989 (Fed. Cir. 2009)	"[W]here there was reason to select and modify the lead compound to obtain the claimed compound, but no reasonable expectation of success, the claimed compound would not have been obvious."
Altana Pharma AG v. Teva Pharmaceuticals USA Inc.	566 F.3d 999 (Fed. Cir. 2009)	"Obviousness of a chemical compound in view of its structural similarity to a prior art compound may be shown by identifying some line of reasoning that would have led one of ordinary skill in the art to select and modify the prior art compound in a particular way to produce the claimed compound."





New Guidelines: Obvious To Try

Applies when "there is a recognized problem or need in the art; there are a finite number of identified, predictable solutions to the recognized need or problem; and one of ordinary skill in the art could have pursued these known potential solutions with a reasonable expectation of

Case	Cite	Notes
In re Kubin	561 F.3d 1351 (Fed. Cir. 2009)	"A claimed polynucleotide would have been obvious over the known protein that it encodes where the skilled artisan would have had a reasonable expectation of success in deriving the claimed polynucleotide using standard biochemical techniques, and the skilled artisan would have had a reason to try to isolate the claimed polynucleotide."
Takeda Chemical Industries Ltd. v. Alphapharm Pty. Ltd.	492 F.3d 1350 (Fed. Cir. 2007)	"[T]he obvious to try rationale does not apply when there was no finite number of identified, predictable solutions to the recognized need, and no reasonable expectation of success."
Ortho-McNeil Pharmaceutical Inc. v. Mylan Laboratories Inc.,	520 F.3d 1358 (Fed. Cir. 2008)	"'[F]inite' means 'small or easily traversed' in the context of the art in question."
Bayer Schering Pharma A.G. v. Barr Laboratories Inc.	575 F.3d 1341 (Fed. Cir. 2009)	Even if a large number of options exist, "Where the prior art teachings lead one of ordinary skill in the art to a narrower set of options, then that reduced set is the appropriate one to consider when determining obviousness using an obvious to try rationale."
Sanofi-Synthelabo v. Apotex Inc.	550 F.3d 1075 (Fed. Cir. 2008)	"[E]ven when only a small number of possible choices exist, the obvious to try line of reasoning is not appropriate when, upon consideration of all of the evidence, the outcome would not have been reasonably predictable and the inventor would not have had a reasonable expectation of success."
Rolls-Royce PLC v. United Technologies Corp.	603 F.3d 1325 (Fed. Cir. 2010)	Obvious to try findings can be based on a "known and finite" number of possible options for solving a problem in all art contexts.)
Perfect Web Technologies Inc. v. InfoUSA Inc.	587 F.3d 1324, 1328-29 (Fed. Cir. 2009)	"Where there were a finite number of identified, predictable solutions and there is no evidence of unexpected results, an obvious to try inquiry may properly lead to a legal conclusion of obviousness."





New Guidelines: Consideration of Evidence

Case	Cite	Notes
PharmaStem Therapeutics Inc. v. Viacell Inc.	491 F.3d 1342 (Fed. Cir. 2007)	"Even though all evidence must be considered in an obviousness analysis, evidence of nonobviousness may be outweighed by contradictory evidence in the record or by what is in the specification."
In re Sullivan	498 F.3d 1345 (Fed. Cir. 2007)	All evidence must be considered, including "a statement of intended use."
Hearing Components Inc. v. Shure Inc.	600 F.3d 1357 (Fed. Cir. 2010)	"Evidence of commercial success is pertinent where a nexus between the success of the product and the claimed invention has been demonstrated."
Asyst Technologies Inc. v. Emtrak Inc.	544 F.3d 1310 (Fed. Cir. 2008)	Evidence of secondary considerations of obviousness such as commercial success and long-felt need may be insufficient to overcome a prima facie case of obviousness if the prima facie case is strong."





POSA In Obviousness Analysis

- Eli Lilly & Co. v. Teva Pharmaceuticals USA, Inc., --F.3d— (Fed. Cir. Sept. 1, 2010)
 - □ DC: Granted permanent injunction preventing Teva from manufacturing generic version of Lilly's osteoporosis drug Evista® until the expiration of Lilly's patents.
 - Active ingredient = raloxifene hydrochloride.
 - Initial studies showed very low bioavailability of raloxifene in humans->
 POSA would not have expected success claims not obvious.
 - □ Teva argued that Lilly's own pursuit of raloxifene as a treatment for both breast cancer and osteoporosis indicated that a person of ordinary skill in the art would have a reasonable chance of success,
 - ☐ FC: Affirmed.
 - Cannot "conflate the Lilly scientists, who had 'superior' knowledge and credentials, with the ordinarily skilled artisan[.]"





"Common Sense" Still Needs Articulation

- Trimed Inc. v. Stryker Corp., 95 USPQ2d 1577 (Fed. Cir. 2010)
 - □ Invention: medical device implanted into fractured wrist.
 - □ DC: Summary judgment of invalidity for obviousness.
 - □ Stryker argued: "claimed subject matter would have been obvious because it is, at least in part, a commonsense solution to a known problem."



"Common Sense" Still Requires Articulation

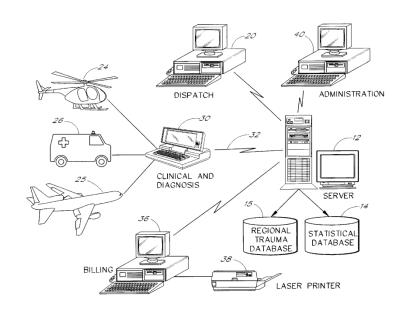
- <u>Trimed</u> (con't)
 - ☐ FC: Reversed.
 - Genuine issues of material fact were raised.
 - "Neither the record before us nor the order of the district court explains why one of ordinary skill in the art at the time of the invention would have found replacing a cast normally used to stabilize a pin with a subcutaneous metal plate to be a logical, commonsense solution to this problem. Merely saying that an invention is a logical, commonsense solution to a known problem does not make it so. The record also fails to explain why the district court summarily dismissed the evidence of secondary considerations of nonobviousness submitted by TriMed. We have repeatedly held that evidence of secondary considerations must be considered if present.





Golden Hour Joint Infringement Background – Patent in Suit

- Golden Hour Data Sys. Inc. v. emsCharts, Inc., --F.3d- (Fed. Cir. Aug. 9, 2010)(DYK, Friedman, Newman)(Newman, dissenting)
- Pat. No. 6,117,073, titled "Integrated Emergency Medical Transportation Database System" directed to a computer system for emergency medical service







Independent claim 1

A computerized integrated data management system for tracking a patient incident, comprising:
 a first module capable of dispatching an emergency transport crew ..., wherein transportation tracking information relating to the dispatch is recorded; and

a second module capable of receiving information from the first module and billing the patient appropriately for costs indicative of the patient incident, including transportation costs.









Independent claim 15

15. A...method ...comprising:

collecting flight information relating to an emergency transport crew dispatch;

collecting patient information from a clinical encounter associated with a patient incident requiring emergency medical care by the emergency transport crew; and integrating the patient information with the flight information to produce an encounter record indicative of the patient's clinical encounter.









Background

Softtech:

- produces computer-aided flight dispatch software called Flight Vector
- coordinates flight information, such as patient pickup and delivery, and flight tracking

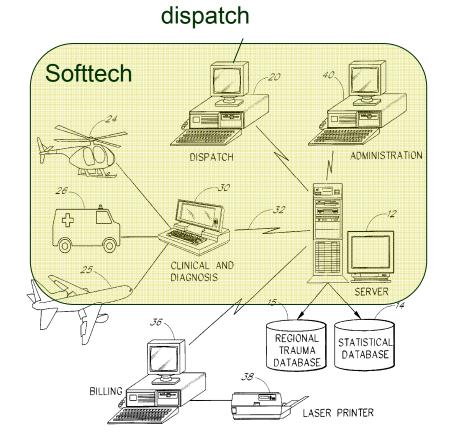


FIG. 1 of '073 Patent



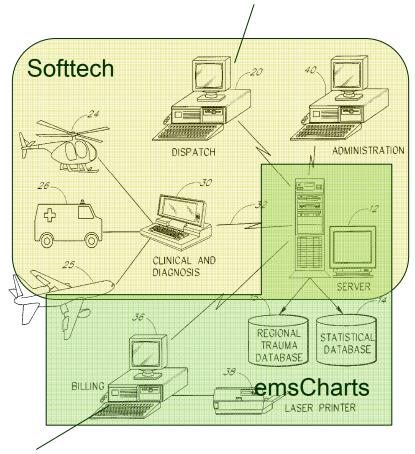


Background

dispatch

emsCharts:

- produces medical manage software called emsCharts
- charts patient information and provides billings



billing

FIG. 1 of '073 Patent





Joint Infringement - Facts

Softtech and emsCharts —> evidence supporting joint infringement:

- □ had a non-exclusive distributorship agreement
- ☐ formed strategic partnership, enabled their programs to work together
- collaborate to sell the two programs as a unit
- ☐ joint price quotes
- emsCharts made sales on behalf of Softtech and received payment for Softtech's software
- □ jointly submitted a bid to an RFP





Joint Infringement - Facts

Softtech and emsCharts —>evidence supporting no joint infringement:

☐ two separate companies.

□ the non-exclusive distributorship agreement defined the relationship as not creating any agency, partnership, joint venture.





Joint Infringement – The Law

- BMC Resources v. Paymentech (Fed. Cir. 2007)
 - Courts faced with a divided infringement theory have also generally refused to find liability where one party did not control or direct each step of the patented process.
 - ☐ This court acknowledges that the standard requiring control or direction ...may ...allow parties to enter into arms-length agreements to avoid infringement. Nonetheless, this concern does not outweigh concerns over expanding the rule.
 - □ The concerns over a party avoiding infringement by arms-length cooperation can usually be offset by proper claim drafting. A patentee can usually structure a claim to capture infringement by a single party.





Joint Infringement – The Law

- Muniauction v. Thomson (Fed. Cir. 2008)
 - □ where the actions of multiple parties combine to perform every step of a claimed method, the claim is directly infringed only if one party exercises "control or direction" over the entire process such that every step is attributable to the controlling party, i.e., the "mastermind."
 - □ Under <u>BMC Resources</u>, the control or direction standard is satisfied in situations where the law would traditionally hold the accused direct infringer vicariously liable for the acts committed by another party that are required to complete performance of a claimed method.





Joint Infringement - Decision

- Jury: emsCharts and Softtech jointly infringe.
- DC: No infringement.
 - □ granted JMOL that there is insufficient evidence supporting "control or direction" either party might have over the other one.
 - "Making information available to the [other] party, prompting the [other] party, instructing the [other] party, or facilitating or arranging for the [other] party's involvement in the alleged infringement is not sufficient [to find control or direction]."





Joint Infringement - Decision

- Golden Hour (con't)
 - ☐ FC: Affirmed on both method and apparatus claims
 - "Where the combined actions of multiple parties are alleged to infringe process claims, the patent holder must prove that one party exercised 'control or direction' over the entire process such that all steps of the process can be attributed to the controlling party, i.e., the 'mastermind.' <u>Muniauction, Inc. v. Thomson Corp.</u>, 532 F.3d 1318, 1329 (Fed. Cir. 2008) (citing <u>BMC Res., Inc. v.</u> <u>Paymentech, L.P.</u>, 498 F.3d 1373, 180-81 (Fed. Cir. 2007)). ...the evidence here was insufficient for jury to infer control or direction.





Joint Infringement

- Golden Hour (con't)
 - ☐ FC: (con't)
 - "We see no need for extended discussion of this issue[.]"
 - Notes emsCharts may have been solely liable for infringement of system claim 1:
 - "emsCharts sold its emsCharts.com program and Softtech's Flight Vector software together, and together these systems comprised the systems of the asserted claims. Such a sale might well create liability on the part of emsCharts for the sale of the patented system, whether or not emsCharts controlled Softtech."
 - BUT, "by agreement, claims 1 and 6-8 were submitted to the jury only on a joint infringement theory. Such a verdict can only be sustained if there was control or direction of Softtech by emsCharts. Under these circumstances, JMOL was properly granted as to the systems claims[.]"





