Freedom-to-Operate Search Strategy

Hitting the Target

The purpose of a freedom-to-operate (FTO) search is to provide to a patent attorney the patent documents needed to render an FTO opinion. That opinion relates to whether there is a legal barrier to commercializing a client's anticipated composition, process, device, or method of manufacture. The simplicity of these statements obscures the complexity of the overall search process. There are other players besides the attorney to be satisfied, including technical experts and business managers who define the parameters and are the ultimate clients.

By Thomas E. Wolff

Determining FTO is a legal process, conducted by an attorney, with a unique set of requirements and outputs. Searchers must direct their efforts to meet those requirements with a good understanding of the search topic, skilled development of the search strategy to target patent documents with high interest to the clients, and clear knowledge of how to select patent documents that will be needed by the attorney to formulate the FTO opinion. The searcher can reduce the net costs to the ultimate client by finding, selecting, reviewing, and highlighting patent art in order to minimize the cost of the attorney's time to evaluate the reported references. At the same time, no searcher can be expected to either identify or evaluate every reference or clear every aspect of the client's planned commercial operation.

The difficulty of defining the search parameters and reviewing candidate references has not been sufficiently emphasized in conference presentations and published papers, including my own paper, "Freedom-to-Operate Patent Searching: My Six Basic Rules" [1] that I published a decade ago. Some of this has been mentioned in the Freedom-to-Operate Fundamentals: Comprehensive Techniques for Researching Freedom-to-Operate course [2] sponsored by the Patent Information Users Group (PIUG). I discuss in this

paper the development of search strategies and the post-search analysis of candidate search results. I believe that the lessons learned from studying the processes of FTO searching are applicable to other kinds of technical and non-technical search services.

