



FENWICK & WEST LLP



Patent Law | 2006

The Year Past and the Year Ahead

January 19, 2006

PATENT LAW | 2006

The Year Past and the Year Ahead

I. Patent Case Law before the Supreme Court and Federal Courts

- A. A Look Back
 - Supreme Court
 - Federal Courts
- B. A Look Ahead
 - Supreme Court
 - Federal Courts

II. Patent Case Law

- A. Extraterritoriality
- B. Claim Construction — *Phillips*
- C. Claim Construction After *Phillips*
- D. Patent and Antitrust
- E. FDA Safe Harbor
- F. Developments in Life Sciences Patent Law

--- 15 minute break ---

III. Prosecution Before the U.S. Patent Office

- A. Changes at the USPTO
- B. Pre-Appeal Briefing
- C. CREATE Act
- D. Business Method Patents
- E. Reexamination Update

IV. Ethics

- A. Spoliation / Document Retention
- B. Rule 11
- C. Inequitable Conduct in Life Sciences Cases

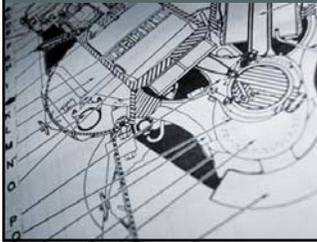
V. Patent Law Reform

--- Lunch Buffet in the Lobby---



PATENT LAW | 2006

The Year Past and the Year Ahead



PATENT LAW | 2006

Program Agenda

- i. Overview: A Look Back and a Look Ahead
- ii. Patent Case Law Updates
- Break
- iii. Prosecution before the U.S. Patent Office
- iv. Ethics
- v. Patent Law Reform

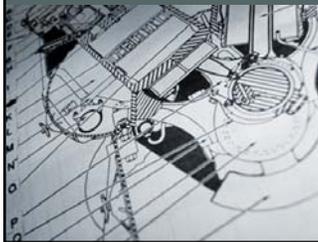
Lunch



Patent Case Law before the Supreme Court and Federal Courts

A Look Back and a Look Ahead

Charlene Morrow
Heather Mewes



Supreme Court Agenda: A Look Back

- Merck KGaA v. Integra Lifesciences I, Ltd., 125 S.Ct. 2372
Section 271 FDA safe harbor
Only patent case decided by SCT in 2004-05 term
- MGM Studios Inc. v. Grokster, 125 S.Ct. 2764
Inducement of copyright infringement
Court draws parallels with patent inducement case law





Federal Circuit Agenda: A Look Back

- NTP, Inc. v. Research in Motion, Ltd., 418 F.3d 1282
 - Extraterritoriality
 - Cert petition filed 12/9/05 (SCT Case No. 05-763)
- Phillips v. AWH Corp., 415 F.3d 1303
 - Claim construction
 - Cert petition filed 11/15/05 on issue of *de novo* review of claim construction (SCT Case No. 05-602)
- Capon v. Eshhar, 418 F.3d 1349 /
In re Fisher, 421 F.3d 1365
 - Utility and written description for biotech patents

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Supreme Court Agenda: A Look Ahead

- Supreme Court already has (relatively) active docket of patent-related cases
 - 2 cases already argued in 2005
 - 2 cases already set for argument in early 2006
 - Call for Solicitor General's view in 3 more cases

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Supreme Court Agenda: Already Argued

- Illinois Tool Works v. Independent Ink, SCT Case No. 04-1329 (argued 11/29/05)
 - Presumption of market power from patent
- Unitherm Food Sys. v. Swift-Eckrich, SCT Case No. 04-597 (argued 11/2/05)
 - Rule 50 motion practice

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Supreme Court Agenda: Certiorari Granted

- eBay, Inc. v. MercExchange, LLC., SCT Case No. 05-130 (cert granted 11/28/05)
 - Rule favoring permanent injunctions for patent infringement
- Laboratory Corp. of America Holdings v. Metabolite Litigation, SCT Case No. 04-607 (cert granted 10/31/05)
 - Patenting laws of nature, natural phenomena and abstract ideas
 - Business methods patents?

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Supreme Court Agenda: eBay v. MercExchange

- **Questions Presented:**

Whether the Federal Circuit erred in setting forth a general rule in patent cases that a district court must, absent exceptional circumstances, issue a permanent injunction after a finding of infringement.

Whether this Court should reconsider its precedents, including *Continental Paper Bag Co. v. Eastern Paper Bag Co.*, 210 U.S. 405, 28 S. Ct. 748, 52 L. Ed. 1122, 1908 Dec. Comm'r Pat. 594 (1908), on when it is appropriate to grant an injunction against a patent infringer

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Supreme Court Agenda: Laboratory Corp v. Metabolite

- **Question Presented:** Whether a method patent setting forth an indefinite, undescribed, and non-enabling step directing a party simply to "correlat[e]" test results can validly claim a monopoly over a basic scientific relationship used in medical treatment such that any doctor necessarily infringes the patent merely by thinking about the relationship after looking at a test result.

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Supreme Court Agenda: SG's Views Requested

- KSR Int'l Co. v. Teleflex, Inc., SCT Case No. 04-1350 (CVSG'd 10/3/05)
 - Obviousness combination test requiring some proven "teaching, suggestion, or motivation"
- SmithKline Beecham Corp. v. Apotex Corp., SCT Case No. 05-489 (CVSG'd 1/9/06)
 - Inherent anticipation without recognition in the art
- FTC v. Schering-Plough Corp., SCT Case No. 05-273 (CVSG'd 10/31/05)
 - Reverse payment antitrust settlements

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Federal Circuit Agenda: A Look Ahead

- LG Electronics, Inc. v. Bizcom Electronics, Inc., Fed. Cir. Case No. 05-1261
 - Fully briefed; argument likely in early 2006
 - Amicus participation

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Federal Circuit Agenda: A Look Ahead

- LG Electronics, Inc. v. Bizcom Electronics, Inc., Fed. Cir. Case No. 05-1261

Fact pattern:

- LG Electronics sued First International Computer and Everex Systems, among others, for infringement of patents relating generally to system bus management, bus access arbitration and buffered write requests.
- Defendants had purchased chip sets from Intel, who had a cross-license with LG Electronics. The cross license obligated Intel to notify its customers that they were not licensed for combinations of Intel components with other components.
- Judge Wilken issued summary judgment that: all apparatus claims except those on buffered write were exhausted, but that no method claim had been exhausted and that no implied license had been created.

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Federal Circuit Agenda: A Look Ahead

- LG Electronics, Inc. v. Bizcom Electronics, Inc., Fed. Cir. Case No. 05-1261

Issues for Appeal:

- Is patent exhaustion a distinct doctrine from implied license?
- Can a license agreement restrict the application of the implied license doctrine?
- Does sale of a necessary article for practice of a method exhaust rights in the method claim?

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Federal Circuit Agenda: A Look Ahead

- Voda v. Cordis, Corp., Fed. Cir. Case No. 05-1238 (petition for permission to appeal granted 03/02/05, argued 1/12/06)

Adjudication of infringement claims based on foreign patents:

- Supplemental jurisdiction may be exercised where there are similar acts both in and out of U.S.
- Cordis seeks per se rule against enforcement of foreign patents in U.S. courts

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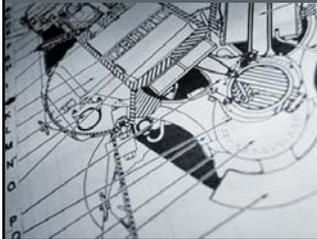


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Extraterritoriality

Liability for Acts
Abroad

Darren Donnelly



Liability for Acts Abroad Increased Significantly in 2005

- NTP, Inc. v. Research in Motion, Ltd., 418 F.3d 1282.
- Eolas Techs. V. Microsoft., 399 F.3d 1325.
- AT&T Corp. v. Microsoft Corp., 414 F.3d 1366.
- Union Carbide Chems. & Plastics Tech. Corp. v. Shell Oil Co., 425 F.3d 1366.
- Fuji Photo Film Co. v. Jazz Photo Corp., 394 F.3d 1368.

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NTP Finds Liability Despite Part of System Being Abroad

- BlackBerry system with critical component in Canada
- § 271(a) — direct infringement — requires make, use, sell . . . be “within the United States”
- System and method claims analyzed differently
 - Element in Canada nominally recited in method claims
- Held: System claim infringed
 - Location of “Use” is “the place where control of the system is exercised and beneficial use of the system obtained” “place at which the system as a whole is put into service”
- Held: Method claim not infringed
 - “a process cannot be used ‘within’ the United States . . . unless each of the steps is performed within this country”
 - Sale of handhelds not enough to “sell” method

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§ 271(f) — Liability for Supply of Components Inducing or Contributing to “Infringement” Abroad

- Remedial statute reversing Supreme Court decision
- Supplying in or from U.S. component(s) of patented invention
- Either
 - (1) So as to actively induce combination of components outside U.S. — § 271(f)(1)
 - OR
 - (2) Knowing components meet requirements for contributory infringement and intending components will be combined abroad — § 271(f)(2)
- Combination abroad would infringe if in the U.S.

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NTP Finds Sale of Product in U.S. Did Not Create Liability Under §271(f)

- Method claim considered — system infringed under 271(a)
- Implicitly read statute to require supply of component steps
- Held: Supply of handhels and software is not “is not the statutory ‘supply’ of any ‘component’ steps for combination into NTP's patented methods”
 - “Difficult to conceive how one might supply . . . steps of a patented method in the sense contemplated by . . . 271(f)”
 - But see* Union Carbide v. Shell

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Potential Damages Recovery For Every Copy Made Abroad of Software "Master" Supplied from U.S. — *Eolas & AT&T*

- Software made in U.S. and sent abroad is "component" for purposes of § 271(f) — *Eolas*
 - “Golden masters” of Windows sent abroad for OEMs to install
 - Code on master is "component" of patented product and, in operation, machine component
- Damages liability attaches for each copy made abroad from U.S. copy sent with that intent — *AT&T*
 - “Supplied . . . from the United States” construed in light of practical realities of software distribution — “To decide otherwise would emasculate § 271(f) for software inventions”
 - Form of supply from U.S. irrelevant — network transfers count; hosting for download does to (in dicta)

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Supply of Product from U.S. for Use in a Method Abroad is Within § 271(f) — *Union Carbide*

- Invention is process for producing chemical with an improved catalyst
- Defendant liable for damages for its foreign affiliates' use abroad of the process with catalysts supplied from U.S.
- *NTP v. RIM* reconciled
 - RIM did not supply components from U.S. to foreign entities
 - Avoid double-counting domestic sales for system used, in part, abroad
 - Dissent from reh'g *en banc* — component in method is step
- § 271(f) equally applicable to all forms of invention

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No International Exhaustion of U.S. Patent Rights — *Fuji*

- Patentee/licensees sold disposable cameras in U.S. and abroad
- Defendant imported cameras into U.S.
 - Some imported cameras permissibly repaired
 - Some ordinarily infringing
- Held: Repair defense only available to cameras first sold in the U.S.
 - Based on exhaustion/first sale doctrine
 - “The patentee’s authorization of an international first sale does not affect exhaustion of that patentee’s rights in the United States”
 - “Fuji’s foreign sales can never occur under a United States patent because the United States patent system does not provide for extraterritorial effect.”

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Important Points and Coming Issues

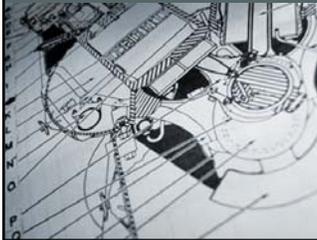
- Business processes to avoid *AT&T* and *Eolas* not trivial
 - Considered practical market response by U.S. companies
 - Broad language in opinions
- Territorial scope of grant warrants review in licenses
- Varied claim form still probably a best practice
- Proof requirements of actual “infringement” abroad under § 271(f)
- Injunctive remedies for acts abroad under § 271(f)
- Relationship between acts abroad and first sale doctrine

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Claim Construction

Still No Magic Formula

Darryl Woo



Claim Construction: Phillips v. AWH Corp.

■ Background

“Panel split” among Federal Circuit judges concerning claim construction approach

- Dictionary disciples – “*Texas Digital*”
- Contextualists

July 12 Federal Circuit *en banc* decision

- Still No Magic Formula



Claim Construction: Phillips v. AWH Corp.

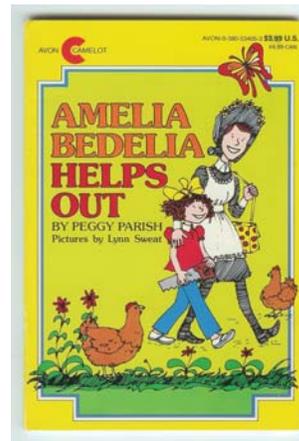
- Parties (and *amic*) invited to brief some of the following questions:
 - (1) Dictionaries or patent specification? If both, in what order, how used?
 - (2) Should claim scope be limited to single disclosed embodiment when no other indications of breadth are disclosed?
 - (3) When, if ever, should claim language be narrowly construed solely to avoid invalidity?
 - (4) Deference to trial court?

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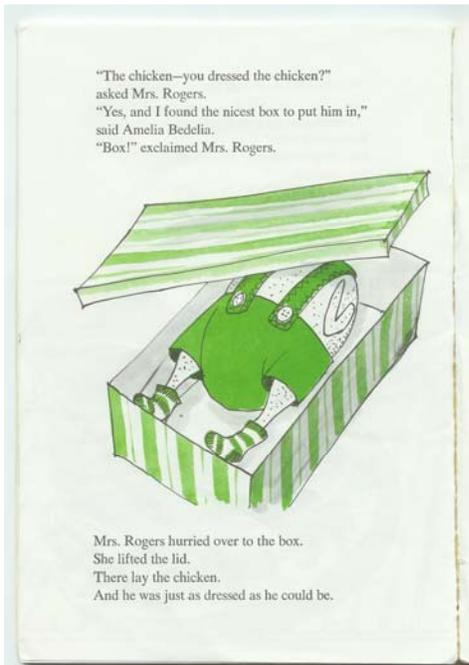


Claim Construction: Phillips v. AWH Corp.

Reliance on dictionaries
and literal meaning
can lead to absurdities



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"Plain and Ordinary" Is Sometimes Far From It

The Literal Meaning of "Dress the Chicken" Is Absurd, But Has a Sensible Meaning to One of Skill In the Art



Context Can Be Critical to the Correct Construction

"Draw the Drapes" is Capable of Two Meanings, Even to One of Skill in the Art.

Which One is Appropriate Depends On Context





No Magic Formula

- "Texas Digital" Dead – Context wins
- Fed. Cir. otherwise did not break new ground
- "Revival" of claim construction hierarchy of *Markman*, *Vitronics* and *Innova*
 - Claims and specification
 - File history
 - Dictionaries, treatises, encyclopedias, experts
- Still a "pure question of law" dice roll
 - Noninfringement summary judgment reversed

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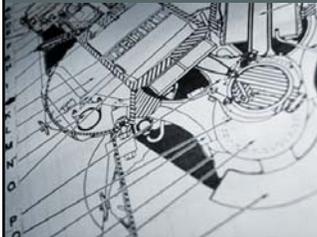


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Life After Phillips

They Really Meant It

Michael Sacksteder





Remember *Novartis*?

- Pre-*Phillips* Federal Circuit Claim Construction Ruling
- Purported to Apply *Texas Digital*
- Followed Tortured Chain of Linked Dictionary Definitions
- Eventually Arrived at “Ambiguity”
- Relied on Specification to Reach Desired Result

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Case Study: *Nystrom v. Trex*

- Issue: What is a “board”?
- Plaintiff: **Not limited to conventional wood boards cut from a log**
 - No “clear disavowal of claim scope in specification or prosecution history”
- Defendant: **A piece of sawn lumber**
 - Specification only disclosed boards made of wood and cut from a log
- District Court: **“a piece of elongated construction material made from wood cut from a log.”**

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Pre-Phillips: *Nystrom I*

- Federal Circuit consulted several dictionaries
- One dictionary defined “board” to include compositions of both wood and other rigid materials
- “Board” construed to encompass all definitions **not inconsistent** with intrinsic record
- Construction: “elongated, flat piece of wood **or other rigid material**”

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Post-Phillips: *Nystrom II*

- Written by Judge Linn – author of *Texas Digital*
- *Nystrom* continued to rely on dictionaries and argue no clear disavowal of claim scope
- Didn’t work this time...

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The New World Order

- "However, as explained in *Phillips*, Nystrom is not entitled to a claim construction divorced from the context of the written description and prosecution history. The written description and prosecution history consistently use the term "board" to refer to wood decking materials cut from a log. Nystrom argues repeatedly that there is no disavowal of scope in the written description or prosecution history. Nystrom's argument is misplaced."

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Written Description

- "Further, the process used to cut such lumber from logs can produce inferior product on the outermost boards, often leading to scrap."
- "With particular reference to FIGS. 1-5, it can be seen that the convex top surface 13 is curved in the same general direction as the curvature of the growth rings GR."
- "FIG. 4 shows the relationship of the outermost boards B cut from a log L."

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Prosecution History

- “The present invention represents a unique and significant advance in the art of exterior wood flooring. Wood floors have been in use for hundreds of years, and except for the development of different installation techniques, i.e., the use of nails, screws, various fastening clips, and/or adhesives, very little has been done to the basic shape of the board itself.”
- “[T]he particular configuration and dimensions of the board result in a uniformly superior product and reduction in waste or rejects due to bark or other flaws along the edges of the board when it is cut from near the outer circumference of a log.”

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What It All Means

- *Texas Digital* approach really is dead
- No need for “clear disavowal of claim scope” for intrinsic record to control
- “Nystrom **consistently used** the term “board” to refer to wood cut from a log. Although there was no clear disavowal of claim scope, there was **nothing in the intrinsic record to support the conclusion that a skilled artisan would have construed the term “board” more broadly** than a piece of construction material made from wood cut from a log.

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Practice Pointers

- Want a narrow construction?
Look for “consistent use.”
- Want a broad construction?
Look for exceptions.
- Want flexibility in the future?
Inject some inconsistency.
- Emerson was right: “A foolish consistency is the hobgoblin of small minds.”

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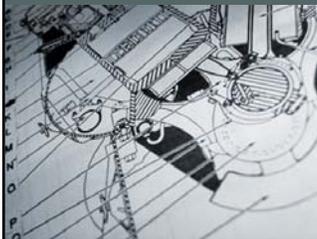


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FDA Safe Harbor

Section 271 Reaches
Beyond Generics

Michael Shuster
Narinder Banait





Merck v. Integra — Overview & Summary

- Expands safe harbor under 35 USC §271(e)(1)
- Use of patented compounds in preclinical research exempt from infringement if:
 - Compound tested could be subject of an FDA submission
 - Tests produce types of information relevant to an IND or NDA

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Merck v. Integra — Overview & Summary

- *Merck KGaA v. Integra Lifesciences I, Ltd.*, 125 S.Ct. 2372
- Exemption includes
 - Experimentation on drugs that are not ultimately subject of an FDA submission
 - §271(e)(1) reaches beyond generics
 - Use of patented compounds in experiments that are not ultimately submitted to FDA

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Merck v. Integra – Overview & Summary

- Application of expanded safe harbor exemption to use of “research tools” to develop information for regulatory process left undecided by Court (fn 7).

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Merck v. Integra – Background

- Merck sponsored angiogenesis research at Scripps Institute starting in 1988
 - Angiogenesis important in many disease processes
- Scripps discovers angiogenesis inhibition by blocking protein on cell surface
 - Scripps animal studies show reversal of tumor growth using “RGD” peptide provided by Merck

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Merck v. Integra — Background

- Second phase sponsored research agreement executed to extend collaboration
- Scripps proposal directed to developing angiogenesis inhibitors
 - In vitro and in vivo* testing of Merck's RGD peptides at Scripps
 - IND submission at end of work
- Merck specifies it will perform toxicology tests necessary for FDA approval to proceed to clinical trials

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Merck v. Integra — Background

- Integra sues Merck for patent infringement
- Merck argues activities fall within §271(e)'s safe harbor
- Merck loses at trial (jury awards \$15,000,000)
- Fed. Circuit affirms that activities not within safe harbor
 - Research was not clinical testing to supply information to FDA
 - General biomedical research to identify new pharmaceutical compounds

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Merck v. Integra — Analysis

- It shall not be an act of infringement to make, use ... or import into the United States a patented invention ... solely for uses reasonably related to the development and submission of information under a Federal law which regulates the ... use ... of drugs.