Dissent

- Golden Hour (con't)
 - □ Judge Newman did not agree that control or direction by one party is always required.
 - "the defendants 'formed a strategic partnership, enabled their two programs to work together, and collaborated to sell the two programs as a unit.' ... The court now holds that such a relationship avoids all liability for infringement, even when the defendants collaborate to practice every limitation of the claims. That ruling is incorrect as a matter of law."





§112 Support For Priority Claim

- Goeddel v. Sugano, --F.3d— (Fed. Cir. Sept. 7, 2010)
 - ☐ Two related patent interference priority contests wherein both parties claimed a recombinant DNA process for directly producing mature human interferon beta, known to have therapeutic value against pathogens and tumors.
 - □ Board: Awarded Sugano priority based on filing date benefit of initial Japanese application.
 - mature hFIF would be "readily apparent" to a person skilled in this field, in view of the Japanese Application's description of the precursor hFIF and a scientific article by Knight identifying the first 13 amino acids of secreted (mature) hFIF.
 - □ Goeddel argument:
 - Sugano's Japanese Application "is devoid of any disclosure of a method of making the claimed subject matter,"
 - "the Japanese Application, including the Knight sequence, does not describe a modified gene that encodes only mature hFIF, does not describe mature hFIF as directly expressed, and does not suggest such products or the production of such products." It only "describes ...the expression of precursor hFIF."
 - □ Sugano argument:
 - persons experienced in this field would have known how to modify the precursor hFIF gene so that it would express mature hFIF, using the teachings in the Japanese Application.





§112 Support For Priority Claim

- Goeddel (con't)
 - ☐ FC: Reversed and remanded.
 - Japanese application does not establish constructive reduction to practice of the subject matter of the counts "for the Japanese Application does not meet the criteria of § 112, first paragraph, as to this subject matter."
 - Section 112, in the context of interference priority, requires that the subject matter of the counts be described sufficiently to show that the applicant was in possession of the invention. That a modified gene encoding the 166 amino acid protein could have been "envisioned" does not establish constructive reduction to practice of the modified gene. The question is not whether one skilled in this field of science might have been able to produce mature hFIF by building upon the teachings of the Japanese Application, but rather whether that application "convey[ed] to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." Ariad Pharm., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc); ...The Japanese application does not describe a bacterial expression vector that directly produces the mature hFIF, nor does it suggest producing a modified gene to directly encode the 166 amino acid mature hFIF.





§112 Support For Priority Claim

- Goeddel (con't)
 - □ FC: (con't)
 - "The Board erred in ruling that priority is established if a person of skill in the art could "envision" the invention of the counts. ... Enzo Biochem, Inc. v. Gen-Probe Inc., 323 F.3d 956, 968 (Fed. Cir. 2002) and University of Rochester v. G.D. Searle & Co., 358 F.3d 916, 923 (Fed. Cir. 2004), ...do not hold that envisioning an invention not yet made is a constructive reduction to practice of that invention. ... Precedent in evolving science is attuned to the state of the science, but remains bound by the requirement of showing 'that the inventor actually invented the invention claimed.' Bradford, 603 F.3d at 1269; see Fiers v. Revel, 984 F.2d 1164, 1170 (Fed. Cir.1993)."





Claim Construction: Preamble

- American Medical Systems Inc. et al. v. Biolitec Inc., -F.3d—(Fed. Cir. Sept. 13, 2010)
 - □ Claims: "A method for photoselective vaporization of tissue, comprising:..." and "An apparatus for photoselective vaporization of tissue, comprising..."
 - "photoselective vaporization" does not appear anywhere else in the claims of the patent.
 - □ DC: No infringement.
 - Preamble limiting.
 - "photoselective vaporization" means "using a wavelength that is highly absorptive in the tissue, while being absorbed only to a negligible degree by water or other irrigant."
 - Biolitec's device did not practice "photoselective vaporization."
 - □ accused laser system operated at a wavelength (980 nm) at which the energy is absorbed to more than "a negligible degree by water or other irrigant."





Claim Construction: Preamble

- American Medical (con't)
 - ☐ FC: Reverse and remand preamble not limiting.
 - Whether to treat a preamble term as a claim limitation is "determined on the facts of each case in light of the claim as a whole and the invention described in the patent."
 - "There is no suggestion in the prosecution history of the patent that the inventors added the phrase 'photoselective vaporization' in order to distinguish their invention from the prior art."
 - "claim drafters did not rely on the preamble language to define or refine the scope of the asserted claims."
 - "Third, and most importantly, the descriptor "photoselective" does not embody an essential component of the invention. Instead, the term "photoselective vaporization" is simply a descriptive name for the invention that is fully set forth in the bodies of the claims."





Claim Construction: Preamble

- American Medical (con't)
 - ☐ Judge Dyk, dissenting
 - Preambles should always be considered limiting.
 - "we have not succeeded in articulating a clear and simple rule."
 - □ "There is, after all, little to be said in favor of allowing an applicant, in the claim drafting process, to include material in the claims that is not binding," Judge Dyk said.
 - □ "Neither the Supreme Court nor our court sitting en banc has ever addressed the preamble limitation issue," he added. "I think the time may have come for us to eliminate this vague and confusing rule."
 - "it seems clear to me that 'photoselective vaporization' should be construed as a claim limitation; by adding this terminology during prosecution of the '764 patent, the patentee conceded that the term gave life, meaning, and vitality to the claims."





- Abbott Labs. v. Sandoz, Inc., 566 F.3d 1282 (Fed. Cir. 2009)(en banc), cert. denied, Astellas Pharma, Inc. v. Lupin Ltd., 130
 S.Ct. 1052 (U.S. Jan 11, 2010)
 - □ Two separate cases heard together on appeal
 - DJ action filed by Lupin seeking noninfringement of Pat. No. 4,935,507
 - PI motion filed by Abbot against Sandoz et al. in N.D. III. asserting '507 patent
 - ☐ '507 Patent: directed to crystal cefdinir
 - Claimed priority to JP '199 Application which disclosed both Crystal A and Crystal B cefdinir and claimed both forms very specifically with powder x-ray diffraction patterns.
 - '507 patent specification, however, removed disclosure of Crystal B form.





□ '507 Patent Claims:

- Claim 1: Crystalline cefdinir characterized by powder x-ray diffraction patterns.
- Claim 2: Crystalline [cefdinir] which is *obtainable by* acidifying a solution containing 7-[2-(2-aminothiazol-4-yl)-2-hydroxyiminoacetamido]-3-vinyl -3-cephem-4-carboxylic acid (syn isomer) at room temperature or under warming.
- Claim 5: Crystalline [cefdinir] which is *obtainable by* dissolving 7-[2-(2-aminothiazol-4-yl)-2 -hydroxyiminoacetamido]-3-vinyl-3-cephem-4-carboxylic acid (syn isomer) in an alcohol, continuing to stir the solution slowly under warming, then cooling the solution to room temperature and allowing the solution to stand.

☐ FDA approved Lupin's ANDA for generic cefdinir

- Lupin's product: Almost exclusively Crystal B form of cefdinir.
- Lupin's product: Made by a process different from '507 claims.
- Abbott's product: Crystal A form of cefdinir.





- Abbott Labs. v. Sandoz, Inc. (con't)
 - □ ED VA: Summary judgment noninfringement
 - Construed "crystalline" to mean "Crystal A as outlined in the specification."
 - Construed claims 2-5 as product-by-process claims.
 - "obtainable by" limited the claims to the specified processes and process steps following Atlantic Thermoplastics.
 - □ ND III: Denied preliminary injunction.
 - Parties agreed to adopt EDVA claim construction.
 - N.D. III adopted EDVA claim construction.
 - Abbott appealed construction of "crystalline" and "obtainable by."





- Abbott Labs. v. Sandoz, Inc. (con't)
 - □ FC: *Sua sponte* took product-by-process issue prior to issuance of panel decision to address "the proper interpretation of product-by-process claims in determining infringement.
 - Majority: Michel, Rader, Bryson, Gajarsa, Linn, Dyk, Prost, Moore.
 - Dissent: Newman, Lourie, Mayer
 - □ Abbott argued that *Scripps* controls: "product-by-process claims are not limited to product prepared by the process set forth in the claims."
 - □ FC: "This court takes the opportunity to clarify en banc the scope of product-by-process claims by adopting the rule in *Atlantic Thermoplastics.*"





- Abbott Labs. v. Sandoz, Inc. (con't)
 - □ FC: "Supreme Court consistently noted that process terms that define the product in a product-byprocess claim serve as enforceable limitations."
 - Also found support in *In re Thorpe,* 777 F.2d 695, 697 (Fed. Cir. 1985) "For this reason, *even though product-by-process claims are limited by and defined by the process*, determination of patentability is based on the product itself."
 - PTO's policy "in permitting product-by-process claims to definine a patentable product, . . . , has developed with full cognizance of the fact that in infringement suits some courts have construed such claims as covering only a product made by the particular process . . . and not to the product per se."



П



- Abbott Labs. v. Sandoz, Inc., (con't)
 - ☐ FC: (con't)
 - "Because the inventor chose to claim the product in terms of its process, however, that definition also governs the enforcement of the bounds of the patent right. This court cannot simply ignore as verbiage the only definition supplied by the inventor."
 - "...it is both unnecessary and logically unsound to create a rule that the process limitations of a product-by-process claim should not be enforced in some exceptional instance when the structure of the claimed product is unknown and the product can be defined only by reference to a process by which it can be made. Such a rule would expand the protection of the patent beyond the subject matter that the inventor has 'particularly point[ed] out and distinctly claim[ed]' as his invention[.]"





- Abbott Labs. v. Sandoz, Inc. (con't)
 - □ Judge Newman strongly dissented to the *sua sponte* ruling.
 - "Rule of Necessity": Allowed reference to process steps in a claim to a new products whose structure was not fully known at the time of filing-patentability and infringement were based on the product itself.
 - En banc ruling adopts rule for "all situations 'the basic rule that process terms limit product-by-process claims,' whether the product is novel or known, and whether or not the new product could have not been fully described by its structure alone. The court eliminates the long-accepted expedient for new products whose structure is not fully known."
 - En banc ruling would also result in claims construed differently for validity and infringement because patentability at the PTO for a product-by-process claim is in reference to the product. MPEP § 3113





- Abbott Labs. v. Sandoz, Inc. (con't)
 - ☐ Judge Lourie dissent:
 - There should be a distinction between product-by-process claims for old products and new products
 - "When a product is new and the inventor claims it by a process of preparation, I fail to see why the product-by-process claim should not be interpreted as a product claims that can be infringed even when the product is made by means other than that recited in the claim."
 - "It may be that with today's analytical techniques there is little need for product-by-process claims."





- Therasense, Inc. v. Becton, Dickinson & Co., 593 F.3d 1289 (Fed. Cir. 2010)
 - [Note, Therasense, Inc. v. Becton, Dickinson & Co., 593 F.3d 1325 (Fed. Cir. 2010)(LINN, Dyk, Friedman), issued on the same day entering judgment on a jury verdict of infringed but invalid for Abbott's patent, 5,628,890.]
 - DC: Abbott's patent unenforceable for inequitable conduct.
 - ☐ FC: Affirmed.
 - Abbott failed to disclose statements made to the European Patent Office ("EPO") during a revocation proceeding of the European counterpart to the prior art patent.
 - Statements made to the EPO were "highly material" because they contradicted representations made to the U.S. PTO regarding the disclosure of the prior art patent.





- Therasense (con't)
 - ☐ Disposable blood glucose test strips:
 - Claims in patent in suit: an electrochemical sensor for testing whole blood without any membrane over the electrode.
 - □ Prior art patent (also owned by patentee):
 - "Optionally, but preferably when being used on live blood, a protective membrane surrounds both the enzyme and the mediator layers, permeable to water and glucose membranes"





- Therasense (con't)
 - □ **U.S. prosecution** (13 years), patentee argued to PTO:
 - the "[o]ptionally, but preferably" language [of the prior art patent] was "mere 'patent phraseology' that did not convey a clear meaning."
 - prior art taught that active electrodes designed for use with whole blood require a protective membrane.
 - "There is no teaching or suggestion of unprotected active electrodes for use with whole blood specimens in this patent or the other prior art of record in this application."





