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Emerging Life Sciences Companies

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Chapter 8

Checklist for Planning and Conducting an Effective FTO Search

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CHECKLIST FOR PLANNING AND CONDUCTING AN EFFECTIVE FTO SEARCH

The following sets forth aspects of planning for and conducting an effective FTO search:

Objectives: Identify, Value, and Reduce Risk

A. Institute an ongoing program to identify, value, and reduce risk for each of the Company's products

   1. Identify the material issues for each product

   2. Keep in mind that products are more than the sole commercial product itself. They also include the activities that the Company utilizes in its product development (such as upstream compounds [e.g. intermediates], methods of making compounds, methods of testing compounds, cell lines and other reagents, and particular animal models). In addition, the applications of the products, such as their purposes and methods of use (e.g., treating disease), all need to be evaluated.

   3. Develop a knowledge base associated with each product line

      a. Ascertain the scope of the Company's protection

      b. Ascertain the scope of third-party positions

   4. Review and evaluate on a regular basis; IP continues to evolve rapidly

   5. Assemble information and/or reports, and have regular meetings with lab staff and (importantly) management

B. Identify, evaluate, and manage risks to the extent possible

C. Deal with small problems before they grow; deal with big problems immediately

Scope and Perspective of the Evaluation

A. Patents, patent applications, and invention disclosures

   1. See next section in this outline

B. Trademarks

C. Agreements

1. License agreements
2. Employment contracts
3. Joint research development agreements
4. Material transfer agreements (MTAs)
    a. Both "incoming" and "outgoing"?
    b. Are there restrictions on use?
    c. Are the Company's activities documented?

D. FDA matters

1. Consistency between what is said to FDA and the USPTO
2. Matching claim language to labeling
3. Evaluating the interplay of FDA exclusivity and patent exclusivity for maximum exclusivities

E. Litigation

1. If litigation is present, there is generally a very heightened risk analysis

F. Copyrights, trade secrets, know-how, domain names, and so forth

G. Other issues

1. Equipment and tax liens
2. Security interests

U.S. Patents and Patent Applications

A. General strategy

1. What is the goal of each application (e.g., exclusivity, licensing to third parties, partnering, deal flow, "trade bait")?
2. Why and where is the Company filing it?

B. Are there limitations to potential patent rights based on the file history of the patent prosecution file at the USPTO?

C. Ownership of U.S. rights

1. Owned/developed under a joint research agreement or licensed-in/out?
2. Check assignments from employees
3. Licenses

4. Government's or others' rights (e.g., security interests)

D. Scope of patent protection

1. Adequate claims and breadth/validity of claims
2. Territory
3. Term of license

E. Patent term not abandoned or expired

F. Patent term extensions evaluated and checked

G. Probable new rules being enacted by the USPTO

1. "Third-Party Opposition Proceedings" similar to European Opposition procedures
   a. Difficult to evaluate without track history
   b. Actual risk/benefit analysis will depend on rules enacted
   c. New area that will need to be addressed
2. "First to file" vs. "first to invent"
   a. No more interference proceedings if enacted
   b. Will require new procedures internally and with outside counsel on timing of filing new inventions

H. New continuation and claim rules have been enacted by the USPTO that will force companies to evaluate patent prosecution and litigation strategies.

Foreign Patents and Patent Applications

A. What inventions get foreign filed?

1. "Triage" approach: most companies cannot afford to file everything everywhere, need for realistic evaluation of which inventions get foreign filed
2. Evaluation of what countries protect what kind of inventions

B. Where do patents get filed?

1. Are there foreign partners involved?
2. Where will data be generated?
   a. Experimental data?
   b. Contract Research Organizations (CROs)?
   c. Clinical trials?
3. Where will the products be made?

C. Status/evaluation of patents in the same/similar technology

1. Check for oppositions, litigation, issuance

Trademarks

A. Appropriate searches conducted at appropriate times

B. Possibility of classifications changing/expanding over time

C. Owned or licensed-in

1. Obligations?

2. Term?

D. Registered or not

E. Territory

F. Oppositions

1. Against seller's trademark

2. Against third-party trademarks

License Agreements

A. Ownership and use of IP

1. Right to prosecute?

2. What if disputes on strategy?

B. Assignable/sublicensable?

1. To whom and for what? Where?

C. Other key license terms

1. Definitions must be evaluated closely

2. Exclusive/nonexclusive/noncompete

3. Scope of rights and territory

4. Improvements

5. Field of use

6. Royalties and milestone payments, amount, and duration

7. Obligations

8. Term of agreement

9. Termination provisions

FDA Matters

A. Approved product exclusivities

1. New chemical entity (NCE) granted five years of market exclusivity, regardless of patent status
2. New use of previously approved product is granted three years of data exclusivity
3. Orphan drug status allows seven years of exclusivity
4. Pediatric exclusivity gives an additional six months on top of other exclusivities

B. Orange Book listings

C. Changes in the rules now dictate what type of patents must be listed and what type cannot be listed

D. Abbreviated New Drug Applications (ANDAs)

E. Status of patent expiration?

F. Patent term extensions due to FDA delay

IP Litigation

A. Determine if there is any and then evaluate risk

B. Consider strategies to end or mitigate risk

Accept or Allocate the Risk

A. Value risk—Risk associated with major product or intermediate testing method that will not be done commercially?

B. Isolate the risk—Beware of "contamination" of related patents

C. Escrow funds—More discussion of these than utilization

D. Representations and warranties that will work

E. Indemnification—Be careful of signing these

F. Insurance

G. Acquire rights—If licensable, weigh license fees versus cost of fighting

H. Design around—"Research tree decisions"

Objective Achieved?

A. IP protection identified

1. Material issues characterized

2. Chain of title clear
3. Exclusivity period understood
4. Scope of protection understood

B. Negative issues identified
1. Obtain verifiable and acceptable explanation
2. Cure the defects (if possible)
3. Evaluate and manage risks