–35 U.S.C. § 271(e)(1)

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Merck v. Integra — Analysis

- Supreme Court says statute's text makes clear that exemption extends to all uses of patented inventions reasonably related to development and submission of *any* information under FDCA
- **Preclinical studies** of patented compounds appropriate for submission to FDA necessarily included within exemption (because "reasonably related")
- IND requires summaries of pharmacological, toxicological, pharmacokinetic, and biological qualities of drug in animals

Rejects Integra's argument that preclinical work exemption limited to drug safety in humans

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Merck v. Integra — Analysis

- Extension to experimentation on drugs not ultimately subject of FDA submission

Even at late stages in development of new drug, scientific testing is process of trial & error

Contrary rule would limit exemption to generics

Drugmaker must have reasonable basis for believing patented compound may work

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Merck v. Integra — Analysis

- Extension to use of patented compounds in experiments not included in submission to FDA

Statutory language says “development and submission”

Not always clear to parties exactly which kinds of information required to get FDA approval

Especially true at preclinical stage where contents of IND turns on novelty of drug, extent to which it has been studied, known or suspected risks, and developmental phase of drug

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Merck v. Integra — Policy

- Hatch Waxman Legislation (led to § 271(e)) – intent was to speed approval of generics upon expiration of patent
- Newman’s dissent in Fed. Cir. decision

Patent system’s purpose to provide incentive to create new knowledge and public benefit through new products and

Add to body of published scientific/technological knowledge

Right to conduct research to achieve such knowledge need not/should not await expiration of patent (extension of Hatch Waxman)

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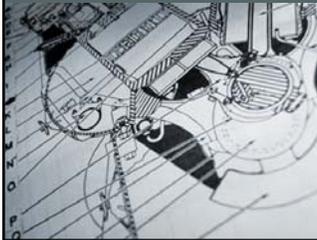


Merck v. Integra — Practice Pointers

- Compound must be type that could be subject of FDA submission
- Experiments must produce types of information relevant to IND or NDA

pharmacological, toxicological, pharmacokinetic, and biological qualities of drug in animals

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Antitrust Issues

FTC v. Schering-Plough

Illinois Tool Works

U.S. Philips v. ITC

Tyler Baker

Narinder Banait



FTC v. Schering-Plough

- Antitrust implications of patent settlements
- Special context of Hatch-Waxman Act
- FTC objects to settlements involving “reverse” payments to generics that allegedly infringe
- A number of companies have entered consent decrees, but S-P fought the FTC



FTC v. Schering-Plough

- After 10 week trial, ALJ ruled for S-P
- FTC reversed
- 11th Circuit reversed FTC
- FTC (conspicuously without DOJ participation) is seeking Supreme Court review
- Any settlement between competitors can raise antitrust issues, but Hatch-Waxman presents special issues

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FTC v. Schering-Plough

- Hatch-Waxman provides for the marketing of a generic drug using the Abbreviated New Drug Application (ANDA) approach.
- The generic manufacturer must demonstrate that its product is pharmaceutically equivalent to the branded product
- In order to reference an NDA, the generic manufacturer must file one of four alternative certifications
- Cases involve “Paragraph IV Certification”—Patent in NDA is alleged to be invalid or the generic equivalent product does not infringe
- Result is preemptive patent litigation

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FTC v. Schering-Plough

- Two Settlements: Upsher-Smith and ESI
- Upsher-Smith
 - Allowed to enter 5 years before expiration
 - S-P paid \$60 million and received a package of licenses of Upsher-Smith products
- ESI
 - Allowed to enter 3 years before expiration
 - S-P paid \$30 million - \$5 million which was roughly equal to legal fees and \$10 million which was contingent on ESI receiving FDA approval by a set date and \$15 million for licenses
- FTC concluded that reverse payments are inherently a payment for later entry than otherwise

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FTC v. Schering-Plough

- Upsher-Smith licensed other patents to S-P, raising valuation issue
 - ALJ found fair value and no net payment—and therefore no antitrust issue
 - FTC reversed, found a net payment, and found it to be inherently anticompetitive
 - 11th Circuit found no substantial evidence supporting FTC on valuation
 - 11th Circuit found settlement within patent period reasonable

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FTC v. Schering-Plough

- ESI record is very thin
 - FTC said it probably would not have brought the case as a matter of prosecutorial discretion
 - Payment came after a long mediation supervised by a Magistrate Judge
 - Payment was conditioned on ESI getting FDA approval, which S-P considered unlikely

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FTC v. Schering-Plough

- The 11th circuit opinion
 - Traditional litigation perspective
 - Settlements are valued and encouraged
 - Patents are presumed valid
 - Absent extraordinary circumstances, settlements within patent period are legitimate
 - Patentee could have excluded for the entire period

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FTC v. Schering-Plough

- The FTC's position

Patents are "probabilistic" rights

Many patents, particularly drug patents are found invalid

The expiration date is not the only variable

Profits on successful patented drugs are very high

Prices drop drastically when generics enter

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FTC v. Schering-Plough

- FTC's position (cont'd)

Economic incentives suggest that payments to generics are sharing monopoly profits

Incumbent companies can afford to and will pay generics what they would have made through entry

Hatch-Waxman and the 2003 Medicare amendments were meant to encourage early generic entry

Consumers benefit from early entry

Court should have deferred to agency expertise

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Illinois Tool Works v. Independent Ink

- Case presents classic patent / antitrust interface
- Antitrust theory: tying with patent
 - Tying Product: Patented printer heads for bar codes
 - Tied Product: Unpatented ink for printing

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Illinois Tool Works v. Independent Ink

- Elements of *per se* rule
 - Two products
 - Conditioning sale of one (tying) on purchase of other (tied)
 - Significant market power in tying product**
 - Not insubstantial amount of commerce affected

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Illinois Tool Works v. Independent Ink

- Presumption of market power in patent
 - Case law supports, but
 - Antitrust commentators and agencies have rejected for years
 - Federal Circuit followed but questioned precedent
 - The Supreme Court took the case—apparently to reverse

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Illinois Tool Works v. Independent Ink

- Antitrust standard of “Demonstrable Economic Effect” since *Sylvania* decision in 1977
- Legal “monopoly” but not “economic monopoly”
 - No economist would support
 - Many patented products have reasonable non-infringing substitutes
- Congress changed rule for patent misuse claims in §271(d)

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Illinois Tool Works v. Independent Ink

- DOJ, FTC, and PTO urged overruling
- Likely result: No presumption
- Established standard of proof: 30% or more of relevant market

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U.S. Philips v. ITC

- Package licensing as misuse when non-essential patents included in package
 - Patents on CD-R and CD-RW discs
- Plaintiffs claimed non-essential patents were included
 - Package therefore “tied” essential to non-essential, foreclosing competition with non-essential alternatives
- ITC found misuse based on both *per se* and Rule of Reason analysis
- Fed. Cir. reversed on both grounds

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U.S. Philips v. ITC

- Court refused to treat as *per se* illegal
- There was independent proof of market power, so *Independent Ink* issue not presented
- “Fundamental difference” between an obligation to purchase a product and a non-exclusive license to practice a patent
- Package not fundamentally different from patentee surrendering non-essential patents or announcing that would not enforce
- No evidence that part of royalty was for non-essential patents

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U.S. Philips v. ITC

- Court rejected ITC assumption that individual licenses would be available for lower price than package
 - Royalty did not vary depending on the number of patents used
 - Value of package is “largely, if not entirely” based on essential patents
 - Rational for patentee to charge value of practicing technology for essential patent
 - Court refused to require allocation

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U.S. Philips v. ITC

- Court also identified policy issue for rejecting ITC *per se* ruling
 - Existing law permits patentee to insist on licensing all necessary patents as a group
 - Continuing developments after license may create new “alternatives”
 - Under ITC ruling, licenses lawful when executed could be misuse later
 - Incentive for litigation because all patents in package would be unenforceable

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U.S. Philips v. ITC

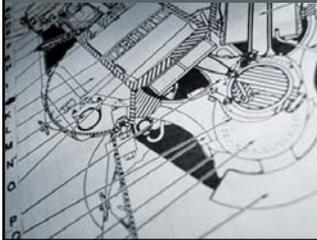
- Court rejected Rule of Reason ruling
 - No evidence of commercially available alternatives
 - Pro-competitive advantages of package licenses
 - Lower transaction costs
 - Efficiency in reducing litigation costs and uncertainties

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DNA Sequence Inventions

Evolutionary Developments in
2005 Case Law

Michael Shuster
Sergio Garcia
Narinder Banait



Utility Requirement

- *In re Fisher*, 421 F.3d 1365 (Fed. Cir. 2005)
- 35 U.S.C. § 101: invention must have a substantial and specific utility.





In re Fisher

- Affirms decision of BPAI denying patent directed to five ESTs
- Absent identification of underlying function of genes, “claimed ESTs have not been researched and understood to the point of providing an immediate, well-defined, real world benefit to the public meriting the grant of a patent.”
- Decision endorses 2001 PTO Utility Examination Guidelines

77



In re Fisher

- Without presenting specific function for underlying gene, invention lacks “specific and substantial utility” and so also fails enablement requirement of 35 U.S.C. § 112 as it incorporates the utility requirement of 35 U.S.C. § 101
- Specific utility
 - Not so vague as to be meaningless, and one that can be used to provide well-defined and particular benefit to the public
- Substantial utility
 - Use that has a significant and presently available benefit to the public

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In re Fisher

- Monsanto (real party in interest) argued ESTs analogous to microscope because useful as research tools (*e.g.*, monitoring gene expression and identifying presence or absence of polymorphism)
- Fed. Cir. rejects arguments

ESTs merely starting point for further research, providing no presently available benefit therefore no “substantial” utility under § 101

Uses not specific because any EST from genome could perform any of the recited utilities

- No assertion of utility setting apart five claimed ESTs from 32,000 disclosed ESTs

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Written Description Requirement

- *Capon v. Eshhar v. Dudas*, 418 F.3d 1349 (Fed. Cir. 2005)
- *In re Wallach*, 378 F.3d 1330 (Fed. Cir. 2004)

35 U.S.C. § 112: DNA is only sufficiently described if “a precise definition is given, such as a structure, formula, chemical name, or by physical properties.”

80



Capon v. Eshhar v. Dudas

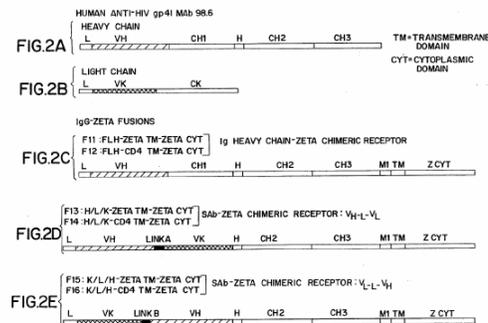
- Vacated and remanded a BPAI ruling in an interference concerning a chimeric gene, where BPAI cancelled all the claims of the two competing parties for failing to provide adequate written description as required by 35 U.S.C. § 112.
- BPAI found must include a listing of the specific nucleotide sequence of claimed DNA.
- Fed. Cir. found the *per se* rule requiring recitation of the nucleotide sequence to be incorrect when the sequence is already known in the field.

81



Capon v. Eshhar v. Dudas

- Chimeric gene – artificial gene that combines segments of DNA in a way that does not occur in nature.



82



Capon v. Eshhar v. Dudas

- Fed. Cir. said BPAI failed to take into account the state of scientific knowledge regarding chimeric genes, and the precedent cited by the Board was no longer applicable because the science of chimeric genes had evolved.
- Fed. Cir. said the invention was not “discovering which DNA segments are related to immune response, for that is in the prior art, but in the novel combination of the DNA segments to achieve a novel result.”
- Fed. Cir. also said written description must be done on a case by case basis, and it was an error for the Board to rule that § 112 imposes a per se requirement for reciting claimed DNA sequences.

83



In re Wallach

- Affirms decision of BPAI denying patent directed to DNA sequences encoding TNF binding protein II.
- Fed. Cir. said the written description requirement for claims to DNA molecules was not satisfied by disclosure of a partial amino acid sequence of the encoded protein.
- Fed. Cir. clarified that a functional description of a DNA molecule may be sufficient to satisfy the written description requirement, but only where there is a known structure-function relationship from which the structure of the claimed DNA molecules could have been predicted.

84



In re Wallach

- Inventors disclosed a protein, a partial amino acid sequence of the protein and other descriptive properties of the protein, such as the molecular weight and the protein's ability to inhibit the cytotoxic effect of tumor necrosis factor (TNF).
- Upon the basis of this disclosure, the inventors were able to obtain patent protection for the protein.
- Inventors argued that the complete amino acid sequence is an inherent property of an isolated, fully characterized protein, and can get genus of DNA encoding the protein.

85



In re Wallach

- Inventors argued they had fully functionally characterized TBP-II, therefore had possession of all DNA sequences encoding TBP-II.
- PTO rejected because the specification failed to disclose:
 - 1) the complete amino acid sequence of TBP-II or
 - 2) the actual DNA sequence,therefore, the inventors had not demonstrated possession of all DNA sequences encoding TBP-II.

86



In re Wallach

- The Fed Circuit determined that absent a description of the complete TBP-II amino acid sequence or any “known or disclosed correlation between the combination of a partial structure of a protein, the protein’s biological activity, and the protein’s molecular weight, on the one hand, and the structure of the DNA encoding the protein on the other,” the Board’s decision to affirm the rejection of DNA claims was proper.

87



FENWICK & WEST LLP

Update on Patent Prosecution before the U.S. Patent & Trademark Office

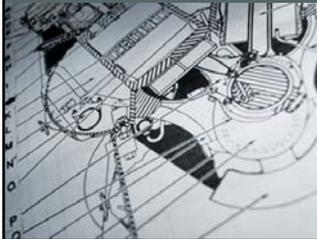
Backlog of Patent
Applications Increases

Changes in Patent
Examination Procedures

Robert R. Sachs

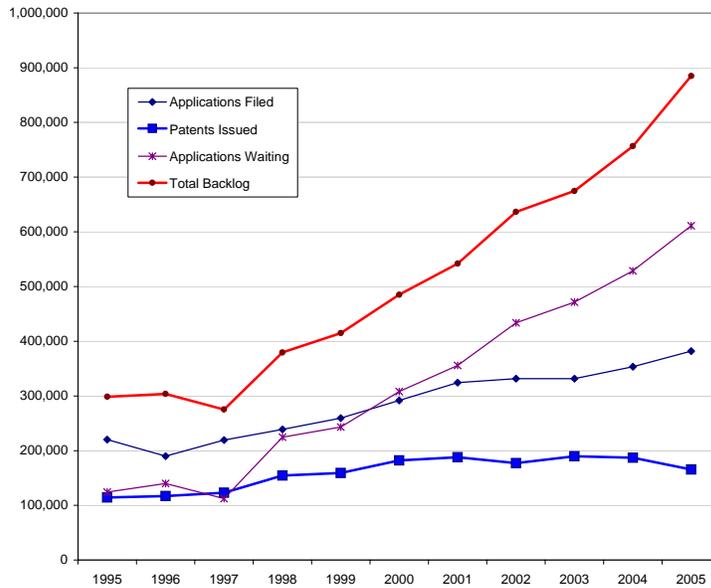
Daniel R. Brownstone

Robert A. Hulse





U.S. Patent & Trademark Office Trends in Patent Application Filing, Issuance and Backlog



89



Patent Application Pendency in 2005

Technology	Average Time to 1 st Action (months)	Average Total Pendency (months)
Biotechnology and Organic Chemistry	23.0	32.3
Chemical and Materials Engineering	19.7	29.7
Computer Architecture Software and Information Security	32.7	43.5
Communications	30.5	42.3
Semiconductor, Electrical, Optical Systems	14.5	24.9
Transportation, Construction	18.4	26.9
Electronic Commerce	48.4	67.5
Mechanical Engineering, Manufacturing and Products	18.3	26.3
Overall FY 2005 Averages	21.1	29.1
PTO FY 2005 Goals	20.7	31.0

90



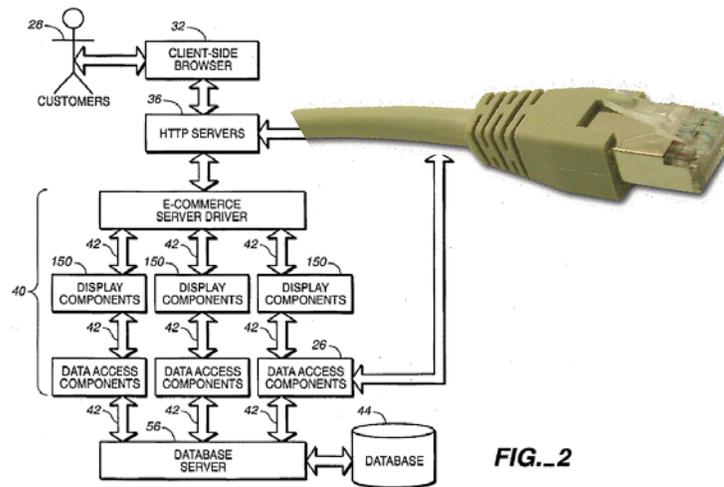
Patent Application Inventory in 2005

High Inventory Art Areas	Months of Inventory	Low Inventory Art Areas	Months of Inventory
Drugs, Bio-affecting and Body Treatment	57-65	Organic Chemistry	18
Radiation Imagery	39	Adhesive Bonding and Coating Apparatus	13
Computer Task Management	54	Manufacturing Control Systems	13
Interactive Video Distribution	88	Information Storage and Retrieval	14
Control Circuits	42	Electrical Conductors	8
Business Methods	27 – 106	Conveying	11
Medical Instruments, Diagnostic Equipment	44-51	Thermal and Combustion Technology	8

91



How to Get Your Patent Issued Quickly



92



Patent Office Initiatives

- Outsourcing PCT searches to Australian, Korean patent offices
- Proposed direct access to patent files in EPO and Japan
- Prior art search templates
- Allowing interviews before First Office Action

93



Other Patent Office Updates

- Petitions to make special
- Electronic filing updates
 - Web-based assignment filing
 - Beta test for web-based application filing
- "Patent Quality Index"
 - Wagner, Penn. Law School
 - 'Objective and Data-Driven'

94



Pre-Appeal Brief Conferences

- Pilot program started in July 2005
 - Initial results “appear to be promising” and program extended “until further notice”
- Used when there is a “clear deficiency in the prima facie case in support of the rejection”
- Must be filed with Notice of Appeal
- Include up to five pages of argument
- Panel reviews argument, decides whether to withdraw rejection or continue with appeal
- Timing: Should receive decision within one month

95



Changes to Implement CREATE Act

R E V I E W

- Treats subject matter developed under a JDA as “commonly owned” for purpose of 35 U.S.C. § 103(c) safe harbor
- Requirements for § 103(c)’s safe harbor:
 1. Joint Research Agreement **in effect on or before** invention was made
 2. Invention made as a result of the activities undertaken **within the scope** of the agreement
 3. Application discloses or is amended to disclose the parties to the agreement
- **Effective Date:** Applies to any patent **granted** on or after December 10, 2004

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Changes to Implement CREATE Act

- **Interim Rule:** Jan. 11, 2005
- **Final Rule:** Sep. 14, 2005
- Final Rule relaxes the requirements in the Interim Rule
- Disclosure in Specification
 - Specification must be amended to add parties to the agreement, but . . .
 - Eliminates requirement to disclose (1) the execution date of the agreement and (2) a concise statement of the field of the claimed invention

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Changes to Implement CREATE Act

- Terminal Disclaimer (37 C.F.R. § 1.321(d))
 - A Terminal Disclaimer used to obviate a double patenting rejection based on a reference disqualified under the CREATE Act must waive the right to enforce the application separately from the disqualified patent, but . . .
 - Eliminates the requirement to waive the right to license separately
 - Eliminates the requirement of filing a Terminal Disclaimer in the disqualified patent

98



Business Methods Still Patentable...Who Knew?

- Ex parte Lundgren
- “Interim” Guidelines on Patentable Subject Matter

99



Background on Business Methods

- *State Street Bank & Trust Co v. Signature Financial Group*

System that calculates daily net asset value—**patentable**

“We hold that the transformation of data, representing discrete dollar amounts, by a machine through a series of mathematical calculations into a final share price, constitutes a practical application of a mathematical algorithm, formula, or calculation, because it produces a **useful, concrete and tangible** result—a final share price.”

100



Background on Business Methods

- *AT&T Corp. v. Excel Communications*

Method to determine primary interexchange carrier—**patentable**

“In Alappat, we held that more than an abstract idea was claimed because the claimed invention as a whole was directed toward forming a specific machine that produced the **useful, concrete, and tangible** result of a smooth waveform display.

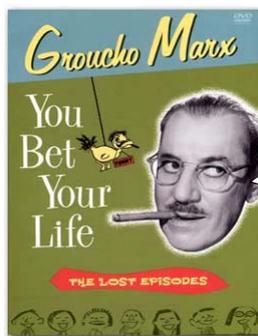
Thus, we are comfortable in applying our reasoning in Alappat and *State Street* to the method claims at issue in this case.”

101



Ex parte Lundgren

- Patent application on “method of compensating a manager” based on performance of company relative to peers.



102



Ex parte Lundgren

- Examiner admits that invention produces “useful, concrete, tangible result”
- But then rejects claims as not being in “technological arts”
- Board of Patent Appeals and Interferences: Reverses

“Our determination is that there is currently no judicially recognized separate ‘technological arts’ test to determine patent eligible subject matter under § 101. We decline to create one.”

103



PTO Responds to Ex parte Lundgren

- Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility
- Directs examiners to identify “practical application” by
 - Transformation of article or physical thing into a different state; or
 - Production of useful, concrete, tangible result
- “Useful”: specific, substantial, and credible
- “Tangible”: limited to a specific physical implementation or state
- “Concrete”: reproducible result

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Interim Guidelines

- Examiners **may not** use certain patentability tests
 - “technological arts”
 - “mental steps” or “human steps”
 - Freeman-Walter-Abele “mathematical algorithms”
 - “machine implementation”
 - “per se data transformation”

105



Careful Claim Drafting Remains Key

- A claim that recites both a system and method for using that system is invalid.
- *IPXL Holdings, L.L.C. v. Amazon.com, Inc.*, 2005 U.S. App. LEXIS 25120 (Fed.Cir 2005).
- “The **system of claim 2** wherein the predicted transaction information comprises both a transaction type and transaction parameters associated with that transaction type, and **the user uses the input means** to either change the predicted transaction information or accept the displayed transaction type and transaction parameters.”