PARTICIPANTS, ROLES, AND RESPONSIBILITIES

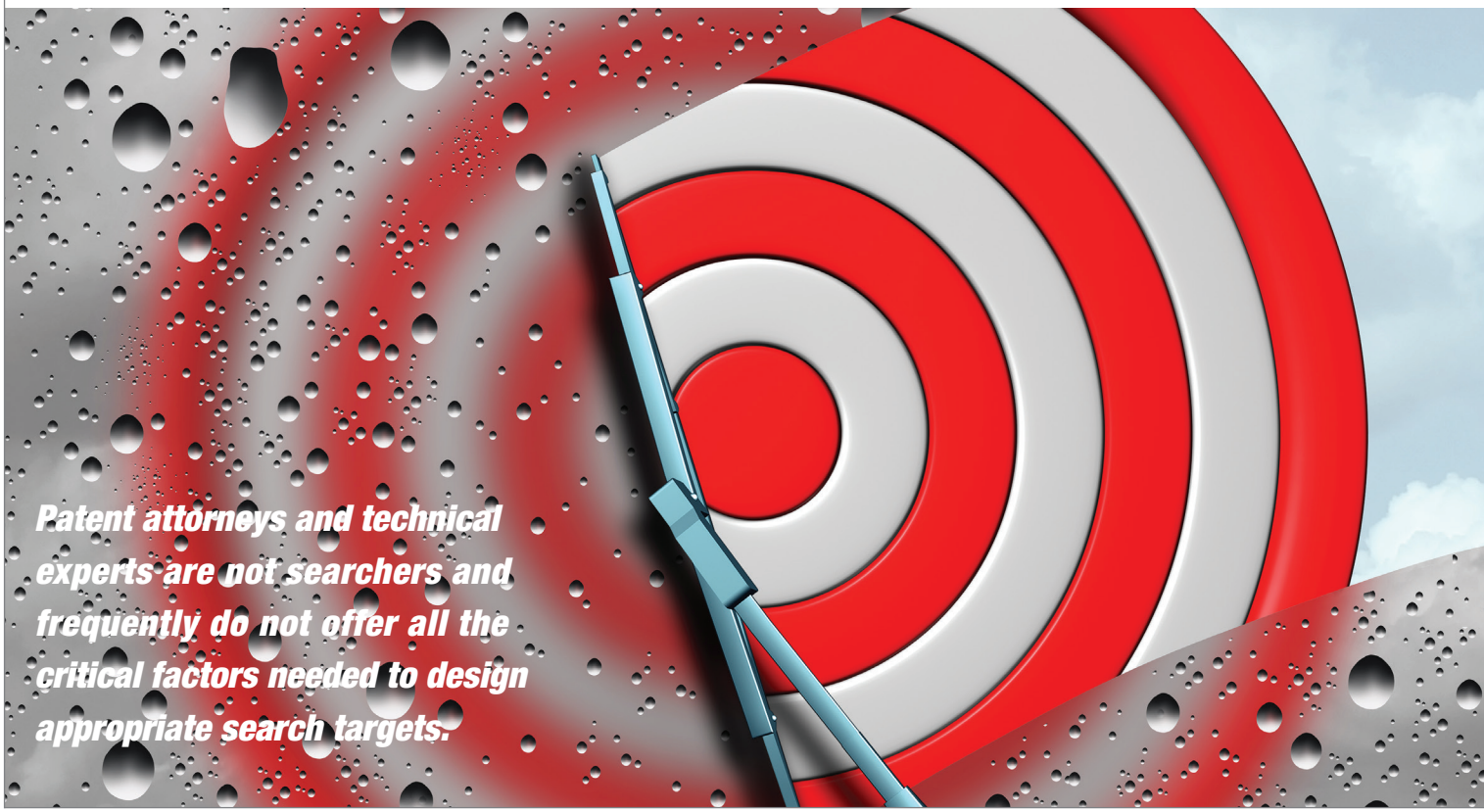
The FTO search process often involves a chain of requestors, in contrast to other search requests that usually have only one direct client. FTO search requests originate directly or indirectly from a commercial manager, who would be supported by technical staff and patent legal counsel. Management usually asks about FTO when the business is considering commercializing new products or processes. This could be early in the research process or close to the time of pending commercialization. It could also be in support of merger and acquisition decisions. The question is whether there are any patent barriers to carrying out the new venture. Direct synonyms to FTO are freedom-to-practice (FTP) or right-to-use; others are clearance, infringement, and non-infringement, each of which suggests avoidance of conflicting patents.

The patent attorney usually takes the lead and ultimately renders the FTO opinion, while being supported by the patent searcher. Each patent affords the right to the patent owner to exclude others from making, using, offering for sale, or selling an invention; it is not a right to practice the invention. Therefore, the searcher's goal is to find patents or active pending applications that could provide others with the right to exclude your client's company from doing what it wants to do where it wants to do it. Because the enforceability of patents is country-specific, the searcher focuses on the countries and regions being considered for manufacture, sale, or use. Patent applications filed under the Patent Cooperation Treaty (PCT), which have the country code WO (world), are almost always searched because they are intended for transfer to country or regional patent offices for prosecution, usually within the first 32 months.

Along the way, the searcher makes judgments involving the choice of candidate records to report but does not offer legal opinions about the actual applicability of patent documents, particularly in the United States. By being selective, the searcher keeps the patent attorney from reviewing patents of no interest or relationship to the matter. The result of that patent analysis is provided in an FTO or non-infringement opinion by the attorney. An FTO search and opinion help the business monitor and mitigate risk. In the end, there is never any absolute certainty; the process serves as a risk assessment based on available data and best analysis. Future commercialization comports with the comfort level of the attorney and business management. To enhance this comfort level, attorneys tend to work with patent searchers, whose skills and judgment they trust.

WHAT IS THE SEARCH TARGET?

The search process is one of narrowing the universe of patents to subsets: the search topic, the search target, and the search goal. The topic is the technical area. The search target is the raw set of candidate patent records (created by database producers to collect related patent documents into patent families) that must be narrowed by the searcher to a reason-



ably small collection of patent documents. The search goal is the selected set of records that the patent attorney will rely on to render the FTO opinion.

