



INTELLECTUAL PROPERTY AUDIT METHODOLOGY

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INTELLECTUAL PROPERTY AUDITS

WHAT IS AN INTELLECTUAL PROPERTY AUDIT?

BENEFITS OF INTELLECTUAL PROPERTY AUDITS

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WHAT IS AN INTELLECTUAL PROPERTY AUDIT

 **Intellectual Property Audits:**

1. *The identification, evaluation and cataloging of a company's entire intellectual property (IP) portfolio.*
2. *The presentation of the results of such effort in an easily understood format so that at a glance, users of the audit would be able to understand the context and importance of each piece of intellectual property.*
3. *The use of such results as a baseline from which subsequent changes in intellectual property management can be measured.*



BENEFITS OF AN INTELLECTUAL PROPERTY AUDIT

- ❑ *Increasing the value of a company can be attributed to its intellectual property and other intangible assets. Without effective management of these assets, much of this value can be overlooked, poorly leveraged, or even lost.*
- ❑ *Identification and valuation of a company's intellectual property has become a greater concern to management due to recent changes in the securities laws.*
- ❑ *Without accurate information about its intellectual property, a company may be overspending on patent prosecution and maintenance fees, or ineffectively employing limited company resources to the management of intellectual property assets.*
- ❑ *An audit establishes a baseline from which the financial and strategic impact of subsequent changes in intellectual property can be measured.*

METHODOLOGY TO CONDUCT THE IP AUDIT

STEP 1: INVENTORY THE COMPANY'S INTELLECTUAL PROPERTY

STEP 2: GROUP INTELLECTUAL PROPERTY BY CLASS

STEP 3: NAME EACH INTELLECTUAL PROPERTY ASSET

STEP 4: PREPARE PROCESS CHART FOR EACH CLASS OF IP

STEP 5: PREPARE A WRITTEN DESCRIPTION

STEP 6: PREPARE INDIVIDUAL ASSET REPORT

METHODOLOGY TO CONDUCT THE IP AUDIT

Step 1: Inventory the company's intellectual property

- Identify all of the company's patent, trade secrets and licenses.
- Create a spreadsheet organizing all of the company's intellectual property.

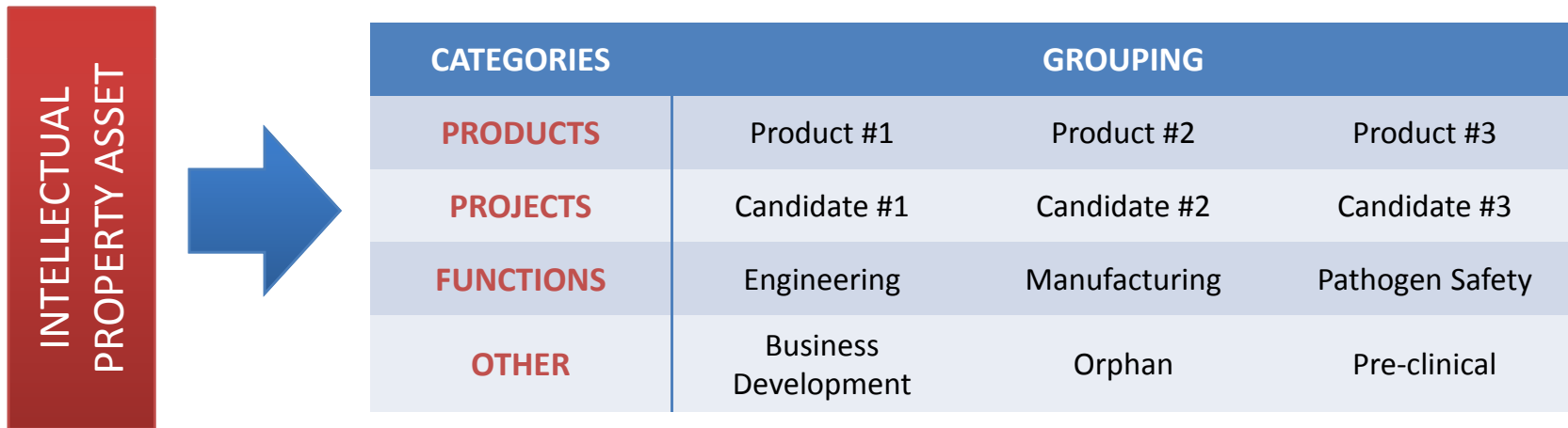
IP Name	Type of IP			Inventor Name	Application Serial No.	Patent No.	Invention Date	Filing Date	Country Code	Issue Date	Licensor	Status
	Patent	Trade Secret	License									
	X											
		X										