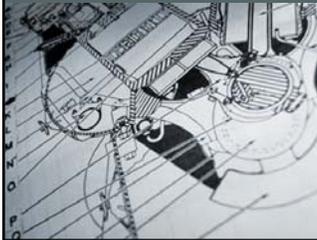
106

Reexaminations before the U.S. Patent and Trademark Office

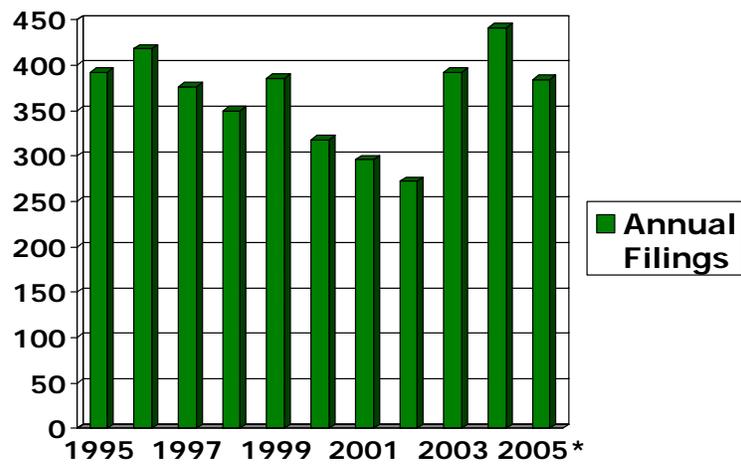
The Process
Continues to Evolve

Rajiv Patel

Rimma Budnitskaya



Ex Parte Reexamination Filing Data

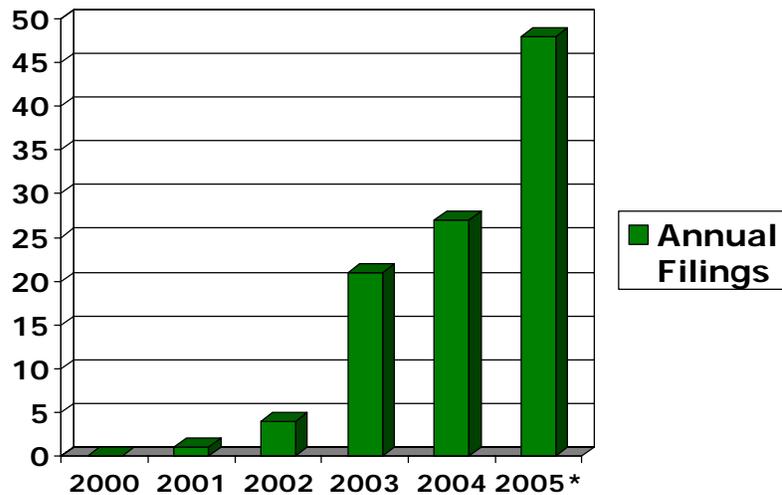


* Through June 30, 2005

108



Inter Partes Reexamination Filing Data



* Through June 30, 2005

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Update on Reexaminations

- 21.7 months
Average pendency of *ex parte* reexamination requests (from filing date to issuance of a reexamination certificate)
- 22.9 months
Average pendency of *inter partes* reexamination requests (from filing date to issuance of a reexamination certificate)

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Update on Reexaminations

- Where we may be going:
 - More companies looking for alternatives to patent litigation to challenge some patents
 - Inter partes* reexam gained momentum in 2005—half of the 101 requests were filed in 2005
 - Congress may still need to address collateral estoppel issues with *inter partes* reexam

111



Update on Reexaminations

- Streamlining of Reexams continues at the USPTO—New rules govern filing of a second/subsequent request for reexam while the earlier filed reexam is still pending
- The substantial new question (SNQ) for a second / subsequent request for reexamination **must be new and different** than any SNQ that was raised, or existed, during any prior pending or concluded reexamination proceeding
- Reliance on prior art cited in the pending reexamination proceeding (old art) does not preclude the existence of the SNQ exclusively based on that old art
- Determination will be upon a fact-specific inquiry done on a case-by-case basis

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Update on Reexaminations

- New rule adapted to eliminate the practice of filing additional reexamination requests for the purpose of prolonging the examination proceedings
- As a consequence, a patent owner will now be prevented from obtaining entry of an amendment by filing another request for reexamination based on the same substantial question of patentability raised/existing in the pending reexamination proceeding

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Update on Reexaminations

- To provide relief to the patent owner, USPTO plans to propose a revision to the patent rules to provide for the filing of a request for continued reexamination (RCR) which would be similar to the request for continued examination (RCE) practice for applications

114



Update on Reexaminations

- Until these new rules become effective, patent owners can use either:
 - (1) the petition procedure under 37 CFR 1.181 to seek review of a denial of entry of an amendment; or
 - (2) the petition procedure under 37 CFR 1.182 to seek relief that is not currently provided by an existing rule, but that would be provided when a new request for continued reexamination (RCR) practice is in effect

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Update on Reexaminations

- Introduction of new rules that aim at eliminating subsequent reexamination requests that raise the same substantial new question of patentability, may lead to:
 - Filing more requests for continued reexamination once this practice is in effect; and

116



Update on Reexaminations

- USPTO will have to allocate more resources to perform a fact-specific inquiry to determine whether any subsequent request for reexamination based on old art raises SNQ of patentability (for example, USPTO will have to determine whether old art is presented in a new light, in a different way, as compared to its use in the earlier examination proceeding, in view of a material argument or a new interpretation).

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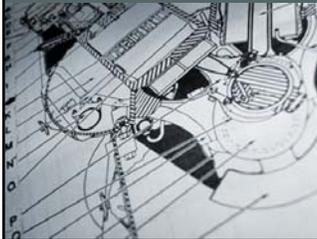


FENWICK & WEST LLP

Ethics Issues in Patent Law

Document Retention
and Prefiling
Investigation

David Schumann





What is spoliation?

- Willful destruction of evidence or a failure to preserve potential evidence for another's use in pending litigation

Duty to preserve evidence;

Nevertheless, intentionally destroyed evidence.

Rambus, Inc. v. Infineon et al, 222 F.R.D. 280, 287-88 (E.D. Va. 2004) ("Rambus I").

119



Duty to Preserve

- When does the duty to preserve documents arise?

During pending litigation;

When litigation is reasonably anticipated

- "[A]rises not only during litigation, but also extends to the period before litigation when a party **reasonably should know that the evidence may be relevant to anticipated litigation.**" *Silvestri v. General Motors Corp.*, 271 F.3d 583, 591 (4th Cir. 2001).
- "[S]ome notice that documents were potentially relevant" to litigation. *Rambus, Inc. v. Hynix et al*, Case No. C-00-20905 (N.D. Cal., January 6, 2006) ("Rambus II")

120



Duty to Preserve

- "Once a party reasonably anticipates litigation, it has a duty to suspend, as to documents that may be relevant to the anticipated litigation, any routine document purging system that may be in effect; failure to do so constitutes spoliation." *Rambus I*, 222 F.R.D. at 280, 287-88.
- "The duty to preserve evidence . . . does not extend beyond evidence that is relevant and material to the claims at issue in the litigation." *Rambus II* at 38 (citing *Zubulake*, 220 F.R.D. at 217-218).

121



Document Retention Policy

- "A legitimate consequence of a document retention policy is that relevant information may be kept out of the hands of adverse parties." *Arthur Anderson v. United States*, 125 S.Ct. 2129, 2135 (2005).
- "A document retention policy adopted or utilized to justify the destruction of relevant evidence is not a valid document retention policy." *Rambus II* at 29.

122



Ramifications of Spoliation

- Sanctions

- Monetary:

- Penalties
 - Attorney fees and costs

- Litigation:

- Exclusion of evidence; delay of start of trial; mistrial
 - Issuance of adverse inference jury instruction(s); presumption that disclosure would have been damaging
 - Default Judgment/Dismissal of Claims, SJ Unclean Hands

- Criminal Penalties

- Ethical Violations

123



Two Conflicting Rambus Decisions

- *Rambus v. Infineon* (E.D. Va. 2001-4)
- *Rambus v. Hynix* (N.D. Cal. 2006)

124



Rambus Licensing Campaign

- January – February 1998: Rambus met with counsel to develop licensing plan
- Strategy
 - Notice, Negotiation, Litigation
 - Seek Royalty
- Rambus advised to implement a document retention policy and clean issued patent files

Rambus II at 7-8.

125



Document Retention Policy

- Rambus's reasons for adopting a document retention policy
 - Reduce expense of retrieving electronic data stored on obsolete or corrupted back-up media
 - Reduce search costs in the event that Rambus was someday required to respond to subpoenas or document requests
 - Absence of policy might be cited by a future litigant as evidence of spoliation

Rambus II at 9.

126



March 4, 1998 Strategy Presentation to Board of Directors

- Royalty rate
- No action until DRAM manufacturers were locked into DRAM ramp. (projected to be late '98, but didn't actually happen until early 2000).
- Timetable (4-6 months):
 - Procure customer sample parts
 - Reverse engineering parts and creating claim charts
 - Notify potential infringer
 - Conducting two negotiation/licensing meetings
 - Commence litigation

Rambus II at 11.

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Rambus Document Retention Policy

July 22, 1998	Rambus adopts Document Retention Policy
Sept. 3-4, 1998	First Shred Event.
Aug. 26, 1999	Second Shred Event.
Jan. 2000	Hitachi suit filed.
Aug. 2000	Infineon and Hynix suits filed.
Dec. 2000	Shredding of documents pursuant to office move.

Rambus II at 2, 18, 23.

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Rambus Patent Prosecution Files

April 1999	Rambus instructs patent counsel to clean issued patent files. Conception, RTP, and prior art documents retained.
July 28, 1999	Cleaning of patent files suspended.
February 2000	Patent counsel sends contents of all files selected for cleaning to Rambus.
June 23, 2000	Patent file cleaning resumes.

Rambus II at 21.

129



Rambus's Duty to Preserve

- Did Rambus reasonably anticipate litigation when it implemented its document retention policy in 1998?

Rambus v. Infineon (E.D. Va. 2001): Yes

Rambus v. Hynix (N.D. Ca. 2006): No

130



Rambus's Duty to Preserve

- Both Courts acknowledged that Rambus may have had some valid reasons for enacting its document retention program.

See *Rambus I*, 220 F.R.D. at 286; *Rambus II* at 29-30.

- Issue: Did it do so when litigation was reasonably foreseeable?

Rambus I, 220 F.R.D. at 286: Yes

Rambus II at 30: No

131



Rambus v. Infineon

- "The record shows that Rambus implemented, a 'document retention policy,' in part, for the purpose of getting rid of documents that might be harmful in litigation."

Business plan: after JEDEC patents issue, demand royalties from manufacturers.

Court cited testimony that one reason for the document destruction was that the documents might be discoverable in future litigation.

- "Clearly, Rambus contemplated it might be bringing patent infringement suits during this time frame if its licensing efforts were not successful."

Rambus I, 155 F.Supp.2nd at 682.

132



Rambus v. Infineon

- On March 1, 2005, the court orally granted Defendant Infineon's motion to dismiss Rambus' patent infringement claims based on Plaintiff's spoliation.
- Less than three weeks later, before a written decision could issue, the parties settled the five-year old litigation.

See AP, "*Rambus, Infineon settle long-running patent dispute*" (Mar. 1, 2005).

133



Rambus v. Hynix

- No express definition of "potential litigation" in 9th Circuit
- "when a party should have known that the evidence would be relevant to future litigation." (2nd Cir.).
- "learns that litigation is **probable**"

"**probable**" = "more than a possibility" (ABA Civ. Disc. Std. No. 10, 1999)

Rambus II at 30.

134



Rambus v. Hynix

- “[T]he path to litigation was neither clear nor immediate.”
 - RDRAM ramp was not sufficiently developed
 - Some patents had yet to issue
 - Product samples were not available
 - No claim charts of infringing products
 - No board approval/no litigation budget
 - No DRAM manufacturer had yet rejected Rambus’s licensing terms

Rambus II at 31.

135



Rambus v. Hynix

- “Rambus did not actively contemplate litigation . . . before its negotiation with Hitachi failed, namely in late 1999.”
- “The destruction of documents on the 1998 and 1999 Shred Days pursuant to the policy did not constitute unlawful spoliation.”

Rambus II at 34.

136



Rambus v. Hynix

- Documents Shredded in the December 2000 Office Move?
 - Destroyed after the commencement of litigation (August 2000)
 - Hynix failed to show that they were material to Rambus's patent claims

Rambus II at 35.

137



Rambus v. Hynix

- Patent prosecution files
 - "It is also probable that [Rambus's Document Retention Policy] resulted in the destruction, at a minimum, of notes of inventor meetings and correspondence . . . regarding patent applications."
 - Because Rambus had retained and produced conception, RTP, and prior art docs, Hynix was not deprived of material non-privileged documents.
 - All other documents cleaned from the patent files would have been privileged, and thus, not discoverable.

Rambus II at 38-40.

138



Federal Rule of Civil Procedure 11

- Rule 11 requires an investigation prior to filing a complaint
 - (b) By presenting to the court (whether by signing, filing, submitting, or later advocating) a pleading, written motion, or other paper, an attorney or unrepresented party is certifying that to the best of the person's knowledge, information, and belief, formed after an inquiry reasonable under the circumstances,
 - ...
 - (3) the allegations and other factual contentions have evidentiary support or, if specifically so identified, are likely to have evidentiary support after a reasonable opportunity for further investigation or discovery;

139



Rule 11 – Prefiling Investigation

- Prefiling investigation requirements in patent cases
 - The “key factor in determining whether a patentee performed a reasonable pre-filing inquiry is the presence of an infringement analysis.” *Q-Pharma, Inc. v. Andrew Jergens Co.* 360 F.3d 1295, 1302 (Fed. Cir. 2004).
 - Rule 11 requires, “at a minimum, that an attorney interpret the asserted patent claims and compare the accused device with those claims before filing a claim alleging infringement.” *Q-Pharma at 1300-01.*

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Prefiling Investigation Cases

- Analysis based on advertisements
Centillion v. Qwest et al, 2000 U.S. Dist. LEXIS 846 (S.D. In. 2006).
- Analysis based on paper/article
Pelegriani v. Analog Devices, 2006 U.S. Dist. LEXIS 726 (D. Ma. 2005).
- Prefiling construction of claim terms
Biomedino v. Waters, 2005 U.S. Dist. LEXIS 33629 (W.D. Wa. 2005).
- Reverse engineering of only exemplary product
Monster Cable v. Qwest, 2005 U.S. Dist. LEXIS 23466 (N.D. Ca. 2005).

141



Analysis Using Promotional Materials - Advertisements

- *Centillion v. Qwest*

Qwest alleged insufficient pre-filing investigation b/c Centillion failed to obtain and analyze a copy of accused software (billing analysis software).

Centillion relied on third-party analysis and Qwest's publicly available information (e.g. ads and website).

Court described these documents as "advertising fluff" that required "too many inferences that should have been investigated."

Note: Advertisements alone are generally insufficient evidence of infringement. *View Eng'g.*, 208 F.3d at 985 (Fed. Cir. 2000); Cf. *Q-Pharma v. Andrew Jurgens*, 360 F.3d 1295 (Fed. Cir. 2004) (finding analysis of ads and packaging mat'ls sufficient).

142



Analysis Based on Paper

- *Pelegriini v. Analog Devices*

Court required Pelegriini to demonstrate good faith basis for its inducement claim three years after the commencement of suit and immediately after amending complaint (with leave).

Pelegriini's analysis relied entirely on a paper authored by ADI scientists. (ads also). The paper did not refer to any accused product nor ADI customer.

"Comparing the '069 patent to the descriptions contained in the article is thus useless because the article is completely silent as to 'the accused subject matter' against which the patent must be compared."

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Prefiling Construction of Claim Terms

- *Biomedino v. Waters*

Waters argued that Biomedino's prefiling investigation was not sufficient because Waters and its expert disagreed with the interpretation of some claim terms. ("binding a species substantially specifically" and "molecule bound substantially specifically").

Recognizing that parties frequently dispute the meaning of claim terms, the Court held that disputed claim terms does not establish that plaintiff's claims are frivolous or legally unreasonable.

144

Reverse Engineering of Only Exemplary Product

- *Monster Cable v. Qwest*

Monster Cable reverse engineered one accused product and relied upon descriptions in data sheets for other accused products.

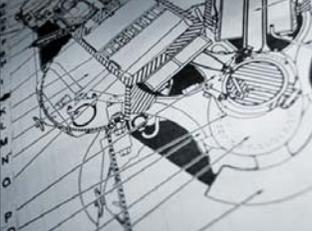
AudioQwest argues Monster Cable must reverse engineer each accused product.

Although reverse engineering a single product will not always be adequate, here the Court found the products similar enough that reliance on data sheets to establish common characteristics sufficient.

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FENWICK & WEST LLP



Ethics Issues in Patent Law

Inequitable Conduct
in Life Sciences
Litigation

Michael Shuster

Novo Nordisk Pharm. v. Bio-Technology Gen'l.

- *Novo Nordisk Pharm., Inc. v. Bio-Technology Gen'l. Corp.*, 424 F.3d 1347 (Fed. Cir. 2005)
- Fed. Circuit affirm's lower court's holding that Novo Nordisk's USPN 5,633,352 is unenforceable due to inequitable conduct
- Finding based on conduct during prosecution and during interference proceeding
- Turned on use of past tense language to describe work not actually carried out (prophetic example)
- Novo presented expert testimony during interference about example, but again failed to disclose that it never successfully performed that work

147

Novo Nordisk Pharm. v. Bio-Technology Gen'l.

- Novo files PCT application in 1983 teaching LAP enzyme to produce product
 - PCT claims priority back to 1982 Danish application
- Novo files application in 1992 teaching DAP I enzyme to produce product
 - Amended to claim priority back to 1982
 - Ultimately issues as '352 patent on May 27, 1997
- Interference with BTG declared July 2000
- BPAI awards Novo priority March 2002
 - Board notes Novo's inconsistent statements re enablement but found BTG's evidence unconvincing

148

Novo Nordisk Pharm. v. Bio-Technology Gen'l.

- BTG appeals BPAI decision (April 1, 2002) and district court eventually reverses
 - 1983 application not enabled because POSITA unable to produce product using application's disclosure
 - Determination based on finding that Novo itself unable to synthesize product using 1983 application disclosure
- Novo sues BTG (April 30, 2002) and BTG counterclaims that patent is invalid and unenforceable

149

Novo Nordisk Pharm. v. Bio-Technology Gen'l.

- Example 1 (1983 PCT) describes production, purification and evaluation of pre-product and treatment with LAP enzyme to obtain product
 - "[t]he fusion product was purified from this extract ... the purified fusion protein was evaluated to be more than 98% pure, ... this product was then treated with leucine aminopeptidase (LAP)"

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Novo Nordisk Pharm. v. Bio-Technology Gen'l.

- But for next five months following filing, Novo's scientists were unable to make product using pure LAP and only succeeded using LAP enzyme prep contaminated with DAP I
 - Discovery leads to filing of 1986 PCT and US counterpart '230 application– DAP I
- 1990 Novo declaration ('230 application)
 - Only LAP from Sigma works
 - Pure LAP doesn't work to convert pre-product to product
- '230 application ultimately goes abandoned – unable to overcome 103 rejection based on Daum patent – disclosing LAP to cleave fusion protein

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Novo Nordisk Pharm. v. Bio-Technology Gen'l.

- Novo then files '856 application (November 1992)
 - Interview to address where 1982 priority document provides enablement
 - Points to 1983 PCT to provide general concept and to Example 1 as specifically directed to claimed product
 - Priority claim back to 1983 PCT and 1982 Danish application used to overcome rejection, resulting in issuance of '352 patent

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Novo Nordisk Pharm. v. Bio-Technology Gen'l.

- Prosecution inequitable conduct
- Conduct—Novo failed to alert examiner that Example 1 steps not performed and that purity result was prediction.
- Materiality

Examiner relied on Example 1 in deciding whether 1983 PCT application enabled invention, allowing priority claim that antedated reference

Novo knew or should have known that examiner would have considered fact that Example 1 was prophetic important in evaluating enablement – especially in light of fact that Novo never succeeded using Example 1 methodology

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Novo Nordisk Pharm. v. Bio-Technology Gen'l.

- Interference inequitable conduct
- Conduct—Novo's failure to inform Board of inability to produce product using Example 1 methodology
- Materiality

Example 1 analyzed for enablement and Novo presented expert testimony on point knowing that Example never successfully performed.

Knew or should have known Example and Testimony material to enablement which was sole focus of interference

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Novo Nordisk Pharm. v. Bio-Technology Gen'l.

- Intent
 - Deceptive intent inferred from failing to disclose prophetic nature of Example 1 to PTI or Board
- Knowledge of law is chargeable to inventor
- Inventors represented by counsel presumed to know the law

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Purdue Pharma v. Endo Pharm. Inc.

- *Purdue Pharma v. Endo Pharm. Inc.*, 410 F.3d 690 (Fed. Cir. 2005)
- Affirms trial court decision of unenforceability for inequitable conduct
- Invention is for a controlled release drug formulation that uses a narrower range of doses (4-fold range) to achieve same clinical results as prior art dosage forms (8-fold range)
- Invention provided easier dose-ranging (titration) cf. prior art formulation
- Issue related to language Purdue used to falsely imply if not suggest that experimental results had been obtained

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Purdue Pharma v. Endo Pharm. Inc.

- Detailed description

"It has now been **surprisingly discovered** that the presently claimed controlled release oxycodone formulations acceptably control pain over a substantially narrower, approximately four-fold [range] (10 to 40 mg every 12 hours-around-the-clock dosing) in approximately 90% of patients. This is in sharp contrast to the approximately eight-fold range required for approximately 90% of patients for opioid analgesics in general."

--USPN 5,549,912, col. 3, ll. 34-41 (emphasis added)

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Purdue Pharma v. Endo Pharm. Inc.

- Rule 56 – Materiality

...[N]ot cumulative to information already of record ... and ...

(2) It refutes, or is inconsistent with, a position the applicant takes in:

- (i) Opposing an argument of unpatentability relied on by the Office, or
- (ii) Asserting an argument of patentability

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Purdue Pharma v. Endo Pharm. Inc.

- Purdue relied on its discovery of four-fold dosage range throughout prosecution as “a prominent, and at times, the only, argument in favor of patentability before the PTO, resulting in allowance of claims.”
*Purdue Pharma, 2004 U.S. Dist. LEXIS 10, 2004 WL 26523, at *24*
- Obviousness response in parent set out “surprising discovery” under headings that included phrases “Surprisingly Improved Results” and “Results Obtained”

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Purdue Pharma v. Endo Pharm. Inc.

- Kaiko declaration in parent: emphasized difficulty of predicting pharmacological characteristics of opioids and cautioned “the most meaningful therapeutic conclusions” should be based on “the results of the most adequate and well-controlled therapeutic evaluations.” *Id.* at 697.
- Declaration referenced attachment (invention disclosure of CIP patents-in-suit) describing clinical studies comparing resulting drug concentrations of controlled release with prior art formulations. Concluded with “Clinical Significance” that lowered dose range was most efficient method of managing pain requiring repeated dosage.

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Purdue Pharma v. Endo Pharm. Inc.

- Repeatedly referred to dosage range as “result” and described same using precise, quantitative, and comparative language
- Noted “clinical significance” in close proximity to a description of clinical studies performed by Purdue, suggesting discovery supported by experimental results
- Arguments to PTO provided enough of suggestion that clinical trials were performed to render failure to disclose that discovery based on inventor’s “insight” and not scientific proof a failure to disclose material information

Material because inconsistent with statements suggesting otherwise

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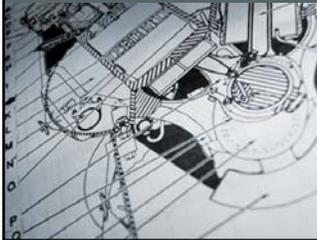


Purdue Pharma v. Endo Pharm. Inc.

