

Freedom-to-Operate Searching: What's in the Tube?

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Freedom-to-Operate

- Synonyms: freedom-to-operate (FTO), freedom-to-practice (FTP), clearance, infringement, noninfringement, right-to-use
- Are there any identifiable patent barriers to the commercialization of products or processes?
 - *Relevant unexpired* patents in the *locations* targeted for manufacture, sale or use
 - *Relevant patent applications* that could become barriers
 - Patent documents that claim the matter explicitly or implicitly with support from the specification

Searcher's Goal: Support the Attorney

- The patent attorney renders an FTO opinion.
- Attorney relies on a comprehensive FTO search.
- Search goal: Find claims in enforceable patents or potentially-enforceable patent applications on the basis of which your client's commercial composition, process, etc. might be successfully sued for infringement.
- Searcher makes judgments about candidate records without explicitly offering legal opinions.
- Process ends with a risk assessment: there is never any certainty of the end result, only a comfort level of the attorney and management based on available data and best analysis.

FTO Searching has been Well Covered

- Many previous PIUG Conference presentations
- PIUG Freedom-to-operate Fundamentals Course
- Publications and Books
- See bibliography slides

My Motivation

1. What I have been doing:
Formulation searches
2. What I have seen:
Vendor's search reports
3. What I have learned:
Missing from my previous presentation and published paper

Formulations Searches

- Multi-component compositions in tubes, bottles, cans, dispensers...
- Request based on label (?)
- Cf. Matt McBride at PIUG 2017 Annual Conference
- Analogous to machines, devices, processes, or methods with multiple parts, components, or steps



Vendors' FTO search reports

- Did not indicate good topic understanding and strategy.
- Approach: more is better.
 - Searched all or too many components
 - Used more databases, more codes, more indexing, and took more time at more cost in lieu of thoughtful strategy development
- Odd practices
 - Excerpts from the specification instead of from claims
 - Categorized references, e.g. relevant or related

Missing Topics

- My PIUG 2007 Northeast Conference or others presentations did not cover:
 - Search strategy development
 - Discussion of safe-harbor references

FTO Searching: My Six Basic Rules

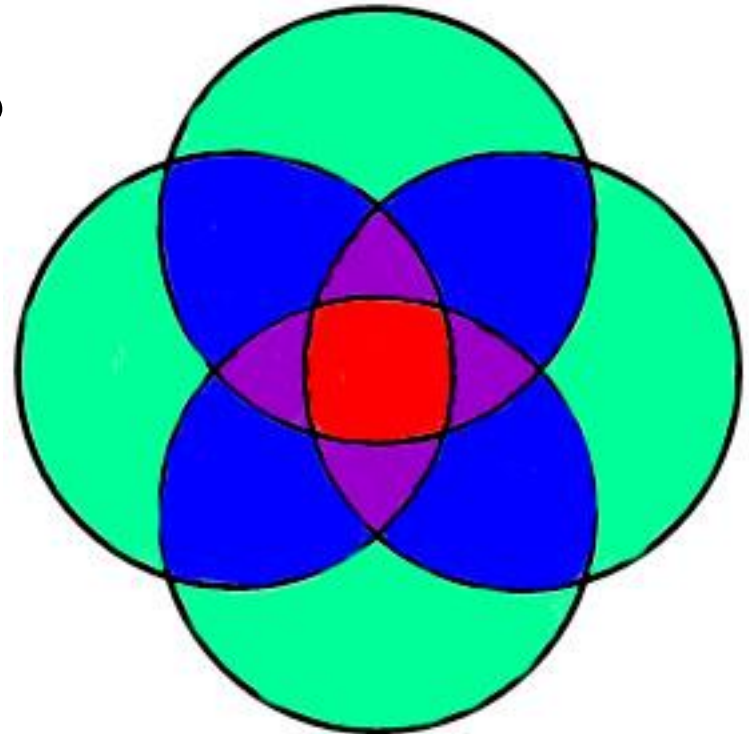
1. Verify and verify again the scope with the customer
2. Don't miss the obvious references
3. Carry out search in two independent parts
4. Be sure you know why you are rejecting each reference and think twice about it
5. Present the results in the fashion that your customer can best use
6. Expect to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

Searching: What is the Target?