- In the event trade secrets have not previously been inventoried, solicit and screen records of invention to identify trade secrets and memorialize into formal trade secret registry.
- Inventory licenses and purge expired agreements.
- Further purge expired patents.

METHODOLOGY TO CONDUCT THE IP AUDIT

Step 2: Group intellectual property by class

- ❑ Assign each piece of the company's intellectual property to one of four categories:
 - 1. Products:** any marketed product
 - 2. Projects:** any project beyond the conceptual stage
 - 3. Functional Areas:** any intellectual property related activity of the company that affects more than one product or project (e.g. upstream manufacturing processes, pathogen testing, quality and bioanalytics).
 - 4. Other:** any asset that does not fit in the above categories.



METHODOLOGY TO CONDUCT THE IP AUDIT

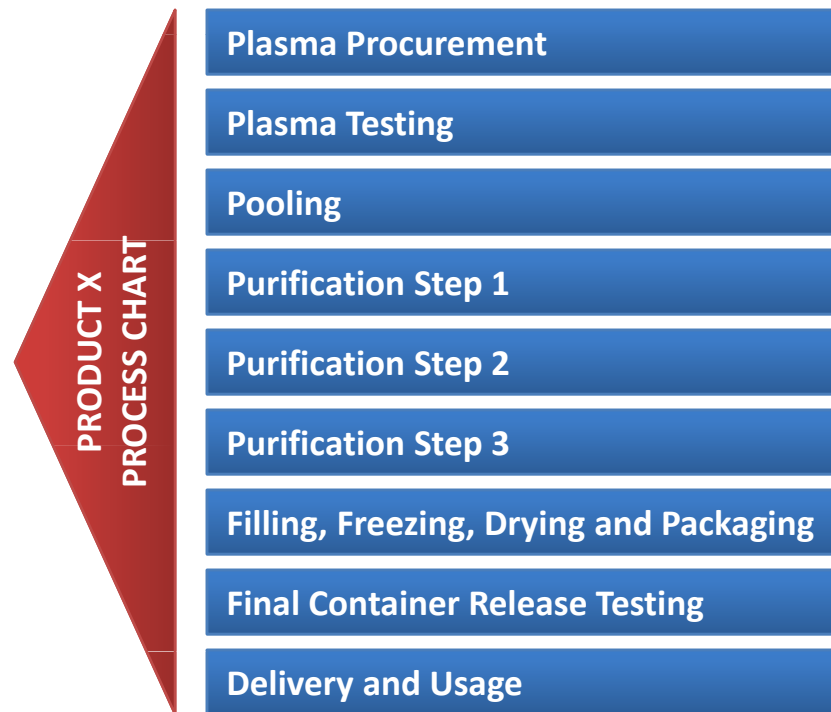
Step 3: Name each intellectual property asset

- ❑ **Patents.** A three letter code that designates which group the patent belongs (e.g. a particular product or project) followed by the last three digits of the patent number or patent application number.
- ❑ **Trade Secrets.** The same three letter code designating the group followed by the inventor disclosure number that was the genesis for the trade secret in question.
- ❑ **Legal Opinions.** The same three letter code designating the group, followed by the type of opinion and the date it was last updated.