The search target may be straightforward, such as in the case of a simple new chemical or device or a new use for either of them. More often, the subject matter is complicated by many components, parts, steps, conditions, and the like. This would include chemical formulations or personal care products for which the list of ingredients may be very long. It could also include many mechanical and electronic devices that have long parts lists and operating manuals. Such matters call for extra care and skill in defining the search target. This is why I consider Rule 1, "Verify and verify again the scope with the customer," to be critical. The searcher must understand the search goal before defining the search target and proceeding with search strategy development. Patent attorneys and technical experts are not searchers and frequently do not offer all the critical factors needed to design appropriate search targets. The skill of the patent searcher comes into play by asking the right questions before proceeding.

Consider a common way that people go about searching. The usual visual is the Venn diagram of overlapping circles. I have shown a four-component Venn diagram (see Figure 1 at right) that is more representative of relatively complicated formulations, processes, or devices than an often seen three-component Venn diagram that seems to be standard in such discussions.

One search approach is brute force: Search for every component, represented by the central red square. A case could be made for requiring all four components, such as for finding any obvious records, as emphasized by Rule 2: "Don't miss the obvious references." References with all the components might be appropriate for novelty or invalidity searches or helpful for making arguments for the concept of a "safe harbor." I have seen some searches in which this look-for-everything approach is supported by using multiple databases and as many value-added resources as possible. This could be consistent with Rule 3: "Carry out the search in two independent parts." However, searching broad and wide seems to be done on the mistaken understanding that searching extremely thoroughly for *all* the components is a substitute for searching for the *right* components. What it does is add to the cost and time spent, but it does not get at the important aspect of searching for the right target.

Searching for all of the components is not sufficient for FTO searching, because patents that claim fewer than all of the components may well have an impact on FTO. Furthermore, a search for all of the components may result in zero hits, which does not mean there are no patents of interest. Another common approach is to arbitrarily relax the number of required components in accordance with the size of the resulting candidate answer sets. Should candidate patents contain just three components (A), two components (B), or even just one (C)? How does one decide on the basis of the size of the candidate sets? In truth, it is not just a matter of the number of hits. Not all components are of equal importance. Each component must be fully understood in the context of the overall matter to be cleared for commercial operation.

The more complicated six-component Venn diagram shown in Figure 2A below may look daunting. Such matters may often be simplified by careful analysis of the components. Components may be categorized as active or inactive, or as critical, auxiliary, supplementary, helpful, or even as optional. Some may be relatively new and be covered by simple claims in recent patents, while others may be mature and likely to be claimed in enforceable patents only in combination with other components or conditions. Finally, some may be members of a class that should be searched as a class in addition to each named component.