Intent

- Purdue argued no intent because of good faith belief in truth of statements re four-fold dosage range and benefits provided
- Intent turned not on belief in truth or actual truth of statements but rather whether there was evidence of intentional withholding of material information as to source of “surprising discovery”
- Consistent/repetitive nature of communications support conclusion that Purdue made deliberate decision to withhold and misrepresent origin of “discovery”

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Patent Law Reform

What's Proposed and
What's Likely to
Happen

Lynn Pasahow
Stuart Meyer



History

- Media coverage of "ailing" patent system
- AIPLA initiatives (e.g., "town hall" meetings)
- 2004-2005 proposals
 - Congressional
 - Industry
- Issues
 - Patent quality
 - Litigation cost
 - Efficiency of the patent system
 - International Harmonization



Context

- Fundamental constitutional balance
 - Teach the world your invention in exchange for limited exclusionary right
- Compare the rest of the world
 - First to conceive/reduce to practice v. first to invent
 - One year grace period
 - No publication
- Three recent reform proposals
 - HR 2795 – Patent law reform (and now S2109 as of December 15, 2005)
 - Judicial committee hearings on qualifying judges for patent cases or creating special patent trial courts
 - PTO rules proposals

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Key Controversial Issues in HR 2795

- Limitations on injunctions
- Post-grant oppositions
- First inventor to file
- Elimination of best mode
- Willful infringement
- Reasonable royalties
- Venue

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House Committee on the Judiciary

- Oversight hearing October 6, 2005 entitled, "Improving Federal Court Adjudication of Patent Cases"
- Observations:
 - High cost of patent litigation
 - District courts reversed 35% of time in patent matters
- Proposals
 - Patent Trial Courts
 - Patent judges (specialists)
 - Patent-certified judges (generalists)

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Patent & Trademark Office Proposal

- Backlog reduction
- PTO turns tables and blames practitioners
- Limitation on number of claims
- Limitation on continuation applications
- Applicants to provide patentability reports
- Written comments accepted through May 3

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Implications of Reform Proposals

- Early application filing
- Third-party submissions/opposition
- Monitoring of published applications
- Forum shopping
- Changes in presumption of validity
- Continuation applications
- Post-grant opposition



Ex Parte Reexamination Filing Data - June 30, 2005

- 1. Total requests filed since start of ex parte reexam on 07/01/81 7611
 - a. By patent owner 3188 42%
 - b. By other member of public 4258 56%
 - c. By order of Commissioner 165 2%

- 2. Number of filings by discipline
 - a. Chemical Operation 2389 31%
 - b. Electrical Operation 2400 32%
 - c. Mechanical Operation 2822 37%

3. Annual Ex Parte Reexam Filings

Fiscal Yr.	No.	Fiscal Yr.	No.	Fiscal Yr.	No.	Fiscal Yr.	No.
1981	78 (3 mos.)	1989	243	1997	376	2005	384 YTD
1982	187	1990	297	1998	350		
1983	186	1991	307	1999	385		
1984	189	1992	392	2000	318		
1985	230	1993	359	2001	296		
1986	232	1994	379	2002	272		
1987	240	1995	392	2003	392		
1988	268	1996	418	2004	441		

- 4. Number known to be in litigation.....1655 22%
- 5. Determinations on requests 7358
 - a. No. granted6702.....91%
 - (1) By examiner 6596
 - (2) By Director (on petition) 106
 - b. No. denied656.....9%
 - (1) By examiner 621
 - (2) Order vacated 35

6. Total examiner denials (includes denials reversed by Director)				727
a. Patent owner requester		419		58%
b. Third party requester		308		42%
7. Overall reexamination pendency (Filing date to certificate issue date)				
a. Average pendency			21.7 (mos.)	
b. Median pendency			17.0 (mos.)	
8. Reexam certificate claim analysis:	Owner	3rd Party	Comm'r	
	<u>Requester</u>	<u>Requester</u>	<u>Initiated</u>	<u>Overall</u>
a. All claims confirmed	23%	29%	13%	26%
b. All claims cancelled	7%	12%	20%	10%
c. Claims changes	70%	59%	67%	64%
9. Total ex parte reexamination certificates issued (1981 - present).....				5129
a. Certificates with all claims confirmed			1337	26%
b. Certificates with all claims canceled			514	10%
c. Certificates with claims changes			3278	64%
10. Reexam claim analysis - requester is patent owner or 3rd party; or Comm'r initiated.				
a. Certificates _ PATENT OWNER REQUESTER				2240
(1) All claims confirmed			521	23%
(2) All claims canceled			161	7%
(3) Claim changes			1558	70%
b. Certificates _ 3rd PARTY REQUESTER				2756
(1) All claims confirmed			799	29%
(2) All claims canceled			327	12%
(3) Claim changes			1630	59%
c. Certificates _ COMM'R INITIATED REEXAM				133
(1) All claims confirmed			17	13%
(2) All claims canceled			26	20%
(3) Claim changes			90	67%



Inter Partes Reexamination Filing Data - June 30, 2005

1. Total requests filed since start of *inter partes* reexam on 11/29/99 101

2. Number of filings by discipline

a. Chemical Operation	25	25%
b. Electrical Operation	29	29%
c. Mechanical Operation	47	46%

3. Annual Reexam Filings

<u>Fiscal Yr.</u>	<u>No.</u>	<u>Fiscal Yr.</u>	<u>No.</u>	<u>Fiscal Yr.</u>	<u>No.</u>
2000	0	2002	4	2004	27
2001	1	2003	21	2005	48 YTD

4. Number known to be in litigation.....27.....27%

5. Decisions on requests 95

a. No. granted	91	96%
(1) By examiner	91	
(2) By Director (on petition)	0	
b. No. not granted	4	4%
(1) By examiner	2	
(2) Reexam vacated	2	

6. Overall reexamination pendency (Filing date to certificate issue date)

a. Average pendency	22.9 (mos.)
b. Median pendency	22.9 (mos.)

7. Total *inter partes* reexamination certificates issued (1999 - present)..... 2

a. Certificates with all claims confirmed	0	0%
b. Certificates with all claims canceled	2	100%
c. Certificates with claims changes	0	0%



FENWICK & WEST LLP

Authorized Generics: Antitrust Issues and the Hatch-Waxman Act

NARINDER S. BANAIT*

An authorized generic (AG) is a pharmaceutical product that was originally marketed and sold by a brand company, but is relabeled and marketed under a generic product name. One problem with AGs is that they do not have to abide by the 180-day market exclusivity provision granted by the Hatch-Waxman Act to the first generic on the market. AGs could thus undercut the public policy rationale underlying the Hatch-Waxman Act, and have the potential of threatening the generic industry as a whole.

An AG, also known as “authorized copy” or “brand-in-bottle,” may be marketed by the brand company itself or through a subsidiary, or the brand company may license the product to another company for marketing in return for royalties. The AG is sold at a lower cost, and as an alternative, to the branded product. The brand companies may choose to launch an authorized generic for a variety of reasons, including to settle patent litigation with a generic company by partnering with it, to participate in the generic market once generic competition starts, or to maintain manufacturing capacity for the drug substance or the drug product. For example, of the 57 largest selling drugs in the United States, more than 30 are scheduled to lose patent protection by 2008, representing total sales of more than \$60 billion. The launching of AGs allows the branded companies to maintain cash flow, albeit at a lowered rate, once generic competition starts. Similarly, generic companies may choose to partner with the brand company to launch an AG to settle litigation, to market a product they otherwise might not have been able to enter, or to increase their product portfolio.

HATCH-WAXMAN ACT

In 1984, Congress enacted Hatch-Waxman with the intent, *inter alia*, to open up the market for products that were previously patent protected. Between 1962 and 1984, approximately 150 drugs went off-patent. However, there were no generic drugs, and the off-patent drugs continued to be sold at high prices. This resulted in a *de jure* and *de facto* ability to exclude beyond the exclusivity provided by the patent term. Generics cost less than the branded drugs. For example, in 2001, the generic prescription drugs totaled 45% of all prescriptions filled at a cost of about \$11.1 billion, while branded drugs totaled 55% of the prescriptions filled at a cost of about \$121 billion, or approximately 91.6% of cost of drugs. The legislative intent of Hatch-Waxman was to balance the competing policy interests of manufacturers of brand-name drugs and those of the generic trade group. The intention was to maintain inducements necessary for the brand companies to research and develop new therapies, and enable lower cost generic products to reach the market.

Hatch-Waxman allowed generic manufacturers to file an Abbreviated New Drug Application (ANDA). The ANDA requires the generic company to demonstrate that its product is “*bioequivalent*” to a referenced NDA’s brand name product. Proof of bio-equivalence for a drug is much easier to establish than the requirements for an NDA: *i.e.*, the *active* (not inactive) ingredients must be proven “bioequivalent” by performing tests on twenty-four people exhibiting blood absorption rates within twenty percent of such rates exhibited for a “pioneer”

brand named drug. Thus, ANDA is a far less expensive process than filing an NDA.

In addition, Hatch-Waxman was a legislative reaction to *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858 (Fed. Cir.1984). In *Roche*, the Federal Circuit, on appeal from the United States District Court for the Eastern District of New York, (572 F. Supp 255 (E.D.N.Y. 1983)), held that:

“Bolar’s intended ‘experimental’ use is solely for business reasons... Bolar’s intended use of [the drug is], to derive FDA required test data, is thus an infringement of the ‘053 patent. Bolar may intend to perform experiments but unlicensed experiments conducted with a view to the adoption of the patented invention to the experimenter’s business was a violation of the rights of the patentee to exclude others from using his patented invention.”

The Federal Circuit refused to construe the experimental use exception to cover activities required for submission to regulatory agencies. Thus, a generic company could not begin the experiments to obtain data required for FDA drug approval until after the expiration of the patents protecting the marketed product. As a result, the protection provided by patents extended beyond the statutory time.

In response to *Roche*, Hatch-Waxman defined the use by a generic manufacturer with the intention to file an ANDA of clinical information already in an NDA as a non-infringing use. The ANDA must reference the NDA of the patented drug listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations*, which is generally known as the “Orange Book.” The Orange Book provides a list of the applicable patents to licensed drugs. In order to reference an NDA, the generic manufacturer must file one of four alternative certifications provided for under Hatch-Waxman:

- **“Paragraph I Certification”- No patent in the NDA.** This certification pertains to a drug listed in the “Orange Book” that does not have an accompanying patent as part of the NDA. *The FDA shall approve any ANDA making this certification.*
- **“Paragraph II Certification”- Term of patent(s) in NDA has expired.** The certification covers an NDA that contains one or more expired patents. *Again, FDA shall approve any ANDA making this certification.*
- **“Paragraph III Certification”- Patent(s) in NDA remains extant.** This certification indicates that the generic manufacturer seeks ANDA approval after the applicable patent(s) expires. *The FDA can only approve an ANDA with a Paragraph III Certification after all patent(s) in the NDA have expired.*
- **“Paragraph IV Certification”- Patent in NDA is alleged to be invalid or the generic equivalent product does not infringe.** By using this certification a generic manufacturer can either challenge the validity of applicable patents in the NDA or certify that the generic equivalent product will not infringe any patent held by the pioneer drug company whose patent(s) is part of the NDA. The generic manufacturer contemporaneously with its Paragraph IV Certification must notify the innovator manufacturer that it is filing a Paragraph IV certification with its ANDA.

Under Hatch-Waxman, as originally enacted, the first generic company that filed an ANDA obtained a period of 180 days during which it could exclude any other prospective generic market entrant from marketing the same generic product based upon the same pioneer drug. The 180-day exclusivity commenced upon a generic manufacturer’s first sale of the generic after receiving the FDA’s approval of its ANDA. However, under the original Hatch-Waxman provision, if the generic company holding the exclusivity period never

put the drug up for sale, all other generic manufacturers who have filed an ANDA for the same drug would be precluded from marketing another generic version of the same pioneer drug.

The 30-month stay ordered by the FDA upon the filing of a Paragraph IV Certification lawsuit could result in substantially delaying the marketing of a generic drug. The filing of the infringement suit triggered the “30 month stay” period. During this period the FDA cannot approve the ANDA until the earlier of: (1) the date the patent expires; (2) a court determination of non-infringement or patent invalidity; or (3) 30-months after notification to the patent holder of the Paragraph IV Certification. The 30-month stay results from the filing of an infringement suit by the original patentee within 45 days of the prospective generic manufacturer filing a Paragraph IV Certification. While Hatch-Waxman requires all NDA applicants to list all patents that are part of an NDA for a branded drug in the “Orange Book”, it does not provide a mechanism for ascertaining the accuracy of the listing. There is no way for an ANDA filer to challenge an improper listing of a patent in the Orange Book. The Federal Circuit held in *Mylan Pharmaceuticals, Inc. v. Thompson* 268 F.3d 1323, 60 USPQ 2d 1576 (Fed. Cir. 2001), and affirmed in *Andrx Pharmaceuticas, Inc. v. Biovial Corp.* 276 F.3d 1368, 61 USPQ 2d 1414 (Fed. Cir. 2002) and in *Minnesoat Minin and Manufacturing and Riker Labs, Inc. and Alpharpharm, Ltd. v. Varr Laboratories, Inc.* 303 F.3d 1294, 64 USPQ 2d 1270 (Fed. Cir. 2002) that there is no private cause of action for delisting a patent from the FDA’s Orange Book under the FFDCA. Some companies developed a strategy for unlimited consecutive 30-month stays, thereby keeping generics from ever receiving ANDA approval.

MEDICARE ACT OF 2003

The Medicare Act of 2003 amended Hatch-Waxman in order to address some of these deficiencies and to further reduce the barriers to more generic drugs

entering the marketplace. The new law eliminates multiple 30 month stay periods by providing that ANDA applicants can only provide Paragraph IV Certification in respect of patents listed in the Orange Book at the precise time the ANDA was filed. The new law also prohibits the patent holders from obtaining more than one 30-month stay by including a different patent for a drug that is the subject matter of the ANDA.

The new law requires the company submitting a Paragraph IV Certification to provide notice of the ANDA application to the NDA holder and patent owners within 20 days of the receipt of notice from the FDA that its application has been filed. Previously, the law was silent as to when the ANDA applicant was required to give such notice so that the applicant could file its ANDA without immediately risking patent litigation.

The new law also requires that the NDA holder bring an infringement suit within 45 days against the ANDA applicant. If an infringement action is not commenced, then the ANDA applicant may bring its own declaratory judgment action against the NDA holder. A precondition is that the ANDA applicant must allow the NDA holder to review the confidential ANDA to determine if a patent infringement suite should commence. The ability of the generic company to bring a declaratory judgment action avoids it from going through the regulatory process, receive an approval, and then upon the first sale of the generic product, get embroiled in an infringement suit initiated by the brand company. Thus, the ANDA applicant can better manage the risk of future uncertainties, such as litigation, while seeking FDA approval, prior to its scale-up to manufacture and incurring expenses of marketing a product.

Under the new law, the 180 day exclusivity period does not begin until the first commercial marketing, thereby allowing an ANDA applicant to scale-up its manufacture of an approved drug without sacrificing part of the exclusivity period. Further, the exclusivity period begins upon the applicant’s commercial marketing of either the

NDA product or the ANDA product. This is a subtle point in the new law, and addresses the situation in which a first ANDA applicant agrees to market the brand-name drug instead of its own ANDA product.

The exclusivity period is forfeited under the Medicare Act of 2003 if the first ANDA applicant does not market its drug within 75 days after of the ANDA approval, or if the first applicant's ANDA is withdrawn or deemed withdrawn by the FDA for substantive reasons such as (i) the first applicant amends or withdraws its Paragraph IV Certification, (ii) the Orange Book listed patents expire, or (iii) the ANDA applicant is found to have entered into an agreement that violates the antitrust laws.

The new law further clarifies that if more than one applicant files a "substantially complete" ANDA for a previously unchallenged drug on the same day each shares the same 180 day exclusivity period, and it begins on the first day of marketing by one of the two applicants. This provision moots any question of which application was filed first on any particular day. Further, agreements among ANDA applicants and brand-name drug companies or other ANDA applicants as to the exclusivity period, or the manufacturing, marketing, or sale of the brand-name or generic drug must be filed with the Federal Trade Commission and the Department of Justice within 10 days of execution.

ANTITRUST ISSUES

The law gives a 180-day exclusivity to paragraph IV ANDA filer. The argument for the 180-day exclusivity grant is that companies need an incentive in order to develop generic products and to reward them for taking the risk of an infringement suit. Further, it provides an incentive to the generics to challenge potentially invalid patents. Aside from greater revenues and profits generated during the 180-day exclusivity period, the generic company can also establish itself with a larger customer base thereby retaining a greater market share after the exclusivity ends. Further, it helps the

company develop a brand, enhance reputation in the industry, and increase customer good will. Thus, the 180-day exclusivity period is very important to the generic companies.

The economic and other tangible benefits of the six-month exclusivity are significantly reduced by the introduction of the authorized generic products. The entry of a second generic reduces the revenues of the first generic company by about 80%. The introduction of AG during the 180-day exclusivity period is similar to two generic companies competing for the same market, and reduces the benefit to the paragraph IV ANDA filer. Mylan Pharmaceuticals reportedly lost an estimated \$30 million in revenues when Proctor & Gamble licensed Watson to sell the authorized generic version of nitrofurantoin for urinary tract infection treatment just as Mylan was about to bring its own generic version to the market.

The position of the FDA is that the AGs do not have to abide by the 180-day market exclusivity to the first generic. The FDA reached the conclusion because it lacks the authority to regulate changes in approved products that do not potentially affect the safety or the effectiveness of the product, as in AGs. Moreover, the FDA stated that AGs appeared to promote rather than impede competition. Therefore, the FDA's current policy is to deny petitions to prohibit the sale of AG during the 180-day exclusivity period. (see denial of petition by Mylan Pharmaceuticals, Docket No. 2004P-0075/CP1, and by Teva Pharmaceuticals, U.S.A., Docket No. 2004P-0261/CP1).

The fact that authorized generics may compete with ANDA generic products, even during the 180-day exclusivity period was affirmed by the U.S. District Court for the District of Columbia in *Teva Pharmaceuticals v. FDA* (D.D.C. December 23, 2004), and by the U.S. Court of Appeal for the District of Columbia Circuit (June 3, 2005). The court held that Pfizer may market

its own authorized generic version of its epilepsy drug Neurontin (gabapentin) during the 180-day exclusivity period granted to Teva Pharmaceuticals.

Judge Keeley in *Mylan Pharmaceuticals Inc. v. Food and Drug Administration*, Civ. No. 1:04cv174 (N.D. W. Va.) (filed August 5, 2004; withdrawn without prejudice Aug. 30, 2004), reportedly suggested that there might be antitrust issues with AGs. For one, the introduction of the AGs during the 180-day exclusivity period could be an attempt to remove the economic incentive for paragraph IV certification for other drugs thereby maintaining market share in other brand markets. Secondly, selling the branded product at generic prices could be predatory pricing. However, it could be difficult to prove these antitrust issues.

The generic company will have to show that the introduction of AG is a willful anti-competitive conduct that prevents the generic from fairly competing in the relevant market for the drug. Factually, AGs do not prevent a generic version from being introduced into the market; AGs decrease the revenues and the profits of a generic during the exclusivity period. The generic company is thus able to enter the market, but will likely not reap the economic and non-tangible benefits of being a paragraph IV filer. This will likely not meet the legal test under the Sherman Act.

The second theory of predatory pricing may not be of help to the generic companies either. A predatory pricing claim under §2 of the Sherman Act alleges that the brand company priced its AG in an unfair manner with an object to eliminate or retard generic competition and thereby gain and exercise control over the price. Proving predatory pricing is a two pronged test. The generic must prove that the prices complained of are below an appropriate measure of the brands costs and that the brand had a reasonable prospect of recouping its investments in below cost prices. Thus, even assuming that the generic could show that the price of the AG was below cost, it must also show that

by pursuing this scheme, the brand company had a reasonable prospect of recovering its losses by slowing the growth of the generics. The second prong of the test is hard to meet.

For the particular product for which the exclusivity was granted, additional generic companies will come in after 6 months, thereby further decreasing the price of the drugs. Therefore, the brand company is not likely to be able to increase the price after the 180-day exclusivity period ends. Although the AG causes severe loss to the first generic company, it will be very difficult to show that eventually there will be a rise in prices sufficient for the brand to recoup the costs.

The launch of every paragraph-IV generic expected to be a blockbuster has been met with the availability of an AG since the fall of 2003. This has financially hurt the generic companies, and could work against the public policy of the Hatch-Waxman Act by removing the economic incentive from challenging the validity and enforceability of weak patents. However, the courts have upheld the rights of the brand companies to introduce AGs, and challenging AGs on antitrust issues is likely to fail as well. Congressman Waxman has publicly stated that AG's violate the purpose of the 180-day exclusivity period. Therefore, the best cause for the generic companies might be to work with the government to amend the laws specifically prohibiting AGs during the exclusivity period.

*Narinder Banait is an associate at Fenwick & West LLP in Mountain View, California. His practice focuses on life sciences patent prosecution and patent litigation. He can be reached at nbait@fenwick.com.

THIS UPDATE IS INTENDED BY FENWICK & WEST LLP TO SUMMARIZE RECENT DEVELOPMENTS IN THE LAW. IT IS NOT INTENDED, AND SHOULD NOT BE REGARDED, AS LEGAL ADVICE. READERS WHO HAVE PARTICULAR QUESTIONS ABOUT THESE ISSUES SHOULD SEEK ADVICE OF COUNSEL.

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FENWICK & WEST LLP

Correct Inventorship Prevents Patent Application Headaches

Daily Journal - Oct 8, 2004

BY ROBERT HULSE

Although companies race to the U.S. Patent and Trademark Office to build their patent portfolios, technically, a company is not granted a patent. In the United States, only the inventor or inventors may apply for a patent for their invention.

In common practice, of course, a company usually files a patent application for an invention on behalf of the inventors, usually employees of the company. But this begs the question: Who are the true inventors for a patent application?

Unfortunately, this inventorship question can upset the sensitivities and egos of people within a company, inflaming interoffice politics and dividing research and development teams. Being named an inventor can be a source of pride, and many companies offer financial incentives for employees who submit invention disclosures on their new ideas.

It is not surprising, therefore, that most people would like to be included on a patent application as a joint inventor, even when their connection to the invention is slight. Conversely, being left off a patent application can cause hurt feelings and create resentment. Many of these problems stem from a lack of understanding of patent law — namely, the test for exactly what makes an inventor an inventor.

The inventorship test is designed to answer a narrow legal question, not to recognize in a broad sense all types of employee achievement. As such, there is a fundamental disconnect between what activity constitutes invention and what activity is otherwise meritorious for an employee of a technology company. Knowledge of the legal standard coupled with an understanding of this disconnect should help to resolve the inherent conflicts that can arise with inventorship issues.

The legal standard for inventorship is complex and can be a difficult question even for an experienced patent practitioner. The U.S. Court of Appeals for the Federal Circuit recently recognized, “The line between actual contributions to conception and the remaining, more prosaic contributions to the inventive process that do not render the contributor a co-inventor is sometimes a difficult one to draw.” *Eli Lilly & Co. v. Aradigm Corp.*, 376 F.3d 1352 (Fed. Cir. 2004).

But every day, patent applicants do draw this line, and they often do so incorrectly.

Inventorship is simple when a single person develops a idea unaided by others. That person is clearly a sole inventor. But this sole-inventor scenario is not often found in a company where groups of people work together to develop a product. Joint inventorship issues thus arise, and it becomes necessary to evaluate whether the contribution of each individual in the group constitutes sufficiently inventive activity.

