

NEW JERSEY INTELLECTUAL PROPERTY LAW ASSOCIATION

PATENT LITIGATION SEMINAR

MARCH 10, 2010



A Behind the Scenes Look at *Bilski v. Kappos*

J. Michael Jakes

**Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P.
Washington, D.C.**

BACKGROUND

Claim at Issue

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:

a) initiating a series of transactions between said commodity provider and consumers of said commodity wherein said consumers purchase said commodity at a fixed rate based upon historical averages, said fixed rate corresponding to a risk position of said consumer;

(b) identifying market participants for said commodity having a counter-risk position to said consumers; and

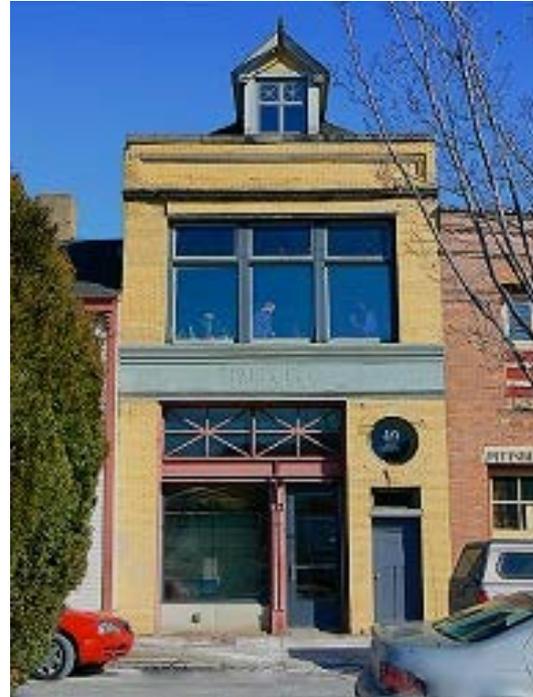
(c) initiating a series of transactions between said commodity provider and said market participants at a second fixed rate such that said series of market participant transactions balances the risk position of said series of consumer transactions.

***In re Bilski*, 545 F.3d 943
(Fed. Cir. 2008) (*en banc*)**

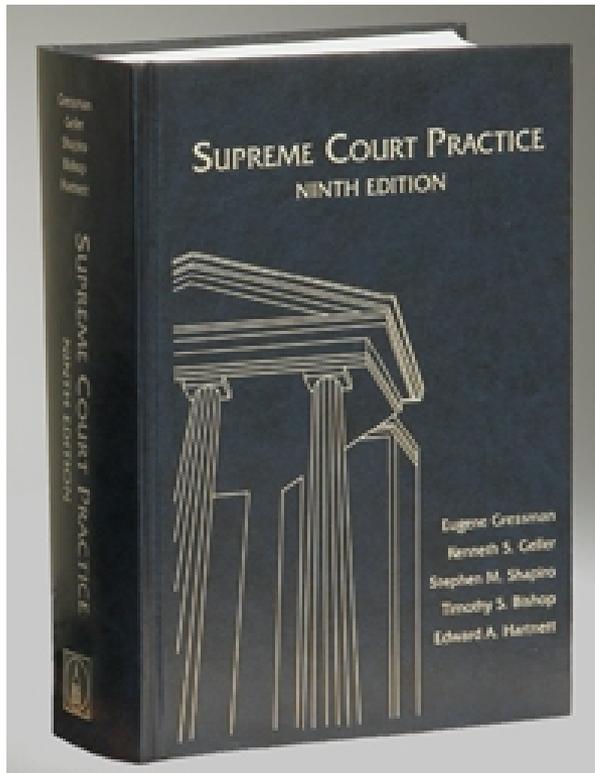
A process is patentable under 35 U.S.C. § 101 only if:

- (1) it is tied to a particular machine or apparatus, or
- (2) it transforms a particular article into a different state or thing.



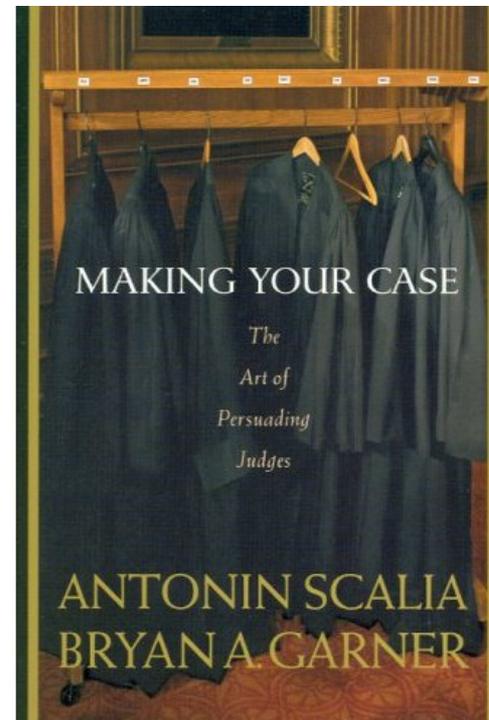


CERT. PETITION



**Supreme Court Practice
Ninth Edition**

Making Your Case: The Art of Persuading Judges



Questions Presented

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.

MERITS BRIEFS

Petitioners' Brief

Machine-or-transformation test conflicts with Supreme Court precedent holding that patentable subject matter is broad and flexible

Machine-or-transformation test conflicts with Patent Act's definition of business method patents in 35 U.S.C. 273

A claim involving a fundamental principle is patent-eligible if it recites a practical application of the fundamental principle

Practical application: applied to a useful result; applied in an apparatus or product; applied in an art or process

The Bilski claims are patent-eligible under section 101

Patent Office's Brief

Section 101 protects only industrial and technological processes

Machine-or-transformation test is “framework”

Machine-or-transformation test has been the Supreme Court's definitive definition of process for over a century

Petitioners' practical application test has no limiting standard to prevent bad patents

Case only involves non-technological business methods

Software, biotechnology not affected

Only bad patents will be disrupted

AMICUS BRIEFS

17 *Amicus* Briefs Supporting Petitioners

Accenture and Pitney Bowes	Franklin Pierce Law School
AwakenIP LLC	Georgia Biomedical Partnership
Borland Software	Houston IP Law Association
Boston Patent Law Association	John P. Sutton, Esq.
Caris Diagnostics, Inc.	Novartis
Double Rock Corporation et al.	Timothy F. McDonough, PhD
Dr. Ananda Chakrabarty	University of South Florida
Eagle Forum & Legal Defense Fund	Washington State Patent Law Association
Entrepreneurial Software Companies	

27 Amicus Briefs Supporting Neither Party

20 Law and Business Professors	Legal On Ramp
AIPLA	Medtronic Inc.
AIPPI and AIPPI-US	Monogram Biosciences Inc. and Genomic Health
Austin IP Law Assoc.	On Time Systems
BIO, Advanced Medical Technology Association, Wisconsin Alumni Research Foundation and Regents of the University of California	PhRMA
Business Software Alliance	Prof. Kevin Emerson Collins
Conejo Valley Bar Association	Prometheus Labs
Dolby Laboratories	Raymond C. Meiers
Federal Circuit Bar Association	Regulatory DataCorp, American Express, Palm, Rockwell Automation, and SAP
FICPI	Robert R. Sachs and Daniel R. Brownstone
IBM	San Diego IP Law Association
Intellectual Property Law Assoc. of Chicago	Telecommunication Systems, Inc.
IPO	Teles AG
	Yahoo! Inc.

23 Amicus Briefs Supporting Patent Office

11 Law Professors and AARP	Foundation for a Free Information Infrastructure
Adamas Pharmaceuticals and Tethys Biosciences	Prof. Lee Hollar and IEEE-USA
American Bar Association	IEEE-US and Prof. Hollar
American Insurance Association, The Hartford, Jackson National Life Insurance, Pacific Life Insurance, Sun Life Assurance, Transamerica Life Insurance	Internet Retailers (LL Bean, Overstock.com, J.C. Penney, Crutchfield, Newegg, Hasbro, Talbots)
American Medical Assoc., American College of Medical Genetics, American Society of Human Genetics, Mayo Clinic	IP Section of Nevada State Bar
Bank of America, Barclays Capital, The Clearing House Association, Financial Services Roundtable, Google, MetLife, Morgan Stanley	Knowledge Ecology International
Bloomberg L.P.	Mark Landesmann
CASRIP of Univ. of Washington School of Law	Profs. Menell and Meurer
Computer and Communications Industry Assoc.	Microsoft, Philips and Symantec
Entrepreneurial and Consumer Advocates	Red Hat
	Software & Information Industry Association
	Software Freedom Law Center
	William Mitchell College of Law IP Institute

Software and Computer Industry

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

**Computer-
implemented 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

Biotechnology and Medical Technology

**M-or-T test
too restrictive,
Chakrabarty
“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

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

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

Academia

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

20 Law and Business Professors
(Prof. Mark Lemley)

Prof. Kevin Emerson Collins
Franklin Pierce Law Center

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

Univ. of Washington Law
School (CASRIP)

11 Law Professors and AARP
(Prof. Joshua Sarnoff)
Prof. Menell and Meurer
Wm. Mitchell College of Law

ORAL ARGUMENT



*The Georgetown
Supreme Court Institute*



Approximately the same number of questions for each party

Justice	Number of Questions
Sotomayor	21
Breyer	13
Roberts	13
Kennedy	11
Stevens	8
Ginsburg	7
Scalia	6
Alito	1
Thomas	0

