Freedom-to-Operate

My Six Basic Rules
What risks will a company take if it decides to commercialize a new product or process? Specifically, what need it fear from patent litigation? Freedom-to-operate (FTO) opinions provide risk assessments relating to infringement of granted patents and potential infringement of pending patent applications. FTO opinions are an important part of making good business decisions. In the U.S., only patent attorneys are qualified to provide legal FTO opinions; patent agents can only offer opinions related directly to patent prosecution. (For more details on the role of patent agents, read David Hricik’s 2007 article, "Patent Agents: The Person You Are” in the Georgetown Journal of Legal Ethics [vol. 20, no. 2, pp. 261-286]). Nonetheless, patent searchers exercise critical judgment in performing FTO searches, also known as freedom-to-practice, clearance, infringement, non-infringement, or right-to-use searches.

The goal of the FTO search is to find relevant unexpired patents or patent applications that could become commercialization barriers in the countries targeted for the manufacture, sale, or use of the proposed commercial venture. This article will describe some of the major steps that searchers should take to ensure that their FTO search reports provide attorneys with the information they need to make appropriate FTO analyses. I use a hypothetical case study based on an actual search event on high-density polyethylene fuel tanks (see the Six Rules of Success sidebar at right).

These six rules for successful FTO searching also apply to all search processes, but I describe them herein with particular reference to FTO searching. Apply the rules throughout the search process and use conservative judgment and iteration as appropriate.
Case Study
HDPE Fuel Tanks

A hypothetical client intends to produce vehicle fuel tanks by blow molding polyethylene and related copolymers. Manufacturing and sale plans are limited to North America and Europe.

The polymer could be ethylene homopolymer or copolymer comprising ethylene and not more than 10% by weight of an alpha-olefin having from three to 20 carbon atoms. The polymer has a density of 0.945 to 0.970 g/cc, thus falling in the range of high-density polyethylene (HDPE) characterized as having a density greater than or equal to 0.941 g/cc. In addition, the polymer has intrinsic viscosity of 2 to 6 dL/g. It may be prepared by classic Ziegler-Natta catalysts, i.e., titanium chloride (TiCl₃, TiCl₄) catalyst and alkylaluminum (AlEt₃, Et₂AlCl, EtAlCl₂, etc.) cocatalysts with or without supports or modifiers.

The client has provided a known patent on “Ethylene Polymer and Fuel Tank Comprising the Same” (US 5547722, published Aug. 20, 1996) from Mitsubishi Chemical Industries.

Rule 1:
Verify and Re-Verify the Scope With the Customer

The customer interview is critical to understanding the scope of the search. I may interview the patent attorney and/or the search professional at the client organization and then supplement that information by contacting the client's technical experts or commercial managers. I prepare a draft cover letter clearly defining the search subject, including elaborating on the subject details, as well as geographic and patent expiry limitations. A clear explanation of the search scope becomes the basis of the search strategy. Once completed, I get feedback on the cover letter and search scope from the client to ensure that I cover the topic appropriately. As necessary, I revise the search scope and strategy at that point and throughout the search process.

In the case of this hypothetical FTO search, I determined that the search scope should include the concepts and terms listed in Table 1 below.

The critical concepts are the polymer composition, density, and intrinsic viscosity and the manufacture of blow-molded or hollow articles — not just vehicle fuel tanks. The attorney in the search on which this case is based agreed that I would not search for any specific polymerization catalysts, but that I should note the catalyst composition during the post-search evaluation of candidate patent references. We decided to limit this first search to major Western patent authorities covering recent EP, US, and PCT (Patent Cooperation Treaty, designated WO) patents and patent applications. We chose to limit the search to patent documents filed since 1985 in order to capture all likely unexpired patents or pending patent applications and to eliminate the large number of expired on-topic documents. Searching back 22 years should be adequate to find potentially in-force patents. We agreed to defer searching for patents from Canada, Mexico, or specific European countries until the attorney had evaluated the results of the initial search. I deferred determination of legal status and possible expiration due to non-payment of maintenance fees until after the attorney had made a first analysis of reported patent documents.

| Table 1: Search Scope: HDPE Fuel Tank |
|-------------------------------|---------------------------------|
| **Initial Definition**        | **Search Scope**                |
| Ethylene homopolymer or copolyol | C2 homopolymer, C2/C3+ olefin copolymers |
| Density 0.945-0.970 g/cc      | “High density”, HDPE, 0.94, 0.95, 0.96, 0.97, 0.98 cm³ |
| Intrinsic viscosity 2–6 dL/g  | Intrinsic viscosity but values in post-search only |
| Ziegler-Natta catalysis       | Post-search consideration only |
| Fuel tank                     | Vehicle or fuel tanks, drums, reservoirs; blow molded or hollow articles |
Rule 2:
Don’t Miss Obvious References

Nobody wants a client to come back with a critical reference that you missed and that they found for free on a USPTO or Espacenet website. I usually carry out a quick initial search with the broadest acceptable search terms on one of the subscription patent websites such as Delphion, MicroPatent, QPat, or PatBase, or on the USPTO or Espacenet websites when subscriptions are not available.