Joint inventorship is provided for in the Patent Act, 35 U.S.C. Section 116, which states in relevant part, “When an invention is made by two or more persons jointly, they shall apply for patent jointly and each make the required oath, except as otherwise provided in this title. Inventors may apply for a patent jointly even though (1) they did not physically work together or at the same time, (2) each did not make the same type or amount of contribution, or (3) each did not make a contribution to the subject matter of every claim of the patent.”

Notably, the Patent Act does not expressly establish a minimum threshold of inventive activity needed to make someone a joint inventor. Anyone who contributes to any aspect of the invention may be a joint inventor, even though that aspect may be only a small part of the overall invention. But because an inventor may contribute to any part of the invention, it is necessary to define the invention with precision.

In a patent application, the invention is defined by the claims. This leads to the corollary that someone can be a joint inventor if that person contributes only a single claimed feature of one claim in a patent application. Of course, if that claimed feature is ever canceled from the application's claims, that person is no longer an inventor.

Although there is no minimum contribution requirement, the law does outline the nature of the contribution required of each inventor. In some areas of patent law, invention is defined as conception of an inventive idea coupled with a reduction to practice to create a working example of that idea. But the Federal Circuit has explained that only the mental aspect of this activity is relevant to determining inventorship: "Conception is the touchstone of inventorship, the completion of the mental part of invention." *Burroughs Wellcome Co. v. Barr Laboratories Inc.*, 40 F.3d 1223 (Fed. Cir. 1994).

As the court held, the inventors are those who thought of the idea, not those who only realized the idea. As such, discovery that an idea works and reduction of that idea to practice are irrelevant for inventorship.

Joint inventorship also requires some element of joint behavior, such as collaboration between or among the joint inventors. As the *Eli Lilly* court explained, "[a] joint invention is the product of collaboration of the inventive endeavors of two or more persons working toward the same end and producing an invention by their aggregate efforts."

While joint inventors need not work directly together at the same time and in the same place, there must be some collaboration or concerted effort between them. For example, a latter worker who was unaware of the efforts of an earlier worker in the same company is not a joint inventor with the earlier worker.

This brief summary of the law illustrates that the inventorship question has many pitfalls, and there are several ways to name inventors on a patent application improperly. But through diligence, companies can watch out for and avoid the more common errors. While not an exhaustive list, many of the common errors involve three types of people who are often misnamed as inventors: the "supervisor," the "implementer," and the "expert."

The supervisor is typically the leader or technical head of a research and development team whose duties include directing development activities of the team and approving

their ideas. The supervisor is therefore intimately involved with the development of the team's new ideas.

As an experienced technologist, the supervisor often provides a general statement of the problem to be solved and guides the efforts of the team in the course of solving that problem. And when the team produces an invention disclosure for a patent application, it is no surprise to see that the supervisor is listed as an inventor.

This is especially true when the researchers come from an academic environment, where attribution for research is more freely given to a lead professor.

The supervisor undoubtedly has played an important role in the development of the new idea. But mere direction of the inventive activity of others is not itself inventive activity, nor is the approval of that inventive activity after it has occurred. Again, inventorship requires conception of the idea, and the typical contributions of a supervisor do not necessarily qualify.

Of course, a supervisor certainly may contribute to the conception of an idea, especially where the invention lies within the high-level concept rather than in the implementation details. However, a supervisor should not be listed as a joint inventor without first identifying such a contribution.

The implementer is another person who is often identified improperly as a joint inventor. The implementer brings to physical reality what others have conceived, often spending a significant amount of time and effort toward that end. But no amount of work can transform reduction to practice of an idea into its conception: "One does not qualify as a joint inventor by merely assisting the actual inventor after conception of the claimed invention." *Ethicon Inc. v. United States Surgical Corp.*, 135 F.3d 1456 (Fed. Cir. 1998).

This result seems unfair, because the implementer may in fact contribute much more time and resources to the product development cycle. But again, one should consider the disconnect between the law and reality: The law of inventorship is concerned with satisfying a legal test, not with bringing the invention to market or making money for the company. Like the supervisor, of course, the implementer may be a joint inventor, but not as a result of the implementation efforts.

For example, many problems are not discovered until an idea is carried out, and the implementer's solution to these problems and other improvements on the original concept may become part of the invention itself. Of course, these improvements are part of the invention only if they are claimed in the patent application.

The expert is another commonly mislabeled inventor. The expert is typically an independent contractor or a university professor who is tapped for the expert's vast scientific knowledge in the field of the invention. Because of the technical nature of the expert's contribution, which directly concerns the subject matter of the invention, the sufficiency of the contribution is rarely questioned. But it should be.

Someone who explains what is known in the art, even if known only by a select few experts, is not an inventor. Explanation of known science is not conception of the invention, which necessarily involves elements or combinations that go beyond the known state of the art. *Hess v. Advanced Cardiovascular Systems*, 106 F.3d 976 (Fed. Cir. 1997). Like the supervisor and the implementer, the expert's contribution to conception of the claimed invention must be clearly identifiable, or the expert is not an inventor.

Unlike intentional errors, an innocent mistake of including or even omitting an inventor does not by itself invalidate a patent. Despite this, however, it is best to resolve the issue correctly before filing a patent application.

Determining the correct inventorship before filing a patent application can foreclose future headaches, including the costs associated with correcting inventorship, or, worse, the cost of litigating the issue if the patent is ever asserted. Improper inventorship also can call the ownership of a patent into question, because every inventor has an equal, undivided interest in a patent unless and until that property interest is transferred by law.

Careful consideration should be made, therefore, not only to include any inventors who contributed to the conception of the claimed invention but also not to misidentify individuals who have not made such a contribution. Last, everyone involved in this determination should recognize the inventorship question for what it is, a legal test, not a measure of a one's worth or contribution to the company.

Robert Hulse is an associate in the intellectual property group of Fenwick & West in Mountain View.

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Extraterritorial Expansion of U.S. Patent Law

BY JAE WON SONG*

With the advent of the global economy, the design, manufacturing, marketing, and sales activities of businesses are being performed increasingly overseas. Naturally, the owners of U.S. patents are increasingly attempting to enforce their U.S. patents against activities carried out at least in part, if not entirely, outside the U.S.

Such attempts at first sight appear futile given the basic principle that U.S. patent rights are confined to the U.S. and its territories and infringement of a U.S. patent cannot be predicated on acts wholly done in a foreign country. See *e.g.*, *Dowagiac Mfg. Co. v. Minn. Moline Plow Co.*, 235 U.S. 641 (1915). However, recent Federal Circuit cases show that such attempts may sometimes be successful. See *e.g.*, *AT&T Corp. v. Microsoft Corp.*, 414 F.3d 1366 (Fed. Cir. July 13, 2005) and *NTP, Inc. v. Research in Motion, Ltd.*, 2005 U.S. App. LEXIS 15920 (Fed Cir. August 2, 2005).

AT&T involves AT&T's U.S. Reissue Patent No. 32,580 and Microsoft's Windows® software. The Windows® software included certain speech codecs which, when installed on a computer, are alleged to infringe AT&T's '580 patent. Microsoft supplied a limited number of master versions of the Windows® software to authorized foreign "replicators," who pursuant to their licensing agreements with Microsoft, replicated the master versions to generate multiple copies of Windows® for installation on foreign-assembled computers. The master versions were created in the U.S. and sent abroad on so-called "golden master" disks or via electronic transmission.

During the course of AT&T's lawsuit against Microsoft for patent infringement, Microsoft moved *in limine* to exclude evidence of purported liability under 35 U.S.C. §271(f), which provides:

"(1) Whoever without authority supplies ... in or from the United States ... the components of a patented invention ... 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 ... in or from the United States any component of a patented invention that is especially made or especially adapted for use in the invention ... knowing that 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."

The motion *in limine* was subsequently converted into a motion for partial summary judgment of noninfringement under §271(f), which the district court denied.

On appeal, Microsoft first argued that software is intangible information that cannot be a "component" under §271(f). However, the *AT&T* court quickly rejected this argument, relying on *Eolas Techs. Inc. v. Microsoft Corp.*, 399 F.3d 1325 (Fed. Cir. 2005). *Eolas* had held that "statutory language did not limit section 271(f) to

patented ‘machines’ or patented ‘physical structures,’” such that software could very well be a “component” of a patented invention under §271(f).

Microsoft’s second argument was that no actual “components” had been “supplied” from the U.S. as required by §271(f), because the foreign-replicated copies of Windows® software, which were made from a master version supplied from the U.S. and installed on the foreign-assembled computers, had all been “manufactured” abroad. The court rejected this argument, stating that given the nature of the technology, for software “components,” the act of copying is subsumed in the act of “supplying,” such that sending a single copy abroad with the intent that it be replicated invokes §271(f) liability for the foreign-made copies. Microsoft’s suggestion that software sent by electronic transmission must be treated differently for the purposes of §271(f) was also rejected; *AT&T* held that liability under §271(f) does not depend on the medium used for exportation. The court’s view was that its interpretation of “supplied ... in or from the United States” of §271(f) in the context of software is consistent with Congress’ motivation for enacting §271(f), i.e., to prevent copiers from avoiding U.S. patents by manufacturing the components of patented products (e.g., the Windows® software) in the U.S. and then shipping them abroad for assembly.

Software companies should pay particular attention to the *AT&T* case, since exportation of software may constitute patent infringement under §271(f), regardless of whether it is in the form of an installation copy or a master copy and regardless of whether it is by a computer-readable medium or by electronic transmission. They should consider the amount of their exposure, if any, from patent infringement arising from exportation of software to foreign countries. Licensors and licensees of software should consider how they should allocate risks of infringing a U.S. patent that could arise from exportation of software to foreign

countries, and incorporate appropriate indemnification provisions in their license agreements.

Another case, *NTP*, involved NTP’s U.S. patents that are directed to integration of e-mail systems with RF wireless communication networks. NTP alleged that Research in Motion (“RIM”), through its BlackBerry system, had infringed its patents under 35 U.S.C. §271(a), which provides:

“... whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention ... infringes the patent.”

In the district court, RIM moved for summary judgment of non-infringement, arguing that it could not be an infringer under §271(a) because the BlackBerry Relay, which was alleged to meet the “interface” limitation in the system claims and the method claims of the NTP patents, is located in Canada and thus the infringing activity did not occur within the United States. The BlackBerry Relay routes email messages from a mail server to a partner’s wireless network for delivery to the user’s handheld device. The district court denied the motion and held that the fact that the BlackBerry Relay is located in Canada does not preclude infringement.

On appeal, RIM contended that infringement under §271(a) can occur only if the allegedly infringing activity occurs within the U.S. and that the standard is not met because the BlackBerry Relay component is housed in Canada. RIM argued that, for §271(a) to apply, the entire accused system and method must be contained or conducted within the U.S.

As to the system claims in the NTP patents, *NTP* held that the use of a claimed system under 271(a) is the place at which the system as a whole is put into service, i.e., the place where control of the system is exercised and beneficial use of the system is obtained. According to the *NTP* court, the use of NTP’s asserted system claims

occurred within the U.S., because RIM's customers located within the U.S. controlled the transmission of the originated information and also benefited from such an exchange of information. Therefore, *NTP* held that the location of the BlackBerry Relay in Canada did not, as a matter of law, preclude infringement of the system claims under §271(a).

As to the method claims in the *NTP* patents, however, a different conclusion was reached. The court distinguished methods or processes from systems in which the components are used collectively. The court stated that a process is a sequence of actions and that the use of a process necessarily involves doing or performing each of the steps recited in the method claims. Therefore, *NTP* held that a process cannot be used "within" the United States as required by §271(a) unless each of the steps is performed within the U.S. Because each of *NTP*'s asserted method claims recites a step that utilizes an "interface" which is only satisfied by the use of RIM's BlackBerry Relay located in Canada, the method claims, as a matter of law, could not be infringed by use of RIM's system. *NTP* also added that RIM's performance of at least some of the recited steps of the method claims as a service for its customers cannot be considered selling, offering to sell, or importing the invention under §271(a).

Companies that operate systems with certain components of the systems located outside the U.S. should be alerted by *NTP*, since *NTP* suggests that the mere presence of certain components of the system outside the U.S. does not preclude patent infringement of system claims under §271(a) so long as control of the system is exercised and beneficial use of the system is obtained in the United States. Simply moving a component of an infringing system outside the U.S. would not avoid patent infringement under §271(a).

Both *AT&T* and *NTP* show courts' willingness to expand the reach of U.S. patent law to cover infringing activity that at least in part occurs outside the U.S. Companies

involved in technology license agreements or patent infringement actions in the U.S. should consider the risks arising from overseas business activities in their license agreements or litigation strategies.

*Jae Won Song is an associate at Fenwick & West LLP in Mountain View, California. His practice focuses on patent prosecution and patent litigation. He can be reached at jsong@fenwick.com.

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Strategic Intellectual Property Planning

STUART MEYER AND CHRISTOPHER TOBIN

The recognition of intellectual property as an intellectual asset, and an asset generally, is paramount to successful strategic intellectual property planning. Intellectual property should be thought of as having the characteristics of an asset, and should be so managed. An effective strategic intellectual property plan will therefore prompt the development, acquisition, maintenance, and exploitation of intellectual property assets, just as a traditional business plan would do with tangible assets. Each piece of intellectual property should be viewed as something that furthers company goals and confers value to its owner. That value may be independently and discretely recognizable, or may be an embedded part of a comprehensive business strategy.

Companies often fail to understand why they should obtain and enforce intellectual property rights. For example, it is common for established companies to have dozens of patents without knowing their value. This is an unfortunate outcome, and leads to corporate legal departments and outside counsel being viewed as cost centers rather than value-producers. The recognition of intellectual property as an asset of the company should be recognized not only by a company's legal department, but also by corporate management.

True strategic planning requires a robust understanding of intellectual property, as well as the characteristics and goals of the company. The specifics of an intellectual property plan will vary widely from company to company, and it would be impossible to provide a single derailed recipe for successful strategic planning that would be applicable to all companies. Therefore the approach here will be to identify several important goals for establishing a viable strategic intellectual property plan.

View the IP Organization as a Profit Center

Corporate legal departments are generally viewed by management as cost centers rather than profit centers.

Simple economics dictates that this should never be the case, and generally such a perception is incorrect. Benefits provided by legal departments are often overlooked. For instance, the cost of writing and negotiating a well-reasoned contract clause may be a known number of attorney hours, but benefits such as the absence of litigation may be difficult for management to recognize and value.

Regarding intellectual property, many companies claim annual licensing revenue of hundreds of millions of dollars; indeed, IBM is reported to have recently generated approximately \$1.5 billion in annual licensing revenue. Moreover, licensing revenue is just a part of the potential value contribution of intellectual property. Others include access to otherwise unavailable technology through cross-licensing, leverage in joint development agreements, and prevention of lawsuits by competitors. Accordingly, it is readily accepted that intellectual property has great value-producing potential, so corporate departments that develop intellectual property should be viewed as one of the many value creating enterprises of an organization.

Create an Appropriate Organizational Infrastructure

The organizational infrastructure for managing a company's intellectual property assets will vary greatly with company size. For example, smaller companies will often wholly delegate the intellectual property asset management function to outside counsel. Larger companies usually have sophisticated legal departments, which often include separate units for handling intellectual property development, litigation and licensing functions.

It can be especially difficult for these larger companies to organize an integrated strategic plan. Although the value of intellectual property on the whole is clear, lower level management will often focus on the short-term bottom line for their particular business unit, and be reluctant to fund the development of intellectual property. For this reason, many larger companies will budget intellectual property

development efforts and manage developed assets in a centralized fashion. This allows the company to leverage the full portfolio in licensing negotiations, in lieu of piecemeal approaches by numerous smaller business units, and allows central control over licensing determinations. Even if these functions are centrally managed, it is critical to integrate with and use the contributions of the individual business units, as 'local knowledge' is often critical for making decisions in the intellectual property management process.

Establish a Culture of Innovation

Efforts to develop intellectual property assets should be integrated throughout an organization. Since developing intellectual property naturally requires intellectual contributions, it is critical for companies to establish an entrenched culture of innovation.

There are many ways for companies to overcome the difficulties in establishing a company-wide innovation culture. For one, high-level management must express clear interest in and support of an intellectual property development program, and indicate that many if not all employees are expected to substantially contribute to the program. This expression should be reinforced with the involvement of multiple levels of management, and the necessary budget and human resources to process potentially inventive contributions.

Several tools can be used to establish the culture of innovation. Aggressive internal promotion using existing vehicles helps to give intellectual property development efforts notoriety and respect within the organization. For example, intellectual property development efforts can be given a prominent presence on the company intranet. Regular, company-wide innovation contests, with monetary awards, prizes and special recognition for winners also help to establish the culture. Even external advertising can help—the Hewlett Packard 'Invent' campaign being a notable example.

Incentive programs are also important for establishing the culture of innovation. Such programs are numerous and varied. For patents, incentives include monetary awards for submission of inventions, and at subsequent milestones. Other incentives, such as providing plaques to employees who are named as inventors on granted patents, are also helpful. Intellectual property development efforts should also be an important element in the employee evaluation process.

'Implementation' awards are also a good incentive, plus they assist in collecting information helpful in valuing intellectual property assets. These awards are given where intellectual property is used in company or competitor products, or is an important part of a revenue-generating license. They provide a natural incentive for employees to submit information about use and potential infringement of intellectual property assets.

Establish a Body for Making Strategic Decisions

A crucial component to intellectual property planning is the establishment of a body for making strategic decisions, preferably in the form of an intellectual property committee (often called a patent committee). The committee may be variously composed, but should incorporate the input of intellectual property attorneys, inventors and managers. Often, the actual committee will include the manager of the intellectual property development program, a number of patent attorneys who respectively handle particular business units whose inventions are being considered, and administrative staff for organizing and recording the results of patent committee meetings. The input from inventors and managers is typically sought prior to an actual patent committee meeting, often using specialized forms that solicit information such as expected potential for obtaining broad patent coverage, pertinence to company products or a previously designated 'key' technology, implementation plans, etc.

Regardless of the composition of the committee, each invention must be carefully and broadly considered, in light of all forms of intellectual property protection. For example, a manufacturing process that is not detectable in a finished product may merit trade secret protection in lieu of patent protection, because infringement would be difficult or impossible to detect. Indeed, a patent would be counterproductive in such a case, as a patent application becomes public when it is granted (18 months after filing in many instances), which means that it would teach competitors how to use an important process to make competing products that would not contain evidence of infringement.

Other developments will merit copyright, trademark, trade dress or other forms of protection. Analogizing once again to other business investments, diversification is essential to the long-term value of an intellectual property portfolio. Consider a company that has taken great precautions to protect the confidentiality of its trade secrets. Even if all of the company's recommended precautions are taken, trade secrecy remains inherently fragile and limited in

scope. Therefore, the company would be wise to consider complementary and supplementary forms of protection. In a product's early development, trade secrecy may provide reliable protection, but later in the product life cycle such trade secrecy may be eroded by reverse engineering or unintended disclosures, whereupon patent protection can remain available. Both published and unpublished works may also be protected by copyright. Therefore, a confidential manual describing a manufacturing process may enjoy copyright and trade secret protection, and the underlying process may also merit patent protection if possible and desired.

Surprisingly, the antithesis of trade secrecy—full public disclosure—may in some situations provide a company with benefits that far exceed those provided by trade secrecy. Many companies choose to disclose immediately fundamental aspects of their technology, and even publish those aspects, in the hope that their technology will be adopted as an industry standard, and in the hope that their publications will prevent or dissuade others from seeking patent protection for identical or similar technology. Typically, these companies rely on their head start in developing the technology and seek to protect themselves from potential competition by providing superior quality and developing market demand for their goods and services. In such situations, trademarks and service marks may be used as legal protection for the goodwill generated by the company in promulgating such technology. As a notable example, Intel, recognizing the existence of 'clone' microprocessors from competitors, developed a program by which computer makers who use Intel microprocessors may label their machines with a stylized logo stating 'Intel inside.'

Intellectual property assets also must be maintained, and should be subjected to regular consideration of whether protection should be sustained, expanded or terminated. For example, a patent committee may reconsider an invention when international patent filings become due for a previously filed patent application. The committee (or another body) may also be responsible for managing ongoing intellectual property development efforts. When patent maintenance fees become due, an assessment can be made as to whether the patent remains useful to the company. The costs for determining the scope of coverage and maintaining patents or other intellectual property should be considered in an intellectual property asset management plan.

Similarly, a company should anticipate possible intellectual property disputes as far in advance as possible. That may entail periodic searches of federal records to discover the patent and copyright activities of competitors, seeking licenses from those developing interesting technologies before the company has a specific need for such technology, and designing around the patents held by companies known to aggressively assert their patent rights.

Develop a Value Extraction Scheme

It would be senseless for a company to develop and acquire a strong intellectual property portfolio without expecting and ultimately receiving some return on its investment. An important part of exploiting value is being able to identify and articulate what the value of an asset is. An intellectual property audit can be used to identify and categorize intellectual property assets and may contribute to a foundation of additional knowledge that is used to exploit the assets.

The most common form of value extraction is through a licensing program. 'Carrot' and 'stick' approaches are often used to describe two basic types of program. In a 'carrot' approach, attractive intellectual property assets are marketed to potential licensors, often bundled with other technology or know how. This offering may be made in areas that the company is not interested in pursuing from a product perspective. Alternatively, they may be presented in light of a strategy to extend a core competency of the company, such as through a joint development agreement. In a 'stick' approach, intellectual property assets are asserted against other companies, often without technology bundling or the expectation of joint development. The stick approach can be used to strictly build a licensing revenue stream, but may also be part of an attempt to gain a competitive advantage in the marketplace for a particular product or service.

Licensing revenue may also be established through the formation of strategic alliances with other intellectual property asset holders. Alternatively, a company may participate in a formal standards setting environment, and submit essential patents for a share of licensing revenue pertaining to the standard.

Value may also be realized through intellectual property asset donations, such as a charitable donation of an intellectual property asset to a qualifying entity for a corresponding tax write off for the fair market value of the asset. Alternatively, an intellectual property asset may

be sold outright, in lieu of licensing, where the covered technology is no longer in an area of company interest. Still further, the property may be used as collateral for financing a product development, possibly in the same field in which the intellectual property was initially developed. Finally, a strong intellectual property asset portfolio confers value by providing recognition as a technology leader, providing a broad bargaining chip for large scale cross licensing negotiations, and acting as a deterrent to aggressive litigation by competitors.

