Key Patent and IP Issues in M&A Transactions

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Outline of Presentation

1. IP Due Diligence in General
   • Triggering Events
   • Key Issues
   • Attorney-Client Privilege

2. Specific Issues re: Patent Review

3. Other IP

4. Disputes

5. Practice Tips
Part 1. IP Due Diligence in General

- Events triggering IP due diligence
- Types of IP assets
- Key issues in due diligence review
- Attorney-client privilege
Events Triggering IP Due Diligence

• Corporate Deals
  ▪ Purchase/Sale of IP Assets
  ▪ Purchase and Sale of Tangible Assets Having Tag-Along IP Rights or Obligations
  ▪ Private and Public Offerings of Interest in Company
  ▪ Mergers and Acquisitions
  ▪ Joint Ventures
  ▪ Equity Investments
  ▪ Joint Development

• Other Events
  ▪ Launch of New Product
  ▪ IP Dependent- Asset Monitoring
  ▪ Litigation Events
  ▪ Challenges to IP at USPTO – Reexamination, Inter Partes Review, Trademark Oppositions, European Patent Oppositions
Types of IP Assets

- Patents
- Trademarks
- Trade Secrets
- Trade Dress
- Copyrights
- Domain Names
- Moral Rights
- Regulatory Filings
Key Issues in IP Due Diligence Review

- All intellectual property of the company associated with the involved asset or deal
- Any identified intellectual property of a third party that might affect the free sale of the asset, conduct of the business, or consummation of the deal
- Prior art that might affect validity of intellectual property rights
- Any governmental rights – Bayh-Dole march-in-rights? NIH regulatory limitations – regulations on licensing research tools
Key Issues in IP Due Diligence Review

- Agreements affecting the ownership and use of intellectual property
  - Employment Agreements
  - Consultant Agreements
  - Confidentiality Agreements
  - Material Transfer Agreements
  - License and Assignment Agreements
  - Distribution and Franchise Agreements
  - Joint Venture Agreements
  - Settlement Agreements (Litigation & Other Disputes)
  - Merger, Consolidation, Asset Purchase Agreements
  - Governmental Agreements
  - Software Agreements
Key Issues in IP Due Diligence Review

- Governmental filing records
  - Patent specifications
  - File histories of patent and trademarks
  - Copyright registrations – scope
  - Statements made in U.S. files vs. counterpart applications in foreign countries
  - Pre-AIA (2013) Statutory Invention Registrations
  - Continuation and divisional applications
    - Any pending?
    - Any double patenting issues?
Key Issues in IP Due Diligence Review

- Governmental filing records
  - Reexaminations, Post Grant Challenges, Inter Partes Reviews
  - Reissue applications
  - Invention disclosures
  - Patent terms
    - Extensions for Regulatory Delay
    - Extensions under Hatch-Waxman
    - Orphan Drug Extensions
    - Pediatric Exclusivity Extensions
Key Issues in IP Due Diligence Review

• Governmental filing records
   USPTO Assignment and Maintenance Records
   Foreign Annuity Payment Records
   State UCC filings
   IND, NDA, BLA, 351k Application under Biologics Price Competition and Innovation Act of 2009; 510(k)/PMA (medical devices)
Key Issues in IP Due Diligence Review

- Corporate SOPs
  - IP Committee protocol – grading of applications
  - Trade Secret Protection Procedures
  - Confidentiality Agreements SOP
  - Employee Hiring – Bound to Assign Patents & Copyrights;
  - SOP for Employee Severance
  - Non-competes – Validity
  - Protocol for handling Regulatory Notices (e.g. ANDA notices) and FDA warning letters/Form 483;3500A reports (medical devices); FAERS reports(drugs); VAERS reports (vaccines)
  - Advertising and Marketing Compliance – FTC actions; DDMAC warning letters, (pharmaceutical v. medical device – application to restricted medical devices)
  - Marking Compliance
  - IP Compliance – Continual Use of Trademarks, Appropriate Assignment of Goodwill with Mark, Patent Policing
Key Issues in IP Due Diligence Review

• Disputes – Pending and Threatened
  ▪ Formal and informal Notice and Demand Letters Alleging Infringement
  ▪ Pending U.S and Foreign Court litigations/arbitrations – whether complaint served or not
  ▪ Pending and threatened reexaminations, inter partes reviews, and post grant reviews – oppositions overseas
  ▪ Prior settled disputes
  ▪ Patient adverse reports
What About Waiver of Privilege?