- Therasense (con't)
 - □ **To the EPO**, in order to show validity of the EP counterpart of the same prior art patent, patentee argued:
 - the "[o]ptionally, but preferably" language was "unequivocally clear"
 - Court found the patentee clearly explained that membranes were merely "preferred", not necessary, for live blood... and that a membrane was not necessary for testing whole blood in vitro.





- Therasense (con't)
 - FC: "To deprive an examiner of the EPO statements statements directly contrary to Abbott's representations to the PTO on the grounds that they were not material would be to eviscerate the duty of disclosure. Moreover, if this could be regarded as a close case, which it is not, we have repeatedly emphasized that the duty of disclosure requires that the material in question be submitted to the examiner rather than withheld by the applicant."





- Therasense (con't)
 - □ District Court findings with respect to intent:
 - "that the statements made to the PTO concerning the prior art '382 patent were absolutely critical in overcoming the examiner's earlier rejections of the claims of the '551 patent;
 - that the EPO statements would have been very important to an examiner because they contradicted the representations made to the PTO;
 - that [the patent agent] and [the declarant] both knew of the EPO statements and consciously withheld them from the PTO;
 - 4) that neither [the patent agent] nor [the declarant] provided a credible explanation for failing to submit the EPO documents to the PTO; and
 - that [the patent agent]'s and [the declarant]'s explanations for withholding the EPO documents were so incredible that they suggested intent to deceive."





Therasense (con't)

□ FC: Intent findings were "amply supported" by the transcript of the trial testimony and the fact that Abbott used a declarant who was not one of ordinary skill in the art instead of using one of the inventors.





- Therasense, petition for en banc rehearing granted, April 26, 2010, hearing scheduled for Nov. 2010.
 - Order vacated.
 - Questions to be briefed:
 - Should the materiality-intent-balancing framework for inequitable conduct be modified or replaced?
 - If so, how? In particular, should the standard be tied directly to fraud or unclean hands? *See* Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co., 324 U.S. 806 (1945); Hazel-Atlas Glass Co. v. Hartford-Empire Co., 322 U.S. 238 (1944), overruled on other grounds by Standard Oil Co. v. United States, 429 U.S. 17 (1976); Keystone Driller Co. v. Gen. Excavator Co., 290 U.S. 240 (1933). If so, what is the appropriate standard for fraud or unclean hands?





- \blacksquare Questions to be briefed (con't):
 - □ What is the proper standard for materiality? What role should the United States Patent and Trademark Office's rules play in defining materiality? Should a finding of materiality require that but for the alleged misconduct, one or more claims would not have issued?
 - □ Under what circumstances is it proper to infer intent from materiality? *See*<u>Kingsdown Med. Consultants, Ltd. v. Hollister Inc.</u>, 863 F.2d 867 (Fed. Cir. 1988) (en banc).
 - □ Should the balancing inquiry (balancing materiality and intent) be abandoned?
 - □ Whether the standards for materiality and intent in other federal agency contexts or at common law shed light on the appropriate standards to be applied in the patent context.





Cases Cited by Federal Circuit

- Fed Cir cited for inquiry: Should the standard be tied directly to fraud or unclean hands?
 - □ <u>Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.</u>, 324 U.S. 806 (1945)
 - "the equitable maxim that 'he who comes into equity must come with clean hands.'...necessarily gives wide range to the equity court's use of discretion in refusing to aid the unclean litigant. It is 'not bound by formula or restrained by any limitation that tends to trammel the free and just exercise of discretion.'" quoting Keystone Driller
 - "public policy against the assertion and enforcement of patent claims infected with fraud and perjury"
 - □ Knowing purchase of "perjured" application and failure to disclose perjury to Patent Office → not the "standard of conduct requisite to the maintenance of this suit in equity."





Cases Cited by Federal Circuit

- Hazel-Atlas Glass Co. v. Hartford-Empire Co., 322 U.S. 238 (1944), overruled on other grounds by <u>Standard Oil Co. v. United States</u>, 429 U.S. 17 (1976)
 - "Every element of the fraud here disclosed demands the exercise of the historic power of equity to set aside fraudulently begotten judgments. This is not simply a case of a judgment obtained with the aid of a witness who, on the basis of after-discovered evidence, is believed possibly to have been guilty of perjury. Here, even if we consider nothing but Hartford's sworn admissions, we find a deliberately planned and carefully executed scheme to defraud not only the Patent Office but the Circuit Court of Appeals."
 - "The public welfare demands that the agencies of public justice be not so impotent that they must always be mute and helpless victims of deception and fraud."
 - "The total effect of all this fraud, practiced both on the Patent Office and the courts, calls for nothing less than a complete denial of relief to Hartford for the claimed infringement of the patent thereby procured and enforced."





Cases Cited by Federal Circuit

- Fed Cir cited for inquiry: Under what circumstances is it proper to infer intent from materiality?
 - □ Kingsdown Med. Consultants, Ltd. v. Hollister Inc., 863 F.2d 867 (Fed. Cir. 1988) (en banc)
 - "Whether the intent element of inequitable conduct is present cannot always be inferred from a pattern of conduct that may be described as gross negligence. That conduct must be sufficient to require a finding of deceitful intent in the light of all the circumstances. We are not convinced that deceitful intent was present in Kingsdown's negligent filing of its continuation application or, in fact, that its conduct even rises to a level that would warrant the description 'gross negligence.'"
 - "Kingsdown's counsel may have been careless, but it was clearly erroneous to base a finding of intent to deceive on that fact alone."
 - "It is not possible to counter the "I didn't know" excuse with a "should have known" accountability approach when faced with a pure error, which by definition is done unintentionally."





Amici File in **Therasense** Rehearing

■ IPO:

☐ Tie doctrine more closely to its equitable roots.

□ Supreme Court standard is "unclean hands" – "unclean hands" is the "correct standard for barring relief based on inequitable conduct."





Amici File in <u>Therasense</u> Rehearing

■ IPO:

- □ Adopt single standard for materiality: "but for"
 - "but for" the alleged inequitable conduct, a claim would not have issued.
 - Aligns with <u>Precision</u> and <u>Keystone</u>
 - "cite everything, say nothing" practice has overwhelmed examiners with irrelevant references.
 - "the "reasonable examiner" standard has become almost the sole standard invoked by this Court,...and an unfortunate consequence of reliance on this 'reasonable examiner' standard is that inequitable conduct has become a fullblown plague on the patent system. ...Since 2000, there has been a ten-fold increase in the number of cases in which inequitable conduct has been pled as a percentage of total patent cases."





Amici File in <u>Therasense</u> Rehearing

- IPO (con't)
 - □ Standard for intent should be clear and convincing evidence of a specific intent to deceive the USPTO.
 - Should not infer intent solely from a high level of materiality.
 - Some Federal Circuit case law set a low threshold for intent "that appears to be based unduly on a high level of materiality," e.g., <u>Praxair</u>, <u>Ferring</u>
 - Adopt the holding in <u>Ariad Pharm. v Eli Lilly</u>, 560 F.3d 1366, 1380 (Fed. Cir. 2009), <u>vacated on other grounds</u>, 595 F.3d 1329 (Fed. Cir. 2009): "a district court must make 'independent findings of both materiality and intent."





Amici File in <u>Therasense</u> Rehearing

- IPO (con't)
 - □ Balancing only <u>after</u> independent clear and convincing evidence of objective "but for" materiality and intent to deceive.
 - "Balancing should not, however, be used as a backdoor means to conflate intent and materiality by inferring intent solely from a high level of materiality."





Duty Of Disclosure

Everyone involved in drafting and prosecuting
 US patent application owes a duty of disclosure
 to the USPTO



□ 37 C.F.R. § 1.56: 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[.]







Who Has Rule 56 Duty?

- Individuals associated with the filing or prosecution of a patent application are:
 - Inventors
 - attorney or agent and
 - every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application.





Who?

- Avid Identification Systems v. Crystal Import Corp., 603F.3d 967 (Fed. Cir. 2010)(PROST, Mayer, Linn)(Linn concurring-in-part, dissenting-in-part)
 - □ DC: Duty of disclosure found owed by a corporate employee not substantively involved in the preparation or prosecution of the application.
 - □ Information about a trade show demonstration (102(b) prior art) by the company president was withheld from the Patent Office with deceptive intent.
 - □ Avid appealed that company president owed a duty of candor.





"Substantially Involved"

Avid (con't)

□FC:

"We read 'substantively involved' to mean that the involvement relates to the content of the application or decisions related thereto, and that the involvement is not wholly administrative or secretarial in nature."





Evidence of Substantial Involvement

- Avid (con't)
 - ☐ FC:
 - Dr. Stoddard
 - Was personally responsible for the disputed prior art demonstrations;
 - □ Was in contact with at least one of the inventors during preparation of the application;
 - □ Signed the small entity status affidavit;
 - □ Had the idea of how the invention would function;
 - ☐ Hired inventors to reduce his idea to practice; and
 - □ Was included on substantive communications related to the preparation of the European counterpart .





Then Materiality and Intent

Avid (con't)

☐ FC:

"Once a court finds that the individual had a duty of candor, the court must proceed to the dual prongs of materiality and deceptive intent, to determine whether that duty was violated. This subsequent analysis, in particular the deceptive intent inquiry, encompasses the concerns raised by the dissent. If an individual is unable to assess the materiality of the information at issue, then he would lack the deceptive intent required to find that he committed inequitable conduct. Therefore, the dissent's main objection to our 'substantive involvement' test is misplaced."





Dissent: Rule 56 Two Criteria "Substantively Involved In The Preparation Or Prosecution Of The Application" AND "Associated With The Inventor [Or] Assignee"

- Avid (con't)
 - □ Dissent: Stoddard meets the second criterium, not the first.
 - "[Stoddard] neither engaged in the preparation or prosecution of the '326 patent application nor sufficiently apprised of its technical details or legal merits to allow him to assess what information would be considered material to its patentability."





Judge Linn's Dissent (con't)

- Avid (con't)
 - □ Judge Linn, in dissent:
 - The majority's holding disregards "whether those factors relate to the person's awareness of the merits of the application in question or engagement in any specific activity relating to that application."
 - "The majority goes even further to extend the duty generally to 'those on the commercial side of patented product development,' because they are 'the types of people most likely to have knowledge of § 102(b) prior art.' With all due respect, I find no basis in the rule or in any policy for such an expansive reading of Rule 56(c)(3). (emphasis added)."





Judge Linn's Dissent (con't)

- Avid (con't)
 - □ Judge Linn, in dissent:
 - "Rule 56(c)(3) uses the phrase 'substantively involved.' <u>The use of the word 'substantive</u>[]' <u>limits the set of individuals who have a duty to disclose to those who possess a specific understanding of the substance of the application.</u> (<u>emphasis added</u>) This has nothing to do with the question of whether any particular piece of information is material, but relates to the separate question of whether a person is substantively involved; i.e., sufficiently apprised of the details of the application as to be in a position to make that assessment. Reading the separate parts of Rule 56 in harmony is not improperly conflating them, as the majority suggests."





Petition for Rehearing and Petition to Join Review in *Therasense*

- Avid Identification Systems, Inc. v. Crystal Import
 Corp., --F.3d- (Fed. Cir. July 16, 2010)(per curiam)
 - □ Before Judges RADER, NEWMAN, MAYER, LOURIE, BRYSON, GAJARSA, LINN, DYK, PROST, and MOORE.
 - □ Motion to join in the pending en banc review in <u>Therasense</u> or, alternatively, to stay the mandate of this case is denied.
 - □ Petition for rehearing by panel or en banc is denied.





Petition for Rehearing and Petition to Join Review in *Therasense*

- Avid (con't)
 - □ Judge Newman, dissenting from denial of request for stay.
 - Therasense "bears on the precise issue of Avid's appeal, that is, the criteria for 'inequitable conduct' during patent prosecution... The law as applied in Avid is subject to conflicting precedent, a conflict whose resolution is reasonably likely to alter the result."
 - "As applied to Avid, it is grievously unjust to eradicate this patent on grounds that may soon be changed by the en banc court."
 - "On the undisputed fact that the challenged information is not invalidating, the court's holding of inequitable conduct is sufficiently questionable to warrant a stay[.]"





