

**BETWEEN A ROCK & A HARD PLACE?**  
**Best Practices for Competitive Patent  
Analyses and FTOs for University Startups**



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## Summary

- Importance for University Startups of Understanding Competitive Patent Landscape
  - Startup tightrope
  - Importance of both patent protection and freedom to operate
- Law of Willfulness and Obligations Created for Startups
- Best Practices for Startups
- Role of TTO



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## The Startup Tightrope

- Regardless of exit strategy, startup's comprehensive IP strategy is critical
  - Any liquidity event includes an investor, licensee or purchaser who will be focused on (1) pursuit of patent protection, and (2) freedom to operate
- Fundraising Catch-22
  - To protect technology and reduce risk of patent infringement – startup needs \$\$\$
  - To get \$\$\$ – startup needs to protect technology and reduce risk of patent infringement
- FTO/Competitive Analysis Catch-22
  - To identify competitive patents of interest, Need FTO/patent landscape analysis to identify any patents of interest
  - Willfulness law can create expensive and oppressive obligations for startup relating to comprehensiveness of analysis



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## Patentability vs. Freedom to Operate (“FTO”)

- Patent provides only a right to exclude others
  - To prevent third parties from practicing your invention
- Patent does **NOT** provide an affirmative right to make, use, or sell any commercial embodiment of your invention (does **NOT** provide **FREEDOM TO OPERATE**)
  - Freedom to operate is a completely separate analysis
  - You could have 100 patents and NOT have freedom to operate
- A company does not **NEED** a patent to commercialize a technology, but it **DOES** need freedom to operate



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## Patentability vs. Freedom-to-Operate

### Stents

- Sample Stent Claim

- An expandable graft for use in a vessel comprising:
  - (a) a thin-walled tubular member having wall surface with a plurality of slots,
  - (b) the tubular member having a first diameter for delivery, and
  - (c) a second, expanded diameter for expanding the vessel



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## Patentability vs. Freedom-to-Operate

### Stents

Drug-eluting stent

- Sample Drug-Eluting Stent Claim

- An expandable graft for use in a vessel comprising:
  - (a) a thin-walled tubular member having wall surface with a plurality of slots,
  - (b) the tubular member having a first diameter for delivery, and
  - (c) a second, expanded diameter for expanding the vessel
  - (d) wherein the tubular member is embedded with an active agent



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## Startup Fundraising & FTO

- Essential activity of startups: fundraising
- IP strategy vs. funding = catch 22 discussed above
- IP Strategy – startups must consider target (INVESTORS)
  - Investors - freedom to operate as important or more important than patent applications/patent portfolio
- How is a competitive patent landscape analysis and/or an FTO analysis possible for a startup on a budget?



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## Solution: Landscape Analysis

- Preliminary analysis considering competitive patent landscape – patent mapping
  - Need fixed commercial embodiment to perform analysis
  - Don't spend too much (VCs will do their own analysis)
- What are investors looking for?
  - You have given serious consideration to IP – both patent protection *and* third party patents – and have taken fundamental/necessary steps



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## Competitive Analysis

- Potential Concern: Results of Landscape Analysis
- Blocking Patents
  - Definition - a patent that prevents you from making, using, or selling your product
  - Options:
    - Design Around
    - Patent Opinion of Non-Infringement or Invalidity (No License)
    - License
- Potential Solution: Freedom to operate (“right-to-use”) opinions – litigation risk analysis



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## Freedom to Operate

- FTO can be found in two ways:
  - No infringement
  - Invalidity of patent
- The heart of a FTO analysis is what is claimed
- Claims must be “construed” to figure out what they mean
  - Factors that go into construction are:
    - Definitions in the specification
    - What was said during prosecution (“prosecution history”)
    - Other factors



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## Legal Framework for FTOs - Willful Infringement

- **Willful Infringement** – infringement that occurs when the infringer is aware of and acts in disregard of the patent and has no reasonable basis for believing it has a right to engage in the infringing acts.
- **Damages** – upon a finding of willfulness, the default position is that fees should be awarded
  - Treble damages and/or attorney fees
- **Willfulness Defense Factors**
  - Reasonable Care to Respect Patent Rights
    - Responsible Action
    - Good Faith
    - Due Care
  - Sound Legal Advice Timely Obtained
  - Independent Development or Designing Around
  - Reasonable Belief That Infringer Had A Right To Act As It Did
- Totality of Circumstances



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## Defense to Willfulness – Opinion of Counsel