Justice	Number of Questions
Petitioner	43
Sotomayor	16
Breyer	7
Roberts	6
Scalia	5
Kennedy	4
Ginsburg	3
Stevens	2
Respondent	37
Roberts	7
Kennedy	7
Stevens	6
Breyer	6
Sotomayor	5
Ginsburg	4
Alito	1
Scalia	1

General Topic by Party (Top five)	Number of Questions
Petitioner	
Patent Eligibility Hypothetical	18
Policy	13
Precedent	8
Statutory Construction	7
Bilski Claim	4
Respondent	
Machine or Transformation Test	27
Precedent	16
Is Bilski the right 101 case?	5
Machine or Transformation Test Alternative	5
Procedural Fact	2

Hypotheticals

Alphabet

Electronic Signals

Estate plans

Tax avoidance

Choosing a Jury

Winning friends and influencing people

Teaching Antitrust Law

Phone calls

Insurance risk management with differential calculus

Speed dating

Training Horses

PRESS COVERAGE



Bilski Supreme Court Preview: Finnegan Lawyer Challenging 'Machine or Transformation' Patent Test Says He's Ready

Ben Hallman

11-06-2009

If the Litigation Daily were prepping for our first Supreme Court argument--no snickering, please--in a case that's considered one of the critical business controversies of the Court's term, we would be a damn sight more nervous than J. Michael Jakes of Finnegan, Henderson, Farabow, Garrett & Dunner. On Monday, Jakes is arguing Bilski v. Kappos, a closely-watched IP case that will help decide whether business methods are patentable. But on Thursday afternoon, when we called him, Jakes was at his desk, sounding decidedly nonplussed about his first U.S. Supreme Court argument.

WHAT'S NEXT?

More Pending Cases at Supreme Court

1. *In re Ferguson*

- Petition for writ of certiorari filed on June 2, 2009
- Conference held on September 29, 2009

2. *Classen Immunotherapies, Inc. v. Biogen IDEC*

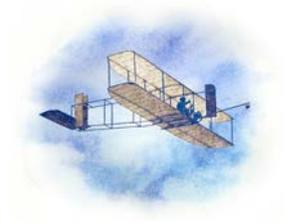
- Petition for writ of certiorari filed on May 11, 2009
- Conference held on November 24, 2009

3. *Prometheus Labs., Inc. v. Mayo Collaborative Service*

- Petition for writ of certiorari filed on October 22, 2009
- Conference held on January 22, 2010

Cases stayed at Federal Circuit

1. *Fort Properties, Inc. v. American Master Lease*
 - Method of creating real estate investment instruments
2. *CyberSource Corp. v. Retail Decisions, Inc.*
 - “Computer readable medium” claim and method performed over the Internet
3. *Every Penny Counts, Inc. v. Bank of America Corp.*
 - System claim including a network and computing means
4. *DealerTrack v. Huber*
 - Computer-aided method using display device and terminal device



Ariad v. Eli Lilly

The Proper Interpretation of Section 112, paragraph 1

John M. Whealan

Associate Dean for Intellectual Property Law

George Washington University Law School

35 U.S.C. S 112, 1



- The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Federal Circuit Debate



- Written description / enablement are separate distinct requirements, with WD measured by the “possession” test

or
- (i) Written description of
 - (i) the invention, and
 - (ii) the manner and process of making and using the invention
 - are both measured by whether it is “in such full, clear, concise, and exact terms as to enable any person skilled in the art . . . to make and use the same

Federal Circuit Debate (cont.)



- Debate began with the decision in *Regents of the University of California v. Eli Lilly*, 119 F.3d 1559 (Fed. Cir. 1997)

Federal Circuit Debate (cont.)



- Debate was expressed mostly in opinions related to denials of petitions for rehearing en banc
 - Enzo Biochem, Inc. v. Gen-Probe Inc., 323 F.3d 956 (Fed. Cir. 2002)
 - Moba, B.V. v. Diamond Automation, Inc., 325 F.3d 1306 (Fed. Cir. 2003)
 - University of Rochester v. G.D. Searle & Co., 375 F.3d 1303 (Fed. Cir. 2004)

Federal Circuit Debate (cont.)



- And debate was discussed extensively in the academic literature, e.g.,
 - Arti Rai, Intellectual Property Rights in Biotechnology: Addressing New Technology, 34 Wake Forest L. Rev. 827 (Fall, 1999)
 - Dan L. Burk and Mark A. Lemley, Policy Levers in Patent Law, 89 Va. L. Rev. 1575 (2003)
 - See also Rader concurrence listing all of the articles written on Lilly WD decision

Federal Circuit Debate (cont.)



- Ariad v. Lilly
 - Ariad won at trial; patent found valid and infringed
 - Federal Circuit reversed and invalidated patent based on WD
 - Judge Linn wrote a concurrence saying he continued to think court's current interpretation of 112, 1 was incorrect (citing Enzo, Moba, and Rochester)

En banc Petition



- In past cases, six of the twelve judges of this Court have either voted to grant en banc review of this Court's written description jurisprudence (Newman, Rader, Bryson, Gajarsa, and Linn, JJ.), or have expressly noted that future en banc review may be appropriate because this Court's written description standards are unsatisfactory. (Dyk, J.).
- The United States has also called for en banc review to construe the statutory text and to clarify multiple conflicting views present in this Court's written description cases.
- The controversy over this Court's written description cases will not abate until the matter is definitively addressed either by this Court en banc, or by the Supreme Court.
- This case provides a good vehicle for this Court to address the controversy.

Two Competing Statutory Interpretations



- Ariad's.....

The specification shall contain

a written description

of the invention, and

of the manner and process of making
and using it,

in such full, clear, concise, and exact terms as to
enable any person skilled in the art to which it
pertains, or with which it is most nearly connected, to
make and use the same

Two Competing Statutory Interpretations



- Lilly's

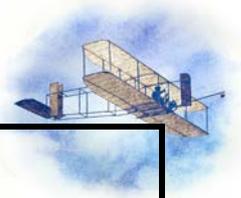
The specification shall contain

a written description of the invention, and

a written description . . . of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same

Note: underlined words do not appear in the statute

Comparison



Ariad

The specification shall contain a written description of

the invention, and

of the manner and process of making and using it,

in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same . . .

Lilly

The specification shall contain a written description of the invention, and

The specification shall contain a written description of . . . the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same . . .

Supreme Court Precedent



- Pre 1836
 - Evans v. Eaton
 - Interpreted 1793 Patent Act
 - WD of invention and how to make and use had 2 requirements
 - (1) “to enable” the invention and
 - (2) “to distinguish” the invention from all things previously known.
 - “Distinguishing” requirement (2) was eventually deleted and replaced by claiming requirement

Supreme Court Precedent



- Post 1836 -- two categories of cases:
 - (1) Police priority
 - Gill v. Wells
 - Permutit
 - Schriber-Schroth
 - (2) Claim scope = contribution
 - Morse
 - Tilghman v. Proctor
 - The Telephone Cases (Bell),
 - The Incandescent Lamp Patent,
 - Holland Furniture
 - Smith v. Snow

112, 1 as properly interpreted



- (1) Polices priority of new and amended claims
 - the identification aspect of the description requirement ensures that the claims are directed to the same invention that is described in the earlier filed specification.
- (2) Ensures claims match the inventors contribution
 - must identify the common principle that defines the invention and distinguishes it from the prior art
 - common principle must be present in all the claimed embodiments
 - specific claims require a specific disclosure, generic claims require generic disclosure.

Thank You



- Contact information:
 - jwhealan@law.gwu.edu
 - 202-994-2195

*The (A)(B)(C)s of Patent Term
Adjustment*

KAYE SCHOLER LLP

Patricia A. Carson

Graham M. Pechenik

New Jersey Intellectual Property Law Association

Patent Litigation Seminar

Monday, March 8, 2010

Calculating Patent Term

- Before 1994, patent term was **17 years from the Date of Issuance**
- In 1994, Congress amended Patent Act to provide for a term of **20 years from the Filing Date**
- 20-year term may be modified by:
 - Terminal disclaimer
 - Patent term extension (PTE) under 35 U.S.C § 156
 - **Patent term adjustment (PTA) under § 154(b)**

PTA Provisions Added by AIPA

- In 1999, to protect inventors from loss of patent life due to PTO delays, Congress passed the Patent Term Guarantee Act, as part of the **American Inventors Protection Act (“AIPA”)**
- AIPA amended § 154(b) to:
 - Provide separate and distinct patent term guarantees
 - Provide for PTA when PTO exceeds specified time limits (or where applicant contributes to delay)

AIPA Provides Certain Guarantees

- “Guarantee” of prompt PTO responses: §154(b)(1)(A)
 - Known as “**A-delay**”, “14-4-4-4 delay” or “prosecution delay”
- “Guarantee” that patent issue in three years: §154(b)(1)(B)
 - Known as “**B-delay**” or “3-year delay”
- “Guarantee” that patent term not lost due to interferences, successful appeals, or secrecy orders: § 154(b)(1)(C)
- Guarantees subject to an “**overlap**” limitation: § 154(b)(2)(A)
- Reduction of PTA for applicant delay: § 154(b)(2)(C)

“(A) Delay” is Defined by the Statute

“(A) GUARANTEE OF PROMPT PATENT AND TRADEMARK OFFICE RESPONSES –

Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to the failure of the [PTO] to *[take specific actions during prosecution]* . . . the term of the patent shall be extended 1 day for each day after the end of the period specified . . . until the action . . . is taken.”