METHODOLOGY TO CONDUCT THE IP AUDIT

Step 4: Prepare a process chart for each class of intellectual property

- ❑ The **process chart** describes the relevant components of the product, project or functional area and indicates where in such process each asset is associated.
- ❑ The chart should be drafted to inform the reader at a glance how they fit within the overall process or function.
- ❑ **Example of Process Chart:**



METHODOLOGY TO CONDUCT THE IP AUDIT

Step 5: Prepare a written description

- Provide additional technical details and specificity not explored by the Process Chart.*
- Capture the process and the contribution of each intellectual property asset with significant details.*

METHODOLOGY TO CONDUCT THE IP AUDIT

Step 6: Prepare individual asset report

- For each intellectual property asset, prepare a written report comprising a legal, commercial and technical review.
 1. **Legal Review.** Assess the continued enforceability and legal strength of the patent, and the jurisdiction in which the patent has been issued or application filed.
 2. **Technical Review.** Determine whether or not the asset in question is still relevant to the company's processes or operations.
 3. **Commercial Review.** Assess the competitive contribution of the asset (e.g. whether or not the loss of the asset would hurt the company or aid its competitors).

METHODOLOGY TO CONDUCT THE IP AUDIT

Step 6: Prepare individual asset report (cont'd)

- *Based on the previous assessments, give each asset an overall rating:*
 - A. *Asset is material and loss would be a reportable event if public company.*
 - B. *Asset is important to current operations and provides a measurable impact on the company's profitability or competitiveness.*
 - C. *Asset has future or speculative value, but not currently a part of a marketed product or, alternatively, it may be a potential business development opportunity unrelated to the core business.*
 - D. *Marginal value to the company, probably with continued maintenance fees in core markets for defensive purposes only, but no new expense is warranted.*
 - E. *Asset to be purged.*

Asset Identification Number: _____
 Asset Title: _____
 Type of Asset: _____

Intellectual Property Asset Audit Form

TYPE OF ASSET

Issued Patent				Pending Patent					Trade Secret	Legal Opinion		License		Other
Patent No.	Issue Date	Expiration Date	Foreign Jurisdictions	Patent Application No.	Patent Publication No.	Filing Date	Publication Date	Foreign Jurisdictions	IPMC Meeting Date of Designation	Attorney/Law Firm	Date:	Licensor	Effective Date	Description

LOCATION OF ASSET

Product	Project	Functional Area	
<input type="checkbox"/> Product 1	<input type="checkbox"/> Project 1	<input type="checkbox"/> Zone 1	<input type="checkbox"/> Pathogen Safety
<input type="checkbox"/> Product 2	<input type="checkbox"/> Project 2	<input type="checkbox"/> Zone 2	<input type="checkbox"/> Bioanalytics
<input type="checkbox"/> Product 3	<input type="checkbox"/> Project 3	<input type="checkbox"/> Zone 3	<input type="checkbox"/> Technology

	Technical Review	Commercial Review	Legal Review
Contact Information	Name: Address: Phone:	Name: Address: Phone:	Name: Address: Phone:
Review	RELEVANCE and IMPORTANCE of Asset on the company's processes and operations. Does the asset still fall within the Written Description?	Competitive Contribution of Asset. Would loss of asset hurt the company or aid competitors?	Key Claims, Differences between Patents in Various Countries. Enforceability Issues. Anticipated Expense to Prosecute/Maintain (Next Twelve Months).

IPMC Classification of Assessment: A B C D E

IPMC Approval (Signature and Date) _____

PROFESSIONAL BIOGRAPHIES & CONTACT INFORMATION

LIFE SCIENCES LAW, PLLC PROFESSIONALS

3/3/2009

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Sheila Mikhail

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Sheila has over 20 years of experience in corporate and securities law and management consulting. Prior to establishing LSL, Sheila practiced law with Ropes & Gray in Boston. She was also Law Clerk to the Honorable Martha Craig Daughtrey, 6th Circuit, US Court of Appeals.

Sheila has represented a variety of pharmaceutical, biotechnology and life sciences entities, including start-ups and publicly traded companies, as well as venture capital funds and investment banks. She has participated in numerous public offerings, venture capital investments, mergers and acquisitions, leveraged buyouts, asset purchases, technology transfer and private placements of securities. To date, she has completed over 2000 licensing, development, evaluation, research, clinical trial, technology transfer and other intellectual property agreements.

