Built In the Lab:
Tips for Laying the Groundwork for Powerful Patents

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Tips for Laying the Groundwork for Powerful Patents

• Identify your opportunity
  – FTO/clearance considerations

• Planning your research to increase your potential claim scope

• Collaborating with counsel to maximize the value of your patent estate
Identify Your Opportunity

• Developing Valuable I.P.
  – Intellectual Property and other intangibles are important to company value
  – Studies of the assets of S&P 500 companies demonstrate that intangibles continue to increase as a proportion of the assets of companies nationwide
Identify Your Opportunity

Components of S&P 500 Market Value

- **1975**: Tangible Assets 17%, Intangible Assets 83%
- **1985**: Tangible Assets 32%, Intangible Assets 68%
- **1995**: Tangible Assets 32%, Intangible Assets 68%
- **2005**: Tangible Assets 20%, Intangible Assets 80%
- **2009**: Tangible Assets 19%, Intangible Assets 81%

Source: Ocean Tomo
Identify Your Opportunity

• Learn the landscape
• Own your parcel
• Alter the landscape if needed
Identify Your Opportunity

- Learn the landscape
  - When?
    - Timing considerations
  - Where?
    - Identify key markets for searches/literature reviews
Identify Your Opportunity

• Own your parcel
  – Seek rights to properties identified that could block your work
    – License/covenant not to sue
  – Identify white space and plan your research
  – File strategically, maintain thoughtfully
Identify the Opportunity

• Alter the landscape
  – Clear obstacles
    • Opinions of counsel
    • Reexamination proceedings
    • European post-grant oppositions
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Claim Scope-Priority Tension

• Greater disclosure of the functional elements of your invention and how they can be altered while still retaining function will support broader claim scope

• Performing additional research to obtain this data delays your priority date
Adequate Disclosure – Legal Standard

• Written Description
  – The disclosure “reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter.”

• Enablement
  – A skilled person could “make and use” the invention without “undue experimentation”
Adequate Disclosure – Legal Standard

- These are very fact based analyses; the outcome will be very case specific
- For biomolecules, actual primary structure is strongest evidence of “possession”
Adequate Disclosure – Legal Standard

• The level of skill and knowledge in the art, and the predictability of the art are important considerations

• The more you disclose, the more you will likely be able to claim
Adequate Disclosure – Example

• Problem often arises in the context of claiming a genus of molecules
  – You have identified a molecule of interest
  – Should you file now, or get more data/candidates to disclose?
  – What is the likely breadth of your claims if you disclose this molecule (i.e. can you claim related molecules)?
More Likely to Meet the Standard

- DNA molecules that include the exact sequence disclosed
- The degenerate DNA molecules that code for a disclosed protein
- Antisense oligonucleotides to a disclosed gene sequence
- Antibodies specific to a disclosed peptide
Less Likely to Meet the Standard

• Claiming a broad genus of molecules for a given purpose
  – E.g. peptides 80% identical to a disclosed peptide sequence for treating a disease
• Generic method of inhibiting the activity of disclosed molecule
• Claiming solvates and hydrates of a molecule
Adequate Description – Real Example

- US 7,790,961
- 83 DNA sequences and lots of experimental data disclosed
- Claimed all polynucleotides that code for a toxin and hybridize “under stringent conditions with the full complement of” any of three separate sequences
Adequate Description – Real Example

• Pending application
• 2 protein sequences some experimental data disclosed
• Rejected claim: all polypeptides 95% identical to a disclosed sequence
Claim Scope-Priority Tension

• What options might your counsel suggest to reduce this tension?
  – Consider what claim scope is necessary (without being shortsighted)
  – Find efficient methods of obtaining more disclosure and leverage them
Reducing the Tension

• Consider narrower claims consistent with goals
• File a provisional application
• Leverage the structure-function experiment called evolution
• Determine the easiest design-arounds and add them to your assays while they are up and going
• Consider disclosing data from candidates that did not meet all criteria
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Collaborating with Counsel

• Often determining what is “legal” isn’t as simple as Asok might have us believe:
Collaborating with Counsel

• Part of the Team:
  • Research and Development
  • Product advancement
  • Patent preparation/filing
  • Strategic patent maintenance and portfolio development
  • Non-traditional roles
Collaborating with Counsel

• Research and Development
  – Identifying patentable subject matter
  • Counsel to augment the data developed to provide optimal disclosure for the application
  • Assure inventor/disclosure/responsible conduct obligations to the U.S. Patent and Trademark Office are met
Collaborating with Counsel

• Product advancement
  – FTO/Clearance
Collaborating with Counsel

- Patent preparation/filing
  - Prosecution timing/watch for pitfalls that could bar patenting
  - Filing strategy: maximize potential value of I.P.
Collaborating with Counsel

• Strategic patent maintenance and portfolio development
Collaborating with Counsel

• Non-traditional roles
  • Participate in product meetings
  • Assist/support patent committee
  • Assist in developing intellectual property budget
• Critical evaluation of portfolios
• Review and monitor licenses
Questions?