§ 154(b)(1)(A)

i.e., Restoration of **one day of patent term for each day of delay**

Specific Guarantees Under § 154(b)(1)(A)

- First action within fourteen months of filing
- Response to applicant's reply or appeal within four months
- Action following appellate decision within four months
- Issuance of patent within four months of issue fee payment
- Thus known as “14-4-4-4” rule

“(B) Delay” is Defined by the Statute

“(B) GUARANTEE OF NO MORE THAN 3-YEAR APPLICATION PENDENCY –

Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to the failure of the [PTO] to issue a patent within 3 years after the actual filing date of the application . . . the term of the patent shall be extended 1 day for each day after the end of that 3-year period until the patent is issued.”

§ 154(b)(1)(B)

i.e., Delay begins after three years and provides for restoration of **one day of patent term for each day of delay**

The Statute Provides an “Overlap” Limitation to the Separate Guarantees Under (A), (B) and (C)

(2) LIMITATIONS –

“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.*”

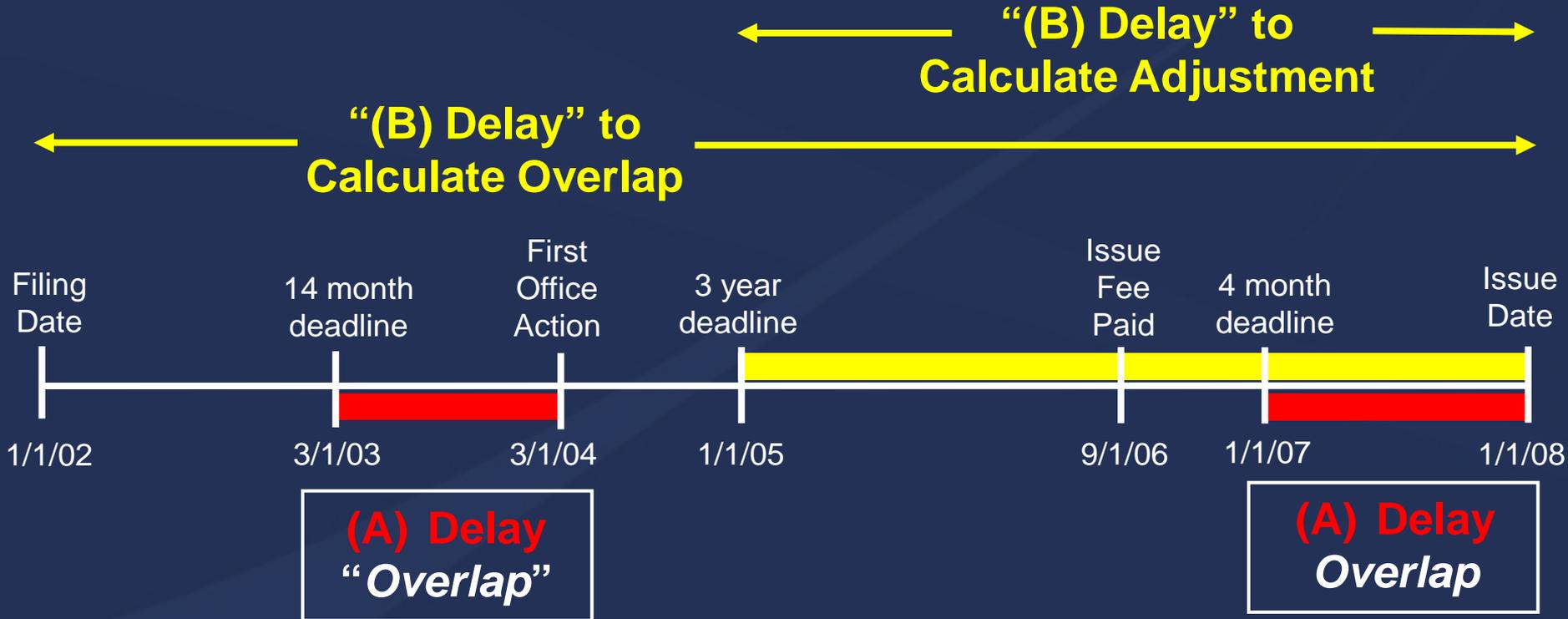
§ 154(b)(2)(A)

i.e., Where delays under (A), (B) and (C) **overlap**, cannot receive more than one day of adjustment for a single day of delay

How the PTO Had Applied the Rule

The PTO had applied the rule to give a patentee credit for either “A delay” or “B delay,” *whichever is larger* (minus applicant delay), but *never both* “A delay” and “B delay”

PTO Interpretation



PTO Result = 3 Years of Adjustment

Wyeth Challenge to PTO Interpretation

- Wyeth filed suit in D.C. District Court to challenge PTO's interpretation of how PTA is calculated and when various "periods of delay" "overlap" under § 154

Wyeth's View of the Application of the Overlap Limitation to (A) and (B)



Wyeth Result = 4 Years of Adjustment

Outcome in D.C. District Court

- Judge Robertson held that:
 - PTO has no general substantive rulemaking power
 - No *Chevron* deference, but it would not have saved PTO interpretation
 - PTO interpretation cannot be reconciled with plain text of the statute
- Summary judgment granted in favor of Wyeth
- PTO appealed to the Federal Circuit

Wyeth v. Dudas, 580 F. Supp. 2d 138 (D.D.C. 2008)

Appeal to Federal Circuit

- On appeal, PTO argued that:
 - Statute ambiguous
 - PTO interpretation is reasonable and within scope of rulemaking authority
 - PTO should be accorded *Chevron* or *Skidmore* deference
- Wyeth argued that:
 - Statute unambiguous
 - PTO interpretation contravenes the statute's plain meaning
 - No *Chevron* or *Skidmore* deference
- Amicus briefs were filed:
 - Hospira, Inc. in support of PTO and reversal
 - PhRMA and BIO in support of Wyeth and affirmance
- Argument before Rader, Plager, and Moore held on 10/7/09

Federal Circuit Opinion

On January 7, 2010, Federal Circuit affirmed district court:

- **Statute unambiguous:** “no ambiguity in the terms ‘periods of delay’ and ‘overlap’”
- **PTO interpretation contravenes plain meaning:** “clear that no ‘overlap’ happens unless the violations occur at the same time”
- **No Chevron or Skidmore deference:** “this court detects no reason to afford special deference to the PTO’s interpretation”
- **Legislative history supports Wyeth’s interpretation:** “apparent that the statutory language should provide a *minimum* seventeen-year term for most patents”
- **Potential for inequities irrelevant:** “this court does not take upon itself the role of correcting all statutory inequities, even if it could”

The *Wyeth* Decision is Final

- DOJ and PTO announced on January 20th that they would not seek further review of the *Wyeth* decision
- Federal Circuit issued mandate on March 1, 2010

How the PTO is Implementing the Decision

- To request recalculation under PTO's interim procedure:
 - Patent must be issued prior to March 2, 2010
 - Must submit request no later than 180 days after issuance
 - Only for A+B overlap errors at issue in *Wyeth*
 - No fee required
 - Form available at www.uspto.gov/patents/announce/pta_wyeth.pdf
- Interim procedure announced on January 26th and will apply pending modification of PTO computer system, which it said would be complete by March 2, 2010

Can the PTO Do This?

- Questions raised about PTO's authority
- § 154(b) requires PTO to provide “one opportunity to request reconsideration”
- For issued patents, PTO has already offered “one” opportunity to request reconsideration
- Interim procedure could thus be considered “second” opportunity to request reconsideration, and would not be permitted if statute read as allowing only one opportunity
- The impact is an open question

How Are Patentees Helping Themselves?

- 133 follow-on lawsuits have been filed by third parties against the PTO relying on *Wyeth* as of March 2010
- Most cases were stayed pending the *Wyeth* appeal, and have not yet been reopened
- 17 cases have already been remanded; motions for remand or orders to show cause are pending in 9 other cases

Effect of Remand

- On remand, the PTO has an affirmative duty to respond to the specific issues remanded

See, e.g., Tex Tin Corp. v. E.P.A., 992 F.2d 353, 355 (D.C. Cir. 1993)

- Court has discretion to retain jurisdiction over a case, but whether it will be exercised typically depends on the scope of the remand and the need for oversight

See, e.g., Baystate Medical Center v. Leavitt, 587 F. Supp. 2d 37, 43 (D.D.C. 2008)

- Court also may retain residual jurisdiction to enforce terms of remand order

Int'l Union, United Auto., Aerospace, & Agric. Implement Workers of Am., U.A.W. v. O.S.H.A., 976 F.2d 749, 750 (D.C. Cir. 1993)

Jurisdiction Retained on Remand?

Medarex (D.D.C. No. 08-2174-CKK)

- Consent motion filed to remand case to PTO
- Proposed order included express language that “the Court will retain jurisdiction of this matter during remand”
- The Court entered a docket order vacating the patent term calculation, remanding to the PTO for recalculation in accordance with *Wyeth*, and retaining jurisdiction

Jurisdiction Retained on Remand?

Biogen Idec (D.D.C. No. 09-0754-RMC)

- Proposed order included express language as to effect of remand, in case the PTO “grants Plaintiff a patent term adjustment shorter than the term requested in Plaintiff’s complaint”
- The Court entered docket order remanding case, and:
 - Retaining jurisdiction
 - Ordering parties to notify Court within ten days of PTO decision on remand
 - Staying case pending further order

Jurisdiction Retained on Remand?

