

Morgan Lewis



# Emerging Life Sciences Companies

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## Chapter 9

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Conducting and Managing a  
Patent FTO Search

## Chapter 9

# CONDUCTING AND MANAGING A PATENT FTO SEARCH

### The Search(es)

What, when, and where to search are all issues that are debated frequently when FTO searches are discussed. When a technology is in the early research phase, the outcome is generally not set. It can be speculative at best to predict what the final product will be, which may mean that a company diverts significant time and resources into searching a large number of research projects, only a few of which are destined to become candidate products. Alternatively, waiting too late to search is also a problem, as it usually means that the project and its derivative products are too far down the development and/or regulatory pipeline to change. At this point, if licensing is necessary, often the Company has spent so much in research and development that it has added a great deal of value to the product. This makes the company vulnerable in negotiations with whoever holds the license—often resulting in licensing terms that are very expensive—and in the worst case, the license is not available. Thus, timing searches and FTO analyses is a matter of striking a balance between cost and inflexibility.

In general, therefore, FTO searches are done both informally and iteratively over time, with small, frequent, informal searches usually culminating in a more focused formal search and/or opinion.

Informal searching is done early to identify severe problems—the type of third-party coverage that results in a high likelihood of project termination. For example, if a competitor has broad patent coverage in a disease area in which it is actively pursuing research, the likelihood of obtaining a license is low, and the risk is high. Alternatively, understanding that a university has a patent position for a useful assay and that nonexclusive licenses are available is generally positive. Thus, informal and nonextensive searching is generally done early and often. This leads to a number of advantages, including getting timely notice of patents and/or applications that affect the Company, allowing the Company to keep up to date on previous searches, identifying the issues and risks prior to investing significant Company resources, and anticipating interference issues to avoid the statutory bar under 35 U.S.C. § 135(b). Continuous monitoring is also helpful to keep apprised of patents and/or applications that may affect early projects. In addition, investors may require different levels of searching during different funding cycles. Informal searching in no way eliminates the need for formal searching when product launch is contemplated.

Finally, the importance of including the scientists in the process is key; frequently, research can change directions, and without scientific input on a regular basis, the search strategy can quickly become outdated or obsolete.

Thus, continuous monitoring should be put in place to allow a flexible and responsive evaluation as needed.

### ***Search Strategies: Presearch Activities***

To ensure FTO searches result in identifying the most relevant third-party patents, the Company should perform the following presearch activities:

#### **Overall Search Strategy**

- A. Identify the purpose of search
  - 1. Product development
    - a. Generally earlier stage, less rigorous
  - 2. Product marketing
    - a. Generally late stage, more rigorous
  - 3. Clinical testing
    - a. More rigorous due to cost of trials
  - 4. Acquiring product/technology
    - a. Early stage
    - b. Late stage
- B. Funding

#### **Level of Diligence**

- A. “No stone unturned” vs. “lay of the land”
- B. Budget
  - 1. Often plays a big part
- C. Potential scope of liability
- D. Contractual obligation(s)
- E. Third-party due diligence
- F. Preexisting knowledge of third-party patents

#### **Location and Type of Activities**

- A. Research and development activities: § 271(e)(1)

- B. Clinical trials: § 271(e)(1)
- C. Manufacturing: § 271(e)(1)
- D. Sales
- E. Importation into United States: § 271(g)
- F. Exportation from United States

### **How Do These Activities Affect Search Strategy?**

- A. Type of claims: product/composition, method of making, method of using

### ***Formulating the Search***

Formulating the search is the most important—and frequently the most difficult—component of the process. Generally, utilizing a number of parameters is a good idea. The search usually will include:

### **Keywords**

- A. It is important to keep in mind that terms often evolve (e.g., “polymerase chain reaction” (PCR) will not pick up the Mullis patents)
- B. Also use synonyms, abbreviations, obscure gene names, and so forth

### **Potential Inventors/Entities**

- A. Scientific literature identifies possible inventors
- B. Web search may identify inventors and entities (e.g., companies, research institutions)
- C. Search business databases (LEXIS Biotech Business) to identify commercial interests

### **Time Frame of Invention**

- A. Scientific literature identifies invention time frame
  - 1. Relevant cloning date of gene, discovery of disease mechanism, synthesis of compound, and so forth
- B. Use time frame to limit ongoing searches
- C. Use publication record to guide analysis
  - 1. Validity of issued patents
  - 2. Patentability of published application claims

### **Sequences**

- A. Identify relevant sequences: product sequence, biological target sequence
- B. Identify variability allowed:

1. Consensus sequences?
  2. Percentage identity, homology?
  3. Selection from multiple sequences (e.g., human)
  4. Identify possibility for design-around
- C. Select query sequences:
1. Obtain computer-readable form from GenBank
  2. Nucleic acid: core sequence (ORF) or portion actually used if less than full length

### **Structures**

- A. Identify “core” structure
- B. Has SAR been done?