- Opinion is only one factor in willfulness determination
  - Existence of opinion – by itself – is no guarantee of finding of no willfulness
- Must be “**competent**”
  - Delivered by qualified lawyer (*Underwater Devices, Inc. v. Morrison Knudsen Co.*, 717 F.2d 1380, 1390 (Fed. Cir. 1983))
  - Based on accurate and complete understanding of all relevant facts fully and frankly disclosed by client (*Westvaco Corp. v. Int'l. Paper Co.*, 991 F.2d 735, 743 (Fed. Cir. 1993))
  - Cannot be conclusory or lack supporting details (*Central Soya Co. v. A. Hormel & Co.*, 723 F.2d 1573, 1577 (Fed. Cir. 1983))
- Key factor – reasonable belief of infringer that actions are permissible
  - Opinion must be “thorough enough, as combined with other factors, to instill a belief in the infringer that a court might reasonably hold the patent is invalid, not infringed, or unenforceable.” (*The Johns Hopkins University v. CellPro, Inc.*, 152 F.3d 1342, 1362-63 (Fed. Cir. 1998))



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## Trends in Law of Willfulness

- **1983** – Accused Infringers Have Affirmative Duty
  - Upon receiving notice of patent existence, accused infringer has an affirmative duty
  - Includes duty “to seek and obtain competent legal advice from counsel” before initiating any potential infringing activity
  - Underwater Devices Inc. v. Morrison-Knudsen Co., 717 F.2d 1380 (Fed. Cir. 1983)
- **2007** – Accused Infringers Have No Affirmative Obligation
  - No affirmative duty to obtain an opinion of counsel in order to avoid willfulness.
  - Objective recklessness test: two-prong test ignoring infringer’s state of mind at time of infringement, requiring patent holder to show:
    - 1) that the defendant “acted despite an objectively high likelihood that its actions constituted infringement of a valid patent,” and
    - 2) “that this objectively-defined risk . . . was either known or so obvious that it should have been known to the accused infringer.”
  - In re Seagate Technology LLC, 497 F.3d 1360, 1371 (Fed. Cir. 2007)



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## The Halo Subjective Standard (2016)

- New Subjective Test: Subjective Intent and Knowledge of Accused Infringers at the Time of Infringement
  - Eliminated objective recklessness standard of Seagate, calling it “unduly rigid.”
  - Focused on “egregious” conduct.
  - “[S]ubjective willfulness, whether intentional or knowing, may warrant enhanced damages, without regard to whether his infringement was objectively reckless.”
  - “The Seagate test further errs by making dispositive the ability of the infringer to muster a reasonable defense at trial, even if he did not act on the basis of that defense or was even aware of it.”
  - Halo Electronics, Inc. v. Pulse Electronics, Inc., 136 S.Ct. 1923 (2016)



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## Impact of Halo on Startups?

- Halo's new subjective standard and focus on infringer's knowledge and intent at time of infringement creates **higher hurdle** for startups
- **Direct evidence** of intent is beneficial
  - Better than circumstantial
  - Opinion of counsel is one form of direct evidence
- **No requirement** for opinion of counsel in Halo
  - But obtaining an opinion or deciding NOT to get an opinion is typically a factor in the willfulness decision



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## Egregious Behavior – Knowledge Plus More?

- Post-Halo determinations of willfulness have typically required more than simply (1) knowledge of the patent, and (2) continued infringement despite that knowledge
- Knowledge + Copying + Filing an IPR = Willfulness
  - Defendant (1) copied a specific DNA construct from inventors' article and (2) filed an IPR against the asserted patent about 2 years prior to the lawsuit
  - Juno Therapeutics, Inc. v. Kite Pharma, Inc., Case No. 2:17-cv-07639-PSG-KSx (C.D. Cal. 2020)
- Knowledge + Attempt to Regain Rights to Patent = Willfulness
  - Defendant (1) extended exclusive license for own patent to licensee, (2) later attempted to negotiate own right to commercialize, and (3) made false allegations to licensee's customers that licensor was authorized to sell patented devices
  - Diamondback Indus., Inc. v. Repeat Precision, LLC, Case No. 6:19-cv-00034-ADA (W.D. Tex. 2020)



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## Egregious Behavior – Knowledge Plus More?

- Knowledge + Inference of Copying + Failure to Investigate or Notify Engineers After Infringement Allegation from Patentee = Willfulness
  - Defendant (1) may have copied patented technology based on reasonable inference from evidence, and (2) did not investigate infringement assertions from patentee or warn employees of same
  - EagleView Technologies, Inc. v. Xactware Solutions Inc., Civil Action No. 1:15-cv-07025 (D.N.J. 2020)
- Knowledge + Assertions of Copying = **NO Willfulness**
  - Court – defendant was behaving in manner consistent in industry – actions were simply gathering of competitive intelligence based on evidence
  - Bioverativ Inc. v. CSL Behring LLC, Civil Action No. 17-914-RGA (D. Del. 2020)



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## Egregious Behavior – Knowledge Plus More?