Columbia University (D.D.C. No. 09-2281-EGS)

- Proposed order included express language that “this matter will not be dismissed while on remand”
- Nonetheless, Court entered docket order stating that:

“In view of this remand, plaintiff’s action is hereby **DISMISSED** without prejudice subject to a motion for reconsideration for good cause shown upon completion of the agency’s recalculation and adjustment.”

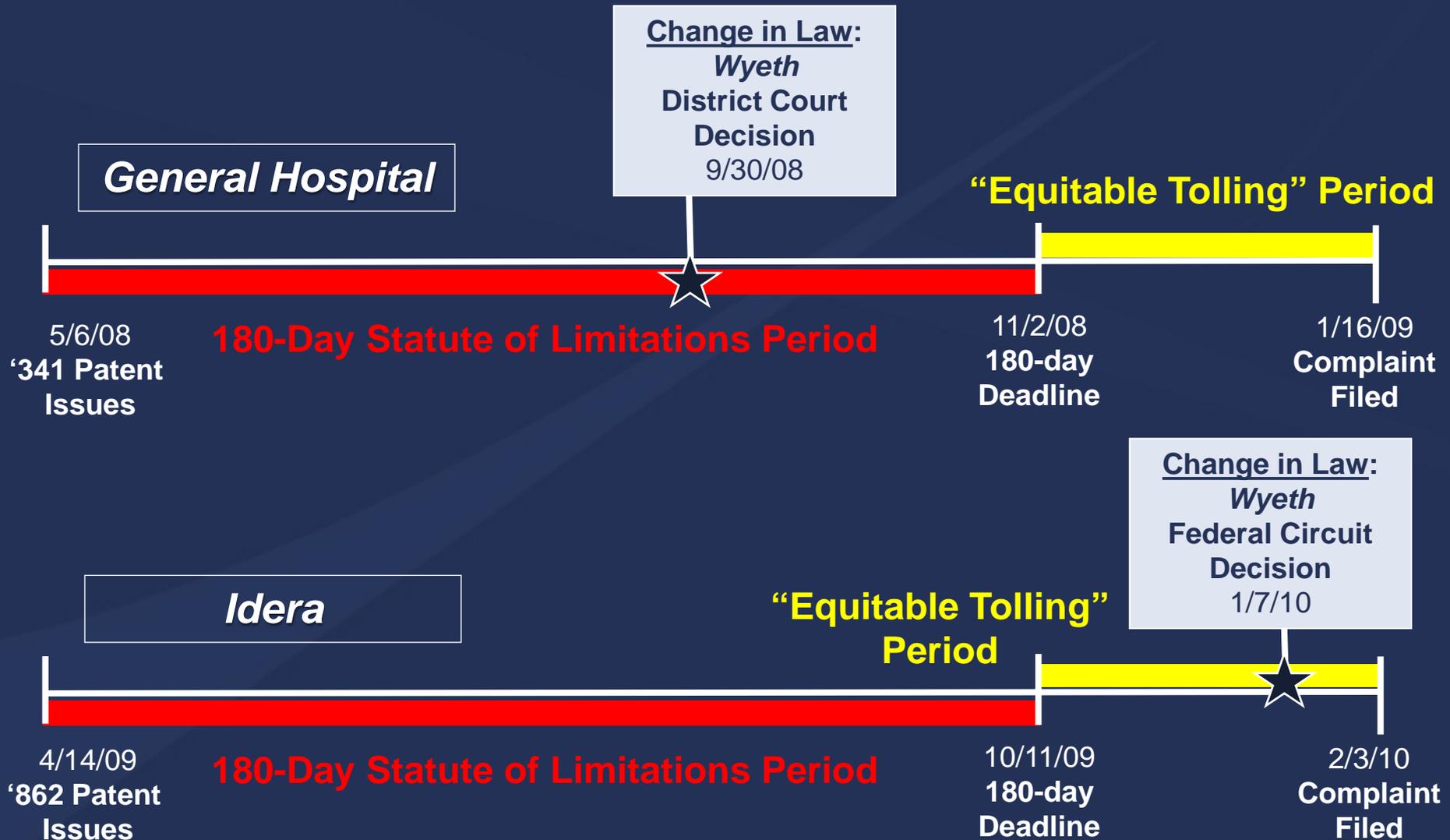
What if the 180-Day Deadline is Missed?

- At least two follow-on cases have raised “**equitable tolling**” as a means to avoid consequences of statute of limitations
 - *General Hospital Corp.* (D.D.C. No. 09-0109)
 - *Idera Pharmaceuticals* (D.D.C. No. 10-0166)

Equitable Tolling

- Exception to general rule of strict application of statutes of limitations
- Court can exercise equitable power to prevent manifest injustice
- Generally must show **diligence** and **extraordinary circumstances** *Pace v. DiGuglielmo*, 544 U.S. 408, 418 (2005)
- General Hospital and Idera have asserted that equitable tolling should be applied because of **change in law**

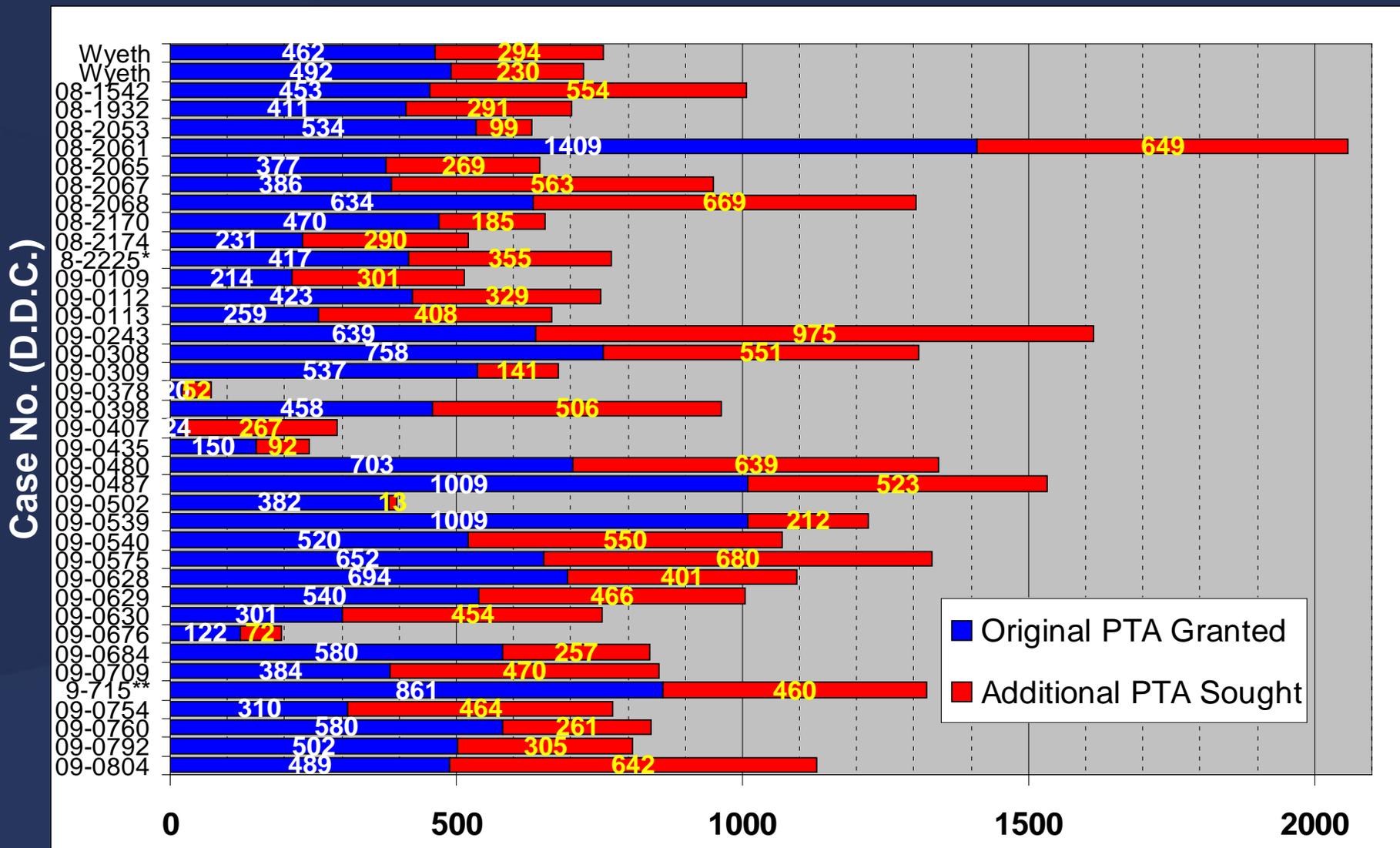
Equitable Tolling in *Gen'l Hospital* and *Idera*



Follow-on Cases

- In PTA cases filed to date:
 - Average **Original** PTA Granted: ~ 15 months
 - Average **Additional** PTA Sought: ~ 12 months
 - Range of less than two weeks to over four years of additional PTA sought

Sample Follow-on Cases: Amount of PTA



* Average of 7 patents at issue
 ** Average of 6 patents at issue

Cases that Allege Errors with PTA Calculations Beyond *Wyeth* A+B

- Issues raised in follow-on cases are not limited to the A+B overlap errors as in *Wyeth*
- For example, in *Memory Pharmaceuticals*, allegation made that PTO erroneously found 120 days to be “applicant delay”
- These cases should be treated differently as the entire action cannot be remanded to the PTO based on *Wyeth*

Moral of the Story: It can pay to challenge authority

- Additional days of patent term can have enormous value, particularly for pharmaceutical and biotech patents
- One study estimates that for patents on blockbuster drugs, every extra month of PTA is worth at least \$35 million in revenues, or \$10.5 million in profits

<http://ipfinance.blogspot.com/2010/02/patent-term-adjustment.html>

Patricia A. Carson

Graham M. Pechenik

NJIPLA Patent Litigation Seminar, March 8, 2010

NEW JERSEY INTELLECTUAL PROPERTY LAW ASSOCIATION

PATENT LITIGATION SEMINAR

MARCH 10, 2010

Bench vs. Jury

Juanita R. Brooks

Fish & Richardson PC

Are They That Different?