Sheila understands not only the legal challenges facing life sciences companies, but also the operational issues addressed by such companies on a daily basis. She has served as Chief Executive Officer of Asklepios BioPharmaceutical, Inc., a gene therapy company, where she was able to successfully raise almost \$8 million and take a therapeutic for Duchenne's Muscular Dystrophy into human clinical trials. She has also served as Chief Executive Officer of NanoCor Therapeutics, Inc., a spin-out from Harvard University, where she completed a \$8.5 million equity investment from Medtronic, Inc.

Prior to practicing law, Sheila worked as a consultant for Arthur Andersen in Chicago where she specialized in mergers and acquisitions, cross-border transactions and integration issues. She also worked with A.T. Kearney and the Acumen Group where she advised emerging companies on the commercialization of new technologies and Fortune 100 companies on turn around and operational strategies to improve profitability.

Sheila received a B.S. from the University of Illinois at Urbana-Champaign, with highest honors; a finance M.B.A. from the University of Chicago, with honors; and a J.D. from Northwestern University, with honors. Sheila is admitted to the bars of Massachusetts, Arizona, New York and North Carolina. She is a member of the American Bar Association Committees on business law; private equity and venture capital.

Vanessa Hamilton Andersonvanderson@LifeSciLaw.com

Vanessa is an experienced intellectual property, corporate and regulatory attorney and brings a broad range of experience to Life Sciences Law. Prior to joining LSL, Vanessa was with Keller and Heckman, LLP, a regulatory firm in Washington D.C. Vanessa has also worked for boutique firms specializing in patent and complex commercial litigation and as a Technology Transfer Associate at a flagship land grant university.

Vanessa's experience includes providing nationally recognized consumer products clients with assistance in drafting and negotiating intellectual property licensing agreements, general business and consulting agreements, confidentiality agreements, material transfer agreements and strategic alliance and co-development agreements. Additionally, she has worked with clients to develop corporate best practices and consumer and employee privacy protocols. Vanessa also brings to the firm extensive experience providing advertising advice as well as trademark selection and prosecution assistance. Vanessa directs the clinical trials group at LSL and in such capacity has worked extensively with CROs and universities in over 37 countries.

Vanessa holds a M.S. in Biochemistry and Molecular Biology with specialization in Biotechnology from Georgetown University as well as a J.D. and B.S. from Louisiana State University. Vanessa is admitted to the District of Columbia and Louisiana Bars, and is a Registered Patent Attorney before the U.S. Patent and Trademark Office.

Cheryl Babo

cbabo@LifeSciLaw.com

Cheryl has more than 13 years of legal experience that ranges from complex commercial litigation to corporate transactional law in the life sciences and high technology sectors. In addition to her work with LSL, Cheryl currently serves as Assistant General Counsel to The Translational Genomics Research Institute in Phoenix, Arizona, where she drafts and negotiates research collaboration agreements; clinical study agreements; CRO, SMO and site agreements; confidentiality agreements; material transfer agreements; intellectual property licensing agreements; master service agreements; research grant subcontracts; and a wide array of general business agreements. Cheryl also advises internal clients on various issues relevant to non-profit entities as well as other general liability and risk concerns.

Prior to her work in the life sciences field, Cheryl worked in-house at Intel Corporation drafting, negotiating and managing compliance with and enforcement of enterprise-wide hardware and software purchasing agreements, licensing agreements, confidentiality agreements and related consulting and services agreements. Before going in-house, Cheryl gained extensive litigation experience counseling and defending clients ranging in size from Fortune 500 companies to small business owners and individuals on matters involving intellectual property, product liability, corporate fraud and professional malpractice claims, among others. Cheryl worked as an associate for Brown & Bain, P.A. (which has since merged with Perkins Coie, LLP) and Bowman & Brooke, LLP, both in Phoenix, Arizona, and was a senior partner with the Grasso Law Firm, P.C. in Tempe, Arizona.

Cheryl received a J.D., *summa cum laude*, from Arizona State University; joint M.B.A. and M.S. Information Management degrees from Arizona State University; and a B.A., *magna cum laude*, in Philosophy from Arizona State University. Cheryl is admitted to the Arizona bar.

Dr. Mary Boguslaskimboguslaski@LifeSciLaw.com

Mary specializes in patent law and licensing and worked for Bayer HealthCare, LLC, as a patent attorney for 21 years. Her experience includes diagnostics, consumer care, biotechnology, citric acid fermentation, food ingredients, central technology, chemical synthesis of pharmaceuticals and allergy products.