FTO: Four-component Venn

- Search all 4 for FTO?
Obvious? Safe-harbor?
Novelty? Invalidity?
- Expand by searching for fewer components:
3 or 2 or just 1?
- It's not just a matter of how many hits you get.
- Proceed on the basis that not all components are equal.



Characterize the Components

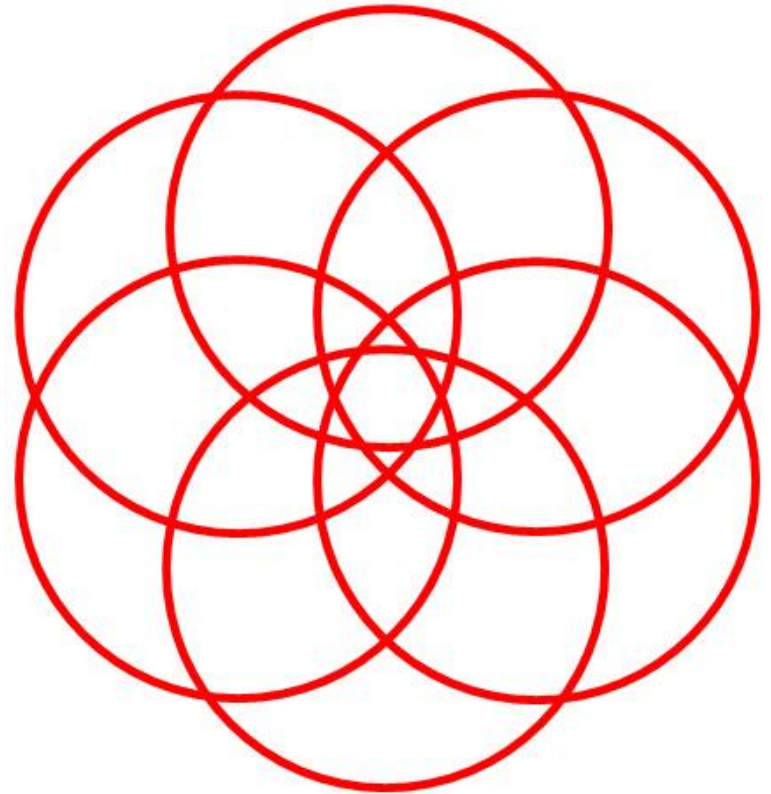
- New or mature?
- Active or inactive?
- Critical, auxiliary or supplementary?
- Member of a class?

Develop Clear Search Target

- Learn like an inventor
 - Understand composition and each component
- Conceptualize infringing patents
- Think like the prosecuting patent attorney
 - Claims designed for broadest coverage and disclaiming the fewest restrictions
 - Independent claims may use classes of components and broad conditions
 - Dependent claims and specification offer greater definition and details
- Strategize like a patent searcher
 - Focus on claims and search for details in specification