- Findings of Fact
- Closing argument
- Conclusions of Law
- Jury Instructions

Differences

- Can't pick your audience
- Can't precondition your audience through voir dire
- Can't expect your audience to know and understand the law

Similarities

- All advocacy has three critical components

Pathos

Ethos

Logos

Pathos

- Does your case make an emotional connection?

Ethos

- Does your case feel “right?”

Logos

- Does your case make sense?

The Romance Discoverable In Patent Cases

- The Honorable Simon H. Rifkind
 - Former District Judge S.D.N.Y.
 - 1954

The Romance Discoverable In Patent Cases

- “My client is the hero of this play, my adversary is the villain.”

The Romance Discoverable In Patent Cases

- Great trial lawyers, in my judgment, do this thing consciously, and deliberately, with subtlety; and because they know what they are doing, they use even triflings to advantage to intensify and accentuate the desired dramatic effect.

The Romance Discoverable In Patent Cases

- I do not think that this case which I have just described is atypical. I think that the same drama, the same excitement, the same romance may be found in pretty nearly any patent case.

The Romance Discoverable In Patent Cases

- Continuing my analogy to the theater I would suggest that all the average patent case needs is a good director.

The Romance Discoverable In Patent Cases

- And the reason why most patent cases do not have good directors is that they are tried by patent lawyers.

The Romance Discoverable In Patent Cases

- My observation has been that patent lawyers are not necessarily effective trial lawyers.

The Romance Discoverable In Patent Cases

- I believe that a good patent lawyer can teach a good trial lawyer all the patent law that he needs to know in a particular case in a very brief and measurable time.

The Romance Discoverable In Patent Cases

- But I doubt that even a very superior trial lawyer can teach a patent lawyer how to try a case in any available amount of time.

The Romance Discoverable In Patent Cases

- Most judges and lawyers who do *not* try patent cases have accepted the notion that the acquisition of the relevant, scientific knowledge requires a prodigious effort; and lawyers who do try patent cases have encouraged this belief, thereby adding magnitude to their own accomplishments and deterring competition from the general bar.

Universal Truths

- Must own the bad facts
- Must tie all facts together with one consistent theme
- Must make them comprehensible

Willful Infringement After *Seagate*

Presented by

Dianne B. Elderkin
Partner, Akin Gump Strauss Hauer & Feld LLP

March 8, 2008

AKIN GUMP
STRAUSS HAUER & FELD LLP

New Jersey
Intellectual Property Law Association
Patent Law Seminar

Seagate



**Objectively high likelihood
that actions constitute
infringement of valid patent**



**Objective risk known
or should have been known**

Seagate Raised the Bar

2006



- 3 of 3 CAFC decisions upheld findings of willfulness, all based on problems with counsel opinions

2008



- 3 CAFC decisions overturned findings of willfulness, based on objective criteria



- 1 CAFC decision overturned/remanded finding of willfulness



- 1 CAFC decision upheld willfulness finding on procedural basis but noted defendant deliberately copied and case was not close

Seagate

“We fully recognize that ‘the term [reckless] is not self-defining.’... We leave it to future cases to further develop the application of this standard.”

Focus on Objective Criteria



- Courts granting summary judgment or JMOL of no willfulness based on objective prong
 - Issues of infringement or validity highly **disputed**
 - Court had **granted SJ of noninfringement** – even though later overturned by CAFC
 - In **prior litigation**, CAFC had vacated PI because of substantial questions as to validity
 - Substantial new issues of patentability found in a reexam

Objective Criteria Don't Always Carry the Day

- Summary judgment or JMOL of no willfulness has been *denied* where:
 - Court denied Defendant's SJ motion of invalidity
 - Defendant knew of or should have known of patent
 - Court had already granted SJ of infringement and invalidity still to be determined
 - Evidence of copying
 - Court found claim construction unreasonable

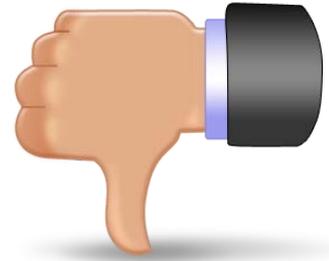
Sometimes subjective criteria carry the day

- legitimate effort to design around
- reliance on competent opinion of counsel
- technical investigation conducted upon learning of patent/formation of belief that product did not infringe
- no evidence that accused infringer knew of the patent
- accused infringer performed a patent review before entering the market with new device

Courts divide over whether post-suit events can be considered

■ *I4i Ltd. P'Ship v. Microsoft Corp.*, (E.D. Tex. 2009)

- “Traditionally and overwhelmingly, ‘objective’ tests focus on the facts and circumstances available to an actor at the time that the action under scrutiny was taken.”



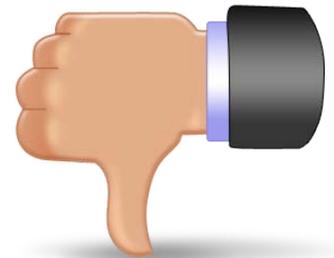
■ *Henrob Ltd. V. Bollhoff Systemtechnik GmbH* (E.D. Mich. 2009)

- Limiting objective inquiry to the defenses articulated at the time of the alleged infringement “improperly conflates the subjective and objective prongs of the willfulness test”



Post-Verdict Conduct Willful?

- *Cummins-Allison Corp. v. SBM Co., Ltd.* (E.D.Tex. 2009)
 - “The verdict of infringement does normally mean that future infringement is willful.”
- *Lexion Med. LLC v. Northgate Techs. Inc.* (Fed. Cir. 2008) (unpub.)
 - “We do not think it was objectively reckless for [defendant] to obtain and rely on the opinion of counsel, which had predicted a favorable outcome in view of the renewed motion for JMOL then pending before the district court.”



Request for P.I. necessary?

- *Anascape, Ltd. V. Microsoft Corp.* (E.D. Tex. 2008) – “The court does not impose a categorical rule that lack of a motion for PI automatically bars post-suit willful infringement”
- *Krippelz v. Ford Motor Co.* (N.D.Ill. 2009) - No general rule that failure to seek PI constitutes forfeiture of claim for willful infringement. “The pursuit of preliminary injunction may fail for reasons other than its lack of merit on the underlying claim.”

Timing of Willfulness Determination?



■ *Seagate*:

- “[O]bjectively defined risk” should be “determined by the record developed in the infringement proceeding.”
- How are close claim construction issues considered by a jury?
- How are close summary judgment issues considered by a jury?
- Record on post-trial motions?

Need for opinion of counsel?



Summary judgment/JMOL of no willfulness has been denied where:

- No opinion of counsel/defense waived
- Counsel opinions not sufficient/short emails
- Opinions not sufficient, e.g., from foreign counsel

Dare to go opinion-less?



- Can you win summary judgment of no infringement based on objective factors?
- If not, how will absence of opinion play out?

Side-effects of no opinion-of-counsel

- No adverse inference, but can be part of “totality of circumstances” considered
- Counsel opinions are relevant for determining whether to enhance damages
- Consider value of opinion witness at trial



Strategic Considerations



- For subjective prong, defendant must have had knowledge of patent or “should have known” of it
- Reliance on competent counsel opinion still prudent



Thank you!

Dianne B. Elderkin
Partner

Akin Gump Strauss Hauer & Feld LLP
delderkin@akingump.com
215.965.1340

AKIN GUMP
STRAUSS HAUER & FELD LLP

New Jersey
Intellectual Property Law Association
Patent Law Seminar



NJIPLA

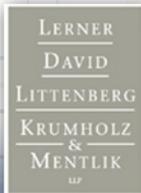
PATENT LITIGATION SEMINAR

March 8, 2010

Has The Federal Circuit Made It More Difficult To Establish Inequitable Conduct?