### **Select Timing and Resources**

- A. Claims only
- B. Full document search (can be unmanageable)

### ***Where and Which Databases to Search***

The Company should perform the following searches:

### **Where Are Sales, R&D Efforts, Partners, and Potential Partners?**

- A. U.S.-based manufacture and sales, sales to Europe
- B. R&D experimental use, clinical research exemption

### **What Is the Activity?**

- A. Importation of data has special rules

### **USPTO Searches ([www.uspto.gov](http://www.uspto.gov))**

- A. Search issued patents and published applications
  1. These are separate databases
  2. Allows queries to claims only, if desired
- B. Sequence searching at USPTO is not really possible
  1. Need to rely on a commercial database, see below
  2. Search “Patent Application Information Retrieval” (PAIR) system (<http://portal.uspto.gov/external/portal/pair>)
  3. Issued patents and published applications

4. Gives status, continuing applications, file histories
- C. Search assignment data (<http://assignments.uspto.gov/assignments>)
  1. Issued patents and published applications
  2. Searchable by assignee/assignor
  3. Note not determinative, just if assignment has been recorded with USPTO
  4. Also check an INPADOC search for title changes
- D. Search classification system (<http://www.uspto.gov/web/patents/classification>)
  1. Starting with a relevant patent, work backwards using the classification system to find related patents

#### **WIPO Searches (<http://www.wipo.int>)**

- A. As publications of U.S. applications lag behind the PCT, this is a good source of information on filings made in the past 18 months

#### **EPO Searches (<http://www.espacenet.com>)**

- A. Can be particularly useful to identify oppositions, which can be used in evaluating the validity of U.S. claims
  1. PCT applications (some full images)
  2. National patent databases (e.g., EP, CA, JP abstracts)
  3. “Worldwide” search capability and INPADOC
  4. EP classification scheme
  5. Online file histories (<http://www.epoline.org/portal/public>)
  6. Public file inspection (<http://ofi.epoline.org/view/GetDossier>)

#### **IP Australia ([http://www.ipaustralia.gov.au/patents/search\\_index.shtml](http://www.ipaustralia.gov.au/patents/search_index.shtml))**

- A. Published patent data
  1. By number
  2. Keyword search
  3. PDFs available in some cases
- B. Classified by IPC
- C. IP organizers (<http://www.ipmenu.com>)
  1. Australian file histories for a fee

### **Canadian Intellectual Property Office (<http://cipo.gc.ca>)**

- A. Bilingual (French/English)
- B. Search Canadian patents and published applications (last 75 years)
- C. Maintenance fee information available
- D. “Availability of license” field provided
- E. Administrative status

### **Website for Worldwide Patent Offices**

- A. <http://www.patentlawlinks.com/patoff.htm>

### **Sequence Searches**

- A. USPTO (<http://seqdata.uspto.gov>)
  - 1. System stores and retrieves large sequence listings and tables that have been included in granted and/or published U.S. patent applications
  - 2. View individual sequences or tables, or download sequence listings, tables, or other mega items
  - 3. Search by document number or publication date
  - 4. NO SEARCHING VIA SEQUENCE!
- B. GenBank: Nonpatent
  - 1. Most comprehensive database available
  - 2. Use nonpatent database to set time of invention
  - 3. Use date (e.g., cloning date and publication) to guide analysis of hits in patent database
  - 4. Use nonpatent database to identify potential inventors
  - 5. Use nonpatent database to identify potential entities (e.g., assignees, licensees)
- C. GenBank: Patent
  - 1. Fairly comprehensive database available
    - a. Sequences from issued patents and published applications available; provided by USPTO and others on weekly basis
    - b. Searchable by accession numbers, sequence, inventors (through links)
    - c. Linked to NCBI services: SNP, HomoloGene, CDD (Conserved Domains), and so forth
  - 2. How to search:

- a. VecScreen: Pull vector sequences
  - b. BLASTN: Nucleotide
    - (i) Long sequence
  - c. Short, exact matches
  - d. BLASTP: Protein
    - (i) Long sequence
    - (ii) Short, exact matches conserved domains
  - e. Translated
    - (i) Translated query vs. protein databases
    - (ii) Protein query vs. translated databases
    - (iii) Translated query vs. translated databases
3. Sequences producing significant alignments

### **Commercial Databases**

- A. Delphion
  1. INPADOC
  2. Patent family data
  3. Derwent access
  4. Dialog access
  5. Search for patents available for licensing
  6. Nonpatent “prior art”
    - a. IBM Technical Disclosure Bulletins
    - b. ISI “Web of Science”
- B. Dialog/Derwent (Thompson)
  1. PCT publications
  2. Full-text patents
  3. Worldwide/family data
  4. Nonpatent publications
  5. Searchable by assignee/inventors
- C. INPADOC (<http://www.european-patent-office.org/inpadoc/index.htm>)

1. Accessed through Dialog
  2. Patent legal status information
  3. Searchable by assignee/inventors
- D. Questel-Orbit (<http://www.questel.orbit.com/index.htm>)
1. Contract patent searching
- E. DGENE (Derwent), CAS Registry
1. Fairly complete databases
  2. DGENE built with same data as released to NCBI
    - a. Allow search via sequence query
    - b. Most data not coded for claim association
  3. Typically used in addition to GenBank patent file
- F. GenomeQuest™
1. Allows comprehensive searching and generation of multiple reports, as well as claim association

### ***Analysis Strategies***

Helpful analysis strategies include

#### **Sorting “Hits” to Allow Efficient Analysis**

- A. Use combination of keyword, structure, and/or sequence
- B. Sort for issued patents only?
- C. Sort for keywords in claims?
- D. Sort for sequences in claims?
- E. Sort for structures in claims?