Improper Claim Of Inventorship

- Advanced Magnetic Closures, Inc. v. Rome Fasteners
 Corp., --F.3d— (Fed. Cir. June 11, 2010)
 - □ DC: patent unenforceable for inequitable conduct.
 - ☐ FC: Affirmed.
 - Bauer withheld highly material information when he "concealed the most critical information: he was not the inventor he claimed to be[.]"
 - Bauer intended to deceive the PTO by claiming that he invented the '773 patent's fastener
 - □ submitted admittedly "reconstructed" evidence of invention sketches.
 - □ No "scientific or technical explanation" of his own patent
 - "evasive, argumentative, and at times contradictory testimony on his status as inventor"
 - □ "Bauer's testimony 'bore clear indicia of fabrication.'"





Improper Claim of Inventorship

AMC (con't)

☐ FC:

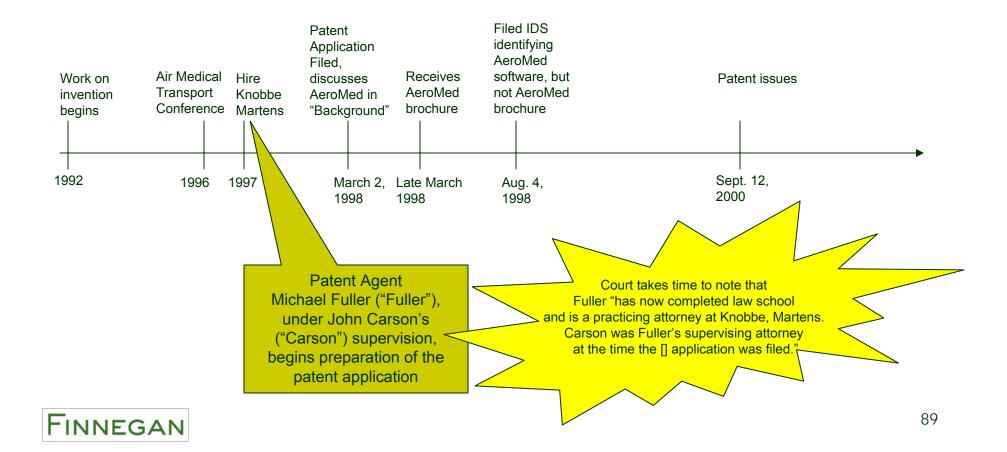
"When an applicant falsely claims that he has invented a device, he can hardly claim the right to enforce a patent to which he was never entitled. We have upheld district court holdings of unenforceability when the named inventors acted with deceptive intent to exclude a true inventor. ...If district courts do not abuse their discretion in holding patents unenforceable when true inventors deliberately exclude co-inventors, a district court can, a fortiori, exercise its discretion to hold a patent unenforceable when a person falsely swears that he invented a device before the PTO. Because AMC and Mr. Bauer attempted to defraud the PTO, the district court was correct in holding the '773 patent unenforceable."





Need Specific Findings on Intent

- Golden Hour Data Systems, Inc. v. emsCharts, Inc., 2:06 CV 381 (E.D. Tex. March 23, 2009)(Judge Ward)
- Chronology of events:





Patent Infringed, But Unenforceable

- Golden Hour (con't)
 - □ Jury verdict: infringed
 - ☐ Bench trial: unenforceable for inequitable conduct.
 - "the court finds that the evidence is clear and convincing that, at least by late March of 1998, both Dr. Hutton and prosecution counsel possessed the AeroMed brochure and knew at the very least what they had told the patent office in the initial patent application was false. No one attempted to correct those misrepresentations that went directly to the patentability of the claims as submitted."





The Controversial AMS Brochure

- Golden Hour (con't)
 - □ The brochure was never submitted in the IDS.
 - Prosecution Counsel admitted it had brochure at time of IDS.
 - □ The IDS admitted awareness of the AeroMed system but supplied verbatim the description of the system on the front page of the brochure but did not supply the damaging information on the second page of the brochure.
 - □ Fuller admitted that he must have copied the information from the front page when he submitted the IDS.
 - The second page info was inconsistent with what was said in the IDS and in the original application





Golden Hour (con't)

- □ Judge Ward acknowledges *Kingsdown* for intent greater than gross negligence:
 - "Intent to deceive cannot be inferred simply from the decision to withhold [information] where the reasons given for the withholding are plausible." Dayco Products, Inc. v. Total Containment, Inc., In addition, "a finding that particular conduct amounts to 'gross negligence' does not of itself justify an inference of intent to deceive; the involved conduct, viewed in light of all the evidence, including evidence indicative of good faith, must indicate sufficient culpability to require a finding of intent to deceive." Kingsdown Med. Consultants, Ltd. v. Hollister Inc., 863 F.2d 867, 876 (Fed. Cir. 1988) (en banc in relevant part).





- Golden Hour (con't)
 - □ Concludes this is more than gross negligence, with a comment about "should have known" along the way:
 - "a high degree of materiality, coupled with evidence that the applicant should have known of that materiality, creates a strong inference of an intent to deceive." <u>Cargill,</u> <u>Inc. v. Canbra Foods, Ltd.</u>, 476 F.3d 1359, 1376 (Fed. Cir. 2007)."





Intent: What Did Counsel Say?

- Golden Hour (con't)
 - □ Court: "Even the most cursory of reviews would have revealed the description of AeroMed's billing and integration—the only thing described in the center column of the one page brochure."
 - □ Fuller also argued that "even if he would have read the description of billing he would not have disclosed it. He maintains the lack of a date renders it immaterial."





- Golden Hour (con't)
 - ☐ Material: brochure contradicts the way prior art described in patent specification.
 - Had brochure at the time the IDS was filed.
 - IDS description exactly duplicates description of the system on the front of the brochure.
 - Selected only the part consistent with what was said in specification
 - Selectivity is strong evidence of deceptive intent
 - Cannot allow deliberate ignorance
 - Ergo, Golden Hour acted with intent to deceive





■ Golden Hour (con't)

☐ Circumstantial evidence establishes that the single most reasonable inference is intent to deceive

☐ Fuller made no attempt to prepare for the hearing

☐ He did not read the prosecution file, only the publicly available file





- Golden Hour (con't)
 - ☐ Cultivated ignorance cannot be rewarded.
 - □ Regarding privilege, Counsel could have had another attorney not involved in the case review the file and remove privileged information before Fuller looked at the file.
 - ☐ Golden Hour committed inequitable conduct.
 - □ Also held no infringement (Golden Hour Data Systems, Inc. v. emsCharts, Inc., 2009 WL 943273 (E.D.Tex. Apr 03, 2009)).





Cover or Contents?

- Golden Hour Data Sys. Inc. v. EMSCharts, Inc., --F.3d— (Fed. Cir. Aug. 9, 2010)(DYK, Friedman, Newman)(Newman, dissenting)
 - ☐ Jury: claims infringed, willful and induced too, \$3.5M award.
 - □ DC: JMOL of no joint infringement, and held the patent unenforceable due to inequitable conduct.
 - □ FC: Affirmed no joint infringement, but vacate inequitable conduct holding, and remand for further findings on intent.





High Materiality

- Golden Hour (con't)
 - ☐ FC: Brochure material
 - Information may be material without qualifying as prior art;
 - Evidence that brochure is prior art (existed in 1996 and patent application filing date in 1998);
 - Contradicted statements made to the PTO;
 - "The present-tense representation that the AeroMed system 'does not provide comprehensive integration . . . with . . . billing' continued unchanged throughout the pendency of the application. ... By not correcting the statement in the specification, applicants continued to maintain its truth in direct contradiction to what is disclosed in the AeroMed brochure. Given the importance of integrated billing to the patentability of the invention, information inconsistent with or contrary to the application's representation of the capabilities of AeroMed's billing system in the specification would have been important to a reasonable examiner."
 - IDS describing brochure also used present tense and omitted description of integrated billing in brochure.



District Court Did Not Actually Find Attorney or Inventor Aware of Contents of Brochure

- Golden Hour (con't)
 - □ FC: Intent
 - "prosecution counsel failed to provide any explanation for withholding the missing information from the brochure"
 - "[e]ven the most cursory of reviews would have revealed the description of AeroMed's billing and integration was inconsistent with the representations in the specification."
 - district court did not credit testimony of attorney or inventor, but did not provide factual findings on "crucial facts"
 - "[t]he key question then is whether Fuller and/or Hutton in fact read the brochure..... Fuller never testified definitively that he did not read the brochure in full."





Need Knowledge of Contents for Intent

- Golden Hour (con't)
 - ☐ FC: Intent (con't)
 - "If one or both read the brochure and deliberately did not disclose the damaging information on the inside, their actions would give rise to an inference of intent to deceive. However, if they did not read the brochure (and did not do so to avoid learning of damaging information), those actions regarding the failure to disclose the information on the inside of the brochure would at most, amount to gross negligence. Gross negligence is not inequitable conduct. See Kingsdown, 863 F.3d at 876."





Need Knowledge of Contents for Intent

- Golden Hour (con't)
 - ☐ FC: Intent (con't)
 - "A fair reading of Fuller's testimony is that he testified that he did not remember reading the inside of the brochure, but that even if he had, he would not have submitted it because it was his practice not to submit undated materials."





Remand Required for Findings on Intent

- Golden Hour (con't)
 - ☐ FC: Intent (con't)
 - "A fair reading of Fuller's testimony is that he testified that he did not remember reading the inside of the brochure, but that even if he had, he would not have submitted it because it was his practice not to submit undated materials."
 - "Quite apart from the highly material nature of the withheld reference, the suspicious late production of the brochure, and the district court's findings as to witness credibility, there is ample evidence that could support finding that Fuller or Hutton or both actually read the brochure and determined to withhold its contents from the PTO, knowing it to be material."
 - BUT, finding of intent is not "compelled."
 - Remand for factual findings on intent.





Evidence In Favor That Attorney And/or Inventor Read Knew Contents of Brochure

- Golden Hour (con't)
 - ☐ FC: Intent (con't)
 - AeroMed primary competitor;
 - 2. Information inventor originally received about the AeroMed system was based on comments by other software developers;
 - "[R]epresentations as to the AeroMed system were central to the claim of patentability in the original application";
 - "[U]nlikely that a patent practitioner would make representations as to the brochure in an IDS without reading the entire brochure"





Dissent

- Golden Hour (con't)
 - □ Judge Newman agreed that intent was not established, but disagreed with remand to give defendants "another shot."
 - □ Disagreed that brochure was material.
 - Disagreed that the "undated AeroMed brochure, obtained at a trade show (the Association of Aeromedical Services) a few weeks after this patent application was filed, and found not to be invalidating prior art, was so clearly and convincingly 'material to patentability' that failure to provide a copy of the brochure while quoting its front page, invalidates the patent that was found valid over the entire content of the brochure."
 - □ At least should stay decision pending resolution of <u>Therasense</u> en banc.





Alternative Reasonable Inference

- AstraZeneca Pharms. v. Mylan Pharms., (D.Del. June 29, 2010)("Crestor® litigation")
 - ☐ Allegation of inequitable conduct based on failure to disclose prior art patent applications and a European search report.
 - □ DC: No inequitable conduct. Alternative reasonable inference from actions.
 - "In a case involving nondisclosure of information, clear and convincing evidence must show that the applicant made a *deliberate decision* to withhold a *known* material reference.'" [citing <u>Star Scientific</u>] (emphasis in original).





Alternative Reasonable Inference

- Crestor litigation (con't)
 - "Court views the evidence of intent in this case on its own strength and concludes that Defendants have not established, by clear and convincing evidence, that ms. Kitamura, Mr. Shibata and Mr. Tamaki intended to deceive the PTO by failing to disclose these references. Although the Court certainly understands how the circumstances raised by Defendants could be suggestive of nefarious conduct on the part of the aforementioned individuals in the Shionogi Patent Department, the Court cannot conclude that the level of clear and convincing evidence of inequitable conduct."
 - □ "In reaching this conclusion, the Court is simply not persuaded that the single most reasonable inference to be drawn from these circumstances is deceptive intent."



Alternative Reasonable Inference

- Crestor [®] litigation (con't)
 - "Defendants also point to the splitting of the '440 application between Ms. Shimizu and Mr. Tamaki contending that 'Mr. Shibata violated the longstanding Shionogi rule requiring that the same person be responsible for handling all corresponding applications' so that he could manipulate and prevent the disclosure of the European Search Report and the Sandoz reference.... However, the countervailing evidence produced by Plaintiffs and viewed as a whole, paints a more innocent explanation of Mr. Shibata as a new and inexperienced manager attempting to handle an understaffed and overworked Patent Department."