Arnold I. Rady
arady@ldlkm.com

Lerner, David, Littenberg, Krumholz & Mentlik, LLP
600 South Avenue West
Westfield, New Jersey 07090



Inequitable Conduct Defense Has Been Particularly Effective in Nonjury Cases, e.g., Hatch-Waxman

■ NONJURY –

- Single trial to court with all evidence and all issues presented
- Court receives full impact of challenger's evidence of patentee's misconduct

■ JURY TRIAL – jury trial & decision of validity/infringement before separate trial to judge on inequitable conduct

- Jury generally favors upholding validity;
- Jury shielded from most negative “conduct”-related evidence
- Jury validity verdict based on all accurate information, will tend to discourage Judge from finding inequitable conduct:
 - (i) essentially eliminates “but for” withholding or misrepresentations; and
 - (ii) confirms the merits of the patented invention, including its patentability over all prior art and correct assertions

Practitioners Are Vulnerable To Future Litigation Charges Of Inequitable Conduct



- Questionable events are magnified in subsequent litigation
- Deceptive intent can be fashioned from innuendo and circumstantial evidence
- Passage of time weakens evidence of vindication/justification or good faith by: lost witnesses, faded memories and missing documents

■ **Uncertainty As To The Judicial Standard That Will Be Applied In Future Litigation**

Overview of Presentation

I. The Federal Circuit's Recent Decisions On Inequitable Conduct

- Court Follows Trend Disfavoring The Inequitable Conduct Defense, With More Stringent Requirements For Pleading, Proofs & The Intent Element
- The Federal Circuit Faces An Internal Conflict And An Imprecise Standard For The Intent Element

II. The Federal Circuit's Inequitable Conduct Jurisprudence Is Destined For Modification

- Federal Circuit - *En Banc* Review
- Patent Reform Legislation
- PTO Rulemaking
- U.S. Supreme Court

Fundamental Elements Of Inequitable Conduct Required To Render Patent Unenforceable

Affirmative
Misrepresentation
of Material
Information

or

Submission
of False
Material
Information

or

Failure to
Disclose
Material
Information

+

+

+

Intent to Deceive or Mislead the Examiner

+

Balancing Levels of Materiality & Intent

See, e.g., Innogenetics, N.V. v. Abbott Labs., 512 F.3d 1363, 1378 (Fed. Cir. 2008) (quoting *Pharmacia Corp. v. Par Pharm., Inc.*, 417 F.3d 1369, 1373 (Fed. Cir. 2005); *Cargill, Inc. v. Canbra Foods, Ltd.*, 476 F.3d 1359, 1363 (Fed. Cir. 2007))

MATERIALITY

Digital Control Inc. v. Charles Mach. Works, 437 F.3d 1309 (Fed. Cir. 2006):

Criteria for determining “materiality” includes judicial precedent and that defined by “old” and “new” versions of Rule 56 (37 C.F.R. § 1.56):

“New” Rule 56 (March 1992): Material information

- Not cumulative
- Establishes *prima facie* case of unpatentability
- Refutes or is inconsistent with position asserted by applicant opposing unpatentability or supporting patentability

“Old” Rule 56 (pre-1992): Information is “material” when

- There is a substantial likelihood a reasonable examiner would consider the information important in deciding whether to allow the application

Intent To Deceive: Analysis & Proofs

INTENT IS SUBJECTIVE

- Knowledge of the target information
- Knowledge that target information was withheld or misrepresented
- Knowledge or appreciation that target information is material
- Specific intent to deceive or mislead the PTO/examiner

MIXED OBJECTIVE/SUBJECTIVE FACTORS

Duty to investigate

- ...or should have known information was material
- impact of high level of materiality
- inferences

- impact of high level of materiality
- inferences
- inferred heightened duty

presence or absence of good faith, credible explanations and excuses

Federal Circuit's Decisions Since May 2008 Show A Strong Trend Disfavoring The Defense

From May '08 to end of 2008, 17 appeals were considered by Federal Circuit that included a review of an inequitable conduct issue:

- 11 cases - Fed. Cir. affirmed the lower court findings of no inequitable conduct
- 4 cases – Fed. Cir. reversed or vacated lower court findings of inequitable conduct
- 1 case – rulings on other grounds
- 2 cases – upheld finding of inequitable conduct

*Praxair, Inc. v. ATMI, Inc. and
Aventis Pharma v. Amphastar Pharmaceuticals*

In 2009, Fed. Cir. Continued Trend To Discourage Parties From Asserting Defense

- ***Rothman v. Target Corp.*** - - Reversed finding of inequitable conduct, affirming decision of patent invalidity
- ***Larson Mfg. Co. v. Aluminart Prods. Ltd.*** - - Vacated dismissal of case based on the inequitable conduct defense
- ***Ariad Pharms., Inc. v. Eli Lilly & Co.*** - - Affirmed Dist. Ct. finding there was no inequitable conduct
- ***Dickson Indus., Inc. v. Patent Enforcement Team, LLC*** - - Reversed the Dist. Ct. finding of inequitable conduct and remanded, because, *inter alia*, patentee was prejudiced with inadequate time to prepare for trial where alleged misconduct occurred during contemporaneous reexamination
- ***Wavetronix v. EIS Elec. Integrated Sys.*** - - Upheld lower court dismissal of inequitable conduct defense on summary judgment
- ***Cardiac Pacemakers, Inc. v. St. Jude Med., Inc.*** - - Affirmed dismissal of inequitable conduct from new trial for procedural reasons

Fed. Cir. Decisions In 2009 Focus On Good Faith and Credible Excuses To Defeat Intent

- ***In re Bose***, 580 F.3d 1240 (Fed. Cir. 2009) (reversed TTAB finding of inequitable conduct based on false affidavits of use because they were based on an “honest misunderstanding or inadvertence” by the attorney and not “willful intent to deceive”)
- ***Vita-Mix Corp. v. Basic Holding, Inc.*** 581 F.3d 1317, 1332 (Fed. Cir. 2009 (denies finding of inequitable conduct where declarant testified that he believed statement in his submitted declaration to be true at the time; no evidence of intent to deceive))

August 2009 *Exergen* Decision Raises Requirements For Pleading Inequitable Conduct

Exergen Corp. v. Wal-Mart Stores, Inc. , 575 F3d 1312,1327 (Fed Cir. 2009) (by J. Linn, joined by Judges Michel & St. Eve-by designation)

- Clarified requirements for pleading an inequitable conduct defense to follow the pleading requirements for fraud, under Fed. R. Civ. P. 9(b).

Recent Cases Illustrate A Divided Court & Imprecise Legal Standard For Intent

McKesson Info. Solutions, Inc. v. Bridge Med., Inc., 487 F.3d 897 (Fed. Cir 2007) - Federal Circuit affirms inequitable conduct (withholding case)
By Judges Clevenger & Bryson, with J. Newman Dissenting

Aventis Pharma S.A. v. Amphastar Pharms., Inc., 525 F.3d 1334 (Fed. Cir. 2008) - Fed. Cir. affirms inequitable conduct (affidavit case)
By Judges Prost & Moore, with J. Rader Dissenting – May 2008

Star Scientific, Inc. v. R.J. Reynolds Tobacco Co., 537 F.3d 1357 (Fed. Cir. 2008) – reverses judgment of unenforceability/inequitable conduct (withholding case)
By Judges Michel, Schall & Dyk - August 2008

Praxair, Inc. v. ATMI, Inc., 543 F.3d 1306, 1313-14 (Fed. Cir. 2008) - affirms judgment of inequitable conduct (withholding case)
By Judges Bryson & Dyk, with J. Lourie dissenting - Sept. 2008

Larson Mfg. Co. v. Aluminart Prods. Ltd., 559 F.3d 1317 (Fed. Cir. 2009) – reverses inequitable conduct (withholding case) - By Judges Schall & Clevenger, with J. Linn concurring, with suggestion for *en banc* review of doctrine – Mar. 2009

Therasense, Inc. (now known as Abbott Diabetes Care, Inc.) v. Becton, Dickenson & Co. – affirms inequitable conduct (withholding case)
By Judges Dyk & Friedman, with J. Linn dissenting - decided Jan. 25, 2010

McKesson: Establishing Intent By Inference & Objective Considerations

***McKesson Info. Solutions, Inc. v. Bridge Med., Inc.*, 487 F.3d 897 (Fed. Cir 2007) - Federal Circuit affirms inequitable conduct
By Judges Clevenger & Bryson, J. Newman Dissenting**

- **Information withheld**: highly material prior art cited by examiner in the co-pending application
- **Facts re Attorney's Excuse**: Attorney had no recollection of prosecution, no records and during litigation found prior art cumulative
- **Basis For District Court's Finding of Intent**:
 - Attorney got credit for citing the co-pending application
 - Attorney criticized for failing to have a paper trail with explanation for withholding
 - MPEP provisions imposed greater duty on attorneys
 - to record reasons for not disclosing information
 - by specifically encouraging disclosure of office actions in related applications.