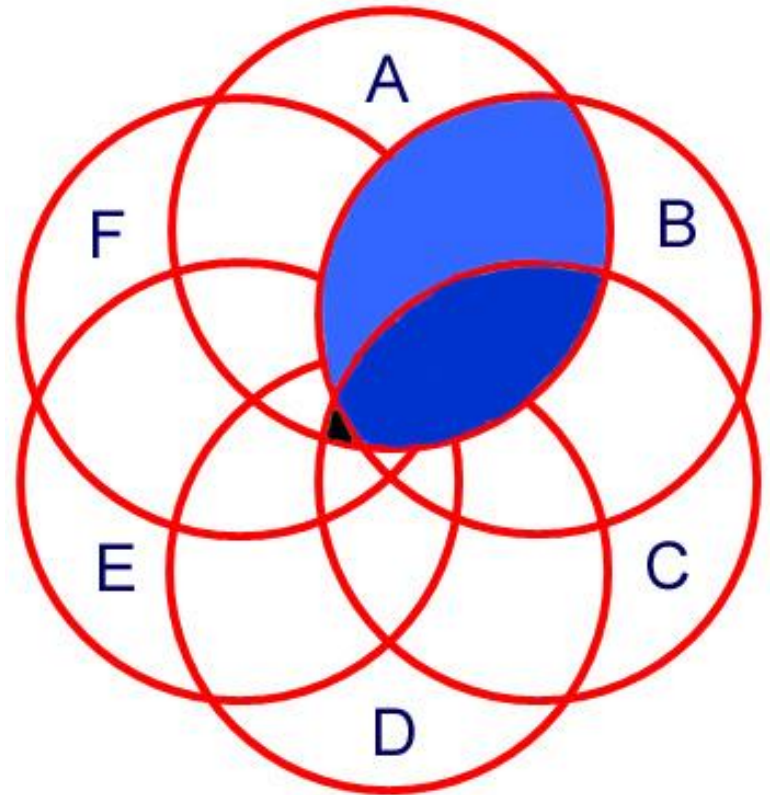
FTO: Six Components (A – F)

- Critical: A
- Important: B or C
- Common or mature:
D, E, and F (e.g., salts,
buffers, solvent, etc.)



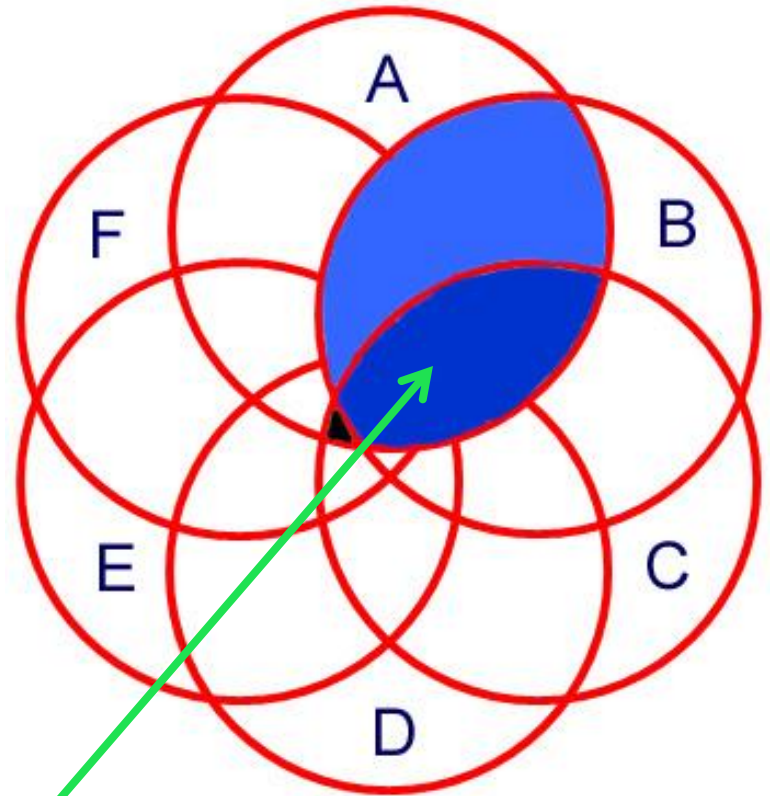
FTO: Six Components (A – F)

- Critical: A
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- Search boils down to **A and (B or C)**