Alternative Reasonable Inference

- Crestor ® litigation (con't)
 - "In addition, Defendants emphasize Mr. Shibata's role in comparative testing of the compound claimed in the S-4522 application with the compounds from the Bayer, Nissan and Sandoz references to suggest that he was attempting to conceal these references. However, an equally plausible inference is that this comparative testing could have been used to confront the prior art and overcome challenges to patentability, particularly given Mr. Shibata's testimony, which the Court finds credible, that he has likely thought, at the relevant time, that the Bayer and Sandoz references had already been disclosed."





Alternative Reasonable Inference

- Crestor ® litigation (con't)
 - "In sum, the court is not persuaded that the evidence presented by Defendants rises to the level of the clear and convincing evidence required to establish inequitable conduct. in reaching this conclusion, the Court credits the testimony of Ms. Kitamura, Mr. Shibata and Mr. Tamaki and finds the rationale concerning the inexperience, increased workload, and resulting confusion in the Shionogi Patent Department to be an equally plausible explanation for the failure of Shionogi to cite the European Search Report, the Bayer reference and the Sandoz reference to the USPTO during the application process that led to the issuance of the '440 patent. Indeed, none of the aforementioned individuals was a Japanese patent attorney or agent, and in fact, the Shionogi Patent Department as a whole employed no one with legal experience in the field of patents."





Alternative Reasonable Inference

- Crestor [®] litigation (con't)
 - "Viewed in this context, which the Court is persuaded is the appropriate context given the testimony and evidence, actions suggestive of malfeasance become no more than a string of mishaps, mistakes, misapprehensions and misjudgments on the part of inexperienced and overworked individuals. Accordingly, the Court will enter judgment in favor of Plaintiffs and against Defendants' on the issue of inequitable conduct."





- Ring Plus, Inc. v. Cingular Wireless Corp., --F.3d— (Fed. Cir. Aug. 6, 2010)(MOORE, Lourie, Gajarsa)
 - ☐ Basis for inequitable conduct allegation: misrepresentation of two references in both the Background of the Invention and in an amendment.
 - Background: identified references and stated "there is no algorithm or software proposed for operating the telephone system.
 - Amendment: claimed system different from references because it "only generates [a] message when the phone line between the caller and the recipient is not busy."
 - □ DC: references disclose software-based algorithms and playing a sound presentation only when the recipient line is not busy. -> material misrepresentations.





- Ring Plus (con't)
 - □ DC: Unenforceable for inequitable conduct.
 - ☐ FC: Reverse and remand.
 - Statement in Background was misrepresentation, but not in the amendment.
 - References of "particular relevance" -> "highly material"
 - Standard applied: reasonable examiner
 - □ "the materiality standard is an objective one: the issue is what a reasonable examiner would have found important, not whether the reference in question was specifically considered during prosecution. " 113





- Ring Plus (con't)
 - ☐ FC: Standard for intent to deceive:
 - "Although intent to deceive can be inferred from circumstantial evidence, the evidence must still be clear and convincing; 'a showing of materiality alone does not give rise to a presumption of intent to deceive.' [citing Praxair and Kingsdown]. Any inference of deceptive intent must be 'the single most reasonable inference able to be drawn from the evidence to meet the clear and convincing standard.' Star Scientific, 537 F.3d at 1366."





- Ring Plus (con't)
 - □ DC: Single most reasonable inference was intent to deceive.
 - □ FC: Disagreed.
 - District court erred in basing "its finding of intent almost entirely on its view that the references unambiguously disclose software. We disagree that the disclosure of software is so plain."
 - No evidence that one of skill in the art would consider the references to unambiguously disclose software.
 - Attorney testified that he understood references to only disclose hardware. No evidence rebutted.
 - "Whenever evidence proffered to show either materiality or intent is susceptible of multiple reasonable inferences, a district court clearly errs in overlooking one inference in favor of another equally reasonable inference." [quoting <u>Scanner Techs.</u>]





Ring Plus (con't)

- "Mr. Schaap's testimony gives rise to the inference that applicants believed that Strietzel and Sleevi did not disclose software for operating a telephone system. Based on the evidence of record, this inference is as reasonable as the court's inference of deceptive intent, particularly in view of the references' ambiguity as to operating software. Thus, the district court clearly erred in finding clear and convincing evidence of deceptive intent."
- ☐ "applicants' statement in Amendment B that they examined Strietzel and Sleevi "very carefully"...is not indicative of intent."





Why Do We Need Patent Term Adjustment?

- Before 1994, U.S. patents received a patent term of 17 years from issue.
 - □ PTO delays in prosecution did not impact patent term.
- In 1994, under GATT/TRIPs, the U.S. changed to a 20-years from filing patent term, to be consistent with the rest of the world.
 - ☐ All of a sudden PTO-caused delays consumed patent term.
- In 1999, the American Inventors Protection Act amended 35 U.S.C. § 154(b), promising patent applicants "a full patent term adjustment for any delay during prosecution caused by the PTO."





Three "Guarantees" of Patent Term Adjustment

- 35 U.S.C. § 154(b)(1):
 - □ (A) Guarantee of prompt Patent and Trademark Office responses, with an award of 1 day of patent term extension for each day of delay due to the failure of the Patent and Trademark Office to meet specific deadlines set forth in (i)-(iv) ("14-4-4-4")
 - □ (B) Guarantee of no more than 3-year application pendency, with an award of 1 day of patent term extension for each day beyond 3 years from filing until the patent issues; and
 - ☐ (C) Guarantee or adjustments for delays due to interferences, secrecy orders, and appeals, with an award of 1 day for each day of the pendency of the proceeding, order, or review.





Delays Under 35 U.S.C. § 154(b)(1)(A)(i)-(iv) "14-4-4-4"

- i. A first Office action will be mailed within <u>14</u> months of the application's filing date or national phase completion date.
- ii. Respond to a reply under § 132, or to an appeal taken under § 134, within 4 months after the date on which the reply was filed or the appeal was taken;
- Act within 4 months after the date of a decision by the Board of under § § 134 or 135 or a decision by a Federal court under § § 141, 145, or 146; or
- iv. Issue a patent within <u>4</u> months after the date the issue fee is paid and all outstanding formal requirements are met.





Three Limitations

Overlap

□ 35 U.S.C. § 154(b)(2)(A): "To the extent that periods of delay attributable to grounds specified in paragraph (1) *overlap*, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed."

Disclaimed term

□ 35 U.S.C. § 154(b)(2)(B): "No patent the term of which has been disclaimed beyond a specified date may be adjusted under this section beyond the expiration date specified in the disclaimer.

Applicant-caused delay

□ 35 U.S.C. § 154(b)(2)(C)(i): "The period of adjustment of the term of a patent under paragraph (1) shall be reduced by a period equal to the period of time during which the *applicant failed to engage in reasonable efforts to conclude prosecution* of the application."





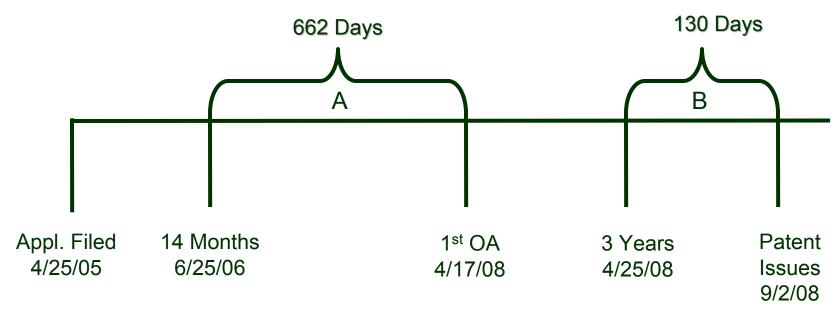
U.S. PTO Rules

- PTO promulgated rules to apply § 154(b)
 - □ 37 C.F.R. § 1.703(f): "To the extent that periods of delay attributable to the [guarantees] overlap, the period of adjustment granted under this section shall not exceed the actual number of days the issuance of the patent was delayed."
 - □ Explanation of 37 C.F.R. 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. § 154(b)(2)(A) (69 Fed.Reg. 34238 (June 21, 2004)):
 - the Office has consistently taken the position that if an application is entitled to an adjustment under the three-year pendency provision of 35 U.S.C. § 154(b)(1)(B), the entire period during which the application was pending before the Office (except for periods excluded under 35 U.S.C. § 154(b)(1)(B)(i)-(iii)), and not just the period beginning three years after the actual filing date of the application, is the relevant period under 35 U.S.C. § 154(b)(1)(B) in determining whether periods of delay "overlap" under 35 U.S.C. 154(b)(2)(A).





Example of Pre-Wyeth U.S. PTO Calculation



Pre-Wyeth PTO Calculation: 662 days total (larger of A or B)

- Entire period from filing to issuance was overlap
- •PTO awarded larger of A or B, never A+B





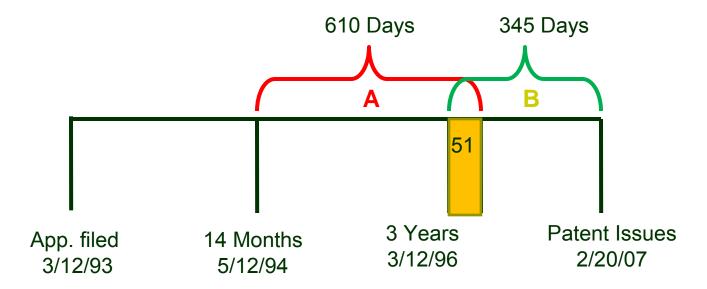
Challenge to U.S. PTO Formula

- Wyeth v. Dudas, 580 F.Supp.2d 138 (D. DC Sept. 30, 2008)
 - □ Wyeth filed action in district court to challenge the U.S. PTO calculation and replace it with their own calculation for '892 and '819 patents.
 - Wyeth argued that "A period" and "B period" overlap only if they occur on the same calendar day.
 - U.S. PTO argued its interpretation is entitled to <u>Chevron</u> deference
 - U.S. PTO also argued that an A delay will necessarily lead to a B delay, so if you follow Wyeth's interpretation, you will get double counting.





Patent Term Adjustment for U.S. Pat. No. 7,179,892



Pre-Wyeth PTO Calculation: 610 days (larger of A or B) minus 148 (applicant delay) = 462 days.

Wyeth calculation: 610 (A delay) + 345 (B delay) minus 51 (overlap) minus 148 (applicant delay) = 756 days.





U.S. Pat. No. 7,179,892

U.S. Pat. No. 7,179,892 filed March 12, 1993, 20-year patent term

March 12, 2013

U.S. PTO calculation extends patent term 462 days 610 (Greater of A or B) -148 (Applicant Delay)

June 17, 2014

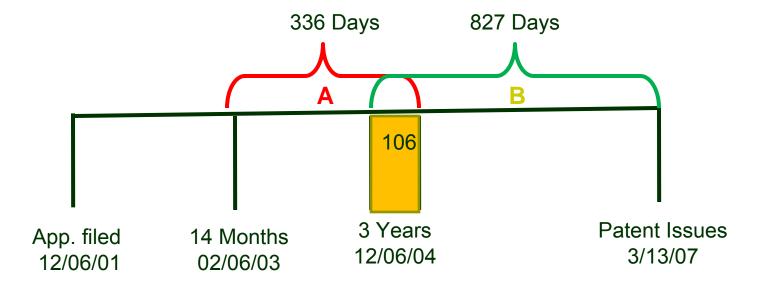
Wyeth calculation extends patent term 756 days (610 (A Delay) + 345 (B Delay)-51 ("overlap")-148 (Applicant Delay)

April 16, 2015





Patent Term Adjustment for U.S. Pat. No. 7,189,819



Pre-Wyeth PTO Calculation: 827 (greater of A or B) -335 (applicant delay) = 492 days

Wyeth calculation: 336 (A delay) + 827 (B delay) – 106 (overlap) – 335 (applicant delay) = 722 days.





