



# BUSINESS ASPECTS OF PATENTS: A PRIMER FOR THE NON-PATENT LAWYER

*John R. Wetherell, Ph.D., J.D.*

*Partner*

*Pillsbury Winthrop Shaw Pittman LLP*

*12255 El Camino Real, Suite 300*

*San Diego, CA 92130-4088*

*858-509-4022*

*858-509-4010 (facsimile)*

*[john.wetherell@pillsburylaw.com](mailto:john.wetherell@pillsburylaw.com)*

# Dr. John R. Wetherell, Esq.

Dr. Wetherell has over 20 years experience in intellectual property law. His counseling experience includes intellectual property acquisition, transactional due diligence, patent infringement and validity analyses, freedom-to-operate opinions, as well as licensing and strategic counseling. Dr. Wetherell's patent prosecution experience includes obtaining U.S. and foreign protection in biotechnology areas such as molecular biology, immunology, nanotechnology, medical diagnostics, microbiology and pharmacology.

Dr. Wetherell received a B.S. degree in Chemistry, and a Ph.D. degree in Microbiology/Immunology, both from the University of Florida, and a J.D. degree from Seton Hall University School of Law. He conducted post-doctoral research, including studies on the humoral and cellular immune responses in periodontal disease, at Forsyth Dental Center in Boston, where he concurrently held an NIH post-doctoral fellowship and a Young Principal Investigator's award. Before becoming an attorney, he gained extensive experience as a research scientist and manager during his five-year tenure in the biotechnology industry.

At Pillsbury Winthrop Shaw Pittman, Dr. Wetherell is Head of Intellectual Property in the San Diego Office, Co-Chair of the National Life Science Practice Group, Chair of the Stem Cell Outlook and Planning Effort (SCOPE) and co-chair of the National Nanotechnology Practice Group.

Dr. Wetherell has written and lectured extensively on patent law, strategy, and related transactional issues for many organizations and institutions around the world.

# PATENTS

- Government grant of the right to exclude others from:
  - Making
  - Using
  - Selling
  - Offering to sell
- Throughout U.S. and its territories

# ADVANTAGES OF PATENTS

- Grants exclusive rights
- Provides defined licensing vehicle
- Protects against foreign infringement of process
- Protects against reverse engineering
- Allows early publication
- Provides federal court remedy

# DEFINITIONS OF A PATENT

- A grant from the U.S. government of the right to exclude others from making, using, selling, or importing a claimed invention throughout the U.S.
- A patent is a negotiated contract between an inventor & the government

# THEORY OF PATENTS - I

- **THE DEAL:** an inventor discloses an invention to the public, & the government grants the inventor the limited right to exclude others from practicing that invention
- **THE BENEFIT:** the public gains knowledge from the disclosure, which provides a basis for additional innovation

# THEORY OF PATENTS - II

- Patents do NOT give an inventor the affirmative right to exploit an invention
- Patents only give the inventor the right to exclude others from practicing an invention

# EXAMPLE OF RIGHT TO EXCLUDE

- B patents an improvement of a machine originally patented by A
- B can prevent A from using the patented improvement
- However, B may not be able to use the improvement, because such use may infringe A's patent

# PATENTABLE SUBJECT MATTER

- Processes

*Example:* a method of making hook &  
loop material (Velcro®)

# PATENTABLE SUBJECT MATTER

- Processes
- Machines

*Example:* a specific machine for making  
hook & loop material

# PATENTABLE SUBJECT MATTER

- Processes
- Machines
- Articles of manufacture

*Example:* the hook & loop material itself,  
after manufacture

# PATENTABLE SUBJECT MATTER

- Processes
- Machines
- Articles of manufacture
- Compositions of matter
  - Example:* a new plastic used to make the hooks or loops

# PATENTABLE SUBJECT MATTER

- Processes
- Machines
- Articles of manufacture
- Compositions of matter
- Improvements in any of the above
  - Example:* an improvement of the machine for making hook & loop material

# PATENTABLE SUBJECT MATTER

- Processes
- Machines
- Articles of manufacture
- Compositions of matter
- Improvements in any of the above

# UNPATENTABLE SUBJECT MATTER

- Purely mental processes
- Laws of nature (as opposed to applications of such laws)
- Mathematical algorithms alone
- Nebulous concepts or ideas, or statements of intended results, without teaching how to apply the ideas or accomplish the results