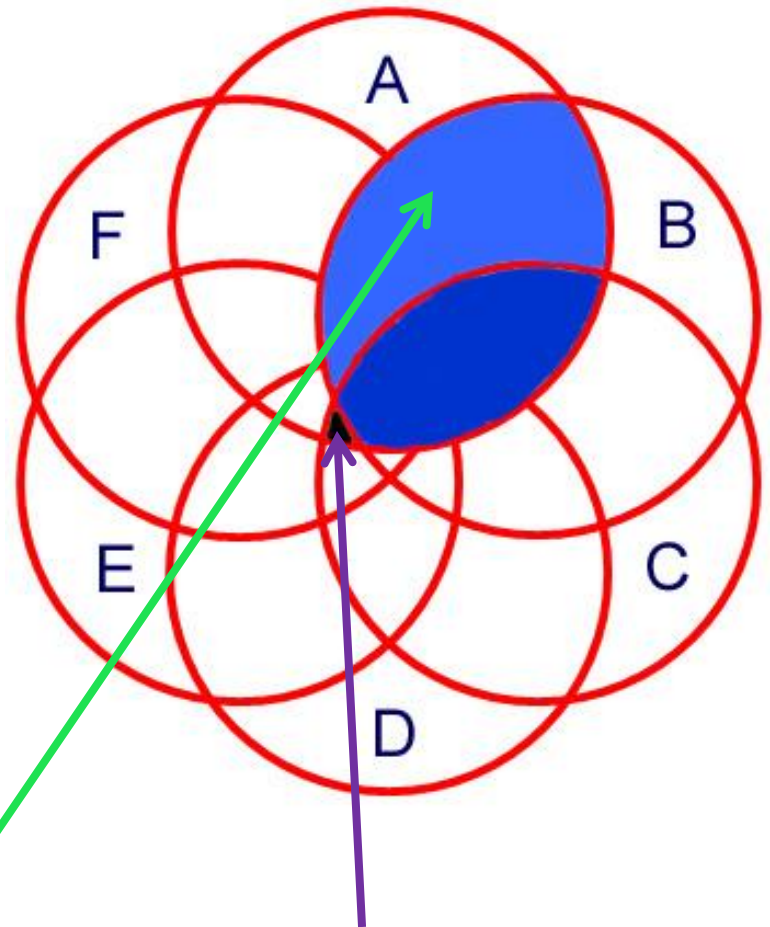
FTO: Six Components (A – F)

- Critical: A
- Important: B or C
- Common or mature: D, E, and F (e.g., salts, buffers, solvent, etc.)
- Search boils down to A and (B or C)
- Consider **A and B and C**



FTO: Six Components (A – F)

- Critical: A
- Important: B or C
- Common or mature: D, E, and F (e.g., salts, buffers, solvent, etc.)
- Search boils down to A and (B or C)
- Unequal sizes of areas without all three: **A and B** vs. **A and C**



Personal Care Products



- Multi-component formulations
- Components listed on retail products

FTO: Dandruff Shampoo

- Anti-dandruff shampoo containing 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.

Learn and Classify

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

Conceptualize: Think Like a Patent Attorney

- A composition for **treating human hair (P)** comprising an aqueous suspension of a **metal salt of pyridinethione (A)**, **an anti-fungal agent, either climbazole (B) or ciclopirixolamine (C)**, and optional agents selected from suspension maintaining agents, conditioning agents, cleansing agents, foaming agents, preservatives, colorants, and fragrances.

Develop Search Concepts

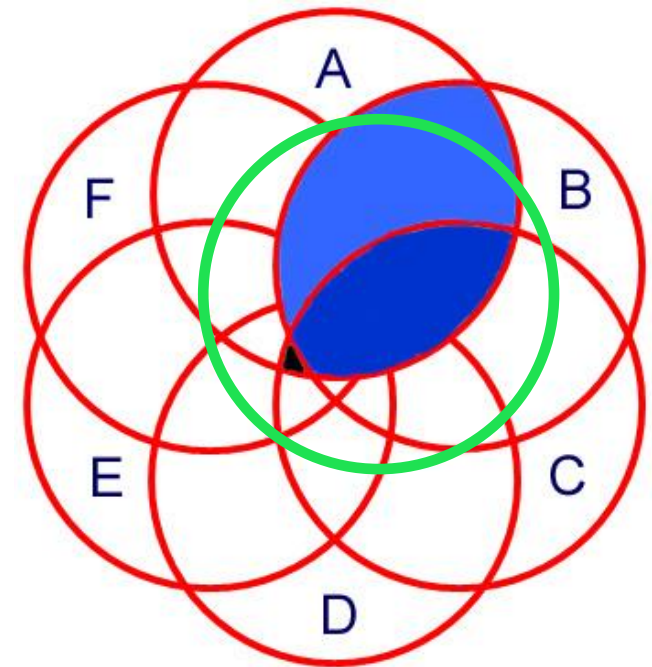
A + (B or C) + P, where P is practice area