U.S. Pat. No. 7,189,819

U.S. Pat. No. 7,189,819 filed Dec. 6, 2001, 20-year patent term

Dec. 6. 2021

U.S. PTO calculation extends patent term 492 days 827 (Greater of A or B) -335 (Applicant Delay)

April 12, 2023

Wyeth calculation extends patent term 722 days 336 (A Delay) + 827 (B Delay) – 106 (overlap) – 335 (Applicant Delay)

Nov. 28, 2023





Challenge to U.S. PTO Formula

- Wyeth (con't)
 - □ DC: Granted summary judgment to Wyeth.
 - □ No *Chevron* deference: PTO "does not have the authority to issue substantive rules, only procedural regulations regarding the conduct of proceedings before the agency."
 - □ PTO's statutory construction is incorrect: "The only way periods of time can 'overlap' is if they occur on the same day."
 - "The problem with the PTO's interpretation is that it considers the application delayed under [the B guarantee] during the period before it has been delayed." *Wyeth*, 580 F.Supp.2d a 141-42.





Patent Term Adjustment

- Wyeth v. Kappos, 591 F.3d 1364 (Fed. Cir. 2010)
 - □ Undisputed that the PTO caused delays triggering both "A" and "B" guarantees.
 - □ FC: Affirmed; rejected the USPTO's interpretation of the "overlap" limitation in § 154(b)(2)(A).
 - "The limitation in section 154(b) only arises when "periods of delay" resulting from violations of the three guarantees 'overlap.' 35 U.S.C. § 154(b)(2)(A). Significantly, the A and B guarantees expressly designate when and for what period they each respectively apply. Thus, this court can easily detect any overlap by examining the delay periods covered by the A and B guarantees."
 - □ The "period of delay" for purposes of the A clause therefore runs from the date the PTO misses the specified deadline to the date (past the deadline) of response to the underlying action.
 - □ The "period of delay" under the express language of the B clause therefore runs from the three-year mark after filing until the application issues.





Patent Term Adjustment

- Wyeth v. Kappos (con't)
 - □ FC: (con't)
 - "clear that no 'overlap' happens unless the violations occur at the same time.
 ...Before the three-year mark, no 'overlap' can transpire between the A delay and the B delay because the B delay has yet to begin or take any effect."
 - "Under the PTO's strained interpretation, B delay can occur anytime after the application is filed. To the contrary, the language of section 154(b) does not even permit B delay to start running until three years after the application is filed. The PTO's position cannot be reconciled with the language of the statute."
 - *Chevron* deference: "Because the language of the statute itself controls this case and sets an unambiguous rule for overlapping extensions, this court detects no reason to afford special deference to the PTO's interpretation."





USPTO's Interim Procedure For Patent Owners To Request Recalculation Of Patent Term Adjustments

- Jan. 28, 2010 announcement: "Procedure to Comply with the Federal Circuit Decision in Wyeth v. Kappos Regarding the Overlapping Delay Provision of 35 U.S.C. 154(b)(2)(A) http://www.uspto.gov/patents/announce/pta wyeth.pdf
 - Patentees can request recalculation based on Wyeth without a fee or petition while they reset their software for calculating patent term extensions!
 - □ PTO expects to complete software modification by March 2, 2010.
 - ☐ Request for available without a fee or petition if:
 - Patent issues prior to March 2, 2010, and request made no later than 180 days after the issue date;
 or
 - Patents in which a previous request for PTA recalculation based on Wyeth was denied no more than
 2 months prior to the request for recalculation
 - ☐ If both periods apply, you get either 180 days from the patent's issue date or two months from the decision dismissing the PTA request, whichever is longer, to file request.





U.S. PTO Announcement July 20, 2010

- Letters from patent applicants and patentees objecting to PTO patent term adjustment determinations will be placed in the file of the applicant or patent owner without further review.
- Applicants or patentees who want the agency to reconsider the determination must use the procedures set forth at 37 C.F.R. §1.705, or by filing a terminal disclaimer at any time disclaiming any period considered in excess of the appropriate patent term adjustment.





U.S. PTO Announcement July 20, 2010

- A revised patent term adjustment determination requires a complex calculation and is not "clearly disclosed" by the PTO records, according to the agency. Moreover, a certificate of correction is permissible under Section 255 only for "a mistake of a clerical or typographical nature, or of a minor character," it added, again quoting the statute.
- This clarification of PTO policy will apply to patent term adjustment letters and requests for certificates of correction that are pending or filed on or after July 20.





U.S. PTO Announcement July 20, 2010

Certificates of Correction Won't Be Granted

□ The PTO acknowledged that, under Section 2733 of the Manual of Patent Examining Procedure, an applicant may request a certificate of correction if a notice of allowance indicates that a patent term adjustment is longer than expected. However, it is not appropriate to provide a recalculation of the patent term through a certificate of correction under either 35 U.S.C. §254 or 255 because such a certificate of correction is available only for a mistake that is "clearly disclosed by the records of the Office," the PTO said, quoting Section 254.





Practice Tips

- Review Notice of Allowance for U.S. PTO's patent term adjustment.
- Review Issue Notification for U.S. PTO's patent term adjustment.
 - □ Include a review of the post-allowance activities and the patent's issue date because the U.S. PTO will not consider 3 year pendency calculations until the patent's issue date is known.





Practice Tips

- If the PTA calculation provides <u>more</u> days extension or adjustment than believed correct, file a letter advising that there appears to be an error in applicant's favor in the patent term. There is no fee for such a letter.
- If the PTO's calculation provides <u>fewer</u> days extension or adjustment than believed correct, consider requesting recalculation.





Practice Tips

- DO NOT FILE A STATUS INQUIRY about a PTA paper filed after allowance. It will cause a minus that cannot be argued.
 - Examiners have nothing to do with PTA calculation or review.
 - Call the PTO's Office of Legal Administration (571-272-7701)
 to ask about the status of pending PTA filings.





Suing the U.S. PTO for Miscalculation of Patent Term

- Idera Pharmaceuticals Inc. v. Kappos, No. 1:10-cv-00166 (D. DC)
 - □ Suing the U.S. PTO for miscalculation of patent term adjustment.
 - □ 594 of patent term adjustment based on formula for calculation invalidated in *Wyeth* decision
 - □ Patent term extension should be 1,174 days because two delay periods were calculated as wholly overlapping.
 - ☐ Terminal disclaimer in second patent means that patent term also impacted.
 - □ U.S. PTO denied Idera's request to reconsider the patent term adjustment.
 - See also, Pfizer, Inc. v. Kappos, 1:09-cv-02283-RJL (D. DC); and Novartis AG v. Kappos, No. 1:10-cv-01138 (D. DC)





U.S. PTO Answer To Lawsuits

- Announcment, July 20, 2010
 - □ Letters from patent applicants and patentees objecting to PTO patent term adjustment determinations will be placed in the file of the applicant or patent owner without further review.
 - □ Applicants or patentees who want the agency to reconsider the determination must use the procedures set forth at 37 C.F.R. §1.705, or by filing a terminal disclaimer at any time disclaiming any period considered in excess of the appropriate patent term adjustment.





U.S. PTO Answer To Lawsuits

- Announcement, July 20, 2010 (con't)
 - □ A revised patent term adjustment determination requires a complex calculation and is not "clearly disclosed" by the PTO records, according to the agency. Moreover, a certificate of correction is permissible under Section 255 only for "a mistake of a clerical or typographical nature, or of a minor character," it added, again quoting the statute.
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U.S. PTO Answer To Lawsuits

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Inducement: Deliberate Indifference Sufficient

- SEB v. Montgomery Ward, 594 F.3d 1360 (Fed. Cir. 2010)
 - □ Pentalpha developed a deep fryer by copying SEB's cool touch features.
 - □ 1997 started to sell deep fryers to Sunbeam.
 - □ Obtained opinion of counsel but didn't disclose to attorney the role of the SEB fryer in the development of Pentalpha's product.
 - ☐ March 10, 1998 SEB sued Sunbeam.
 - ☐ April 9, 1998 Pentalpha notified of Sunbeam suit.
 - □ Pentalpha then sold deep fryers to Fingerhut and Montgomery Ward.
 - □ August, 1998 SEB sued Pentalpha and Montgomery Ward.
 - □ Sept. 10, 1999 SEB filed motion for preliminary injunction.
 - ☐ Pentalpha redesigned its deep fryer.





Inducement: <u>SEB</u>

■ Jury: Pentalpha induced infringement with respect to both fryers, \$4.65M damage award.

District court: entered judgment, reduced award to \$2.65M.





Inducement: <u>SEB</u>

- Fed. Cir.: Affirmed.
 - □ Record showed no direct evidence that Pentalpha had actual knowledge of the patent before April 9, 1998.
 - □ <u>DSU</u> stated that the requirement that infringer "knew or should have known that his actions would induce infringement" necessarily includes the requirement that he knew of the patent
 - □ BUT <u>DSU</u> "did not, however, set out the metes and bounds of the knowledge-of-the-patent requirement."





Inducement: <u>SEB</u>

Specific intent in the civil context is not so narrow as to allow accused wrongdoer to actively disregard a known risk.

- Deliberate indifference = knowledge of patent.
 - May require a subjective determination that the defendant knew of and disregarded the overt risk.





Inducement: <u>SEB</u>

■ Fed. Cir.:

"[A] claim for inducement is viable even where the patentee has not produced direct evidence that the accused infringer actually knew of the patent-in-suit. This case shows such an instance. The record contains adequate evidence to support a conclusion that Pentalpha deliberately disregarded a known risk that SEB had a protective patent."





Inducement: <u>SEB</u>

- Evidence of deliberate indifference.
 - □ Purchased SEB deep fryer in Hong Kong and copied all but the cosmetics.
 - ☐ Hired an attorney to conduct a right-to-use study, but did not tell him that it had based its product on SEB's product.
 - "A failure to inform one's counsel of copying would be highly suggestive of deliberate indifference in most circumstances."
 - ☐ Testimony that Pentalpha president "was well versed in the U.S. patent system and understood SEB to be cognizant of patent rights as well."
 - ☐ No exculpatory evidence.
- Cannot rely on the fact that a fryer purchased in Hong Kong lacked U.S. patent markings





- Sun Pharmaceutical Industries, Ltd. v. Eli Lilly and Co., --F.3d- (Fed. Cir. July 28, 2010)
 - □ DC: claims invalid for double patenting.
 - ☐ FC: Affirmed.
 - □ Lilly's patents covering gemcitabine (Gemzar®)
 - '614 patent claims gemcitabine, as well as a method of using gemcitabine for treating viral infections.
 - '826 patent claims a method of using gemcitabine for treating cancer.





- Sun Pharm. (con't)
 - □ '614 patent issued on February 28, 1989 and expired on May 15, 2010.
 - Claims 1, 2, and 8: class of nucleosides, which includes gemcitabine; Claim 12: gemcitabine; Claims 13 and 14: a method of using the claimed nucleosides, including gemcitabine, for treating Herpes viral infections.
 - Original application filed March 10, 1983, described only gemcitabine's utility for antiviral purposes.
 - Divisional application filed as a continuation-in-part December 4,
 1984, added a description of gemcitabine's anticancer utility to the specification.





- Sun Pharm. (con't)
 - □'826 patent
 - Application filed December 4, 1984.
 - Issued on November 7, 1995.
 - Claims directed to a method of treating cancer with an effective amount of a class of nucleosides, which includes gemcitabine.
 - No terminal disclaimer.





- Sun Pharm. (con't)
 - ☐ FC: "Our prior obviousness-type double patenting decisions in Geneva and Pfizer, which addressed factual situations closely resembling that presently before the court, control this case. In both cases, we found claims of a later patent invalid for obviousness-type double patenting where an earlier patent claimed a compound, disclosing its utility in the specification, and a later patent claimed a method of using the compound for a use described in the specification of the earlier patent. ... We held that a 'claim to a method of using a composition is not patentably distinct from an earlier claim to the identical composition in a patent disclosing the identical use."





- Sun Pharm. (con't)
 - □ FC:
 - "we do not agree [with Lilly's argument] that Pfizer involved a single disclosed utility that was alone essential to the patentability of the claimed compounds."
 - □ In Pfizer, earlier patent's specification unambiguously disclosed more than one utility for the claimed compound.
 - "the analysis in the Pfizer decision shows that obviousness-type double patenting encompasses <u>any</u> use for a compound that is disclosed in the specification of an earlier patent claiming the compound and is later claimed as a method of using that compound." (emphasis added)





Sun Pharm. (con't)

☐ FC:

- "Further...[b]oth Geneva and Pfizer make clear that, where a patent features a claim directed to a compound, a court must consider the specification because the disclosed uses of the compound affect the scope of the claim for obviousness-type double patenting purposes.
- "we have expressly held that, where a patent claims a compound, a court performing an obviousness-type double patenting analysis should examine the specification to ascertain the coverage of the claim."
- "where such examination of the specification is appropriate in an obviousness-type double patenting analysis, the specification that must be considered is that of the issued patent."