- **Common-Interest Doctrine**
  - California has found the doctrine exists when the disclosure relates to a common legal interest and the disclosure is made further to that interest. ([Nidec v. Victor, 249 F.R.D. 575 (N.D. Cal. 2007)](http://example.com))
    - Patent Opinion letter disclosed during negotiations preceding sale of division to third party protected due to common-interest doctrine ([Hewlett-Packard Co. v. Baush & Lomb, 115 F.R.D. 308 (N.D. Cal. 1987)](http://example.com)).
    - **Tenneco Packaging v. S.C. Johnson**, 1999 WL N.D. Ill. 1999 (doctrine applies when opinion subject to confidentiality agreement where limited number of buyer personnel had access)
What About Waiver of Privilege?

- **Common-Interest Doctrine**
  - Must look to law of acquiring company also
    - Some broad, some narrow exceptions
  - E.g. *Libby Glass v. Oneida*, 191 F.R.D. 433 (E.D. Pa 2000), court held trade-dress opinion letter prepared to assuage concerns about a business venture did not qualify under the common-interest doctrine to shield the letter from waiver; *Katz v. AT&T*, 191 F.R.D. 433 (E.D. Pa. 2000) arm’s-length negotiations as being adversarial are precluded under common-interest exception to waiver.
Part 2: Key Issues Related to Patent Due Diligence
Due Diligence with Respect to Patent Claims

• Because of recent case law, important patent claims are now carefully reviewed to assure non-obviousness, enablement, and having written description support

• The subject matter of the claims are now carefully reviewed to assure that the claims are still patentable

• Some claim scopes have changed – Product-by-process claims [*Abbott v. Sandoz*, (Fed. Cir. 2009)] – interpreting claims in accord with *Atlantic Thermoplastics* rather than *Scripps Clinic* case]
Due Diligence with Respect to Patent Claims

• Numerous Patent Cases Decided by Supreme Court in Past 10 years:
  - *KSR International Co. v. Telefex Inc.*, 2007 – subject matter is obvious if there existed at the time of the invention a known problem for which there was an obvious solution encompassed by the patent claims
  - *Microsoft Corp. v. i4i Ltd. Partnership*, 2011 – clear and convincing evidence standard applies to invalidate claims in Court
  - *Bowman v. Monsanto*, 2012 – unauthorized making occurs when farmer reproduces genetically altered seeds
Due Diligence with Respect to Patent Claims

- Numerous Patent Cases Decided by Supreme Court in Past 10 years:
  - *Association for Molecular Pathology v. Myriad Genetics*, 2013 – naturally occurring DNA sequences even when isolated are unpatentable
  - *Limelight Networks v. Akamai Tech*, 2014 – inducement must be tied to underlying direct infringement (unanimous)
  - *Alice Corp. v. CLS Bank International*, 2014 – unanimous decision that set up two step process for determining patentable subject matter – 1. determine if abstract idea, such as algorithm, method of computation or general principle 2. if (1) is in the affirmative – see if claim adds to the idea an inventive concept
  - *Teva Pharmaceuticals USA, Inc. v. Sandoz, Inc.*, 2015 – factual resolutions at district court level can only be overturned by clear error (not de novo review)
Patentability Issues Have Arisen from Supreme Court, and Subsequent Federal Circuit Cases, in Biotechnology and Pharmaceuticals

- Natural products
- Genes
- Highly purified biological materials
- Diagnostic methods
Other Legal Developments Now Question the Validity of Claims Based on Enablement and Written Description Problems