In this case, I conducted a simple search for "polyethylene and fuel and tank" in the title and abstract fields in the Worldwide Espacenet database. This proved very helpful for discovering alternative search terms for the full search strategy. I then searched MicroPatent with a more complicated strategy: "((polyethylene or hdpe or (ethylene near2 (homopolymer or polymer or copolymer)) or hdpe) and "high density") and ((fuel or gasoline or petrol or vehicle or car or automobile) near2 (tank or drum or reservoir)) (in claims, title, abstract; 1981-2007). These initial searches can also help you in preparing cost estimates without spending much time or paying online fees.

Rule 3:
Carry Out the Search in Two Independent Parts

I find it useful to carry out these searches in two complementary, independent steps, one using full-text databases and the other using value-added databases. My initial search uses full-text databases such as those listed above in Rule 2 or on traditional online aggregators, including STN, Dialog, or Questel. Full-text searching requires extensive use of term variations and synonyms, as well as judicious use of Boolean and proximity operators. Since FTO analysis focuses on claims, you must target claims and remember that the disjointed structure of claims means that individual claims seldom include all the target concepts. So I use Boolean operators when searching claims. I supplement the claims search by searching titles and abstracts, and sometimes the full specification, with appropriate proximity operators, e.g., paragraph, sentence, or near operators, to ensure I retrieve patents that include all appropriate concepts. In the hypothetical case, I searched the full specifications of EP, US, and WO patents and applications in MicroPatent using a series of broad strategies such as this one:

(polyethylene or (ethylene near2 (homopolymer or polymer or copolymer)) or hdpe) and "high density" or (density near5 (0.94 or 0.95 or 0.96 or 0.97 or 0.98)) and ((blow near2 (mold or mould) or article))

Subsequently I added the inherent viscosity concept. I selected references based on review of titles and abstracts at this first stage and concluded with a list of candidate patent document numbers.

Searching value-added databases complements full-text searching. It is vital for finding references with non-standard nomenclature, in languages besides those covered by the search terms, and from authorities whose documents are not available in full-text. For the case study, I searched STN databases — Chemical Abstracts (CAPLUS), Thomson Derwent World Patents Index (DWPI), and IFI CLAIMS US Patents (IFICDB) — using CAS Registry numbers and indexing, Derwent polymer indexing, IFI thesaurus terms, and text search terms. These databases index the claimed invention to varying degrees, so not all will necessarily find references relevant to FTO analysis.

For the current example, I searched for polymer compositions containing ethylene homopolymer and copolyolefins with ethylene and one or more alpha-olefin comonomers from propylene to 1-ecosene. These were restricted to high density using search terms "high density" and HDPE as well as specific values for density — 0.94, 0.95, 0.96, 0.97, 0.98 cm³ — with term truncation to allow for three decimal places. Since searching for physical properties is troublesome, I searched simply for intrinsic viscosity and related terminology, e.g., relative viscosity, reduced viscosity, and inherent viscosity, but not for specific values, as I had for the polymer density. I noted specific values during post-search evaluation, however. I used many alternative terms for fuel tanks as well as for blow-molded or hollow articles. As with the full-text search, I judged references by their value-added titles, indexing, and, as appropriate, database abstracts, and produced a list of patent document numbers to carry to the next phase.

I also used PatentCafe with its Latent Semantic Analysis (LSA) search method as a supplement to the full-text databases searched with Boolean logic. PatentCafe claims that LSA...
can find candidate patent documents not readily found by Boolean searching, especially when the target technology involves general concepts that might be described with largely varying nomenclature. I carried out two parallel searches based on known Mitsubishi Chemical Industries patent US 5547722. The first was a "more like this" semantic search that uses all the claims text as search concept language. The second was a semantic search using the first five paragraphs of the "Detailed Description of the Invention" text. I found relatively few additional references of interest. Most of the dozens of EP, US, or WO documents with "relevancy ratings" greater than 90% were not relevant, because they disclosed multilayer, barrier-layered, or polypropylene or polyamide fuel tanks. Interestingly, I did not find source patent US 5547722 as a highly relevant reference in either search. I recognize that the success of LSA searching depends greatly on search concept text. Perhaps my search needed further refinement of the search concept text to succeed.