Sun Pharm. (con't)

☐ FC:

"where necessary in the obviousness-type double patenting analysis, consulting the specification of the issued patent, as opposed to an earlier version of the specification, is consistent with the policy behind double patenting. ...the double patenting doctrine is concerned with the issued patent and the invention disclosed in that issued patent, not earlier drafts of the patent disclosure and claims."





- Pfizer, Inc. v. Teva Pharms. USA, Inc., 518 F.3d 1353 (Fed. Cir. 2008)
 - Restriction requirement during prosecution
 - Compound claims (celecoxib) issued as '823 patent
 - Composition claims issued as '165 patent from divisional application
 - Method claims issued as '068 patent from CIP
 - DC: Infringement and not invalid for obviousness-type double patenting
 - § 121 protected the child patents (filed in response to restriction requirement) from being prior art against each other





- <u>Pfizer</u> (con't)
 - FC: Claims are invalid based on double patenting
 - § 121 explicitly refers to "divisional applications" only and patents issued on such applications
 - Purpose of § 121 was to eliminate the inequity from responding to the PTO's restriction requirement
 - "The need for the protection only existed when a divisional application was filed as a result of the restriction. If the section had included CIPs, which by definition contain new matter, the section might be read as providing the earlier priority date even as to the new matter, contrary to the usual rule that new matter is not entitled to the priority date of the original application. ... If the drafters wanted to include CIPs within the protection afforded by section 121, they could have easily done so."
 - § 121 does not apply to the '068 patent and that the '165 patent may be used to invalidate the '068 patent





- Pfizer (con't)
 - FC: (con't)
 - Obviousness-type double patenting analysis:
 - construes "the claim[s] in the earlier patent and the claim[s] in the later patent and determines the differences."
 - Determine "whether those differences render the claims patentably distinct."
 - "A later patent claim is not patentably distinct from an earlier patent claim if the later claim is obvious over, or anticipated by, the earlier claim."
 - "claim to a method of using a composition is not patentably distinct from an earlier claim to the identical composition in a patent disclosing the identical use."
 - Double patenting is a question of law, which we review without deference.





- <u>Pfizer</u> (con't)
 - FC: (con't)
 - relevant claims of the two patents are not patentably distinct
 - claims of the '068 patent merely recite methods of administering a "therapeutically-effective amount" of the compositions found the '165 patent.
 - the '068 patent merely claims a particular use described in the '165 patent of the claimed compositions of the '165 patent.
 - "The asserted claims of the '068 are therefore not patentably distinct over the claims of the '165 patent."



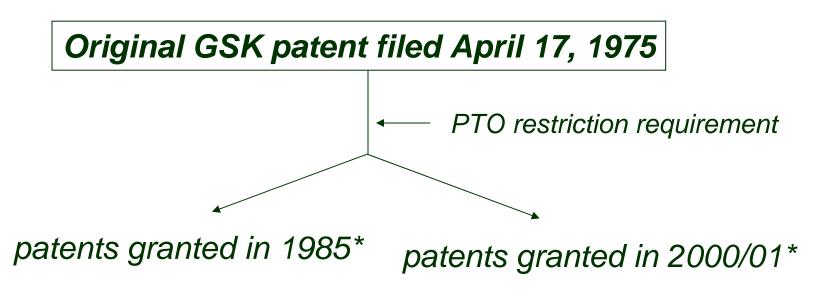


- Geneva Pharms., Inc. v. GlaxoSmithKline PLC, 349
 F.3d 1373 (Fed.Cir.2003)
 - Infamous footnote
 - The distinctions between obviousness under 35 U.S.C. § 103 and nonstatutory double patenting include:
 - The objects of comparison are very different: Obviousness compares claimed subject matter to the prior art; nonstatutory double patenting compares claims in an earlier patent to claims in a later patent or application;
 - Obviousness requires inquiry into a motivation to modify the prior art;
 nonstatutory double patenting does not;
 - Obviousness requires inquiry into objective criteria suggesting nonobviousness; nonstatutory double patenting does not.





Geneva v. GSK (con't)



*No terminal disclaimers filed





- · Geneva v. GSK (con't)
 - Patents relate to antibiotic clavulanic acid and its salts
 - 1985 patents
 - 2000/01 patents
 - During reexamination proceedings for the 2000/01 patents, PTO found common ancestry and a restriction requirement -> § 121 shield
 - DC: granted SJ that 2000/01 invalid due to double patenting
 - Original application did not show that the PTO issued a restriction requirement
 - No § 121 shield
 - One-way obviousness test because the applicant could have avoided the multiple filings





- Geneva v. GSK (con't)
 - Two issues
 - •original application did not contain the "method of use claims" that later appeared
 - examiner did not issue a formal restriction requirement relating to the claims at issue in any document in the record





- Geneva v. GSK (con't)
 - ■§ 121: "If two or more independent and distinct inventions are claimed in one application...
 - Judge Rader:
 - ■"This clause notes that the restriction requirement applies to a single application that formally claims two or more distinct inventions. This indicates that the earlier application must contain formally entered claims that are restricted and removed, and that claims to the second invention reappear in a separate divisional application after the restriction. The text of § 121 does not suggest that the original application merely needs to provide some support for claims that are first entered formally in the later divisional application."





- Geneva v. GSK (con't)
 - FC: Affirmed
 - ■Not entitled to protection of § 121 where the principle of consonance is violated
 - "line of demarcation between the 'independent and distinct inventions' that prompted the restriction requirement must be maintained."
 - If the claims are changed "in material respects" from the claims subject to the restriction requirement, there is no consonance and § 121 will not provide any protection from a charge of double patenting
 - method of use claims were not entered in original application
 - if wanted benefit of § 121, applicants should have requested entry of the claims so that the PTO could issue a formal restriction requirement
 - prosecution history does not document a restriction requirement
 - "This record is deficient. Accordingly, § 121 does not shield the 2000/01 patents against the '720 patent."





- Geneva v. GSK (con't)
 - FC: (con't)
 - Interview Summary: "It was agreed that "simple betalactamase inhibition" composition claims, i.e., new claims 97 through 112, are proper in the present case but that method of use claims, that is a method of effecting beta-lactamase inhibition in humans and animals would not be proper in the present case and therefore an appropriate set of method of use claims corresponding to new claims 97 to 112 will be presented in Divisional Application, Serial No. 964,035."
 - Court found passage did not state that the examiner required restriction between those two sets of claims, nor did it state that any claims are patentably distinct





- ■Geneva v. GSK (con't)
 - ■FC: (con't)
 - 1985 patent claims are invalid for nonstatutory double patenting over the Crowley patent
 - claim subject matter that encompasses a substantial part of the subject matter of the Crowley claim
 - genus-species relationship makes the claims patentably indistinct, because the earlier species within the Crowley claim anticipates the later genus of the 1985 claims



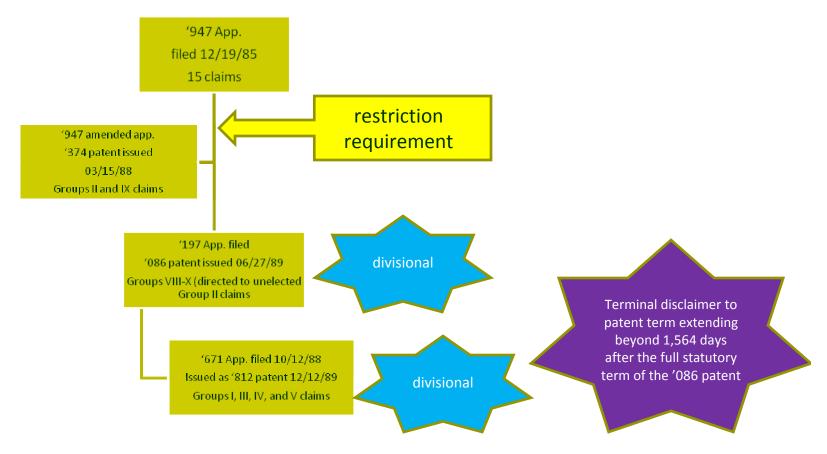


- Geneva v. GSK (con't)
 - ■DC: Another 1985 patent invalid for nonstatutory double patenting over the Fleming patent
 - '720 patent claim differs only as a method of inhibiting betalactamase and in specifying the amount of compound necessary to inhibit the beta-lactamase
 - inhibiting beta-lactamase is an inherent property of potassium clavulanate, and therefore the Fleming claims anticipated the '720 claims.
 - FC: Affirmed. A person of ordinary skill in the art reviewing the disclosure of the Fleming patent would recognize a single use for potassium clavulanate, administration to patients to combat bacteria that produce beta-lactamase. The '720 patent simply claims that use as a method.





Boehringer Ingelheim Int'l GmbH v. Barr Laboratories, Inc.,
 592 F.3d 1340 (Fed. Cir. 2010))



'812 patent granted on a divisional of a divisional





- Boehringer v. Barr (con't)
 - DC: Patent invalid for obviousness-type double patenting.
 - Terminal disclaimer ineffective because filed after '086 patent expired.
 - Safe-harbor provision of 35 U.S.C. § 121 precluded the use of the '086 patent as an invalidating reference.
 - '812 patent claims obvious in view of the method-of-use claims of the '086 patent.





- Boehringer v. Barr (con't)
 - □ FC: Reverse and remand.
 - Agreed that the terminal disclaimer filed too late, but district court erred in determining safe harbor provision of § 121 did not apply.
 - □ Terminal disclaimer filed after the expiration of the first patent could not cure obvious-type double patenting.
 - "By failing to terminally disclaim a later patent prior to the expiration of an earlier related patent, a patentee enjoys an unjustified advantage—a purported time extension of the right to exclude from the date of the expiration of the earlier patent. The patentee cannot undo this unjustified timewise extension by retroactively disclaiming the term of the later patent because it has already enjoyed rights that it seeks to disclaim."





- Boehringer v. Barr (con't)
 - □ FC: Reverse and remand (con't)
 - Section 121 "safe harbor":
 - ...A patent issuing on an application with respect to which a requirement for restriction under this section has been made, or on an application filed as a result of such a requirement, shall not be used as a reference either in the Patent and Trademark Office or in the courts against a divisional application or against the original application or any patent issued on either of them, if the divisional application is filed before the issuance of the patent on the other application
 - § 121 applicable to divisional of a divisional application as long as applications in a divisional chain "honor[ed]... the lines of demarcation drawn by the examiner... in the restriction requirement."





- Boehringer v. Barr (con't)
 - ☐ FC: Reverse and remand (con't)
 - "The statute, in referring to 'two or more independent and distinct inventions,' recognizes that the safe harbor is not limited to only one divisional application. 35 U.S.C. § 121 (emphasis added). Thus, where the third sentence of § 121 refers to a patent issuing on an application filed as a result of a restriction requirement, it is referring to patents issuing from any number of multiple divisional applications and precludes any one from being used as a reference against any other."
 - "The restriction requirement entered in the '947 application ...had the effect of obligating Boehringer to file one or more divisional applications Boehringer did so not by filing separate divisional applications on each of the inventions grouped by the examiner in the restriction requirement, but instead, by filing two successive divisionals to different combinations of the inventions identified in the restriction requirement. In doing so, Boehringer neither violated the examiner's restriction requirement nor risked loss of the safe harbor of § 121."

FINNEGAN



- Boehringer v. Barr (con't)
 - □ FC: Reverse and remand (con't)
 - "None of the inventions claimed as between the '374 original patent, the '086 division, and the '812 division of the division, crosses the examiner's lines of demarcation of inventions identified in the restriction requirement. Thus, consonance is met and the '086 patent cannot be used as a reference against the '812 patent any more than if both patents had issued from direct divisions from the application in which the restriction requirement was made."