McKesson: – Dissent of J. Newman

- [S]imply failing to disclose office action in co-pending application cannot constitute clear and convincing evidence of intent to deceive
- [P]recedent firmly requires that the intent element of inequitable conduct must be established by clear and convincing evidence of deceptive intent -- not of mistake, if there were such, but of culpable intent [citation to *Kingsdown* omitted].
- That standard was not met here. This court returns to the "plague" of encouraging unwarranted charges of inequitable conduct, spawning the opportunistic litigation *that here succeeded despite consistently contrary precedent.*

Aventis Decision - Affirms District Court Holding of Inequitable Conduct

Aventis Pharma S.A. v. Amphastar Pharms., Inc., 525 F.3d 1334 (Fed. Cir. 2008) - Fed. Cir. affirms holding of inequitable conduct

By Judges Prost & Moore, J. Rader dissenting; *cert. denied* in July 2009

- **Information withheld**: Patentee *Aventis* submitted affidavits comparing half lives of claimed and prior art compound but failed to disclose that the compounds were **tested at different dosages**
- **No direct evidence of knowledge or appreciation of materiality**
- **No direct evidence of intent**
- **Excuses/justification**: Dosages inadvertently left out and several reasons why respective dosages were not pertinent
- **District Court's findings**:
 - Affiant & attorney should have appreciated materiality under the circumstances,
 - Inferred intent to deceive,
 - All of affiant's excuses not credible

Aventis: Judge Rader's Dissent Criticizes The Test For Intent Described By Majority

- In *Kingsdown*, this court clearly conveyed that the **inequitable conduct was not a remedy for every mistake, blunder, or fault in the patent procurement** process... Instead this court required “culpable” conduct supported by clear and convincing evidence of intent to deceive the USPTO. [citations omitted]
- Moreover, my reading of our case law **restricts a finding of inequitable conduct to only the most extreme cases of fraud and deception...**

More recently, however, the judicial process has too often emphasized materiality almost to the exclusion of any analysis of the lofty intent requirement for inequitable conduct. **Merging intent and materiality at levels far below the *Kingsdown* rule has revived the inequitable conduct tactic.**

Aventis Pharma S.A. v. Amphastar Pharms., 525 F.3d 1334, 1349-50 (Fed. Cir. 2008)

Star Scientific: Stresses Harshness of Penalty & Limits Inferences Available for Establishing Intent

Star Scientific Inc. v. R.J. Reynolds Tobacco Co., 537 F.3d 1357 (Fed. Cir. 2008) – reverses inequitable conduct

By Judges Michel, Schall & Dyk – August 2008

- **Information withheld**: in letter known by original attorney, but not known by successor attorney
- **No direct evidence of knowledge or appreciation of materiality**
- **No direct evidence of intent**
- **District Court infers intent**: inferred from client's change of counsel, Reynolds' "quarantine theory";
- **Fed. Cir. holds intent cannot be inferred in this case**
 - **Holds only certain inferences can be used to prove intent**:
 - The inference must be based on sufficient evidence
 - The inference must be reasonable in light of the evidence
 - The inference must be **“the single most reasonable inference able to be drawn from the evidence”**

Star Scientific: Focus on the Harshness of the Unenforceability Penalty

Harshness of the unenforceability penalty:

- “[I]t is inequitable to strike down an entire patent for “minor missteps” and “minimal culpability”
- Unenforceability Penalty originated in US Supreme Court “fraud on Patent Office” cases.” See *Hazel-Atlas Glass Co. v. Hartford-Empire Co.*, 322 U.S. 238, 250-51 (1944); and *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 816 (1945)
- “Subsequent case law has broadened the doctrine to encompass misconduct less egregious than fraud...but the severity of the penalty has not changed...”
- “[C]ourts must be vigilant in not permitting the defense to be applied too lightly. . . it is also inequitable to strike down an entire patent where the patentee only committed minor missteps or acted with minimal culpability or in good faith.

Praxair, Inc. v. ATMI, Inc.

- ***Praxair, Inc. v. ATMI, Inc.***, 543 F.3d 1306, 1313-14 (Fed. Cir. 2008) Decided Sept. 2008 – Judges Bryson & Dyk affirm inequitable conduct, J. Lourie dissents
 - **Information withheld**: highly material prior art devices
 - **Appreciation of materiality is inferred**: inventor and attorney knew of devices and knew or should have known they were material in view of statements made to PTO which were contrary to the undisclosed devices
 - **Intent Inferred**: from contrary statement in PTO and no explanation for withholding, relying upon *Ferring*
- **Judge Lourie’s Dissent**:
 - No finding that the applicant knew, or should have known of the materiality
 - No Basis to infer intent
 - Majority “conflated intent with materiality...”
 - “While a smoking gun may not be needed to show an intent to deceive, more is needed than materiality of a reference
 - No balancing of materiality and intent”

Larson Mfg. Co. - Dissent by J. Linn Suggests Need For *En Banc* Review Of Inequitable Conduct Doctrine

Larson Mfg. Co. v. Aluminart Prods. Ltd., 559 F.3d 1317 (Fed. Cir. 2009)

reverses inequitable conduct -

By Judges Schall & Clevenger, with J. Linn concurring.

- District court did not make findings of specific intent for each item withheld, and Fed. Cir. found some withheld items were not material; Fed. Cir. Requires dist. ct. on remand to determine if there was an intent to deceive remaining withheld material items; court provides dist. ct. with standard for determining intent on remand.
- **J. Linn's Concurring Opinion** – suggests *en banc* review of the doctrine
J. Linn disagrees with majority's standard where intent inferred from:
 - (1) withholding of highly material information;
 - (2) the applicant knew of the information [and] . . . knew or should have known of the materiality of the information; and
 - (3) the applicant has not provided a credible explanation for the withholding.”

Therasense, Inc. V. Becton, Dickenson & Co. Fed. Cir. Affirms Inequitable Conduct

By Judges Dyk & Friedman with J. Linn dissenting;

Affirms invalidity of '551 Patent for obviousness and unenforceability based on inequitable conduct: **“This is one of those rare cases in which a finding of inequitable conduct is appropriate...”**

Background: '551 Patent at issue relates to disposable blood glucose test strips; bench trial on all issues regarding '551 Patent

Material information withheld: arguments made by Patentee in revocation proceeding in EPO, were purportedly inconsistent with attorney arguments in USPTO supporting grant of '551 Patent.

Intent based on inferences:

- inventor/attorney had knowledge of EPO statements
- high level of their materiality because EPO statements contradicted the representations made to the PTO, and
- no credible excuse for withholding
- their explanations were so incredible they suggested intent

Therasense, Inc. - Dissent of Judge Linn

Dissent of Judge Linn:

- the requisite level of intent is “specific intent”—not simple negligence, or even gross negligence.
- “specific intent” denotes a subjective rather than objective standard and is generally associated with actions deliberately and consciously taken to achieve a specific result
- Individuals’ beliefs cannot be based on “objective reasonableness”
- the question for purposes of specific intent is, “Is it plausible that the applicant subjectively believed that the reference was immaterial?...”
- Failure to appreciate materiality excuses withholding: a reference may legitimately be withheld is that the “applicant did not know of its materiality. *FMC Corp. v. Manitowoc Co.*, 835 F.2d 1411, 1415 (Fed. Cir. 1987)”

The Federal Circuit's Imprecise & Controversial Principles For Determining Intent

- Balancing of materiality and intent
 - Can add objective factor to subjective intent
 - Can reduce the required threshold of intent

- Objective factors are introduced when the following are established by inferences:
 - Applicant should have known information was material
 - Applicant should have appreciated withholding or misrepresenting information would have deceived the examiner

- Role of good faith and excuses
 - Negative inference if no excuse or good faith asserted
 - Does patent challenger have burden to show no excuse

PART II

THE FEDERAL CIRCUIT'S INEQUITABLE CONDUCT JURISPRUDENCE IS DESTINED FOR MODIFICATION

- Federal Circuit *En Banc* Review
- Patent Reform Legislation
- PTO Rulemaking
- U.S. Supreme Court

Inequitable Conduct Reform Is Not In Presently Pending Legislation

- **The 2009 legislative draft** pending before the Senate does not contain any inequitable conduct language. See Patent Reform Act of 2009, S. 515, 111th Cong. (2009).
- Senator Orin Hatch is advocating inequitable conduct reform in the legislation.
- Illustrative Prior Proposals For Modifying Inequitable Conduct
 - Post-Grant PTO Proceeding to determine inequitable conduct
 - Eliminate inequitable conduct as defense to infringement; conduct (e.g., H.R. 2975)
 - Prerequisite: Invalidity Finding (e.g., S. 3818) create PTO Proceeding after Infringement Litigation to determine inequitable conduct
 - H.R. 2795 narrowed materiality to include only that information that actually results in a patent claim being held unpatentable [§136(d)] and that the examiner must have relied on the information in question when determining patentability [§ 136(d)(3)(B)].

The Doctrine Of Inequitable Conduct Is Ripe For Supreme Court Review

- Supreme Court Has Been Actively Reviewing Federal Circuit Cases Dealing With Matters of First Impression or Which May Be Viewed As Deviating From Supreme Court Precedent
- Internal Inconsistencies in Rulings By Panels of Federal Circuit and Disagreement Among Its Jurists - - See, e.g., Judge Linn's request for *en banc* review of the doctrine
- The Federal Circuit's Jurisprudence Has Drifted From The Supreme Court's Precedent: *Fraud on Patent Office v. Inequitable Conduct*; *Public Interest v. Patentee's interest*; Remedies That May Vary Based On Equitable Discretion
- Congress Has Identified Federal Circuit's Doctrine Of Inequitable Conduct To Be In Need of Reform
- In July 2009, Supreme Court Denied Certiorari in *Aventis Pharma S.A. v. Amphastar Pharms., Inc.*

Supreme Court Has Recognized The Public Interest In Reviewing Conduct In Patent Procurement

Precision Instrument Mfg. Co. v. Automotive Co., 324 U.S. 806, 815 (1945)

A patent, by its very nature, is affected with a public interest. As recognized by the Constitution, it is a special privilege designed to serve the public purpose of promoting the "Progress of Science and useful Arts." At the same time, a patent is an exception to the general rule against monopolies, and to the right to access to a free and open market. **The far-reaching social and economic consequences of a patent therefore give the public a paramount interest in seeing that patent monopolies spring from backgrounds free from fraud or other inequitable conduct, and that such monopolies are kept within their legitimate scope. The facts of this case must accordingly be measured by both public and private standards of equity.**

Supreme Court In *Precision Instrument* Suggests A Range Of Discretion In Reviewing Pat. Off. Conduct

Precision Instrument , 324 U. S. at 815 :

Supreme Court's discusses "unclean hands" doctrine in context of conduct during Patent Office proceedings leading to grant of patent:

- "This maxim [clean hands] necessarily gives wide range to the equity court's use of discretion.... It is 'not bound by formula or restrained by any limitation that tends to trammel the free and just exercise of discretion... Any willful act concerning the cause of action which rightfully can be said to transgress equitable standards of conduct is sufficient cause for the invocation of the maxim by the chancellor.'"
- "Moreover, where a suit in equity concerns the public interest, as well as the private interests of the litigants, this doctrine assumes even wider and more significant proportions. For if an equity court properly uses the maxim to withhold its assistance in such a case, it not only prevents a wrongdoer from enjoying the fruits of his transgression, but averts an injury to the public. The determination of when the maxim should be applied to bar this type of suit thus becomes of vital significance."