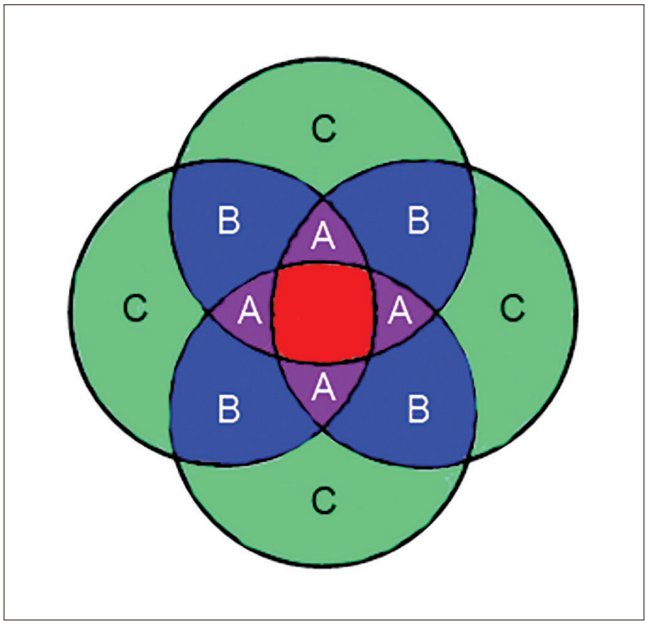


Figure 1: Four-component search matter

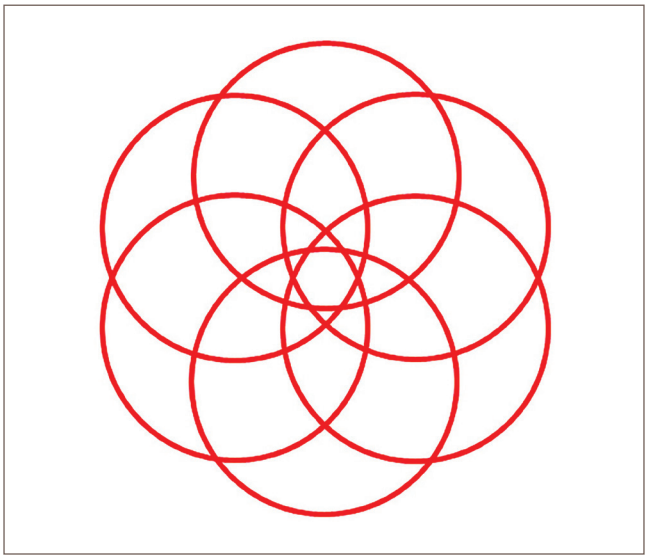


Figure 2A: Six-component search matter

For the sake of illustration, the six components might be resolved to the situation illustrated in Figure 2B below. In this case, the components are determined to be Critical (A), Important (either B or C), or common or mature (D, E, and F). In effect, the search boils down to `A and (B or C)`. If component A is really critical, it could even be necessary to look at every patent containing that component. Searching for the mature components in combinations in case they were recent patented is also advisable. It is helpful to add the concept of a practice area (P) or art group to narrow the search appropriately for the FTO considerations.

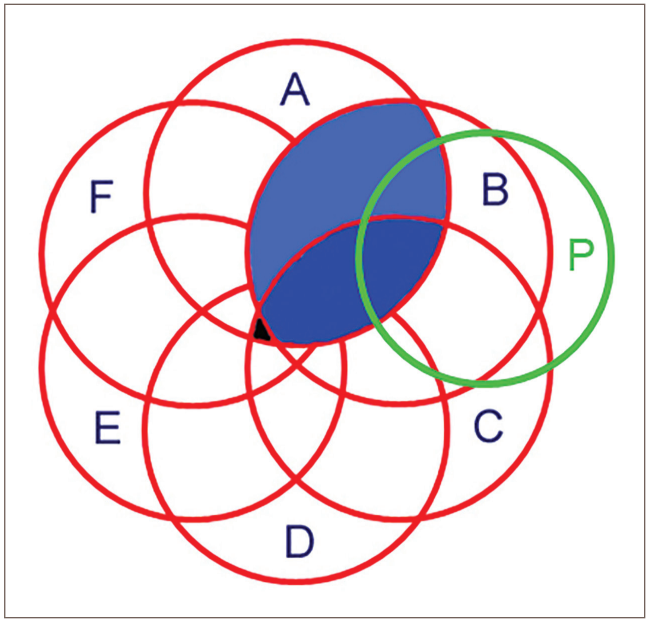


Figure 2B: Six-component search matter as `A and (B or C) and P`

With this analysis, I have basically returned to a three-component Venn diagram. It is interesting to note how the size of the two- and three-component areas appear so different, in contrast to what is often depicted in a symmetrical three-component Venn diagram. On the one hand, these are just representations, and the areas do not necessarily reflect the number of patents within them. On the other hand, it is helpful to recognize that it only takes one patent to destroy the client's FTO, and that this one reference might come from a very small overlap of concepts or a very large one. It is the searcher's job to find such important references regardless of the size of the candidate set.