• Written Description Requirement
  ▪ One of skill in the art must be able to visualize or recognize the embers of the genus from the disclosed representative species. *Ariad v. Eli Lilly & Co.*, 598 F.3d 1336 (Fed. Cir. 2010)

• Enablement Requirement
  ▪ Sufficiency of disclosure – claims that cover more than taught to one of skill in the art are not enabled – must disclose full scope of claimed invention without undue experimentation *Alza Corp v. Andrx Pharm.* (Fed. Cir 2010); *MagSil v Hitachi Global* (Fed. Cir. 2012)
Litigation Risks, Strategies and Considerations

- Small Molecule IP (Hatch-Waxman challenges – MMA December 2003)
- Biotechnology IP (Cabilly therapeutic antibody family of patents – interference, reexamination, multiple rounds of litigation, now IPRs)
- Pre or post America Invents Act? (AIA) (March 16, 2013 U.S. moved from first-to-invent to first-inventor-to-file)
  - Applications filed after March 16, 2013 that assert priority before March 16, 2013 – transition applications – all claims must be fully supported by pre-March 16, 2013 specification
- Who are the individual inventors? Was the patent filed while the individuals were employees of the company?
- Effect of number of patents on IPR
International and Cross-Border Issues and Considerations

- European Patent Office and Other Foreign Country Differences in Claim Construction
- Prior Claim Construction Consistency
- Disclosure of all Prior Art
- International Filing Strategies
Part 3: Other IP

- Trademarks/trade dress
- Trade secrets
- Copyrights
Trademark/ Trade Dress

• Importance of checking out trademarks/ trade dress before marketing pharmaceutical/biologics
  ▪ *Astra Zeneca v. Dr. Reddy’s Labs*, 2016 (Nexium purple capsules)

• Trademark policing
Trade Secret

• Reasonable steps to keep secrecy must be undertaken
  ▪ Computerized passwords
  ▪ Lock door/files
  ▪ CDAs and non-use agreements
  ▪ Keeping access limited to those who have “need to know”

• The information must not be generally known to the public and confer some sort of economic benefit on its holder because it is not publicly known
Copyrights

- Assignment of written materials made by employees
- Assurance that software coded by employees assigned to company
- Procedures to protect against misuse of code of another
- Assure employees respect copyright of others
Part 4: IP Disputes
IP Disputes

• Litigation, Oppositions, Reexaminations, Inter Partes Review, Post Grant Reviews affect valuation of IP
• IPR being used as extortion mechanism
  ▪ Hitting patents said by companies to be “important” or “significant”
  ▪ Hitting patentees who win in a litigation
Publicity and Challenges by Activist Investors

- Use of Inter Partes Review (IPR) to pressure stock prices of publicly traded companies
- Recent Examples:
  - “Coalition for Affordable Drugs” (Kyle Bass)
- Strategies to address activist investors
Substantiating Use of IP

- Need to substantiate that products sold are practicing the patented inventions
- Need to substantiate important trademarks are in continuous interstate use
- Make sure continuation applications are pending on important patents
Part 5: Practice Tips for Company or IP Counsel

• Understand the events triggering IP due diligence
• Identify the type of IP and recognize that there may be cross overs
• Key patent issues driven by constantly changing patent landscape
• Follow the money… which entity owns the IP?
• Always be prepared for disputes
Overview

Nancy Yamaguchi focuses her practice on cross-border mergers and acquisitions, venture capital financings, joint ventures and corporate restructuring. She assists US, EU and Japanese companies in strategic acquisitions, investments and all aspects of business and operations around the world.

She also handles technology transactions, including technology and content license agreements, manufacturing services agreements and joint development agreements, and international supply chain transactions, including supply agreements, distribution agreements and contract manufacturing and toll manufacturing agreements.