Mary's practice includes the structuring, negotiation and drafting of research and development and licensing agreements. She has also substituted in an Ombudsman position (Ethics and Privacy Officer) for Bayer.

Prior to joining LSL, she was Senior Patent Counsel for the Bayer's Biological Products division, for both the North Carolina (plasma products) and California (recombinant FVIII) sites. She handled the contracting needs of the research and development group, as well as licensing transactions for Bayer's plasma products business.

Mary received her B.S. in Pharmacy from the University of Michigan; her Ph.D. in Pharmaceutical Chemistry from the University of California, San Francisco Medical Center; and her J.D. from the University of Notre Dame. She is a member of the patent bar and is licensed in Indiana.

Jerrie Chiu

jchiu@LifeSciLaw.com

Jerrie has extensive corporate and pharmaceutical experience. Jerrie began her legal career at Testa, Hurwitz & Thibault in Boston, MA and then moved on to in-house positions at pharmaceutical and other high-tech companies. Jerrie's pharmaceutical experience extends from basic research to all phases of drug approval and commercialization.

She has worked on regulatory matters related to drug approval and labeling and has significant experience in the review of marketing materials for legal and regulatory compliance. Additionally, Jerrie has worked extensively in clinical trial contracting and in contracting for pharmaceutical manufacturing and distribution, including specialty distribution contracting for biologics. Other areas of substantial contracting experience include managed markets, specialty pharmacy and Medicare Part D. Jerrie understands not only the legal issues facing a company, but also understands the business issues.

Jerrie has served as an officer for a NYSE-listed company and currently serves on the Board of Directors for a non-profit entity. Jerrie is also a registered Patent Attorney. Through her broad-reaching corporate and pharmaceutical experience and her intellectual property expertise, she has been able to successfully negotiate some of the more complex and large-scale transactions in the pharmaceutical industry. The types of transactions she has negotiated include global co-development and co-promotion agreements, technology out-licensing and in-licensing agreements, and cross-border acquisitions.

Jerrie received her BS in chemistry, with honors, from Indiana University and a JD, with highest honors, from the University of Connecticut, School of Law. Jerrie is admitted to the bars of MA and CT and is registered to practice before the USPTO. Jerrie works in association with LSL through her company, Ambitus Legal, LLC.

Jason's practice focuses on commercial and intellectual property transactions and strategic counsel in the pharmaceutical, biotech and life sciences industries, including:

- business development transactions, including in/out-licensing and development agreements, strategic alliances, product/candidate acquisition and divestitures, and research collaborations agreements;
- drug manufacturing, supply chain, processing services, distribution, and co-promotion agreements;
- pharmaceutical and biotech outsourcing arrangements, including contract manufacturing (API, finished product, and delivery systems), clinical services (CRO), and marketing agreements;
- clinical trials contracting and compliance, including master service agreements, clinical trial agreements, investigator led study agreements, central laboratory agreements, clinical packaging and distribution agreements, and advising on clinical SOP development, IRB issues, informed consent forms, and other general compliance issues.

Jason has experience advising clients in a variety of industries, including pharmaceuticals, biological such as recombinant proteins, gene therapy, plasma-based therapeutics, vaccines, ag-bio and ag-chem. Jason has completed clinical trial arrangements with hundreds of clinical sites globally, including the EU, Eastern Europe, Australia, Latin and South America, Africa, Malaysia, Japan, Korea, and China.

Prior to joining LSL, Jason managed business development activities at Becton Dickinson's research and innovation division, BD Technologies, in areas including therapeutics, cell therapy and tissue engineering, biomaterials, drug delivery/devices, diagnostics and instrumentation platforms. He also worked at the University of North Carolina Technology Transfer office, where he structured and negotiated technology transfer agreements with university spin outs.

Jason holds a J.D. from the University of North Carolina, School of Law. He received a M.S. in Technology Commercialization from North Carolina State University College of Management and a M.A. from the University of Hawaii. He holds a B.A. from the University of Pennsylvania. He is admitted to the bar of North Carolina.