PROCESS FOR DEVELOPING SEARCH TARGETS

I propose three steps to develop a clear search strategy.

1. Learn like an inventor. Searchers are usually generalists and do not need to understand the details of the matter to the extent a specialist driving the commercialization does. But the searcher needs to take advantage of available resources and consult with the attorney and/or technical staff in order to understand the overall matter and each individual component.
2. Think like a prosecuting patent attorney. It is very helpful to conceptualize the claims of potentially infringing patents. Remember that attorneys write claims to get the broadest coverage for the applicants while disclaiming the fewest restrictions. Independent claims often cover classes of components and broad conditions. Greater definition and details are provided in dependent claims and in the specification.
3. Strategize like a patent searcher. Target the critical components and focus on claims, while also searching for details in titles, abstracts, and full specifications in full-text sources and indexing in value-added databases, as appropriate.

Let's consider a few examples of commercial products with multiple components to apply this process for developing effective search strategies.

EXAMPLE: CHEMICAL FORMULATION

Multi-component compositions often come in tubes, buckets, bottles, cans, dispensers, and the like. They may have labels listing just active or toxic components, or they may provide comprehensive lists of ingredients. Personal care products often disclose their many components. Here is a list for a hypothetical anti-dandruff shampoo:

> zinc pyrithione, climbazole, ciclopirixolamine, stearyl dimethyl benzyl ammonium chloride, quaternized hydroxyethylcellulose, cocamidopropyl betaine, sodium laureth sulfate, cocamide DEA, imidazolidinyl urea, methylparaben, propylparaben, citric acid, sodium chloride, tetrasodium EDTA, fragrance, and water

These ingredients may be classified as follows:

- Active ingredients: zinc pyrithione, climbazole, ciclopirixolamine
- Conditioning agent: stearyl dimethyl benzyl ammonium chloride
- Suspending agent: quaternized hydroxyethylcellulose
- Cleansing agents: cocamidopropyl betaine, sodium laureth sulfate
- Foaming agent: cocamide DEA
- Preservatives: imidazolidinyl urea, methylparaben, propylparaben, citric acid, sodium chloride, tetrasodium EDTA

The next step is to draft a claim, for search purposes only, that would provide protection for its inventor and exclude your client from manufacturing, using, or selling this formulation:

> **Claim:** A composition for treating human hair comprising an aqueous suspension of a metal salt of pyrithione, an anti-fungal agent, either climbazole or ciclopirixolamine, and optional agents selected from

suspension maintaining agents, conditioning agents, cleansing agents, foaming agents, preservatives, colorants, and fragrances

From this I can develop the following search concepts for an FTO search:

Concept 1. Zinc or other metal salt of pyrithione (A). Because claims to the zinc salt as anti-dandruff agent go back to the 1960s, the searcher probably has to be concerned only about the use of the zinc salt in combination with other active ingredients.

Concept 2. An antifungal agent such as climbazole (B) or ciclopirixolamine (C). As it turns out, some patents indicate that zinc pyrithione is also an antifungal agent, so using antifungal agent as a class term may not be helpful.

Concept 3. Anti-dandruff shampoo (P) as described in the preamble may be helpful as a practice area limiter. The searcher can use text terms and patent classifications, if available, to narrow the answer sets. However in this case, zinc pyrithione is not commonly used for other applications, so the practice area restriction is of limited value.

This analysis leads to `A + (B or C) + P` just as illustrated in Figure 2B. The searcher may want to get approval from the client before pursuing this approach.

EXAMPLE: DEVICE AND METHOD OF USE

The descriptions and uses provided by clients for intended commercial devices almost always involve many parts and many steps, but most of them would be considered well-established in the industry. The key to an appropriate FTO search and FTO opinion is to distinguish the parts, steps, or uses that anybody having ordinary skill in the art would have known about versus those that may have been patented by the competition within the past 20 or so years.