Consider All Asset Management Issues

There are many other intellectual property asset management issues, beyond development, valuation, and extraction. Again, many of these issues are analogous to those confronted with tangible assets. Such concerns are too numerous to catalog exhaustively here, but a few are mentioned as illustrative examples.

One issue concerns where assets will be held. An important and complex issue is whether a separate holding company should be established as the owner of the organization's worldwide intellectual property. Complicated taxation issues will also arise for many intellectual property transactions, both domestically and internationally. Additionally, as accounting standards further recognize the contribution of intellectual property assets to the overall assets of companies, there will be an increasing burden on quantifying that contribution, and a need for expertise as to the treatment of such assets pursuant to a company's financial accounting and reporting obligations.

Allocate Resources Appropriately

It would be foolish to implement an intellectual property plan without considering the level of resources that will be invested to apply to that plan. A proposal for an intellectual property budget should be based on realistic goals rather than an unattainable wish list, with recognition that intellectual property programs often take years to produce an appreciable benefit, and that unanticipated expenses may arise.

Just as 'get rich quick' and 'lose weight fast' schemes often fail, abrupt changes in intellectual property practices often cannot be implemented due to natural constraints imposed by an existing corporate culture. Intellectual property budgets should take this into account by incorporating realistic goals that gradually move the company to better and better procedures.

About the Author

Stuart Meyer is a partner at Fenwick & West LLP. Mr. Meyer specializes in intellectual property matters for technology companies.

If you have any questions about this publication, please contact Stuart Meyer at smeyer@fenwick.com, or call at 650.335.7286.

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International Patent Strategy

BY RAJIV P. PATEL AND NEIL F. MALONEY

Introduction

In today's global marketplace, patent protection continues to be an important part of a company's overall business and intellectual property strategy. However, protection provided by any one patent is limited to within the country in which it was granted. For example, a U.S. patent provides no protection against infringing activities that take place in Great Britain or Japan, or even just over the borders in Canada or Mexico. Thus, to secure patent rights in countries other than the U.S., the company must apply for and be granted patent protection within each particular country of interest. This article provides a basic overview of applying for patent protection outside the U.S. and strategies for determining which countries provide the most value for a particular business.

In reviewing the options below, keep in mind that an application filed in the U.S. may be filed outside the U.S. only under certain conditions. For example, the subject matter of the patent application cannot have been publicly disclosed prior to the effective U.S. filing date. Also, a foreign filing license must be granted by the U.S. government prior to filing the application outside the U.S. Other requirements exist as well, depending on the applicable laws and treaties associated with the countries of interest.

Evaluating Whether to Pursue Protection Outside the U.S.

In deciding whether to obtain patent protection outside the U.S., a company must consider a number of factors. As a preliminary matter, it is important to understand that most foreign filed applications will eventually be published in the U.S. and abroad. As such, a company will forfeit trade secret protection for the subject matter disclosed in a foreign filed application. If, however, the company affirmatively elects

to only file in the U.S., it has the option of maintaining the secrecy of that subject matter until the application issues as a patent. Hence, a company should first decide if publication of the invention before any patent is granted is an acceptable consequence of filing the foreign application.

Next, the company must evaluate in which countries patent protection would likely provide value. Example inquiries for this evaluation include: (1) what countries will products embodying the invention likely be manufactured or sold?; (2) in what countries will other companies likely manufacture or sell competing products?; (3) in what countries will enforcement of patent rights be cost effective and practical? Note that a company's situation may vary by country. Nevertheless, generally foreign patent protection is sought in one or more of the following industrialized countries: Australia, Canada, China, India, Israel, Japan, Korea, Taiwan, and various countries in Europe, including Germany and Great Britain.

Once particular countries are considered for patent protection, the company must evaluate the costs of filing for protection in each country. These costs can be significant depending on factors such as filing fees in the selected countries and translations necessary in countries that do not conduct business in English. Thus, the company must perform a cost benefit analysis to determine what and where patent filings are justified. For ease of discussion, the cost estimates provided herein assume the filing is based on an earlier filed U.S. application.

Pursuing Patent Protection Outside the U.S.

Once it is determined that patent protection outside the U.S. is desirable, there are a number of available options. The

first option is to timely file a patent application directly in the patent office of each country where patent protection is desired. The second option is to file a patent application in a regional patent office. The third option is to file a patent application under the Patent Cooperation Treaty (PCT), to which the U.S. and most other industrialized countries are members. Each option and possible strategies are further described below.

Turning to the first option, in determining whether to file a patent application directly in the patent office of a selected country, a company should consider three factors: (1) certainty with respect to which countries patent protection is desired; (2) a willingness to forgo the option to seek protection in other countries at a later date; and (3) a willingness to pay the associated filing fees and language translation costs, where necessary. Average costs for directly filing an application in a national patent office range from about \$2,000 to \$12,000 per country. The wide range is due to filing fees, attorney fees, and translation costs where necessary. It is important to note these estimates do not include periodic costs to maintain the application and subsequent patent. These fees can range from a few hundred to several thousand dollars. For example, maintenance fees in Japan typically range from several hundred dollars in the first year of a patent term to several thousand dollars in the last year of the patent term.

The second foreign filing option, timely filing of an application directly in a regional patent office, offers economies of scale of examining the application within a single authoritative agency and thereafter formalizing protection in the member countries of the regional patent office. The most well known regional patent office is the European Patent Office (EPO) and its members include Finland, France, Germany, Great Britain, Italy, Sweden, and Spain, among others. For companies seeking protection in France, the EPO is particularly important because France does not allow non-citizens to file an application directly in their country. Hence, the EPO provides the mechanism in which to apply for and pursue patent protection in France.

Filing in the EPO allows the company to submit one application designating any of the member countries of the European Patent Convention instead of filing a separate application in each of the desired national patent offices. The EPO conducts an examination of the application, which

can take several years, and “grants” the patent. Thereafter, the company must “perfect” that grant in the specific member countries of the EPO in which they seek protection. Perfecting the patent grant usually entails paying administrative fees and translating the patent into the appropriate national language. Some countries only require translation of the claims, while others require translation of the entire patent.

From a strategy perspective, if the company is: (1) only interested in European countries; and (2) intends to file in three or more of those countries, then the company should generally file an EPO application designating those countries, rather than filing individual national applications. This allows the company to avoid multiple examination fees, and to defer payment of translation costs until the patent is granted. The cost of pursuing and obtaining an EPO patent grant and perfecting it in three countries typically runs about \$10,000-\$30,000, depending upon the selected countries, the application length, and the duration and extent of the prosecution. Again, as previously noted, these costs are exclusive of fees necessary for maintaining the patent application and patent on a periodic basis.

A third foreign filing option, and probably the most commonly used, is timely filing of an application under the Patent Cooperation Treaty (PCT). Generally, all of the major industrialized countries are members of the PCT. However, a notable exception to PCT membership is Taiwan. Hence, patent protection in Taiwan only can be pursued through a direct national filing (first option) and not a PCT filing.

The primary advantages of a PCT application include delay having to make a decision on where to foreign file a patent application and defer payment of regional or national filing and translation fees. Generally, a company should consider filing a PCT application when any one of the following apply: (1) the company wants to preserve its patent rights in various countries or regions around the world, which are members of the PCT, while assessing the commercial potential of those markets and deferring costs of national or regional patent filings; (2) the company is uncertain of the countries in which patent protection is desired; (3) the company wants to assess the results of the U.S. prosecution before filing in other countries; and/or (4) the company wants to assess the commercial viability of the invention in the U.S. before filing in several countries.

The PCT process is broken into an “international” phase and a “national” phase. The international phase includes two sub-phases, referred to as “Chapter I” and “Chapter II”, the procedures under which have recently changed for PCT applications filed as of January 1, 2004. Chapter I is required, and includes an international preliminary search for prior art. Prior art typically includes public documents that are prior to the priority date of the present application and that appear to disclose in whole or in part the invention of the application. The search is carried out by an international search authority (ISA), which is usually the United States Patent & Trademark Office (USPTO) or the EPO. The search is typically performed within three to nine months of filing the PCT application, and a resulting search report is provided to the company.

The ISA establishes a written opinion based on the search report. The opinion is a preliminary non-binding opinion as to the patentability of the claimed invention. If no Chapter II “demand” is filed, the written opinion is converted into an “international preliminary report on patentability” (IPRP-Ch.1), which is non-binding and has the same content as the ISA’s written opinion. A company may respond to the written opinion, but without a filed demand, the company can only informally comment on the opinion.

If, on the other hand, a demand is filed, then Chapter II commences, where the “international patent examination authority” (IPEA) generally uses the ISA’s written opinion as its initial opinion. Unlike Chapter I, the company can amend the application and formally argue against the written opinion. The IPEA may respond with further written opinions, at its discretion. The IPEA then issues a final “international preliminary report on patentability” (IPRP-Ch.2). This report is also a non-binding opinion as to the patentability of the claimed invention.

Filing an optional Chapter II demand allows the company to formally argue the merits of the PCT application before the IPEA. This may be desirable in order to obtain a favorable IPRP, which may facilitate smooth prosecution at the various national patent offices that show deference to the IPRP. A caveat here is that a few remaining countries still require a demand to be filed in order for the company to defer entry into the national phase. With no timely demand filed, the national phase for these few countries must be entered about 10 months sooner than other countries. Otherwise,

the PCT application will go abandoned. However, this requirement for a Chapter II demand is not applicable to most major member PCT countries in which companies typically pursue protection.

The next phase in a PCT application is the national phase, which is 20 or 30 months from the earliest priority date for most countries. At this time the company must file the application in each region or country where protection is desired, as previously described in the first and second options. Each national patent office may use the PCT search results and/or conduct further searching. A binding examination is then conducted by that patent office, which may or may not provide results similar to the non-binding IPRP, depending on the various patentability requirements of that country and additional prior art that is found.

One strategy some companies employ is simultaneously filing a U.S. patent application and a corresponding PCT application, in which they designate the USPTO as the ISA. Often, the examiner that is assigned to carry out the PCT search is also assigned to examine the U.S. application. Thus, if the PCT search report is favorable, then the examiner may be inclined to grant an early allowance of the U.S. application. Note, however, that this strategy is by no means a sure bet, and a less than favorable PCT search report can just as likely result in an early rejection of all claims. In any event, such strategy may jump start an early prosecution of the corresponding U.S. application, which would otherwise not be examined for two to five years.

Referring briefly to legal costs, the cost of filing a PCT application usually ranges from about \$2,000-\$6,000, depending upon which chosen ISA, the number of countries designated, and the number of pages in the application. In addition, the cost for filing a demand runs about \$1,000-\$3,000, depending upon the chosen IPEA.

Conclusion

A company has various options for pursuing patent protection outside the U.S. Pursuing and securing patent protection outside the U.S. takes on average three to eight years from the initial U.S. filing depending on factors such as the countries in which protection is sought and the legal requirements and procedures for pursuing the application

through issuance before each respective country patent office. In an increasingly global marketplace, companies with long-term vision must seriously evaluate whether patent protection outside the U.S. is a necessary element of their overall patent strategy. With the aide of patent counsel, a company can evaluate the cost-benefit analysis of patent protection outside of the U.S. and determine whether such protection is of value, based on business goals. Thereafter, the company can work with patent counsel to ensure strategic and timely filings of applications outside the U.S. based on their selected options.

Authors

Rajiv P. Patel (650.335.7607, rpatel@fenwick.com) is a partner in the Patent Group of Fenwick & West LLP. **Neil F. Maloney** (650.335.7127, nmaloney@fenwick.com) is Of Counsel in the Patent Group of Fenwick & West LLP.

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Litigation Alert

Patent Infringement Under Section 271(f) and the Exportation of Software – Living in a Material World

HENRY C. SU

On July 13, 2005, the United States Court of Appeals for the Federal Circuit issued an opinion regarding whether the exportation of software code from the United States for distribution and use in foreign markets constitutes an infringement under U.S. patent law. The case, *AT&T Corp. v. Microsoft Corp.*, considered together with the March 2005 decision in *Eolas Technologies Inc. v. Microsoft Corp.*, sets forth the Federal Circuit's current interpretation of 35 U.S.C. § 271(f), as applied to the exportation of software code.

Under *Eolas* and *AT&T*, the exportation of software code may constitute patent infringement under section 271(f) if the software is deemed to be a "component of a patented invention." For purposes of establishing liability under this statute, these cases suggest that it does not make a difference whether the software is shipped overseas as individual, installation-ready copies or as a master copy that can be used to create installation copies. Nor do these cases permit refuge based on whether the software is shipped in a computer readable memory medium (*e.g.*, a CD-ROM) or transmitted electronically (*e.g.*, by email).

Eolas and *AT&T* should be seen as a wakeup call for the software industry because section 271(f) has long been viewed by some as applicable only to tangible components, *e.g.*, the physical parts of a patented machine. A panel of the Federal Circuit now states that software's intangible nature does not exempt it from coverage under section 271(f). Given that a software program often can be viewed as a "component" of a computer-implemented machine or system or a computer-implemented process, section 271(f) may well come into play frequently, providing an independent basis for a claim of infringement by an owner of a software patent. Software companies defending domestic patent infringement actions

will therefore need to consider whether they have exposure arising from the exportation of their software products for distribution and sale abroad.

Furthermore, companies that license software for incorporation into hardware products and systems should consider carefully the scope and limitations of their indemnification provisions. In particular, a hard look should be given to whether the indemnification limits or should limit coverage to domestic sales and excludes or should exclude coverage for claims of infringement based on a combination of the licensed software with other products. Given the increased exposure stemming from *Eolas* and *AT&T*, software licensors and licensees should ensure that their indemnification agreements accurately embody the parties' negotiated allocation of infringement risk.

Section 271(f)

Section 271(f) provides:

- (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 a manner as to actively induce the combination of such components outside 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 compo-

¹ *AT&T Corp. v. Microsoft Corp.* No. 04-1285 (Fed. Cir. July 13, 2005).

² *Eolas Techs. Inc. v. Microsoft Corp.*, 399 F.3d 1325 (Fed. Cir. 2005). The Federal Circuit denied Microsoft's petition for rehearing and rehearing *en banc* on May 3, 2005.

ment is uncombined in whole or in part, knowing that 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.³

Congress enacted this provision of the Patent Act in 1984 to close what was then a loophole in the statute that allowed manufacturers of infringing products to escape infringement by manufacturing the unassembled components in the United States and then shipping the components abroad for assembly into products.⁴

The case that triggered this congressional action was *Deepsouth Packing Co. v. Laitram Corp.*,⁵ in which an unauthorized manufacturer of a patented machine for de-veining shrimp contrived to avoid an injunction against infringement by manufacturing the parts for the machine in the United States and then shipping them overseas in three separate boxes for easy assembly by its foreign customers. The Supreme Court held in 1972 that this ploy avoided the infringement statute in effect at that time because Deepsouth did not make the patented invention in the United States: “We cannot endorse the view that the ‘substantial manufacture of the constituent parts of [a] machine’ constitutes direct infringement when we have so often held that a combination patent protects only against the operable assembly of the whole and not the manufacture of its parts.”⁶

To abrogate this result, Congress enacted section 271(f), which recognized a new species of patent infringement based on the fact pattern in *Deepsouth*. Subsection (f)(1) defines an act of infringement arising from (a) supply in or from the United States of all or a substantial portion of the components of a patented invention and (b) active inducement of an infringing combination of such components outside of the United States. Subsection (f)(2) defines an act of infringement arising from (a) supply in or from the United States of any component of a patented invention that is knowingly and specially made or adapted for use in the in-

vention and (b) intent that such component will be combined into an infringing combination outside of the United States.

Eolas v. Microsoft

At issue in *Eolas* was Microsoft’s Internet Explorer product. Eolas sought to recover damages for Microsoft’s foreign sales of its Windows operating system bundled with Internet Explorer. Microsoft argued that Eolas could not capture foreign sales using section 271(f) because its exportation of golden master disks containing the Windows source code did not constitute the supply of a component of an infringing product. The disk was not itself a physical part of any product; rather, foreign original equipment manufacturers used the disks to copy the Windows code onto computer hard drives that were then sold outside the United States.

Both the district court and the Federal Circuit rejected Microsoft’s argument, holding that the code contained on the master disks was itself a “component of a patented invention” within the purview of section 271(f)(1). Writing for the panel, Judge Rader construed a “patented invention” under section 271(f)(1) to encompass any invention patentable under the Patent Act, which would include computer-implemented processes and computer program products. Even though the “patented invention” in Deepsouth’s case was a machine, the court reasoned, Congress clearly did not limit the statute’s application to just patented machines.

Judge Rader then reasoned that if a computer program product is a “patented invention,” then the computer readable program code (as claimed in claim 6 of the Eolas patent-in-suit) is a “component” thereof.⁷ Under this reading of section 271(f)(1), the Windows code that can be copied from a master disk onto a hard drive “is not only a component, it is probably the key part of this patented invention” because it functions “as an operating element of the ultimate device.”⁸ Judge Rader readily dismissed the suggestion that the application of section 271(f)(1) should be limited to physical components of machines and other structural combinations. The court noted that the plain language of the statute simply does not support such

³ 35 U.S.C. § 271(f) (2005). *Eolas* focused only on section 271(f)(1) whereas *AT&T* construed both subsections (f)(1) and (f)(2).

⁴ P.L. 98-622, Title I, § 101(a), 98 Stat. 3383 (Nov. 8, 1984).

⁵ 406 U.S. 518 (1972).

⁶ *Id.* at 528.

⁷ The patented invention in *Eolas* is a browser that can be used in a fully interactive environment (e.g., viewing news clips or playing games on the Internet).

⁸ *Eolas*, 399 F.3d at 1339.

a reading—that a “component of a patented invention” must be tangible. Moreover, software and hardware are “practically interchangeable in the field of computer technology” because in a functioning computing machine, “software converts its functioning code into hardware and vice versa.”⁹

AT&T v. Microsoft

In *AT&T*, Microsoft again argued that section 271(f) did not apply to its exportation of golden master disks containing the Windows source code to be replicated abroad. The Federal Circuit again upheld the application of section 271(f) to the exportation of Microsoft’s Windows code for assembly and use abroad, although this time Judge Rader dissented.

Microsoft had already lost the argument that its Windows software could not be a “component of a patented invention” under section 271(f).¹⁰ However, it argued in the alternative that even if Windows were a component, no such components were “supplied in or from the United States” because the copies of the Windows program that were actually installed on the computers assembled abroad had themselves been made abroad by licensed foreign replicators. Judge Lourie, writing for the panel, focused his opinion on the infirmities of Microsoft’s second argument.

Judge Lourie decided that the word “supplied” in the statute must be construed in accordance with “its ‘ordinary, contemporary, common meaning,’ which is necessarily context-dependent.”¹¹ In other words, in the context of software distribution, one must consider how software is typically supplied. The court held that software is typically distributed by providing one copy from which multiple copies can be made. “Accordingly, for software ‘components,’ the act of copying is subsumed in the act of ‘supplying,’ such that sending a single copy abroad with the intent that it be replicated invokes § 271(f) liability for those foreign-made copies.”¹² In Judge Lourie’s view, Microsoft cannot read the statute to exclude what is clearly an efficient and expedient method of distributing software—sending one master copy

for subsequent replication instead of sending a separate disk for each copy to be sold overseas.

The court also rejected Microsoft’s argument that the result would be any different if the Windows code were sent by electronic transmission instead of by shipment on a golden master disk. The disk is simply a container for transporting the component; all that matters is that the component in question—in this case, software code—has been exported. Because the software is intangible, it lends itself to an alternative medium for exportation not available to physical components, namely electronic transmission. But the end result is the same: an exportation of a component of a patented invention in violation of section 271(f).

Judge Lourie concluded by pointing out that section 271(f)’s remedial nature justifies a liberal reading that captures Microsoft’s exportation of the Windows code. The court cannot “[permit] a technical avoidance of the statute by ignoring the advances in a field of technology—and its associated industry practices—that developed after the enactment of § 271(f). It would be unsound to construe a statutory provision that was originally enacted to encourage advances in technology by closing a loophole, in a manner that allows the very advances in technology thus encouraged to subvert that intent.”¹³ Nor can the court be concerned with “Microsoft’s impassioned recitation of a parade of horrors that may befall the domestic software industry—such as the relocation of manufacturing facilities overseas[.]”¹⁴

Judge Rader’s Dissent.

Ironically, Judge Rader, who wrote the *Eolas* decision, disagreed with the holding in *AT&T*—that the mere exportation of a single, master copy that is then used to make multiple installation copies of a software program violates section 271(f). His disagreement with the majority centered on the meaning of “supplied,” which he interpreted to mean something other than an act of “copying,” “replicating” or “reproducing.” In his view, “one cannot supply one hundred components of a patented invention without first making

⁹ *Id.*

¹⁰ The patented invention in *AT&T* is a speech codec, a software program that encodes a speech signal into a more compact form for transmission and then decodes the signal back into its original form.

¹¹ *AT&T*, slip op. at 5.

¹² *Id.*

¹³ *Id.* at 8-9.

¹⁴ *Id.* at 9

one hundred copies of the component, regardless of whether the components supplied are physical parts or intangible software.”¹⁵ In other words, “supplying” components for assembly abroad presupposes that the requisite number of copies has already been manufactured and been present in the United States for sale or exportation.

Judge Rader thus chastised the majority for doing exactly what one is not supposed to do when construing and applying the Patent Act—enforcing it in a discriminatory manner against software as a distinct field of technology. The fact that software is easier to make and transport does not justify a special definition of “supplying” that encompasses a subsequent act of making more copies abroad from a single master supplied from the United States. Were the component in question a physical part, section 271(f) could not be read to capture 100 copies of the part that had been manufactured abroad. Only those copies that had been manufactured and then “supplied in or from the United States” would fall within the statute.

In Judge Rader’s view, the majority has improperly imbued the Patent Act with extraterritorial reach over manufacturing or copying activities occurring wholly abroad. “Section 271(f) protects foreign markets from domestic competitors. Section 271(f) does not, or at least did not until today, protect foreign markets from foreign competitors.”¹⁶ The latter protection should come from foreign patents.

Limitations to *Eolas* and *AT&T*? Consider *Pellegrini*

A 2004 Federal Circuit decision that Microsoft cited in support of its argument in both *Eolas* and *AT&T*, albeit unsuccessfully, does appear to set some outer boundaries for liability under section 271(f)(1). *Pellegrini v. Analog Devices, Inc.*¹⁷ concerned the alleged infringement of Pellegrini’s patented brushless motor drive circuits by the combination of Analog’s integrated circuit chips with other components

for brushless motors. Pellegrini invoked section 271(f)(1) as the basis for Analog’s infringement.