Timothy Ferguson

tferguson@LifeSciLaw.com

Tim brings a broad range of business and legal experience to Life Sciences Law, PLLC. Prior to joining LSL, he participated in an entrepreneurial initiative designed to serve the legal and policy requirements of North Carolina's viticulture and nutraceutical industries. At LSL, he has assisted entrepreneurial companies with their organization and subsequent financings.

Tim has assisted several of LSL's clients in preparing for due diligence in connection with financings, licensing transactions and collaborations. He has extensive knowledge in electronic data room management.

Tim holds a Bachelor's degree from The Citadel, where he graduated with honors. He received his J.D. from the University of North Carolina, School of Law. He is admitted to the North Carolina bar.

Nilay Patelnpatel@LifeSciLaw.com

Nilay is an experienced corporate and patent attorney with a background in chemistry. He drafts and negotiates many types of transactional agreements ranging from licensing, strategic alliance and co-development agreements to master service, supply and manufacturing agreements.

Nilay also serves as patent counsel to several biotech start-ups, providing patent portfolio management and patent strategy development.

Prior to joining LSL, Nilay practiced patent law with Cooper & Dunham LLP in New York. His experience includes global patent prosecution of small molecule and protein-based pharmaceuticals. Before practicing law, he worked as a bench chemist at a contract pharmaceutical development laboratory.

Nilay received his B.S. degree in Biochemistry and B.A. degree in Chemistry from North Carolina State University and his J.D. degree from Columbia Law School. He is admitted to the New York and North Carolina bars and is a Registered Patent Attorney before the U.S. Patent and Trademark Office.

Mark B. Turnermturner@LifeSciLaw.com

Mark has extensive business development and technology management experience to complement his legal experience. He focuses on serving the needs of small to mid-size life sciences companies by structuring and negotiating a variety of transactional documents, including licenses and technology transfer agreements, research collaborations, and material transfer, manufacturing and marketing agreements. Mark also has experience managing relationships in support of clinical development.

Prior to joining LSL, Mark worked with Hutchison Law Group in Raleigh, N.C. Prior to attending law school, Mark spent five years as Director of Business Development for a North Carolina biotechnology company and five years as Associate Director of the Office of Technology Development at UNC-Chapel Hill.

Mark holds a J.D. from North Carolina Central University School of Law. He received an M.S. in Public Health from the UNC-Chapel Hill School of Public Health and a B.A. from Boston University.

Ann Abatangeloaabatangelo@LifeSciLaw.com

Ann has more than 9 years of economic consulting experience in areas involving securities fraud, accounting and valuation matters with a background in the biological sciences. Prior to joining LSL, Ann worked in Chicago at Lexecon, Inc., (presently Compass/Lexecon), on Fortune 100 client engagements in industries encompassing: banking, consumer products, healthcare, oil & gas, pharmaceuticals, retail, technology, and financial/insurance institutions.

Ann has experience on actively managing and coordinating financial and accounting analysis-related efforts for preparing, analyzing and interpreting financial data for client's business operations and industries. Additionally, she has worked with clients to manage and evaluate ongoing projects resulting in significant cost savings. Ann has also worked in New York for the commercial bank, Swiss Bank Corp., merged with UBS AG.

Ann received an M.B.A. degree in finance and health administration as well as a B.A. degree in the Biological Sciences with honors from the University of Chicago.

Tamar Mikhail

tmikhail@LifeSciLaw.com

Tamar is a Contracts Administrator with over five years experience in clinical trials, including contract drafting, management, and electronic database management.

Tamar's responsibilities include the following:

- coordinate the contract review process from initial client request through execution;
- review and edit basic modifications to contracts; prepare and distribute routine correspondence, negotiation memoranda, and contract documentation;
- ensure flow of approval and execution of contracts in accordance with client guidelines;
- maintain electronic databases for both contract status tracking and executed contracts;
- assist in creating and implementing reports to clients to provide visibility and improve existing processes;
- assist in identifying and implementation of new contract policy and processes;
- conduct research to support contract audit and/or facilitate client contracting trends as needed;
- and analyze new laws, regulations and contract trends for potential impact on client objectives.

Tamar received a B.A. degree from the University of Illinois.