

FOLEY EXECUTIVE BRIEFING SERIES



**The Fast Track to Commercial Success in the  
Medical Device Market: How to Navigate IP  
and FDA Roadblocks**

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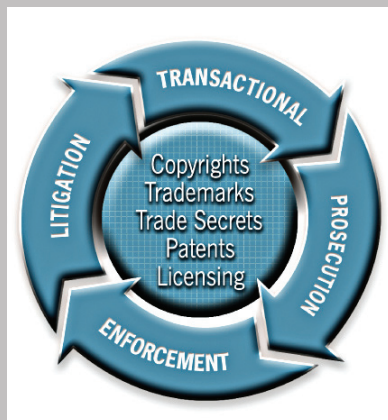


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**IP Asset Life Cycle**



**Landmines can be  
anywhere in the  
life cycle**



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## IP Business Strategy

- Finding a path to commercialization
  - Product clearance searches
  - Practical “design around”
  - Non-infringement/invalidity opinions
- Identify strategic partners/players
  - License/collaborations/joint ventures
  - Mergers & Acquisitions
- Funding events



## Patent Procurement & Management

- Strategic portfolio management
- Formulate protection strategy (cost v. expected benefit)
  - Minefield model
  - Pioneering innovation model
- Identify strategy for each application or apply globally to product group



## Patent and FDA Regulatory

- Keep FDA regulatory counsel involved with relevant portions of IP portfolio strategy
- Example: patent application typically does not need to speculate about the invention's primary mode of action
  - Can limit options when working with FDA, such as FDA Center assignment



## Recordkeeping

- Employment agreements
  - Agreements with employees
  - From previous employers
- Copies of all prior art documents inventors are aware of
- First public/commercial use of inventions
- Inventive Documentation Materials



## Recordkeeping (cont'd)

- Copies of non-disclosure agreements and related documentation (inbound & outbound)
- Materials related to trade secret procedures
- Software licenses – even for off the shelf s/w
- Domain name registrations



## Consider Start-Up Example

- Several employees at large company decide to pursue their “own idea”
- Assume large company agrees that employees can obtain/have rights



## Start-Up Funding

- Does the start-up own the invention?
  - Who are the inventors to each patentable invention?
  - Have rights been assigned?
    - Was assignment executed or, at the time of the invention, did each have an obligation to assign rights to start-up?
    - When did each inventor/employee's obligation to assign rights to former employer end?
      - Be wary of anyone straddling the fence



## Start-Up Funding

- Does the start-up own the invention?
  - Was government funding involved, if so, rights are likely not exclusive to start-up
    - Were all procedures timely followed
      - *Campbell Plastics*, 389 F.3d 1243 (Fed. Cir. 2004)
- Does the start-up own a valid trademark registration?
  - Documents to prove dates of use
- Eventually, there will be adversarial parties scrutinizing and valuing everything related to scope and ownership of IP



# Access to Portfolio Details

Acme Family

Invention ID	Title	Inventors						
INV-70000	A Method of Demonstrating Software	Blight, David; Lippens, Yvan; Mitchell, Daniel R.; Smith, Joseph M.						
Docket No.	Country	Status	App. No.	App. Date.	Pub No.	Pub. Date	Pat No.	Pat. Date
123456-0001/X	United States of America	Inactive	68123456	1/4/1999				
123456-0002/X	PCT	Inactive	PCT/US2000/123456	1/1/2000	WO2000/654321	7/2/2000		
123456-0014/X	Israel	Inactive	123456	12/15/1999				
123456-0003/X	EPO	Granted	99123456.0	1/1/2000			0654321	1/1/2001
123456-0009/X	Germany	Granted	99123456.0	1/1/2000			EPO654321	1/1/2001
123456-0013/X	Spain	Granted	99123456.0	1/1/2000			0654321	1/1/2001
123456-0011/X	Sweden	Granted	99123456.0	1/1/2000			0654321	1/1/2001
123456-0010/X	United Kingdom	Granted	99123456.0	1/1/2000			0654321	1/1/2001
123456-0004/X	United States of America	Pending	11/222222	6/26/2003				
123456-0015/X	PCT	Pending	PCT/US2004/012345	5/5/2004				
123456-0018/X	EAP0 (Eurasian)	Granted	111	5/5/2004			2222	2/2/2005
123456-0005/X	Australia	Not Responsible	2221111	1/1/2005				
123456-0007/X	United States of America	Granted	09/123456	1/1/2000			612347	9/30/2000
INV-70001	Apparatus for Demonstrating Software							
Docket No.	Country	Status	App. No.	App. Date.	Pub No.	Pub. Date	Pat No.	Pat. Date
123456-1000/X	United States of America	Inactive	10/000001	5/2/2000				

# FOLEY ClientSuite



# Transactional: Identify Goals

- Consider yourself a buyer in this situation:
  - Buyer markets successful medical device product, but product patent is about to expire
  - Seller owns a patent for a better process of making the product that will be in force for several more years





## Transactional: Identify Goals

- Buyer's goals:
  - Acquire freedom to use the better process
  - Exclude others from using that process



## Structure Review According to Goals

- Freedom to use the seller's process requires
  - (1) Purchasing rights from seller and
  - (2) Searching to ensure there are no other blocking patents owned by third parties
    - Searching may be hard, e.g., nomenclature issue
- Power to exclude others requires a separate analysis - will third parties be able to circumvent the seller's patent somehow?



## Structure Review According to Goals

- Review of seller's 3<sup>rd</sup> party agreements with others
  - Understand royalty burden of seller to others
  - Understand limitations on ability to exploit assets



## Real World Cross-Border Example

- *Eli Lilly v. American Cyanamid*, 82 F.3d 1568 (Fed. Cir. 1996)
- Lilly successfully acquired freedom to use better process for making its drug by licensing a patent
- However, defective wording in the patent claims permitted third parties to use the process overseas and import the product - no power to exclude others





## Verifying Ownership

- When circumstances allow or when the asset is especially important, do more than a title check
- With patents, look for missing co-inventors by directly questioning the named inventors
- *Ethicon v. U.S. Surgical*, 135 F.3d 1456 (Fed. Cir. 1998)



## When “Defects” (Risks) are Found

- Some defects can be fixed
  - Patents can be broadened through reissue within two years of grant
  - Inventorship can be corrected at any time (provided there was no deceptive intent)
- Some can be addressed contractually or through alternative deal structures
  - Indemnify seller where buyer fears liability
  - Creative warranties or escrows



## Conclusions

- Costs of poor approach may only become apparent years later, when it is too late to repair
- Define goals up-front that intellectual assets are expected to fulfill
- Assess and address weaknesses/strengths of intellectual assets in relation to those goals



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