An example of an established technology is a glass melting furnace. There is still plenty of opportunity for inventing and implementing design and process improvements. For example, a client may have identified a need to help ensure that the contents of a furnace do not freeze during a plant mishap, such as an outage of an oxygen production plant or the disruption of oxygen piped in from offsite. The plan would be to provide for local oxygen storage sufficient to cover a limited oxygen outage and implement an automated process to maintain the contents of the furnace in the molten state without adding new glass or removing any product. The maintenance procedure would be for a reasonable limited time until regular operations could resume.

Here are some of the parts for a hypothetical glass melting furnace and a method for operation with provisions to keep it running during a plant upset.

Silica and other ingredients; storage tanks; conveyance means to furnace; furnace for batch operation with melting, refining, and conditioning zones; conveyance of melted glass from the furnace; oxy-fueled burners; oxygen source; backup local oxygen storage; temperature measurement; temperature control means; etc.

The glass melting apparatus is complicated, and there are many process steps. Rather than listing them all as in the shampoo example, we may start out by categorizing them as follows:

- **Materials:** silica and additives
- **Vessels:** glass furnace with multiple zones, e.g., melting, refining, and conditioning zones; pre- and post-processing storage and conveyance
- **Combustion equipment:** oxygen-fueled burners
- **Regular oxygen source:** production plant or gas lines from off-site sources
- **Emergency oxygen source:** on-site storage
- **Vessel control steps:** maintain molten glass and combustion using locally stored oxygen to feed burners to maintain operating conditions during plant upset; postpone material transfer into or out of the furnace during the interim outage period expected to be sufficient to restore regular oxygen source

Here is a conceivable draft claim that an inventor might have applied for and which could be a barrier to the new commercial implementation.

Claim: A method of operating a glass melting furnace, comprising a regular operating mode and a molten glass maintenance mode, wherein the latter is initiated upon detecting an outage of oxygen required to fuel the burners continuously and comprises storing oxygen on-site in sufficient quantity to maintain operation of the glass melting furnace for a minimum period of 12 hours; ceasing the introduction of batch materials and removal of product; and maintaining the molten glass in a molten state in all

FTO Searching Rules for Success

1. Verify and verify again the scope with the customer.
2. Don't miss the obvious references.
3. Carry out search in two independent parts.
4. Be sure you know why you are rejecting each reference and think twice about it.
5. Present the results in the fashion that your customer can best use.
6. Expect to defend your search.

zones of the furnace by feeding the locally sourced oxygen to active burners such that temperatures in the furnace is maintained at not less than 1100° Celsius.

This could lead to the following search concepts:

Concept 1. Cessation of oxygen and resumption from an alternative source (A)

Concept 2. Keeping glass in a molten state by maintaining minimum furnace temperature (B) or halting any material transfer into or out of the furnace (C)

Concept 3. Design and operation of a glass melting furnace (P)

Once again, a possible search strategy might be `A + (B or C) + P`, because it might not be necessary for any patents of interest to contain both matters B and C to be of concern to the client.

THE SEARCH PROCESS

After the search target is clarified, the fun part starts—the search itself. The earlier FTO search paper dealt with this principally in the discussion of Rule 3: "Carry out the search in two independent parts." This is not sufficient to overcome a poorly characterized search target, but it is still an excellent way to proceed with the search. Given the likelihood that two searchers will almost always find different results, an individual searcher can emulate that by carrying out searches with at least two complementary, independent strategies, often by using multiple databases and indexing schemes, or by using completely different methodologies, such text, indexing, patent citation, and natural language searching. Eventually, the searcher would combine results from multiple sources and eliminate duplicates.

Of course, the searcher should take advantage of all opportunities to learn from the search process. It is helpful to start narrow enough to get manageable result sets, for example, by focusing initially on the central area of the Venn diagram. From this and throughout the process, the searcher may discover and apply new or alternative concepts, synonyms, or indexing. The searcher may expand or narrow the search based on content and number of candidate records, but must avoid making erroneous decisions based on creating threateningly large answer sets. That's where finesse comes in to narrow those sets and still find what is needed.