The problem with Pellegrini’s theory was that Analog’s chips (the supplied components of the patented invention) were manufactured exclusively outside the United States (in Ireland and Taiwan) and were never shipped to or from the United States. Accordingly, the chips were never physically present in the United States such that they could be said to be “supplied in or from the United States.” Judge Lourie, writing for the panel that also included Judge Rader, held that section 271(f)(1) “applies only where components of a patent invention are physically present in the United States and then either sold or exported ‘in such a manner as to actively induce the combination of such components outside the United States in a manner that would infringe the patent if such combination occurred within the United States.’”¹⁸

The fact that Analog is headquartered in the United States, conceives and designs the chips in the United States, and supervises from the United States the overseas fabrication, assembly, testing, marketing, sale and shipment of the chips does not change this conclusion. “The plain language of § 271(f)(1) focuses on the location of the accused components, not the accused infringer.”¹⁹ Moreover, the statute’s use of the term “supplied” “clearly refers to physical supply of components, not simply to the supply of instructions or corporate oversight.”²⁰

Pellegrini thus allows a line to be drawn between the supply of a “component,” whether tangible or intangible, and the supply of instructions. It raises the question whether the transmission of an integrated circuit design (e.g., in the form of RTL code) for manufacturing use overseas would constitute infringement under section 271(f). If the finished integrated circuit itself is the “component” in question, then the mere provision of design specifications for such a circuit might not be viewed as supplying a component of a patented invention in or from the United States.

¹⁵ *Id.*, slip op. (Rader, J., dissenting) at 3.

¹⁶ *Id.* at 8.

¹⁷ *Pellegrini v. Analog Devices, Inc.*, 375 F.3d 1113 (Fed. Cir.), cert. denied, 125 S. Ct. 642 (2004).

¹⁸ *Id.* at 1117.

¹⁹ *Id.*



Tyler A. Baker

Partner, Litigation Group

Co-Chair Antitrust and Unfair
Competition Group

Chair, Appellate Group

Phone: 650.335.7624

Fax: 650.938.5200

E-mail: tbaker@fenwick.com

Emphasis:

Antitrust

Intellectual Property

Complex Civil Litigation

Appellate

Tyler A. Baker is a partner in the Litigation Group of Fenwick & West LLP, a law firm specializing in the representation of high technology companies, corporate taxation, and complex litigation. Fenwick & West is headquartered in Mountain View, California, with offices in San Francisco. Mr. Baker's practice is focused on complex litigation, with a primary emphasis on antitrust and intellectual property law. He has represented both plaintiffs and defendants in civil antitrust trials and has represented individuals and companies that were targets in state and federal antitrust investigations. He has provided antitrust advice to clients on a wide variety of issues, including distribution practices, joint ventures, premerger notification, and substantive merger reviews by the Department of Justice and the Federal Trade Commission. As described below, Mr. Baker has extensive litigation experience in addition to antitrust.

Among the clients he has represented are:

- Barclays Global Investors, N.A.
- Intuit Inc.
- Macromedia, Inc.
- Symantec Corporation
- The Coca-Cola Company

Mr. Baker is one of six California lawyers recognized in *The International Who's Who of Competition Lawyers and Economists 2005*. He also has been recognized as one of the leading antitrust lawyers in the United States by *Best Lawyers in America*, Euromoney Legal Media Group's *Guide to the World's Leading Competition and Antitrust Lawyers*, and Chambers USA's *America's Leading Lawyers for Business*, and as one of the leading dispute resolution lawyers in the United States by *Global Counsel Handbooks*. Prior to joining Fenwick & West, Mr. Baker was a partner in Carrington, Coleman, Sloman & Blumenthal LLP in Dallas, Texas. Based on surveys of lawyers and clients, he was named the "Go-To Lawyer" in Texas for antitrust by *Texas Lawyer* magazine, one of the "Best Lawyers in Dallas" for antitrust by *D Magazine*, and a "Texas Super Lawyer" by *Texas Monthly* magazine.

In addition to antitrust and trade regulation, Mr. Baker has significant experience in intellectual property cases, including trade secrets, trademarks, trade dress, unfair competition, and related business torts. He has also represented clients in a number of other types of cases, including breach of contract, fraud, misrepresentation, breach of fiduciary duty, lender liability, bankruptcy fraud, tortious interference with contract, and federal "whistle blower" cases. He has been involved in numerous appeals in state and federal courts including the Ninth Circuit, and has argued in the Fifth Circuit and several Texas state courts of appeal.

Mr. Baker's experience spans a diverse range of businesses, including the automotive industry (transportation, warranties, and rental cars), book publishing, computer software, data processing, electrical generating equipment, farm equipment, fashion accessories, financial asset management, health care (hospitals, clinics, medical practice specialties, pharmaceuticals, and medical equipment and supplies), insurance, investment banking, light rail systems, mining, motion picture exhibition, packaging equipment, the petrochemical industry (oil and gas production and pipelines, asphalt production and distribution, natural gas processing, drilling bits, and gasoline distribution and retailing), photo finishing, recreational vehicles, semiconductors, shopping center leasing, soft drinks, telecommunications equipment, trading cards, and wine and liquor distribution.

Mr. Baker received his undergraduate education at Southern Methodist University, where he was president of the student government and class valedictorian and graduated with a B.A. with highest honors in economics. He attended Oxford University as a Rhodes Scholar, graduating with a B.A. in Jurisprudence with First Class Honors. He attended American law school at Stanford Law School, where he was a member of the Board of Editors of the Stanford Law Review and graduated with highest honors.

After receiving his law degree, Mr. Baker served as a law clerk to U.S. Judge Charles Renfrew in the Northern District of California. He then served as a law clerk to Justice Lewis F. Powell, Jr. during the 1976 Term of the United States Supreme Court. Mr. Baker was the law clerk with principal responsibility for the Court's opinion in *Continental T.V., Inc. v. GTE Sylvania Inc.*, 433 U.S. 36 (1977), a case that led to important changes in the antitrust law of vertical restrictions.

From 1978 to 1981, Mr. Baker was a law professor at the University of Virginia School of Law, where he taught courses in antitrust, trade regulation, business torts, intellectual property, and torts and wrote on antitrust issues.

From 1981 to 1982, Mr. Baker served as Special Assistant to William F. Baxter, Assistant Attorney General for the Antitrust Division of the United States Department of Justice. He had primary responsibility for the 1982 revision of the Antitrust Division Merger Guidelines. The analytical framework in the 1982 Merger Guidelines still forms the core of the merger policy of the Department of Justice and the Federal Trade Commission and has been adopted by many courts as the correct way to define markets and evaluate market power for mergers and other types of antitrust cases. For this work, the Attorney General of the United States awarded Mr. Baker a Special Commendation for Outstanding Service.

Mr. Baker speaks and writes frequently on a variety of antitrust subjects. He has addressed the Conference Board, the Dallas Bar Association, the Antitrust Law Section of the American Bar Association, The University of Texas Corporate Counsel Program, The New England Antitrust Law Conference, The Southern Methodist University Antitrust Program, the Sedona Antitrust Conference, and the UCLA Institute on Mergers and Acquisitions. His articles have appeared in the *University of Virginia Law Review*, the *Antitrust Law Journal*, the *Sedona Conference Journal* and the *Texas Lawyer*. He has been a contributing editor to the following publications of the Antitrust Law Section of the American Bar Association: *Monograph No. 12, Horizontal Mergers: Law and Policy* (1986); *Monograph No. 23, The Rule of Reason* (1999); and the *2000 Annual Review of Antitrust Law Developments* (2001).

Mr. Baker is a member of the American Law Institute and the Stanford Law School Board of Visitors. He is admitted to practice in California and Texas and numerous federal courts, including the United States Supreme Court.



Narinder S. Banait, Ph.D.

Associate

Intellectual Property Group

Phone: 650.335.7818

Fax: 650.938.5200

E-mail: nbanita@fenwick.com

Emphasis:

Patent Prosecution

Patent Analysis

Patent Counseling

Patent Litigation

Intellectual Property Due Diligence

Narinder S. Banait is an associate in the Intellectual Property Group of Fenwick & West LLP, a law firm specializing in high technology and bioscience matters. Fenwick & West is headquartered in Mountain View and San Francisco, California.

Dr. Banait has legal, and technical experience representing companies in pharmaceutical, biotechnology, and high technology areas that include pharmaceuticals, polymer based inks, photomasks, nanotechnology, chip manufacture, microfluidics, microarray, and genomics. Dr. Banait has represented clients including:

- AGY Therapeutics
- Admunex Therapeutics
- Agilent Lifesciences
- Granite Global Ventures
- Incyte Genomics
- Iconix
- Quantum Dots
- Vanguard Ventures

Dr. Banait has published over a dozen scientific papers in peer reviewed journals. In addition, he has written and prosecuted patent applications related to polymers, peptides, carbon nanotubes, photochemistry, chemical processes and method of manufacture, small molecule and oligonucleotide drug candidates for the treatment of CNS disorders, telomerase inhibitors, treatment for cancer and osteoporosis, and applications on synthetic methods.

Organization and Community Participation

- American Bar Association
- California Bar Association
- EPPIC

Dr. Banait received his undergraduate education at University of Toronto, graduating with a B.S. in chemistry and biochemistry. He received a M.S. in synthetic chemistry and a Ph.D. in organic chemistry, both from the University of Toronto. Dr. Banait was a Post-doctoral fellow at Brandeis University, and at University of California. In addition, he worked as a research scientist at Syntex Research, a pharmaceutical company that was acquired by Roche, where he primarily focused on 5-HT₃ antagonists for the treatment of emesis and anxiety disorders. He received his J.D. from the Santa Clara University in 1997.

Dr. Banait is a member of the State Bar of California and is registered to practice before the U.S. Patent and Trademark Office.



Daniel R. Brownstone

Senior Associate

Intellectual Property Group

Phone: 415.875.2358

Fax: 415.281.1350

E-mail: dbrownstone@fenwick.com

Emphasis:

Strategic Counseling

Patent Prosecution

Intellectual Property Due Diligence

Patent Litigation

Daniel R. Brownstone is a senior associate in the Intellectual Property Group of Fenwick & West LLP. Mr. Brownstone is resident in the firm's San Francisco, California office. With an emphasis on patent strategic counseling and prosecution, Mr. Brownstone's practice also includes intellectual property due diligence and patent litigation.

Among the companies he has represented are:

- Apple Computer, Inc.
- Cisco Systems, Inc.
- Good Technology, Inc.
- Google, Inc.
- Harrah's Entertainment, Inc.
- Hewlett-Packard Company
- Intuit Inc.
- Isis Pharmaceuticals, Inc.
- Symantec Corporation

Mr. Brownstone received his undergraduate education at Duke University, graduating with an A.B. in computer science and economics. He received his J.D. from Washington University in St. Louis. Mr. Brownstone was a legal intern in the United States Senate, where he worked on the Judiciary Committee for Senator Russ Feingold.

Mr. Brownstone's combined backgrounds in computer science and economics give him a unique perspective on patent strategy. His practice emphasizes patent portfolio development based on identifying innovations that are economically strategic to the enterprise, and managing the creation of patent assets to maximize the value of those assets.

Mr. Brownstone is a member of the California Bar, the Federal Circuit Bar and the U.S. Patent Bar.



Rimma Budnitskaya

Associate

Intellectual Property Group

Phone: 415.875.2401

Fax: 415.281.1350

E-mail: rbudnitskaya@fenwick.com

Emphasis:

Patent Prosecution

Patent Counseling

Rimma Budnitskaya is an associate in the Intellectual Property Group of Fenwick & West LLP, a law firm specializing in high technology matters. Ms. Budnitskaya practices out of the firm's San Francisco, California, office. Her practice concentrates on patent prosecution and patent counseling. Ms. Budnitskaya is registered to practice before the U.S. Patent and Trademark Office.

Among the clients she has represented are:

- Alpha Blox
- Fast Chip
- Excite@Home
- Hal Computers
- Canon

Ms. Budnitskaya received her undergraduate education at Moscow Institute of Economics, graduating with a B.S. in computer science and applied mathematics in 1991. She attended law school at Golden Gate University School of Law, graduating with a J.D. with Highest Honors in 1999. While attending law school, she was a member of the Golden Gate University Law Review and the recipient of American Jurisprudence Awards in Criminal Law, Community Property and Debtor's and Creditor's Rights. Ms. Budnitskaya also earned CALI (Center For Computer Assisted Legal Instruction) awards in Legal Writing and Research and Bankruptcy Law.



Darren E. Donnelly

Partner

Litigation and
Intellectual Property Groups

Phone: 650.335.7685

Fax: 650.938.52000

E-mail: ddonnelly@fenwick.com

Emphasis:

Intellectual Property

Patent Litigation

Technology Litigation

Darren E. Donnelly is a partner in the Litigation and Intellectual Property Groups of Fenwick & West LLP, a law firm specializing in high technology matters. Mr. Donnelly practices out of the firm's Mountain View, California office. His practice focuses on patent, technology, and intellectual property litigation and counseling with emphasis in technical computing, telecommunications and inter-networking, and interactive television. The clients Mr. Donnelly has represented include:

- Amazon.com, Inc.
- Cognos, Inc.
- Electronic Arts
- Imedia CSI PTE Ltd.
- Orckit Communications, Inc.
- RespondTV, Inc.
- VIA Technologies, Inc.

Mr. Donnelly is admitted to practice before the United States Patent and Trademark Office. In addition to preparing and prosecuting patent applications in the U.S. and abroad, he has counseled companies on patent portfolio development and management, patent licensing strategies, and patent enforcement strategies.

Mr. Donnelly received undergraduate degrees from Stanford University in mathematical and computational science and economics. He received an M.S. from Stanford where his graduate work focused on the design of intelligent decision systems. He attended law school at Santa Clara University, graduating with a J.D. in 1997.



Robert A. Hulse

Associate

Intellectual Property Group

Phone: 415.875.2444

Fax: 415.281.1350

E-mail: rhulse@fenwick.com

Emphasis:

Patent Prosecution

Intellectual Property Counseling

Patent Litigation

Robert A. Hulse is an associate in the Intellectual Property Group of Fenwick & West LLP, a law firm specializing in high technology matters. Mr. Hulse is resident in the firm's San Francisco, California office. His practice involves prosecuting patents in various technical fields, including electronics, computer software, telecommunications, business methods, and medical devices. He also has experience in intellectual property counseling and litigation.

Mr. Hulse was awarded his Juris Doctor in 2000 from the University of California, Davis School of Law. From 1999 to 2000, he served as the Senior Articles Editor of the U.C. Davis Law Review. His note, *Patentability of Computer Software After State Street Bank & Trust Co. v. Signature Financial Group, Inc.: Evisceration of the Subject Matter Requirement*, is published at 33 U.C. Davis. L. Rev. 491 (2000).

Mr. Hulse received a B.S. in 1996 from Harvey Mudd College, where he double-majored in engineering and economics. He was a Charter Member of the national engineering honors society *Tau Beta Pi*. Mr. Hulse completed his economics major at Claremont-McKenna College. He later received a master of engineering degree in 1997 from Harvey Mudd College, which awarded him a Harvey Mudd College Fellowship.

Before joining the firm, Mr. Hulse was an associate at Lyon & Lyon LLP. He also worked as a systems engineer at Hughes-Avicom International, where he designed in-flight entertainment systems for commercial aircraft.

Mr. Hulse is a member of the California Bar and is registered to practice before the United States Patent and Trademark Office.



Heather N. Mewes

Associate

Litigation Group

Phone: 415.875.2302

Fax: 415.281.1350

E-mail: hmewes@fenwick.com

Emphasis:

Patent Litigation

Pre-litigation Counseling

Heather N. Mewes is an associate in the Litigation Group of Fenwick & West LLP, a law firm specializing in high technology matters. Ms. Mewes practices out of the firm's San Francisco, California, office. Her practice emphasizes intellectual property litigation, including patent, copyright and trademark matters. Among the companies she has represented are:

- Lexar Media, Inc.
- Macromedia, Inc.
- O₂ Micro
- Ocular Sciences, Inc.

Ms. Mewes received her J.D. from the University of California at Berkeley, Boalt Hall, *Order of the Coif*. At Boalt, she served as the Editor-in-Chief of the *Berkeley Technology Law Journal* and as a member of the *California Law Review* and the Moot Court Board. Ms. Mewes received her B.S.F.S. in science and technology in international affairs from Georgetown University, *Phi Beta Kappa*.

Ms. Mewes clerked for the Honorable William C. Bryson, United States Court of Appeals for the Federal Circuit. She is admitted to practice in the courts of the State of California, in the Northern, Central and Eastern Districts of California, and in the Court of Appeals for the Federal Circuit.

Ms. Mewes is a member of the State Bar of California.



Stuart P. Meyer

Partner

Intellectual Property and
Litigation Groups

Phone: 650.335.7286

Fax: 650.938.5200

E-mail: smeyer@fenwick.com

Emphasis:

Patent, Copyright, Trade Secret
Protection

Strategic Intellectual Property
Planning

Intellectual Property Litigation

Intellectual Property Audits

Counseling in Related Areas

Stuart P. Meyer is a partner in the Intellectual Property and Litigation Groups of Fenwick & West LLP, a law firm specializing in high technology matters. Mr. Meyer counsels clients on intellectual property matters, including technology-based litigation, performing strategic intellectual property planning and intellectual property audits for high technology companies, and securing patent, copyright, and other intellectual property rights. Mr. Meyer is a registered patent attorney and practices regularly before the U.S. Patent and Trademark Office.

Mr. Meyer's client portfolio includes a wide variety of high technology companies, from small start-ups to multinational public companies. Mr. Meyer has also represented other organizations prominent in high technology, such as the Massachusetts Institute of Technology, for which he served as counsel in litigation involving the so-called RSA encryption patent, considered to be fundamental to data privacy. Significant corporate clients he has represented include:

- A.C. Nielsen
- Apple Computer
- Canon R & D Center America
- Cisco Systems
- Compuware
- Glaxo Wellcome
- Intuit
- Sun Microsystems
- Symantec

Mr. Meyer has been a guest lecturer on copyright law at the University of California's Boalt Hall School of Law. He has contributed to books and authored numerous articles on intellectual property law. He is frequently invited to lecture on this topic throughout the United States and abroad.

Mr. Meyer was an electrical engineer with an engineering consulting firm in the telecommunications area before entering law school. He received his B.S. in Electrical Engineering from Carnegie Mellon University, his M.S. in Electrical Engineering and Computer Science from Princeton University, and his J.D. from Yale Law School.

His affiliations include the Computer Law Association (of which he is a member of the Board of Directors); the American Intellectual Property Law Association; the American Bar Association Section on Patent, Trademark & Copyright Law; the Association for Computing Machinery; and the Institute of Electrical & Electronics Engineers.



Charlene M. Morrow

Partner

Litigation and
Intellectual Property Groups

Phone: 650.335.7155

Fax: 650.938.5200

E-mail: cmorrow@fenwick.com

Emphasis:

Intellectual Property Litigation

Patent Litigation

Charlene M. Morrow is a partner in the Litigation and Intellectual Property Groups in the law firm of Fenwick & West LLP, a law firm specializing in high technology matters. Fenwick & West has offices in Mountain View, California and San Francisco, California. Ms. Morrow's practice emphasizes litigation, including patent, copyright, trademark and trade secret matters, and general commercial matters, both at the trial court level and on appeal. Among the companies she has represented while at Fenwick & West are:

- Apple Computer, Inc.
- Information Storage Devices, Inc.
- Ocular Sciences, Inc.
- Macromedia, Inc.
- Scenix Semiconductor, Inc.

Ms. Morrow received her undergraduate degree *summa cum laude* from the University of Southern California, *Phi Beta Kappa*, and her law degree from the University of California at Berkeley, Boalt Hall School of Law, where she was the Senior Notes and Comments Editor for the *High Technology Law Journal*, received the Prosser Prize in Computer Law, and was elected to the *Order of the Coif*.

Following law school, Ms. Morrow clerked for the Honorable William W. Schwarzer, United States District Court for the Northern District of California. She is admitted to practice in the courts of the State of California, in the Northern, Central and Eastern Districts of California, in the District of Arizona and in the Ninth and Federal Circuit Courts of Appeals. She is a President Emeritus of the San Francisco Bay Area Intellectual Property Inn of Court. She also speaks and writes regularly on intellectual property issues and is one of four intellectual property litigators mentioned in "Crisis Management: 28 Experts to Call When All Hell Breaks Loose," *Corporate Legal Times* (Jan. 2003).

Ms. Morrow was recently lead trial counsel in back-to-back patent cases in Delaware for client Macromedia, Inc.

Reported decisions in matters Ms. Morrow handled include *LG Elecs. Inc. v. Q-Lity Computer Inc.*, 211 F.R.D. 360, 372 (N.D. Cal. 2002) (denial of third party discovery); *Microchip Technology, Inc. v. Scenix Semiconductor, Inc.*, 2000 U.S. App. LEXIS 14131 (Fed. Cir. 2000); *Apple Computer, Inc. v. Articulate Sys. Inc.*, 234 F.3d 14 (Fed. Cir. 2000); *Atmel Corp. v. Information Storage Devices, Inc.*, 198 F.3d 1374 (Fed. Cir. 1999) (construction of means-plus-function claim); and *Atmel Corp. v. Information Storage Devices, Inc.*, 1998 U.S. Dist. LEXIS 17564 (N.D. Cal.).

Presentations and publications by Ms. Morrow include: "Issues re Expert Disqualification," *California Litigation* (Spring 2004); "Structuring International Activities with U.S. Patent Law in Mind," *Patent Strategy & Management* (Sept. 2002); "New Claim Construction Arguments on Appeal," *Fed. Cir. Bar Association Conference Proceedings* (May 2001); "Willfulness and Opinions of Counsel," *PLI Patent Litigation 2001*; and "Special Considerations in Settling Patent Cases," *California Litigation* (March 2000).

In 2003, Ms. Morrow spoke on patent trials at the ABA IP Section Conference 2003 and on working with experts at the AA litigation Section Conference.



Lynn H. Pasahow

Chair, Litigation Group

Chair, Patent Litigation Group

Phone: 650.335.7225

Fax: 650.938.5200

E-mail: lpasahow@fenwick.com

Emphasis:

Intellectual Property Counseling,
Litigation and Licensing

BioScience, Software and Internet
Technologies

Lynn H. Pasahow is chair of the Litigation Group and leads the firm's Patent Litigation Practice at Fenwick & West LLP. His practice focuses on patent and other intellectual property litigation, counseling, licensing, and mediation, principally relating to bioscience, software, and Internet technologies. Mr. Pasahow led the team that obtained a jury verdict upholding Cetus' patents on its Nobel Prize-winning polymerase chain reaction invention, and the team enforcing Amazon.com's 1-Click® patent against Barnesandnoble.com. Among his licensing projects is the University of California's portfolio resulting from Dr. Stanley Prusiner's prion-related research.