- Section 271(f):
 - (1) Whoever without authority *supplies or causes to be supplied* in or from the United States all or a substantial portion of the *components of a patented invention*, where such components are uncombined in whole or in part, in such manner as to actively induce the combination of such components outside of the United States in a manner that would infringe the patent if such combination occurred within the United States, shall be liable as an infringer.
 - (2) Whoever without authority supplies or causes to be supplied in or from the United States any component of a patented invention that is especially made or especially adapted for use in the invention and not a staple article or commodity of commerce suitable for substantial noninfringing use, where such component is so made or adapted and intending that such component will be combined outside of the United States in a manner that would infringe the patent if such combination occurred within the United States, shall be liable as an infringer.





- <u>Cardiac Pacemakers Inc. v. St. Jude Medical Inc.</u>, 576 F.3d 1348 (Fed. Cir. 2009) (en banc), <u>cert. denied</u> (U.S. 2010)
 - Cardiac's '288 patent directed to implantable cardioverter defibrillators (ICDs).
 - □ Claim 1. A *method* of heart stimulation using an implantable heart stimulator capable of detecting a plurality of arrhythmias and capable of being programmed to undergo a single or multi-mode operation to treat a detected arrhythmia, corresponding to said mode of operation the method comprising:
 - (a) determining a heart condition of the heart from among a plurality of conditions of the heart;
 - (b) selecting at least one mode of operation of the implantable heart stimulator which operation includes a unique sequence of events corresponding to said determined condition;
 - (c) executing said at least one mode of operation of said implantable heart stimulator thereby to treat said determined heart condition.
 - □ Claim 4. *The method* of claim 1, wherein said at least one mode of operation of said implantable heart stimulator includes cardioversion.





- Cardiac Pacemakers (con't)
 - □ Protracted litigation history:
 - Cardiac sued St. Jude for infringement by exporting certain ICDs abroad, which can be used to perform method of claim 4.
 - After several remands Dist. Ct. found St. Jude infringed under 35 U.S.C. 271(f) following *Union Carbide v. Shell Oil*, 425 F.3d 1366 (Fed. Cir. 2005) (applying 271(f) to method clams); also found '288 patent invalid.
 - Fed. Cir. panel decision affirmed infringement under 271(f) and St. Jude requested rehearing en banc.





- Cardiac Pacemakers (con't)
 - □ En banc: "[R]everse and hold that Section 271(f) does not cover method claims and is therefore not implicated in this case."
 - 271(f) enacted in response to <u>Deepsouth Packing Co.,</u> <u>Inc. v. Laitram Corp.</u>, 406 U.S. 518 (U.S. 1972): manufacturer who shipped unassembled parts of a patented shrimp deveining machine abroad was not liable for patent infringement.





Cardiac Pacemakers (con't)

- Eolas Technolgies, Inc. v. Microsoft Corp., 399 F.3d 1325 (Fed. Cir. 2005): Microsoft could not avoid Section 271(f) liability by exporting golden master disks containing software code that were subsequently copied onto computer hard drives and sold outside of the United States. The **software code** included on Microsoft's master disks was a "**component**" of a patented invention under Section 271(f). Liability under method claim not addressed.
- AT&T Corp. v. Microsoft Corp., 414 F.3d 1366 (Fed. Cir. 2005) (AT&T I): **Intangible software code** was capable of being a **component** of a patented invention and such **software** was **"supplied"** for purposes of Section 271(f) when "a single copy [was sent] abroad with the intent that it be replicated." <u>Id</u>. at 1370.
 - Supreme Court reversed decision in <u>AT&T I</u>. AT&T II, 550 U.S. 437 (2007): Microsoft did not supply components from the United States. Supreme Court reserved judgment as to whether "an intangible method or process . . . qualifies as a 'patented invention' under § 271(f)."
- NTP, Inc. v. Research in Motion, Ltd., 418 F.3d 1282 (Fed. Cir. 2005): "[w]hile it is difficult to conceive how one might supply or cause to be supplied . . . the steps of a patented method," "the supply of BlackBerry devices to customers in the United States did not constitute the supply step required by Section 271(f)." Id. at 1322.
- Union Carbide Chemicals & Plastics Technology Corp. v. Shell Oil Co., 425 F.3d 1366 (Fed. Cir. 2006): Section 271(f) was applicable to method claims.





Cardiac Pacemakers (con't)

- □ Cardiac argued for a broad reading of the term "patented invention" in 271(f) because "invention" defined in §101 to include process patents
- ☐ Federal Circuit: statutory language "makes it clear that it does not extend to method patents."
 - "fundamental distinction between claims to a product, device, or apparatus on one hand and claims to a process or method on the other, is critical to the meaning of the statute and dooms Cardiac's argument on this issue."
 - method patents "components" are the steps that comprise the method, not the physical components used in performance of the method.
 - requirement in §271(f) that components be "supplied" eliminates method patents from Section 271(f)'s reach because one cannot supply the step of a method, section 271(f) cannot apply to method or process patents."
 - Legislative history: 271(f) enacted to close <u>Deepsouth</u> and stated it will "prevent copiers from avoiding U.S. patents by shipping over-seas the components of a *product* patented in this country. . . . "





- Cardiac Pacemakers (con't)
 - □ Federal Circuit (con't): "overrule, to the extent that it conflicts with our holding today, our decision in Union Carbide..., as well as any implication in Eolas or other decisions that Section 271(f) applies to method patents."





35 U.S.C. §271(f)

Cardiac Pacemakers (con't)

- ☐ Judge Newman's dissent:
 - "Patented invention" in 271(f) has same meaning as every other part in Title 35 and includes "process inventions." En banc ruling places different definition of "patented invention" in 271(f) than other provisions in Title 35.
 - Supreme Court held that "patented invention" in 271(e) "defined to include all inventions, not drug-related inventions alone." Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 665 (1990).
 - Prior versions of 271(f) excluded process patents by stating "component of a patented machine, manufacture, or composition of matter." Later replaced with "patented invention" indicating intent to include "process patents."
 - Report by PTO for the DOJ on 271(f) states "[n]o reasons exist for treating process patents differently from product patents in this regard[.]"
 - Each step of a process is a "component," which can be "supplied": one party can perform some steps, and "supplies" this component to another part to complete the method.





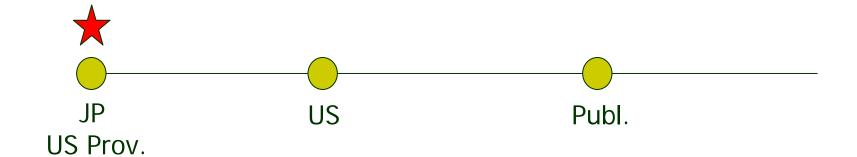
Provisional Application Filing Date Has 35 U.S.C. § 102(e) Effect

- § 102(e) The invention was described in—
 - □ an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or
 - □ a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for the purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language;



PRIOR ART EFFECT § 102(e)







Applying 35 USC § 102(e): U.S. Publications and Patents from § 111(a) Applications

- Guideline: If U.S. patent or U.S. application publication issued from an application under 35 USC § 111(a), and the patent or application does not claim a benefit of an international application, the patent or application publication has a § 102(e) prior art date as of the earliest U.S. effective filing date.
 - □ Effective filing date is the filing date for which priority/benefit is claimed to U.S. provisional or nonprovisional application so long as subject matter used to make the rejection is appropriately supported in the earlier filed application's disclosure (and any intermediate application(s)).





Federal Circuit: 102(e)

- In re Giacomini, --F.3d— (Fed. Cir. July 7, 2010)
 - ☐ Board rejected claim as anticipated.
 - ☐ Giacomini argued that the anticipatory reference, the Tran patent, did not qualify as prior art because Giacomini's filing date antedates the Tran patent's filing date.
 - ☐ FC: Affirmed rejection.
 - Tran patent has a patent-defeating effect as of the filing date of the provisional application to which it claims priority and which was filed before Giacomini's application.





Federal Circuit: 102(e)

Giacomini (con't)

- ☐ Giacomini patent application filing date: Nov. 29, 2000.
- □ Tran patent's filing date: December 29, 2000, with priority claimed to provisional application filed on September 25, 2000.
- ☐ Giacomini tried to rely on *Hilmer*, that the priority date can be different from the effective prior art date.
- □ FC: "Hilmer involved an earlier foreign application while the present case deals with an earlier U.S. provisional application....Treating a provisional application's filing date as both the patent's priority date and its effective reference date does not raise the alleged tension between sections 102(e) and 119. Given the "clear distinction between acts abroad and acts here," Hilmer, 359 F.2d at 879, Giacomini's reliance on Hilmer is misplaced."





■ 35 U.S.C. § 292

(a)Whoever, without the consent of the patentee, marks ...the patent number, or the words "patent," "patentee," [or "patent pending"] or the like, with the intent of counterfeiting ...or of deceiving the public and inducing them to believe that the thing was made, offered for sale, sold, or imported into the United States by or with the consent of the patentee [or is a patented item]; ...Shall be fined not more than \$500 for every such offense.

qui tam

∠(b)Any person may sue for the penalty, in which event one-half shall go to the person suing and the other to the use of the United States.





- Forest Group Inc. v. Bon Tool Co., 590 F.3d 1295 (Fed. Cir. 2009)
 - □ DC: construed § 292 as providing for a fine of not more than \$500 for each decision to mark articles in violation of the statute. Fine of \$500 against Forest.
 - Case law showed per-decision basis in effect since <u>London v.</u> Everett H. <u>Dunbar Corp.</u>, 179 F. 506 (1st Cir. 1910).
 - □ FC: Affirmed false marking, but held that the fine must be calculated per falsely-marked article.
 - Opened door for extremely large damage awards.
 - □ On remand, 2010 WL 1708433 (S.D.Tex. April 27, 2010), fine of \$180/article = \$6840.00





- Pequignot v. Solo Cup, --F.3d— (Fed. Cir. June 10, 2010)
 - □ Pequignot alleged Solo falsely marked at least 21,757,893,672 articles, and sought an award of \$500 per article.
 - □ DC denied Solo's motion to dismiss, "holding that both marking with an expired patent number and marking with the 'may be covered' language could legally constitute false marking."
 - □ DC: Granted Solo's motion for summary judgment of no liability for false marking, after finding no intent to deceive.
 - □ Followed London reasoning, that "offense" meant decisions, so Solo potentially committed 2 or 3 "offenses."





- Pequignot v. Solo Cup (con't)
 - ☐ FC: Affirmed-in-part, vacated-in-part
 - An article covered by a now-expired patent is "unpatented."
 - Affirmed no liability: Articles were marked with expired patent number, but no intent to deceive.
 - "Because the statute requires that the false marker act 'for the purpose of deceiving the public,' a purpose of deceit, rather than simply knowledge that a statement is false, is required.... Thus, mere knowledge that a marking is false is insufficient to prove intent if Solo can prove that it did not consciously desire the result that the public be deceived."
 - "burden of proof of intent for false marking is a preponderance of the evidence."





- Pequignot v. Solo Cup (con't)
 - ☐ FC: District court's determination of the meaning of the word "offense" under §292.
 - District court erred in granting summary judgment to Solo on the meaning of the word "offense."
 - Decision in <u>Forest Group</u>, published after the district court decision, held that every falsely marked product constitutes an "offense" under § 292.
 - But is moot point since there is no liability.





- Pequignot v. Solo Cup (con't)
 - □ Under Clontech Labs., Inc. v. Invitrogen Corp., 406 F.3d 1347 (Fed. Cir. 2005), false marking, combined with knowledge of the falsity, merely creates a rebuttable presumption of intent to deceive.
 - To rebut the presumption, provide "credible evidence that a purpose other than deceiving the public motivated the mismarking."
 - If the false marking relates to numbers of expired patents that previously covered the product(s), the presumption
 - ☐ Solo's successful rebuttal evidence:
 - relied in good faith on the advice of counsel; and
 - acted out of a desire to reduce costs and business disruption.
 - □ Decision may have stopped flood, but exposure still exists.





- Suggestions in aftermath of <u>Pequignot v. Solo</u>
 <u>Cup</u>
 - Review status of marking in current patent portfolio
 - Review company policies on marking
 - Consider benefits patent marking
 - Notice (avoids "innocent" copying), constructive notice, may provide competitive advantage.
 - Document decisions
 - Conduct an annual review of product markings.





Thank You!



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