Nancy was formerly director of M&A for a public company and chief legal officer for a technology company based in California. Having had many years of business experience, Nancy is able to provide customized legal advice and negotiate transactions that are specific and relevant to the technology industry.
Highlights and Representative Transactions

**United States**
- Series of private equity acquisitions and consolidations for micro-cap private equity firm based in San Francisco
- Lead investor counsel for reorganization, bridge loan and investment in biotech/medical company
- Acquisition of and merger into biotech/healthcare company based in Research Triangle, North Carolina
- Acquisition of technology assets and real estate from semiconductor R&D company
- Acquisition of LED company for a public company based in Silicon Valley
- Equity investments by top-tier Silicon Valley venture capital firm in several US Internet and e-commerce companies and biotech/medical companies based in San Diego and Silicon Valley

**United Kingdom**
- Approx. $100 million sale of semiconductor assets, real property and subsidiaries in North Tyneside, United Kingdom to Taiwanese purchaser
- Sale and allocation of tax losses in the UK between US technology company and UK real estate development company

**Japan**
- Sale of $30 million of common stock in Japanese mobile communication company to H&Q Asia Pacific, Goldman Sachs, Sony, Motorola, Tokyo Electric Power, NTT DoCoMo and other US and Japanese investors
- Strategic alliance between entity investments in Japanese public company and Motorola/Freescale
- Sale to Japanese trading company of certain Internet assets of Silicon Valley technology company under Section 363 of the US Bankruptcy Code
- Sale by major Japanese public company of certain telecommunication assets to US technology distributor
- Internal restructuring and asset sales and transfers for Japanese automobile and diesel engine company and debt restructuring agreements with Japanese bank
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**Admitted in:** State of CA, 1996 • State of CT, 1989 • State of NY, 1993

**Year joined:** 2015

**Year became partner:** 2015

**Overview**

Steven’s practice focuses on intellectual property enforcement and defense, including court and administrative action – patent office proceedings (ex parte patent reexaminations, inter partes patent review, trademark oppositions) and ITC. He is also experienced in procurement, licensing, due diligence and counseling, involving diverse intellectual property issues including advertising compliance, anti-counterfeiting, copyrights, domain names, grey goods, patents (utility and design), privacy and data protection, trade dress, trade secrets and trademarks. His litigation and administrative challenge practice has been diverse, running the gamut of technologies involving biotechnology, chemical, electrical, fashion, Hatch-Waxman, mechanical device, medical device and software matters. Steve also carries with him in-house experience, having been the Chief Intellectual Property Counsel for a joint venture ($1.5 billion in sales) between two large pharmaceutical companies. He is licensed to practice in California, Connecticut and New York.

**Recent Publications & Speaking Engagements**

Steve Moore  
Partner, Intellectual Property

Some Recent Patent Litigation Cases

  - Representing Defendant in Hatch-Waxman action concerning fesoterodine (Toviaz®) tablets.

- **Gilead Sciences, Inc. v. Cipla Limited,** Civil Action no. 12-civ-6351 (S.D.N.Y. 2012)
  - Represented client concerning generic Viread® tablet.

- **Monec Holding AG v. Motorola Mobility, Inc.,** Civil Action No. 1:11cv-00789 (D. Del. 2011)
  - Represented plaintiff in a patent dispute involving SIM technology.

- **Abraxis Neodiagnostics, Inc. v. Ikonisys, Inc.,** Case No. 340352 (Maryland Cir. Ct, Montgomery Cnty, 2010)
  - Represented defendant in action alleged theft of trade secrets and incorporation of same into defendant's electronic microscope patented technology related to cancer detection.

  - Represented defendants in Hatch-Waxman action concerning Prevacid ODT®, lansoprazole orally disintegrating tablets. Federal Circuit opinion favorable to Zydus.

- **Radiall SA v. Protokraft LLC,** Civil Action No. 6:09cv00455 (E.D.Va 2009)
  - Represented plaintiff in patent infringement dispute relating to optoelectrical connectors used in aviation.

  - Represented medical device plaintiff in patent infringement and trade secret theft suit regarding intravascular stent.

  - Represented defendant in a patent infringement lawsuit filed by Neural Tandem LLC in telecommunications field.

- **Netratings Inc. v. Tacoda, Inc.,** Civil Action No. 1:2006cv08186 (S.D.N.Y. 2007)
  - Represented defendant in patent infringement case involving electronic monitoring technology.