Supreme Court Imposes Duty To Disclose To Pat. Off. Any Incidents In Pat. Off. Proceedings Of Inequitable Conduct

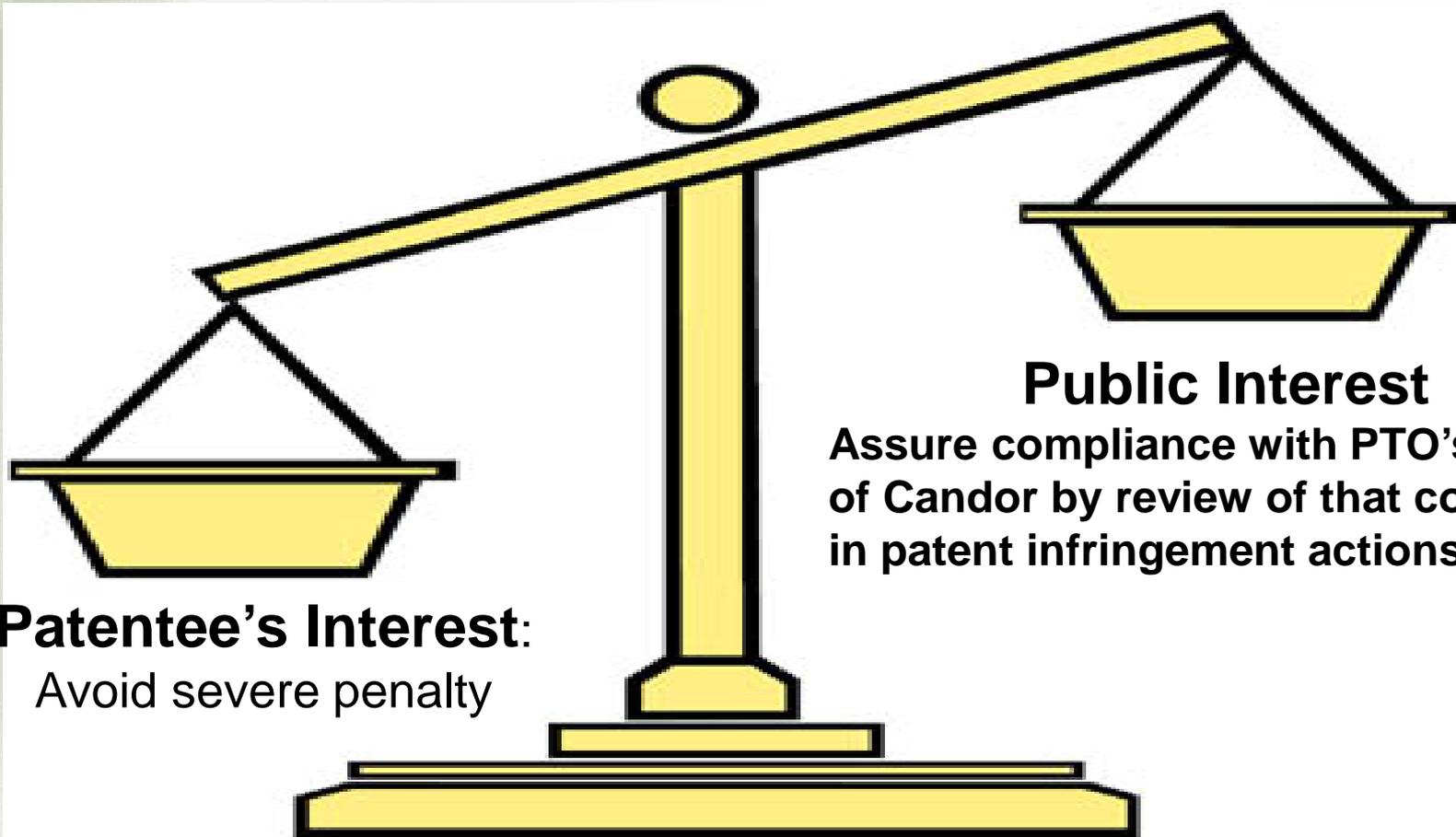
Precision Instrument , 324 U. S. at 815 :

- “Those who have applications pending with the Patent Office or who are parties to Patent Office proceedings have an uncompromising duty to report to it all facts concerning possible fraud or inequitableness underlying the applications in issue. .. Public interest demands that all facts relevant to such matters be submitted formally or informally to the Patent Office, which can then pass upon the sufficiency of the evidence. Only in this way can that agency act to safeguard the public in the first instance against fraudulent patent monopolies. Only in that way can the Patent Office and the public escape from being classed among the ‘mute and helpless victims of deception and fraud.’ *Hazel-Atlas Glass Co. v. Hartford-Empire Co.*, *supra*, 322 U.S. [322 U. S. 246](#).”

Application of Doctrine of Inequitable Conduct Is A Key Tool For Achieving Quality Patent Examination

- **Norton v. Curtiss**, 433 F.2d 779, 794 (C.C.P.A. 1970) (“The highest standards of honesty and candor on the part of applicants in presenting such facts to the office are thus necessary elements in a working patent system. We would go so far as to say they are essential.”)
- **37 C.F.R. § 1.56(a)** (1992 & after) (“The public interest is best served, and the most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability.”)
- **Rene D. Tegtmeyer**, *The Patent and Trademark Office View of Inequitable Conduct or Attempted Fraud in the Patent and Trademark Office*, 16 AIPLA Q.J. 88, 88 (1988): “[t]he purpose of the duty of disclosure requirement, as the Patent and Trademark Office (PTO) views it, is to improve the quality of examination and the validity of patents by assuring that material information is called to the examiner’s attention and considered in the patent examining process.”

In Recent Decisions Federal Circuit Has Weighed Injury to Patentee, Not Effect On Public Interest



Patentee's Interest:
Avoid severe penalty

Public Interest
Assure compliance with PTO's Duty of Candor by review of that conduct in patent infringement actions

Federal Circuit Has Created Its Own Straightjacket With The Single, Severe Penalty of Unenforceability

- "[T]he severity of the penalty has not changed, and thus courts must be vigilant in not permitting the [inequitable conduct] defense to be applied too lightly." *Star Scientific*, 537 F.3d at 1366
- The limiting of the "inequitable conduct" defense to the most culpable and most egregious acts would create no redress for most violations of the PTO duty of candor and good faith
- Patent litigation is the primary proceeding to
 - Discover, review and redress the broad range of conduct the PTO seeks to preclude
 - Encourage and provide incentive for patent applicants and patent practitioners to proceed with caution and with candor in Patent Office proceedings
- Public policy requires patentees/practitioners to answer for conduct that fails to comply with the PTO's duty, even if that conduct does not reach the most egregious level for unenforceability

The Broader Range Of Unacceptable PTO Conduct Should Be Redressed With A Range of Penalties

- Relate severity of the inequitable conduct to the remedy, based on such considerations as its impact on patent examining system for achieving patent quality and costs to party in asserting the defense
- Offensive conduct in PTO constitutes a surrendering of at least some rights in the enforcement of the patent
- Objectives should not only be punishment of the patentee but a deterrent, to discourage others from committing such conduct
- Illustrative penalties
 - Find unenforceable only those claims impacted by misconduct
 - Financial penalty, different from “exceptional case” burden, to award challenger some or all of its costs and attorney fees in asserting the defense
 - Preclude patentee from obtaining injunctive relief
 - Preclude patentee from recovery damages on the basis of lost profits
 - Preclude patentee from recovering to multiple damages for willfulness

Consequences of Questionable Judgment

“Those who are not ‘**up front**’ with the PTO run the risk that, years later, a fact-finder might conclude that they intended to deceive.”

-- *Molins PLC v. Textron, Inc.*, 48 F.3d 1172 (Fed. Cir. 1995)



“There is no reprieve from the **duty of square dealing and full disclosure** that rests on the patent practitioner in dealings with the PTO.”

-- *Kangaroos U.S.A. v. Caldor, Inc.*,
778 F.2d 1571, 1576 (Fed. Cir. 1985)

Does A Practitioner Need A Crystal Ball?



- Should I disclose it?
- Should I argue it?
- Should I submit the statement?
- Should I investigate it?
- Should the declaration contain the statement ?

***Answer: No crystal ball;
when in doubt disclose the
true facts and prior art.***

See *Praxair, Inc. v. ATMI, Inc.*, 543 F.3d 1306, 1313–14 (Fed. Cir. 2008) (stating that an applicant must have a “credible good faith explanation for the withholding”); *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253, 1257 (Fed. Cir. 1997) (doubts concerning whether the information is material should be resolved in favor of disclosure); *LNP Eng’g Plastics, Inc. v. Miller Waste Mills, Inc.*, 275 F.3d 1347, 1361 (Fed. Cir. 2001).