# CONDITIONS FOR PATENTABILITY

- Useful
- Novel
- Nonobvious

# PRODUCT PROTECTION

## WHY GET A PATENT?

# PRODUCT PROTECTION

- Helps prevent others from copying a patent holder's products
- Helps prevent a 2<sup>nd</sup> inventor from denying a 1<sup>st</sup> inventor's right to use a trade secret technology

# MARKETING TOOL

- Can enhance a company's image as a "high-tech" enterprise
- "Patent Pending" creates a "Fear-Uncertainty-Doubt" (FUD) factor among competitors & those who might buy from competitors

# LICENSABLE ASSET

- Generate revenue from licenses
- Licensing often makes sense when the licensed products are not directly competitive
- Licensing can make sense even in directly competitive situations, such as where the patent owner cannot supply market demand

# BARGAINING CHIP

- Attracting venture capital
- Securing financing
- Used defensively to negotiate a cross-license with another company making a claim of infringement

INTELLECTUAL PROPERTY  
DUE DILIGENCE

THE ROLE OF  
INTELLECTUAL PROPERTY  
IN THE DEAL

# INTELLECTUAL PROPERTY DUE DILIGENCE

- VC Transactions
- Spin Offs
- Mergers/Acquisitions
- Collaborations/Licenses
- Initial Public Offering
- Follow on Offering
- License Monetizations

# ROLE OF DUE DILIGENCE

- Instrumental in timely closing transaction
- Respect for third party contracts
- Determine scope of representations and warranties
- Liability for breach of representations and warranty

# IP ANALYZED DURING DUE DILIGENCE

- Patent and Patent Applications
- Trademarks, Service Marks and Trade Names
- Copyrights
- Trade Secrets
- Licensed Technology

# IP DILIGENCE ITEMS

- Litigation, Oppositions, Interferences and Arbitrations
- Ex-Employees or Founders
- Material Contracts
- Known IP Problems
- Written/Oral Legal Opinions on any IP
- Memoranda or Analysis by Company on any IP

# KEY COMMERCIAL QUESTIONS

- Can You Market Your Product Without Infringing?
- Can You Block Competitors From Making/Using/Selling Your Product Or Very Similar Product?

# PATENT DILIGENCE DOCUMENTS

- Patent File Histories
- Assignments
- IP Claim Scope
- Freedom To Operate Analyses

# FREEDOM TO OPERATE

- Are There Claims In Third Party Patents That Dominate Your Product?
- Patent Coverage Of Your Product Is Irrelevant

# BASIC FTO STRATEGY

- Define Product, Method of Making And Using
- “Genericize Product”
- Search For Third Party Patents With Dominant Claims
  - Product, Method Of Making And Method Of Using
  - Search All Components Of Complex Compositions
- Compare Product To Third Party Claims
- Design Around If Necessary
- Watch For “Product Drift”

# PATENT DILIGENCE ITEMS

- Ownership
  - Assignments
  - Co-Ownership
- Validity
  - Pending Applications
    - Maintenance Fees/Annuities
  - Co-Pendency
  - Any Known Potential Bars
  - Publication
  - On Sale
  - Suppression
- Foreign Filing Protection

# LICENSES

- License Validity
- Scope
  - Field of Use
  - Geographic Limitations
  - Exclusive or Non-Exclusive
- Non-Compete Restrictions
- Sublicenses and Transferability Possible
- Limits on Liability
  - Grant-based clause
- Stacking Provision Present

# EMPLOYEE DILIGENCE ISSUES

- Confidentiality Agreements
- Assignments
- Cooperation requirement for employees
- Consulting Agreements

# COMMON COMPANY ISSUES

- Narrow claim scope
- Ignoring known problem patents
- Failing to cover all types of inventions
- Lack of confidentiality procedures
- Slow response to USPTO office actions
- Inappropriate spending on patent prosecution

# SUMMARY: COMPANY TRANSACTION PREPARATION

- Nature of the transaction
- Prepare for due diligence process
  - Domestic and foreign patent files
  - Clinical data room
- Anticipate investor requests
- Freedom to operate analysis

# CONCLUSIONS

- Patents are essential for new product commercialization
- Patents are essential for attracting investors
- Patents are business tools
- Do not buy cheap tools

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