HAUG PARTNERS

IP DUE DILIGENCE

Patent & Regulatory Diligence Representative Therapeutic Areas

MULTIPLE ASSET ACQUISITIONS

- acquisition of portfolio of hormone & prostaglandin products in connection with patent settlement.
- evaluated pharma business of large multi-national corp. (involved 13 compounds, both marketed & developmental).
- evaluated portfolio of antibiotic products.

CARDIOVASCULAR

HYPERTENSION	endothelin receptor antagonist for large pharma co.
ANGINA	acquisition of chronic angina product for large pharma co.
CHOLESTEROL CONTROL	auction bidding acquisition of cholesterol lowering products for large pharma co.
CARDIAC NUCLEAR STRESS TEST	cardiac nuclear stress test agent for large pharma co.

ONCOLOGY

BIOMARKER PLATFORMS/ DIAGNOSTICS	gene signature platform in evaluation of collaboration opportunity for mid-size biotech co.
	companion diagnostic approved for use with an approved small molecule tyrosine kinase inhibitor
ANTIBODY DRUG CONJUGATES	next-gen toxins for large pharma co.
SMALL MOLECULES	numerous products/product candidates for mid-size biotech co.
	prostate cancer agent for large pharma co.
	lung/pancreatic cancer agent for mid-size biotech co.

DERMATOLOGY

PSORIASIS	acquisition of psoriasis product for mid-size pharma co.
ACTINIC KERATOSIS	topical product for mid-size pharma co.

OPHTHALMOLOGY

DRUG DELIVERY	Evaluated multiple sustained release delivery platforms for small biotech co.
CELL THERAPY	hUTC therapy & delivery device for small biotech co.
OLIGONUCLE-OTIDES	oligonucleotide platform/product portfolio for multi-target deal for small biotech co.
BIOLOGICS/ BIOSIMILARS	biosimilars for small biotech co. for multi-billion dollar product opportunity

REGENERATIVE MEDICINE

- hepatocyte growth factor product
- series of growth factor-enhanced orthopedic products
- regenerative medicine skin product
- biologic wound healing products
- vascular regenerative medicine products

HORMONE THERAPY

TESTOSTERONE REPLACEMENT	product opportunity for mid-size specialty pharma co.

UROLOGY

OVERACTIVE BLADDER	overactive bladder agent for large pharma co.

DRUG DELIVERY

INHALATION	potential platform/product opportunity in inhalation field
SUPERCRITICAL FLUID PROCESSING	SCF manufacturing platform & product portfolio for delivery co.
MICRO/NANO PARTICLES	multiple platforms for delivery co.

REGULATORY DUE DILIGENCE

- confirm orphan exclusivity for acquisition target
- confirm ownership of regulatory assets & availability of exclusivity for developmental product
- evaluations of complex bioequivalence

Regulatory due diligence
Patent due diligence
Patent and regulatory due diligence
Pre-litigation Hatch-Waxman patent due diligence

IP DUE DILIGENCE

I. FTO Assessment

II. Assess Product Exclusivity

A. Patent

1.	Review current patent portfolio to evaluate coverage of all aspects of the proposed product
2.	Identify patents to list in Orange Book
3.	Identify claims to product and use and verify that language aligns with language of proposed product label
4.	Compare language of proposed use codes with proposed product label
5.	Consider ongoing prosecution of pending applications and opportunities for additional protection
6.	Patent Term Extension analysis

B. Regulatory

1.	Identify relevant regulatory data protections and terms
2.	Research bioequivalence and sameness requirements for generic/biosimilar approval as appropriate

C. Validity Analysis

1.	Prior art analysis
2.	Review U.S. prosecution histories and identify any issues
3.	Consider relevant, available foreign prosecution
4.	Consider effective filing date and priority for relevant claims
5.	Assess written description and indefiniteness issues
6.	Assess §101 patent eligible subject matter issues

D. Ownership Analysis

1.	Review license, acquisition, employee IP assignment agreements
2.	Review assignment information at PTO

PRE-LITIGATION INVESTIGATION

I. Phase I – Tasks Based on Readily Available and Publicly Available Documents

A. Infringement Analysis

1.	Review Orange Book/Purple Book listed patents
2.	Consider potential unlisted patents
3.	Consider likely claim constructions
4.	Identify claims to approved product and use and verify language aligns with language in product label
5.	Compare language of use codes with product label