REVIEW OF CANDIDATE PATENT CLAIMS

The knowledge and skill of the searcher comes to the fore in the post-search evaluation process. In the case of a patentability search, the searcher reviews art—patent documents, articles, etc.—to find the target elements anywhere in the documents. In contrast, when performing an FTO search, the searcher examines claims and supporting specification of patent art—granted patents and pending applications—to identify non-practiced claim elements, i.e., required aspects of the claims that are not going to be practiced by the client.

Take, for example, searching for a three-wheeled vehicle such as a motor tricycle or motorcycle with sidecar. A patentability search would generally report prior art that describes vehicles with three or more wheels, including cars and trucks, because any vehicle having four or more wheels would be considered to contain three wheels. Vehicles with just three wheels would not be novel, unless there were other distinguishing features. However, a patent with claims that require four or more wheels would not be included in an FTO report on the same subject because its claims have elements not found in three-wheeled vehicles, namely extra wheels.

The same would apply to multi-component matters. Disclosure of extra components may adversely affect an inventor trying to argue novelty, but claims of required extra components would, in most cases, allow a business to argue that its commercial operation fell outside the claimed invention because it did not involve those extra components. Care must be taken for claims that allow for optional inclusion or ranges, including those starting at zero percent. In the previous example, a claim to a vehicle with three or more wheels should be reported because those extra wheels could be considered optional for FTO considerations.

The process of choosing whether or not candidate references should be retained is fraught. This led to Rule 4, "Be sure you know why you are rejecting each reference and think twice about it," and Rule 6, "Expect to defend your search." In general, there is no need to report patent documents with claims that fall outside the anticipated commercial venture because of extra components or different process conditions, compositional ranges, or the like. However, patent searchers must leave legal decisions to attorneys. Therefore, don't be too strict in evaluating claims.

Review each claim in light of definitions or clarification of claim language in the specification, especially when claims language covers broad classes or ranges in which the target concept may belong. Be careful about eliminating a patent due to the requirement of an extra component that might be under consideration for inclusion in the commercial venture. Allow for uncertainty and include fudge factors because ranges may be subject to interpretation in litigation proceedings. Allow for circumstances in which the claimed invention could be construed differently. The specification might be written in a way that extra components might be at zero or negligible concentration, but expanded conditions or ranges might be supported by the specification. This could be a matter of legal interpretation, and claims might be amended during the examination process or in post-grant proceedings. Also allow for modest future changes in the commercial process, based on conversations with the client and understanding how close the venture is to actual commercialization. When in doubt, be conservative and retain "close" patent documents. It is always more comfortable to be questioned about why a patent was retained than why it was missed or excluded, even if you have a good answer.

REPORTING

The searcher should always provide a report in a manner most useful to the client, notably the patent attorney for FTO requests, per Rule 5, "Present the results in the fashion that your customer can best use." Searchers and clients may have different perspectives on the content and format of the final report. I suggest that the report be written well enough to demonstrate the credibility of the searcher in following the client's instructions and in actually doing what was asked. For this reason, I find it helpful to rephrase the search request, and explain the search strategy and the basis of acceptance or rejection of candidate records.

The report may consist of a simple list of patent numbers. A more detailed report may include the details provided by database records, selected excerpts from documents, or summary data tabulated in spreadsheets. I usually provide selected claims and supporting specification text to facilitate the attorney's analysis and to justify inclusion of the patent document in the report. It is standard in the United States to avoid offering any patent legal opinions: Just give the facts.