#### **Analysis Parameters**

- A. Set level of diligence via parameters discussed
- B. Use diligence level to guide analysis, for example:
  1. Restrict analysis on hits >85% Seq ID
  2. Consider enablement and written description support
  3. Rely on available infringement defenses to limit analysis

4. Consider purpose and scope of FTO needed
5. Presearch activities allow management of search and analysis
  - a. Search strategies contain scope and cost
  - b. Set guidelines allow organized analysis of search result

### ***Post Search***

When a search is complete, establish the following “watches”:

- Delphion, foreign associates, will allow weekly reports to follow issuances, and so forth
- Derwent, Dialog, Lexis and Westlaw U.S. patents (Tuesday)
- Publications (EP on Wednesday, PCT and U.S. publications on Thursday)
- Can also use other sources available on Internet or in industry magazines, newsfeeds from Dialog or Factiva, or Yahoo press releases, for example

### ***Who Should Search/Division of Labor***

One issue that arises in many situations is who should be doing the search: in-house counsel or outside counsel? Of course, in some circumstances in early-stage companies, there may be no in-house counsel and the answer is easy. Usually, however, for a variety of legal reasons, a good search strategy and analysis is best done using input from both in-house and outside counsel.

It should be noted that the law on the competency of in-house counsel opinions is changing. For many years, in-house counsel was almost presumed to have a bias, and thus in-house opinions have been in many cases traditionally discounted in willful infringement analyses. However, this has changed somewhat in recent years, particularly in light of several recent cases, and thus it is no longer a hard line. In general, cooperation and a division of labor between the in-house and outside counsel can produce a good result at a reasonable expense.

For example, in-house searchers over time will gain familiarity with the best or most relevant databases for different countries or different technologies. In addition, the availability of specialized databases can allow a company to purchase or subscribe to relevant databases, leading to highly effective searching. These databases may not be cost effective for outside law firms. Furthermore, while pricing models used to be based on time online, search complexity, and size of download, newer pricing is based on subscription fees, again favoring companies who use particular databases frequently over law firms that may utilize such databases less frequently.

Frequently, internal searching is done, with a preliminary analysis of the hits. This analysis can be discussed with outside counsel, and appropriate materials provided. However, to the extent that outside counsel will be writing an opinion, outside counsel has to make an independent deter-

mination of infringement and/or invalidity. Generally, constant communication between in-house and outside counsel is key.

## **Conclusion**

FTO programs can uncover potential issues that may affect the making, using, or selling of proposed products. If implemented in an effective manner, FTO programs can help your Company avoid or mitigate risks and add significant value to your Company. Companies considering implementing FTO programs should consider the following:

### **The Purpose and Scope of FTO Needed**

#### **Presearch Activities Allow Management of Search and Analysis**

#### **Set Guidelines to Allow Organized Analysis of Search Results**

#### **Scope of Search**

- A. Limit to United States?
  - 1. Search U.S.-focused databases
- B. Commercial vs. no-cost
- C. Expand abroad?
- D. How to find international patents/applications?
  - 1. U.S. forward
  - 2. Direct search

#### **Timing: At What Time Is FTO Needed?**

- A. R&D programs may need FTO for short period
  - 1. Present need: program to start ASAP
    - a. Issued patents
  - 2. Future need: program to start in future
    - a. Issued patents and pending applications
- B. Pending applications
  - 1. Published U.S. applications
  - 2. Published PCT applications
  - 3. Issued international applications
  - 4. Published international applications

## Electronic Databases

### Hand Search

#### Outline Search/Analysis

- A. Set parameters
  - 1. Keyword
  - 2. Potential inventors/entities
  - 3. Time frame of invention
  - 4. Sequence
  - 5. Structure
- B. Set timing
  - 1. Search first, analyze second
  - 2. Concurrent search and analysis
- C. Pick resources

#### USPTO (<http://www.uspto.gov>)

- A. Issued Patents and Published Applications (<http://www.uspto.gov/patft/index.html>)
  - 1. Separate databases
  - 2. Keyword searching
  - 3. Allows query to claims only
- B. PAIR-status and file history (<http://portal.uspto.gov/external/portal/pair>)
  - 1. Issued patents and published applications
  - 2. Reexamine file histories
- C. Assignment data (<http://assignments.uspto.gov/assignments>)
  - 1. Issued patents and published applications
  - 2. Searchable by assignee/assignor

#### WIPO (<http://www.wipo.int>)

- A. No single publicly accessible source of PCT applications/publications at WIPO (see EPO)

#### EPO (<http://www.espacenet.com>)

- A. Quick and advanced searching