Mr. Pasahow's clients have included Abbott, Amazon.com, American Express, Aradigm, Athena Neurosciences, Celera, Cepheid, Cetus, Chiron, Cognos, BDM International, Eastman Kodak, Elan, First Data Corp., Genentech, Informatica, Iomega, Large Scale Biology, Lockheed-Martin, NeXT, Pillar Point Partners, Quantum Dot Corporation, Stanford University, Topaz Technologies, University of California, VIA Technologies, Vysis, Warner-Lambert, and Xoma.

Mr. Pasahow is a director of the Bay Area Bioscience Center and the Alzheimer's Association of Northern California, and a member of the advisory board of the University of California's Berkeley Center for Law and Technology. He is also a member of the board of directors of the Boalt Hall Alumni Association. He received his undergraduate degree from Stanford University in 1969 and his law degree from the University of California at Berkeley in 1972. Following graduation, he was a law clerk for the Honorable A.J. Zirpoli, United States District Court for the Northern District of California. He regularly lectures about intellectual property law subjects to groups that have included the Federal Judicial Center, American Association for the Advancement of Science, American Law Institute, Practising Law Institute, and Boalt School of Law. He is among the intellectual property lawyers included in The Best Lawyers in America.

Mr. Pasahow is a member of the State Bar of California.



Rajiv P. Patel

Partner

Intellectual Property Group

Phone: 650.335.7607

Fax: 650.938.5200

E-mail: rpatel@fenwick.com

Emphasis:

Patent Counseling

Patent Analysis

Patent Prosecution

Patent Litigation

Intellectual Property Counseling

Intellectual Property Licensing

Intellectual Property Audits

Intellectual Property Due Diligence

Rajiv P. Patel is a partner in the Intellectual Property Group of Fenwick & West LLP. His practice includes patent portfolio development and management, patent enforcement, and patent and high technology transactions. His practice also includes intellectual property (“IP”) audits and strategies to help companies identify, evaluate and protect key intellectual assets.

In patent portfolio development and management, Mr. Patel has counseled, prepared and prosecuted patents in a wide range of technology areas including wireless communications, electronics, network processors, complex hardware architecture, complex software architecture, electro-mechanical devices, and business methods. He has advised and initiated patent reissue and reexamination strategies and proceedings. He has also partaken in appeals before the Board of Patent Appeals and Interferences. In addition, Mr. Patel is active in developing and overseeing strategies involving foreign patent prosecution and procurement, including for Europe, Japan, China, Taiwan, and India.

In patent enforcement, Mr. Patel litigated in technology areas that include solid-state memories, electronic gaming, Internet delivery networks, and interactive television. In patent and IP transactions, he has negotiating large patent and other IP portfolios, evaluated IP portfolios for acquisition, and conducted diligence for venture funding, mergers & acquisitions, and initial public offerings.

Among the clients Mr. Patel has represented are:

- Logitech, Inc.
- Compuware Corporation
- Fujitsu Ltd.
- Magma Design Automation
- Plaxo, Inc.
- Canon Research Americas, Inc.

Mr. Patel is an Adjunct Professor of Law at the University of California, Hastings College of the Law where he teaches a course on patents. Mr. Patel is also on the faculty of Practising Law Institute and Law Seminars International. In addition, Mr. Patel has authored articles in the field of patent and IP portfolio development and management strategies.

Mr. Patel received his Bachelor of Science (with high honors) in Electrical Engineering from Rutgers University (NJ). He received his Juris Doctor and Master of Intellectual Property from Franklin Pierce Law Center (NH). He is a member of the California Bar and is registered to practice before the U.S. Patent and Trademark Office.

Patent Strategy and Portfolio Development

- Created patent strategy and developing patent portfolio for \$500 million plus product line of a computer peripheral manufacturer.
- Created patent strategy and advised on patent portfolio for on-line auction company. Patent portfolio sold for over \$750,000.
- Evaluated patent portfolio for nanotechnology company in conjunction with industry trends and directions in new technology space where company was shifting focus to and advise on new patent strategy.
- Developing patent strategy and foundational patent portfolio for start-up and early stage and start-up companies in technology fields such as network storage, business process software, and web services.
- Developing and managing patent portfolio for emerging mid-size and large companies in technologies fields such as electronic design automation, processor technology, wireless data communications, optical data processing, and enterprise software tools.
- Sample Patents:
 - U.S. Patent No. 6,246,294 Supply Noise Immunity Low-Jitter Voltage-Controlled Oscillator Design
 - U.S. Patent No. 5,909,151 Ring Oscillator Circuit
 - U.S. Patent No. 5,948,083 System and Method for Self-Adjusting Data Strobe
 - U.S. Patent No. 5,748,126 Sigma-Delta D/A Conversion System and Process Through Reconstruction and Resampling
 - U.S. Patent No. 5,991,296 Crossbar Switch with Reduced Voltage Swing and No Internal Blocking Path
 - U.S. Patent No. 6,055,629 Predicting Branch Instructions in a Bunch Based on History Register Updated Once
 - U.S. Patent No. 6,052,033 Radio Frequency Amplifier System and Method
 - U.S. Patent No. 5,835,852 Integrated Electronic Communication Device and Clip
 - U.S. Patent No. 6,389,405 Processing System for Identifying Relationships Between Concepts
 - U.S. Patent No. 5,995,955 System and Method for Expert System Analysis Using Quiescent and Parallel Reasoning and Set Structured Knowledge Representation
 - U.S. Patent No. 6,275,622 Image Rotation System
 - U.S. Patent No. 6,246,016 Optical Detection System, Device, and Method Utilizing Optical Matching

Highlighted Legal Experience:

Patent and Intellectual Property Transactions

- Led intellectual property audit for Fortune 500 communication company's intellectual property in wireless technology and advised on intellectual property issues in context of tax framework.
- Led intellectual property audit for electronic gaming company and developed intellectual property management structure for company.
- Conducted numerous intellectual property due diligence for high-technology investments by venture capital companies.
- Conducted numerous intellectual property due diligence on behalf of target companies or acquirer companies in high-technology merger and acquisition matters.

Patent Litigation

- *ICTV, Inc. v. Worldgate Communications, Inc.* – advised on patent litigation strategy in interactive television market.
- *SanDisk Corporation v. Lexar Media, Inc.* – patent litigation involving flash memory consumer products.
- *GameTech International, Inc. v. Bettina Corporation* – patent litigation involving electronic gaming.
- *Planet Bingo, LLC v. GameTech International, Inc.* – patent litigation involving casino style games on electronic devices.
- *Akamai Technologies, Inc. v. Speedera Networks, Inc.* – patent litigation involving Internet content delivery services.

Teaching Experience

- Adjunct Professor of Law for “Patent Practice” at University of California, Hastings College of the Law (2001 to present).
- Faculty Member for Practising Law Institute for “Advanced Patent Prosecution,” “Fundamentals of Patent Prosecution,” and “Patent Law for the Non-Specialist” courses (2002 to present).
- Faculty Member for Law Seminars International for “Defending Against Patent Infringement Claims” (2004).
- Course Instructor in “Laws and Emerging Technology” for O’Reilly Emerging Technologies Conference (April 2003).
- Course Instructor in “Intellectual Property Strategies and Management for Federal Publication Seminars (May 2002).

Publications

- Software Escrows as Part of an Intellectual Property Strategy,” Computer Law Association First Asian Conference, Bangalore, India, 2005.
- “Underutilized Patent Reexaminations Can Improve Business Strategy,” Daily Journal, Vol. 110, No. 75, April 19, 2004.
- “Software Outsourcing Offshore – Business and Legal Issues Checklist,” SHG Software 2004 Conference, 2004.
- “A Strategic Look at the Final Rejection,” Advanced Patent Prosecution Workshop, Practising Law Institute, No. G0-10A8, 2003 - 2005.
- “Understanding After Final and After Allowance Patent Practice,” Fundamentals of Patent Prosecution, Practising Law Institute, No. G0-01EV, 2003 -2005.
- “Think Value, Not Cheap, For Long-Term Success,” Succeeding with New Realities, TiEcon 2003, Published by TiE Silicon Valley 2003.
- “The Intellectual Property Audit,” Building and Enforcing Intellectual Property Value, An International Guide for the Boardroom 2003, Published by Globe White Page 2002.
- “Patent Portfolio Strategy for Start-Up Companies: A Primer,” Patent Strategy and Management, Vol. 3, No. 7, Nov. 2002.
- “Potent Portfolio,” Daily Journal, Vol. 106, No. 244, Dec. 15, 2000.
- “Own Idea,” Daily Journal, Vol. 105, No. 10, Jan. 15, 1999.
- “Disclose Lite,” Daily Journal, Vol. 103, No. 55, Mar. 21, 1997.

Organization and Community Participation

- American Bar Association
- American Intellectual Property Law Association
- TiE (“The Indus Entrepreneurs” / “Talent, Ideas, Enterprise”)
- Computer Law Association
- Dean’s Leadership Council for Franklin Pierce Law Center
- Dean’s Committee for Rutgers University, School of Engineering



Robert R. Sachs

Partner

Intellectual Property Group

Phone: 415.875.2410

Fax: 415.281.1350

E-mail: rsachs@fenwick.com

Emphasis:

Strategic Intellectual Property
Portfolio Development

Software Patents

Robert R. Sachs is a partner in the Intellectual Property Group of Fenwick & West LLP, a law firm specializing in high technology matters, headquartered in Mountain View, California.

Mr. Sachs is resident in the firm's San Francisco office and his practice concentrates on strategic patent counseling and prosecution for software technologies. Particular areas of expertise include Internet technologies, multimedia applications, user interfaces, client-server systems, financial products, object-oriented applications and development tools, and EDA. Clients he has represented include:

- Apple Computer
- DreamWorks SKG
- Fannie Mae
- Harrah's Entertainment
- HNC Software
- Intuit
- Incyte Genomics
- Listen.com
- Sun Microsystems
- Vulcan Ventures

Mr. Sachs received his J.D. from Yale Law School in 1990, and has a Masters Degree in software engineering. He received his B.A. in philosophy and his B.A. in psychology from the University of California, San Diego in 1987, where he graduated *summa cum laude*. He received his Masters of software engineering from National University in 1996.

Mr. Sachs is the author of several articles on software patents, including:

"Method Madness" on patenting financial inventions in light of the Federal Circuit decision in *State Street Bank*.

"Global Warning: The Internet's International Nature Presents Complex Patent Problems," on problems in patenting inventions relating to the Internet and E-commerce; and

"Software Support & Analyzing the PTO's Guidelines for Computer Implemented Inventions," analyzing the PTO's 1996 guidelines for examining software patents.



Michael J. Sacksteder

Partner

Litigation Group

Phone: 415.875.2450

Fax: 415.281.1350

E-mail: msacksteder@fenwick.com

Emphasis:

Patent Litigation

Intellectual Property Litigation

Michael J. Sacksteder is a partner in the Litigation Group of Fenwick & West LLP, a law firm specializing in high technology matters. Mr. Sacksteder practices out of the firm's San Francisco office. Mr. Sacksteder's practice focuses primarily on patent litigation, but also encompasses other substantive areas of intellectual property law, including copyright, trade secret, trademark, and unfair competition.

Mr. Sacksteder has participated in trials in United States District Court and has engaged in successful appellate practice before the United States Court of Appeals for the Federal Circuit. He has substantial experience in virtually all aspects of pretrial litigation, including claim construction in patent cases. He has drafted successful motions for summary judgment, engaged in oral argument that led to a favorable claim construction ruling, briefed and argued a successful motion to dismiss in a false advertising case, and helped a client obtain a temporary restraining order and preliminary injunction against the Internet piracy of the client's computer-aided design software. He has also participated in an innovative alternative dispute resolution proceeding that permitted a client to resolve a complex patent dispute without litigation.

Mr. Sacksteder's experience in patent litigation encompasses a variety of technological fields, including semiconductors, computer graphics, mainframe software tools, wireless messaging systems, and optical networks. Representative clients include:

- Cisco Systems, Inc.
- Compuware Corporation
- Good Technology, Inc.
- Macromedia, Inc.
- O₂Micro International Ltd.
- ONI Systems, Inc.
- Apple Computer, Inc.
- Lexar Media, Inc.
- Information Storage Devices, Inc.

Most recently, Mr. Sacksteder served as trial counsel for O₂Micro in the trade secret and patent case *O₂Micro v. Monolithic Power Systems*. The jury awarded O₂Micro \$12 million for the willful misappropriation of O₂Micro's trade secrets and found that all asserted claims of Monolithic Power Systems' patents-in-suit were invalid and not infringed. Shortly before the O₂Micro trial, Mr. Sacksteder served as trial counsel for plaintiff Compuware Corporation in the trade secret, copyright and antitrust case *Compuware v. IBM*. That case was settled in Compuware's favor for \$400 million after being tried to a jury for five weeks.

Mr. Sacksteder received his J.D. *magna cum laude* from Northwestern University in 1997, where he was a member of the Order of the Coif. While in law school, Mr. Sacksteder was editor-in-chief of the Northwestern University Law Review and represented Northwestern in national moot court competitions. Mr. Sacksteder received a B.A. degree, with honors,

from Indiana University in 1984. Prior to attending law school, Mr. Sacksteder worked as a television journalist.

Mr. Sacksteder is a member of the State Bar of California, and is active in the San Francisco Bay Area Intellectual Property American Inn of Court and the Computer Law Association. He is admitted to practice before the United States District Courts for the Northern and Eastern Districts of California and the Eastern District of Michigan, and the United States Courts of Appeals for the Ninth Circuit and the Federal Circuit.



FENWICK & WEST LLP

SILICON VALLEY ► SAN FRANCISCO

David D. Schumann

Associate

Litigation Group

Phone: 415.875.2321

Fax: 415.281.1350

E-mail: dschumann@fenwick.com

Emphasis:

Intellectual Property Litigation

Patent Prosecution

David Schumann is an associate in the Litigation Group of Fenwick & West LLP, a law firm specializing in high technology matters. Fenwick & West is headquartered in Mountain View, California, with offices in San Francisco. Mr. Schumann is resident in the San Francisco office, and his practice includes intellectual property litigation and patent prosecution. He has extensive engineering experience that spans the mobile industrial control, avionics and semiconductor industries. In the area of mobile controls, Mr. Schumann's experience has included system level design and compliance testing of RF products in both narrowband and spread spectrum technologies. His activities in spread spectrum include both direct sequence and frequency hopping techniques. Mr. Schumann has also designed electro-mechanical devices for sensing of rate, position and slope, as well as hardware and software for embedded control applications for the mobile control industry.

Mr. Schumann was also a member of the design team for a fiber-optic gyroscope-based, inertial navigation system. His design activities included design of laser diode stabilizing electronics and hardware to simulate fiber-optic gyroscope outputs for device characterization. He also participated in analog and digital ASIC design and verification.

Leveraging his ASIC design experience, Mr. Schumann worked in the semiconductor industry in the areas of failure analysis and test development. These activities included programming in the Unix and Windows environments.

Mr. Schumann received his J.D. *magna cum laude* from the University of Miami in 2002 where he was an Articles and Comments Editor for the *University of Miami Law Review*. He is also a member of *Order of the Coif*. He received his B.S. in Electrical Engineering *with honors* from the University of New Haven in 1990. Mr. Schumann is a member of the State Bar of California and is registered to practice before the U.S. Patent and Trademark Office.



Michael Shuster, Ph.D.

Partner
Intellectual Property Group

Co-Chair
Life Sciences Group

Phone: 415.875.2413

Fax: 415.281.1350

E-mail: mshuster@fenwick.com

Emphasis:

Biotechnology Patent Prosecution

Strategic IP Counseling

Portfolio Analysis and Due
Diligence

Michael Shuster is a partner in the Intellectual Property Group of Fenwick & West LLP, a law firm specializing in high technology matters. Dr. Shuster is resident in the firm's San Francisco, California office.

Dr. Shuster provides strategic intellectual property legal services to biotechnology and chemical/pharmaceutical companies. His practice includes patent prosecution, portfolio analysis, due diligence, litigation and opinion work. His clients include start-up and established biotechnology companies, venture capital firms and research universities and hospitals.

Dr. Shuster has legal and technical experience in protein and nucleic acid chemistry, high resolution protein structures, proteomics, genomics, combinatorial peptide libraries, vaccine development for viral and autoimmune disorders, transdermal drug delivery systems, liposomal drug formulations and microfluidics devices.

The following are among the clients Dr. Shuster has represented:

- Isis Pharmaceuticals, Inc.
- Eksigent Technologies LLC
- Regents of the University of California (UC)
- University of Southern California (USC)
- Kairos Scientific, Inc.
- Genencor International
- Kleiner, Perkins, Caufield & Byers
- Chiron Corporation

Before becoming an attorney, Dr. Shuster's career experience included graduate research in the laboratory of Professor Eric Kandel at Columbia University as part of a team focused on discovery of mechanisms by which short-term memories are stored, research for which Professor Kandel was awarded the 2000 Nobel Prize in Medicine. Dr. Shuster then moved to the Department of Biochemistry and Biophysics at the University of California, San Francisco, where he pursued his interests in ion channel biophysics and protein structure.

Dr. Shuster received his B.A. from Brandeis University in 1981, *magna cum laude* as well as a Ph.D. from Columbia University in 1986. He received his J.D. *cum laude* from the University of San Francisco School of Law in 1996. Dr. Shuster is registered to practice before the United States Patent and Trademark Office and is a member of the State Bar of California.



Darryl M. Woo

Partner

Litigation Group

Phone: 650.335.7139

Fax: 650.938.5200

E-mail: dwoo@fenwick.com

Emphasis:

Patent Litigation

Intellectual Property Litigation

Darryl M. Woo is a partner in the Litigation Group of Fenwick & West LLP, a law firm specializing in high technology matters. Mr. Woo practices out of the firm's Mountain View, California headquarters and San Francisco office.

Mr. Woo has successfully tried numerous cases to verdict and concentrates his practice on patent litigation and other complex technology litigation, principally in the areas of semiconductors, information technology, life sciences and biotechnology. He has appeared *pro hac vice* as lead counsel in patent litigation across the country, including federal district courts in Arizona, Delaware, Illinois, Massachusetts, Minnesota, Pennsylvania and Texas, on technologies ranging from software to semiconductor fab equipment, voice over IP, fiber optic networking, bio assays, diagnostic tools, medical devices and recombinant DNA. In addition, he has represented a range of clients, including Napster, in copyright, trademark and trade dress infringement cases, trade secret and licensing disputes, unfair competition, trade libel, false advertising, and other complex litigation. Among the companies he has recently represented are:

- Asyst Technologies, Inc.
- Cisco Systems, Inc.
- Google Inc.
- Handspring, Inc.
- Macromedia, Inc.
- ONI Systems Corp.

Mr. Woo has lectured often on trial practice techniques, Internet and e-commerce issues, and other substantive law topics for the Continuing Education of the Bar - California, the Practising Law Institute, and other organizations. He also serves or has served on the boards of directors of a number of charitable organizations, including Sunny Hills Children's Garden and the St. Francis Foundation.

Mr. Woo is a member of the Intellectual Property Sections of the American Bar Association, the State Bar of California and the Bar Association of San Francisco. He is a life member of the Asian American Manufacturers Association and a member of the Mechanics Institute of San Francisco. He previously served as Vice President of Finance and later as chair of the IP section of the National Asian Pacific American Bar Association ("NAPABA"), and previously served on the board of directors of the Asian American Bar Association of the Greater Bay Area.

Mr. Woo is a member of the State Bar of California and is admitted to practice before all federal district courts in California, the United States Courts of Appeals for the 9th and Federal Circuits, and the United States Supreme Court. Mr. Woo received his undergraduate education at the University of California at Berkeley, graduating with a bachelor's degree in biology in 1977. He attended law school at Georgetown University, graduating with a Juris Doctor degree in 1981. Prior to joining Fenwick & West LLP, Mr. Woo was a partner in the Palo Alto office of Cooley Godward LLP.

Representative Engagements

Adobe Systems, Inc. v. Macromedia, Inc.: Mr. Woo represented Macromedia, Inc. as senior trial counsel in these multiple patent litigation matters in the District of Delaware and the Northern District of California. The cases collectively involved seven software patents related to graphical user interfaces and graphics software techniques, sound mixing and WYSIWYG web page creation and editing. Following a May 10, 2002 jury verdict of \$4.91 million in favor of client Macromedia in the Delaware case, the matter settled favorably.

Asyst Technologies, Inc. v. Jenoptik AG, et al.: Represented plaintiff with respect to patents directed to tracking of semiconductor wafers in a SMIF fab. A favorable result for this client on issues related to the proper construction of patent claims under 35 U.S.C. §112, paragraph 6, was obtained before the Federal Circuit, *Asyst Technologies, Inc. v. Empak, Inc.*, 268 F.3d 1364 (Fed. Cir.2001), and the remanded case is now pending in the Northern District of California.

The Procter & Gamble Co. v. The Clorox Company: Represented defendant The Clorox Company in this litigation matter in the Southern District of Ohio involving patents directed to certain aspects of competing household products. The matter settled favorably.

Entelos, Inc. v. Medical Science Systems: Mr. Woo was lead counsel for the plaintiff in this inventorship dispute concerning patents directed to bioinformatics software concerning the prediction of the course of diseases and clinical trial outcomes. Through diligent pre-filing preparation and carefully planned strategy, the case settled favorably almost before it started.

Idexx Labs v. Hansen Vet Immunology, Inc.: Mr. Woo stepped in to take over the lead representation of this patent litigation matter in the Eastern District of California involving diagnostic technologies for the detection of feline immunodeficiency virus. Through refinement and development of existing and additional defenses, he obtained a favorable settlement of this matter on the eve of trial.

MultiTech v. MediaRing.com, Inc.: Mr. Woo was lead counsel for defendant MediaRing.com, Inc. in this case in the District of Minnesota involving patents directed to Voice over IP technology. He was able to obtain a settlement for this client on favorable terms prior to trial.

NCR Corporation v. Handspring, Inc.: Mr. Woo is lead counsel for defendant Handspring, Inc. in this matter pending in the District of Delaware regarding patents asserted against various handheld computing products of the client. The court granted summary judgment for client Handspring, 217 F. Supp. 2d 491 (D. Del. 2002), later affirmed by the Federal Circuit.

Nortel Networks v. Optical Networks, Inc.: Represented defendant ONI Systems Corp. in a multiple patent case involving fiber-optic data networking. As a result of favorable claims construction rulings, the plaintiff dropped all but one of its five patents asserted against the client, and the case later settled favorably.