SAFE HARBOR

Why would the searcher look for lapsed or expired patent documents in an FTO search? Such dead patent documents may be valuable for learning the topic and as the basis for patent citation searching, whether or not they are reported to the client. But why report these expired patents in an FTO report? It seems that such dead art should not have an impact on an FTO analysis, except perhaps when the documents could be revived through administrative means, such as by paying overdue maintenance fees. This supports being cautious about eliminating patent documents that have only recently lapsed.

That being said, there are reasons why some attorneys and their technical and business colleagues would find such references of possible value. Frequently, there is unstated interest in getting patentability or state-of-the-art background information. In that case, the searcher should proceed with care and help the client understand that FTO searches are carried out differently from those other prior art searches. At a client's request, I expand FTO searches to patent landscape search reports, which are essentially the same as FTO search reports, except that I disregard FTO date restrictions, and I do not review the claims of dead references as carefully.

A patent attorney may wish to see on-target, dead patent documents in order to make an argument that they provide a "safe harbor" for the client. Any prior art that discloses exactly the process or product that the client is considering commercializing may keep any subsequent patents on that matter from being granted. Wikipedia defines "safe harbor" in this manner: "no-longer-enforceable art that acts as a 'safe harbor' possibly permitting the product or process to be used based on patents [or non-patent literature] in the public domain."

Technically, I consider that safe harbor references would be prior art that would invalidate each and every conceivable patent claim on which the composition, process, etc., could be alleged to infringe. This definition raises plenty of issues and seems to be a tall order. For example, is it certain that your client's process will not change? The client should understand that the intended commercial venture must not vary significantly from that "safe harbor" prior art: Any improvements or differences could still be the subject of later patents.

How could you even conceive of every troublesome patent claim? The apparent high bar is mitigated by the analysis of the subject matter as described earlier. In the earlier examples, any no-longer-enforceable references that claim A and B and C and P without extra required components might be regarded by the attorney as sufficient to exclude any undiscovered, pending, or future claims from barring the planned commercialization as currently specified. It is up to the attorney and technologists to evaluate any connection of the offered "safe-harbor" references to FTO and their effect on the risk assessment.

CONDUCTING GOOD FTO SEARCHES

A good FTO search starts with a clear understanding of the search target, from which follows development of an effective search strategy, thoughtful searching, review of candidate references, and an informative recap of the search process and results. The searcher stands in for the technologist and patent attorney during the course of trying to find patent references that allow the patent attorney to write the FTO opinion. Therefore, the searcher must use available resources to understand the subject matter and all its components well.

The next step is to conceptualize claims of possible patents that might impact the client's intended commercialization venture. The search strategy should be carried out with consideration of patent claims and supporting specifications, followed by careful review of the identified patents, consistent with the exclusionary nature of claims and full appreciation for what the patent attorney needs to support an FTO opinion. The searcher gains credibility and helps the patent attorney understand the whole process by writing an effective search report. Careful implementation of these steps should keep the searcher's clients coming back for more.

Thomas E. Wolff, Ph.D. *(tom@wolffinfo.com; wolffinfo.com) formed Wolff Information Consulting, LLC in 2006 to provide technical and patent information services on a contract basis, following a career at Amoco Chemical Co., BP, Innovene, and Ineos. He has two U.S. patents and is a registered patent agent.*

Comments? Email the editor (marydee@xmission.com).

Acknowledgments

This paper is based on the presentation "Freedom-to-Operate Study: HDPE Fuel Tanks" presented at the PIUG 2017 Northeast Conference (Iselin, N.J., Sept. 26, 2017). The author offers his sincere thanks to Sandra Unger for mentorship and for her review and comments on this paper and to Dominic DeMarco for his generosity sharing ideas in personal conversations, in discussions at conferences, and for encouraging me to elaborate on his teachings in this paper.

References

1. "Freedom-to-Operate Patent Searching: My Six Basic Rules," *Searcher. The Magazine for Database Professionals*, May 2008, 16(5):34–39.

2. PIUG Freedom to Operate Fundamentals: Comprehensive Techniques for Researching Freedom to Operate: piug.org/fto_search_course.