B. Validity Analysis

1. Prior art analysis
   - a. Review cited prior art and determine need for additional searching
   - b. Preliminary consideration of inventor publications
   - c. Consider response to potential anticipation or obviousness arguments
2. Review U.S. prosecution histories and identify any issues
3. Consider relevant, available foreign prosecution
4. Consider effective filing date and priority for relevant claims
5. Analyze obviousness-type double patenting issue
6. Consider inventorship on relevant patents
7. Develop invention story/objective indicia of nonobviousness story

C. Co-Pendency Analysis

D. Ownership Analysis

1. Review license agreements
2. Identify litigation control and cost issues
3. Review assignment information at PTO
4. Evaluate proper plaintiff for patent enforcement

E. Consider ongoing patent prosecution of pending applications and opportunities for additional protection

F. Document retention analysis and identification of hold strategy for relevant parties

G. Regulatory

1. Assist with regulatory filings for protection (e.g., patent term extension (PTE))

II. Phase II – Tasks Requiring Document Searching, Identification and Interviewing of Witnesses

A. Locate and Review key documents (e.g. support for working examples or declaration, inventor publications, product literature, regulatory filings, lab notebooks)

1. Consider underlying scientific data and verify accuracy of description in examples, declaration, publications, product literature, regulatory filings

B. Further develop scientific arguments made during prosecution

C. Identify and interview key witnesses; establish relationships with 3rd party fact witnesses (e.g., inventors) and retain expert witnesses

D. Coordinate with prosecution counsel

E. Develop story of the invention

F. Review marketing activities

G. Preliminary discovery review (e.g., electronic systems, archives, privilege, relevancy, business sensitivity issues)

ED HAUG

Ed is the Chairman of Haug Partners LLP and was a founding member of the firm in 1997. The firm has offices in New York City, Boston and Washington D.C. and focuses on intellectual property, antitrust, FDA and commercial litigation among other complimentary practice areas. Ed was recently a member of the CAFC advisory council to Chief Judge Prost, is a "ranked trial lawyer" by Chambers, and a member of the National Association of Distinguished Counsel.

BRIAN MURPHY

Partner

Brian Murphy focuses his practice on AIA post grant review proceedings before the PTAB. He served as a Lead Administrative Patent Judge of the PTAB from 2014-2017, supervising a section of Administrative Patent Judges and supporting the Chief Judge as a member of the PTAB management team. Mr. Murphy presided over nearly 200 Inter Partes Reviews, Post Grant Reviews, and Covered Business Method Reviews, drafted more than 60 decisions, and mentored numerous AIA trial section judges. He counsels clients based on his deep working knowledge of AIA post grant review practice, rules, policy, and procedure from his years as a PTAB judge.

ANDREW WASSON

Partner

Andrew has a broad range of experience in both the brand and generic side of pharmaceuticals, especially with respect to issues involving intellectual property law and regulatory law. Having grown up with a father who is a patent lawyer, Mr. Wasson has been involved in patents in one way or another for the better part of his life and has the advantage of being able to deal with complex patent law concepts in a very natural way. Mr. Wasson is registered to practice before the U.S. Patent and Trademark Office and has published extensively in both scientific and legal literature. Mr. Wasson also serves on the Editorial Advisory Board for FDLI's Update Magazine.

DAVID HERMAN

Partner

David Herman heads the firm's Transactional and Licensing practice group. A specialist in the patent law, and regulatory issues related to the pharmaceutical, biotech and medical device industries, Mr. Herman possesses a nuanced grasp of the path of the various issues involved in any agreement. His due diligence work, in close conjunction with the firm's Life Sciences practice group, emphasizes drafting and negotiating skills and demonstrates a deep understanding of the pharmaceutical, biotech, and medical device industries, and others. He also possesses extensive experience in Hatch Waxman settlement agreements, and is the firm's expert in this area.

MATTHEW MCNATT PH.D.

Scientific Advisor

Mattew McNatt is an entrepreneurial scientist who cofounded and is the Chief Science Officer of a fledgling biotech company. Focused on developing cell-lines to shorten the manufacturing timeline and to increase the titer of biologics with an emphasis on antibodies. Dr. McNatt leverages his business background to match the business needs of the client. Dr. McNatt earned his B.Sc. in Biochemistry from Michigan State University, a Ph.D. in Molecular and Cellular Biology from the University of Colorado, and a Postdoctoral Fellowship investigating HIV-1 at the Aaron Diamond Aids Research Center. He has special interest in the growing field of biologics and biosimilars.