Three search concepts:

- Concept 1: **Zinc (other metal?) Pyrithione (A)**
 - Zinc salt claimed in 1960s as anti-dandruff agent
 - Be concerned about use in combination
- Concept 2: **Climbazole (B) or ciclopirixolamine (C) or antifungal agent**
- Concept 3: **Anti-dandruff shampoo (P)**
 - Lots of text terms and patent classes

FTO: Anti-dandruff Shampoo

- A: Zinc Pyrithione
- B: Climbazole
- C: Ciclopirixolamine
- P: Anti-dandruff shampoo



Go Ahead: Search

- Learn from the search process
- Start narrow enough → manageable results
- Expand or narrow search based on number and content of candidate records
- Carry out patent citation searching
- Combine results from multiple sources balanced with budget of time and cost

Make the Report Useful

- For credibility: explain search strategy and basis of acceptance or rejection of candidate records.
- For access: list, summarize or tabulate patent documents of interest per client preference.
- For analysis: bring attention to claims and supporting specification text of interest.

Safe Harbor

- No-longer-enforceable art that acts as a “safe harbor” possibly permitting the product or process to be used based on patents [or NPL] in the public domain (Wikipedia—thanks to Dominic DeMarco).
- Prior art that would invalidate each and every conceivable patent claim on which your composition, process, etc. could be alleged to infringe (Tom Wolff)
- Issues? A Tall Order?
- Not necessarily. Use your analysis. A and B and C and P
- Offer old or other non-enforceable patent art to client.
- Attorney and technologist to evaluate connection to FTO.
- Use it for patent citation searching.

Conclusion

- Consult with and learn from your client.
- Think like a patent attorney to conceptualize the search target.
- Strategize the search concepts.
- Report your results consistent with helping your client focus on matters of interest.

Thank you!

Questions and Comments

(The bibliography is on the next slides.)

FTO Bibliography - 1

Previous PIUG Conferences available to PIUG members

- Lessons and Pitfalls in Freedom to Operate Searching: Always Ask, "Can the Client Get Sued Over This?". *Irene Zajac*, Global Patent Solutions at PIUG 2015 Annual Conference.
- Therapeutic Antibodies: Do's and Don'ts for Freedom-to-Operate and Patentability Searching. Briana Erickson, Nelson Mullins Riley & Scarborough LLP at PIUG 2014 Biotechnology Conference.
- Freedom to Operate; Some Best Practices. Don Walter - Thomson Reuters at PIUG 2010 Northeast Conference.
- Freedom-To-Operate Patent Searches for Selecting Sequences of Drug Targets. Heahyun Yoo, Bristol Myers Squibb at PIUG 2007 Biotech Meeting.
- Freedom-to-Operate Search: HDPE Fuel Tanks. Thomas E. Wolff, Wolff Information Consulting LLC at PIUG 2007 Northeast Conference.

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Publications

- [Freedom-to-Operate Patent Searching: My Six Basic Rules.](#) Searcher. The Magazine for Database Professionals, 16(5) (May 2008): pp. 34-39.
- [Patent Searching: Tools & Techniques.](#) Edited by David Hunt, Long Nguyen and Matthew Rodgers (Landon IP). John Wiley & Sons, Inc. (2007).
- [Patent Search Primer – Guidelines from Practitioners. A White Paper.](#) Intellectual Property Owners Association Patent Search Committee, August 2010.

FTO Bibliography - 3

PIUG Training

- PIUG Freedom To Operate Fundamentals: Comprehensive Techniques For Researching Freedom To Operate, next on November 1, 2017, at Genentech in South San Francisco, CA. See https://www.piug.org/fto_search_course.

Formulations

- Finding Formulations: Challenges and Opportunities. *Matthew McBride*, ScienceIP (CAS) at PIUG 2017 Annual Conference.

Safe Harbor

- [Patent Infringement](#) in Wikipedia.