I combined the results of these search sessions into one list of unique patent document numbers. I then entered all of them into a patent viewer application for detailed evaluation of the claims and specifications. Modern patent viewers, such as Miresoft PatentOrder, STN Viewer, or QPAT, greatly facilitate evaluating full text by color-coded term highlighting and showing full-text and images, including drawings, side-by-side, on the monitor.

**Rule 4:**

Be Sure You Know Why You Are Rejecting Each Reference and Think Twice About It

Searchers make critical judgments when they determine which references to give to clients and which to delete. Be conservative. Let the client have a full set of relevant documents to analyze. For PTO searches, I screen and review each claim of each patent document for likely relevance and examine the specification for definitions or clarification of claim language, especially if the claims language does not explicitly include the target concept but appears to indicate collections or ranges in which the target concept may belong. However, I only use information in the specification when deciding whether to include borderline references in the final report and never to reject references. Rejection in that case would constitute claims language legal analysis that only the attorney is allowed to do.

**Rule 5:**

Present the Results in the Fashion That Your Customer Can Best Use

Once the search is completed, I return to the cover letter to confirm that I covered the search scope appropriately and to put into context the reported references. Because of the commercial importance of these searches, I try to get feedback on the cover letter from other searchers in the client organization. Some search groups require such review as a standard practice prior to sending the report to the attorney. I provide output in a number of formats to fit the needs of the attorney. In some cases, I report just a list of relevant patent numbers because the attorney wants to evaluate each document without any further summary or comments from me. Upon client request, I report a list of rejected references as well. This is easy because I keep records of each reference I examine in detail. In other cases, I tabulate relevant references using application software such as BizInt Smart Charts, STNTable Tool, or export options from the patent search systems. I usually include in the Word document a simple five-column, portrait-oriented table with title, assignee, principal patent number, other family members, and key claims and comments. I transfer the key claims and comments from the annotations that I noted during

*Rule 5. continued on page 38*
Freedom-to-Operate Analysis by Attorneys

A patent attorney recently characterized the freedom-to-operate opinion as "the single most difficult issue for a patent practitioner to deal with on a day-to-day basis." The difficulty relates to the value of the commercial operation and the importance of assuring the client that initiating the commercial operation will not lead to substantial litigation or legal liability.

At the outset, the attorney requires an accurate definition of the process or product to be manufactured, sold, or used and the target countries involved. A change in any of these commercial parameters could require reconsideration and revision of the opinion. The patent attorney generally relies on a comprehensive search carried out using the same commercial parameters. Thus, it is critical that the searcher and attorney are completely consistent in their understanding of the commercial venture.

The attorney carries out an analysis of each patent claim for each identified patent document. The analysis targets literal infringement of the claims by the intended commercial venture. The attorney determines the language, meaning, and scope of each patent claim by current standard analysis practices and in the context of the entire specification and the prosecution history. Terminology in the claims may differ from common usage if defined otherwise in the specification. Communications between the applicant and the patent examiner documented in the prosecution history may have significant bearing on the meaning and scope of claims. The attorney then compares each properly construed claim to the process, machine, product, or composition under analysis for infringement. If the attorney finds no literal infringement, he next considers if a potential infringement might exist under the "doctrine of equivalents," by which the difference between the claimed invention and the commercial venture might be considered insubstantial by courts of law, resulting in litigation and penalties.

FTO opinions always contain uncertainty for a number of reasons. Analysis can never be fully up-to-date because of the 18- or more month delay in patent application publication. In addition, practitioners and searchers can miss relevant patent references. Attorneys must analyze claims by current standard practices, but these could change due to future court cases. In the end, the opinion ends up with a risk assessment intended to help the client decide whether the risk of litigation is acceptable to pursue the commercial venture. Significant modifications in the commercial venture or new relevant patent documents should always trigger further consideration by the attorney.

Rule 6: Expect to Defend Your Search

I carry out the entire search process with the expectation that I will need to defend the search and reference selection processes. After almost every FTO search, despite all the precautions I take to ensure that I deliver what the attorney needs, the attorney questions various aspects of the search scope, strategy, reporting, or the list of patent documents. The cover letter is the starting point for post-search discussion. Once the attorney fully understands the search parameters and results, I may receive additional requests for searching based on new considerations. Even if the FTO search proves completely satisfactory, the attorney may still request an invalidity search on a reference that appears to block a commercial operation.

Conclusion

All service providers focus on understanding what customers need and delivering what they want and expect. The search practices that I have described are effective in satisfying customers for FTO search requests and can also apply to patentability, state-of-the-art, invalidity, and other types of patent search requests. I recommend that searchers add these rules for FTO searches to their checklist of best practices for delivering high-quality search services.

Author

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Acknowledgments

This paper is based on the presentation "Freedom-to-Operate Study: HDPE Fuel Tanks" presented at the Plastics 2007 Northeast Conference (New Brunswick, N.J., Oct. 9, 2007).