- Knowledge + Rejected License Offer + Copying = Willfulness
  - Defendant (1) rejected an offer from patentee to license patent, and (2) copied the invention after patent's inventor gave presentations to defendant
  - Kaist IP US LLC v. Samsung Electronics Co., Ltd., Civil Action No. 2:16-cv-01314-JRG (E.D. Tex. 2020)
- Knowledge + Attempt to License + Withhold Info to Counsel for Opinion = Willfulness
  - Defendant (1) tried to license patent from patentee but negotiations failed, (2) subsequently designed its system (that looked very similar to patented design) in just two weeks, and (3) withheld information from its counsel for purposes of drafting opinion
  - Sunoco Partnership Marketing & Terminals L.P. v. U.S. Venture Inc., Civil Action No. 15 C 8178 (N.D. Ill. 2020)



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## Can You Avoid Willfulness by Attempting to AVOID Knowledge of Patents?

- Willful Blindness is NOT a defense to willfulness
  - **Willful avoidance** of knowledge of potentially relevant third-party patents can lead to a finding of willfulness.
- Complaint alleging defendant had “policy or practice of not reviewing the patents of others (including instructing its employees to not review the patents of others)” was sufficient to deny dismissal of willfulness claim.
  - “A well-pled claim for willful blindness is sufficient to state a claim for willful infringement.”
  - Motiva Patents LLC v. HTC Corp., Case No. 9:18-cv-00179 (E.D. Tex. 2019)
- Defendant’s awareness of patentee as competitor and that patentee had other patents (not the asserted patent) was sufficient for finding of willfulness
  - Federal Circuit found willfulness based on willful blindness as a result of (1) a subjective belief of a high probability that a fact exists and (2) deliberate action to avoid learning that fact.



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## Best Practices for Startups

- Landscape/Competitive Patent Analyses are **still recommended**
  - Sticking your head in the sand will not reduce your risk of willfulness, and in fact could very well **increase** your risk
- Landscape Searches and Analyses **Can and Should** Be Performed within a Budget while Avoiding Willfulness – it’s a **Balance**
  - Step 1 – Perform patent landscape analysis
    - Do third party patent search
    - Review results
  - Step 2 – separate patents into (1) potentially relevant patents, and (2) irrelevant patents
  - Step 3 – Review potentially relevant patents to determine if FTO is necessary
- Subjective intent – create concrete evidence of intent to avoid infringement



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## FTO Necessary – Factors to Consider

- Choose competent counsel
  - Caselaw has indicated that competent counsel is important
  - Outside patent counsel has greater credibility than in-house patent counsel or non-patent counsel
  - Choose counsel experienced with startups
- Ensure the analysis/opinion is competent but within budget
  - A competent opinion is “**thorough enough**, as combined with other factors, to instill a belief in the infringer that a court might reasonably hold the patent is invalid, not infringed, or unenforceable.” (*Johns Hopkins Univ. v. CellPro, Inc.*, 152 F.3d 1342, 1364 (Fed. Cir. 1998))
  - Determined based on **totality of the circumstances**, so all controllable factors must be considered while focusing on efficiency and budget-consciousness
- Subjective intent – create concrete evidence of intent to avoid infringement



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## FTO Necessary – Factors to Consider

- Timing – performing analysis prior to potentially infringing activity weighs in favor of alleged infringer. (*SRI Intern., Inc. v. Advanced Technology Laboratories, Inc.*, 127 F.3d 1462, 1467 (Fed. Cir. 1997))
- Opinion/Analysis should analyze both direct infringement and infringement under the doctrine of equivalents. (*Jurgens v. CBK, Ltd.*, 80 F.3d 1566, 1572-73 (Fed. Cir. 1996))
  - On the other hand, if the opinion/analysis includes sufficient detail (including review of prosecution history, etc.), lack of analysis of infringement under the doctrine of equivalents is not fatal. (*Westvaco Corp. v. Int'l. Paper Co.*, 991 F.2d 735, 743-44 (Fed. Cir. 1993))
- Opinion/Analysis should include review of prosecution history and the prior art of record of each patent of interest. (See *Westvaco Corp.*, 991 F.2d at 743-44)
  - On the other hand, in situation in which the analysis included a suggestion for a design modification (which was followed) to avoid infringement, omission of prosecution history review was deemed acceptable (no willfulness) (*Radio Steel & Mfg. Co. v. MTD Products, Inc.*, 788 F.2d 1554, 1558-59 (Fed. Cir. 1986))
- Discussion of caselaw in analysis weighs in favor of alleged infringer.
- **Oral opinions** can be sufficient defense if otherwise competent (authoritative and not based on mere conclusory statements). (See *Radio Steel*, 788 F.2d at 1558-59)



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## Best Practices – Preliminary Analysis (such as for Potential Investors/Purchasers/Licensees)

- 1) Use Search Firm – don't skimp on this part
  - a) Consider limiting to key competitors to reduce costs of search & analysis
- 2) Rank patents based on level of relevance
  - a) Cull the irrelevant patents
- 3) Separate the remaining patents into two categories:
  - 1) Most relevant – these may require review of prosecution history
  - 2) Fairly relevant – these may only require review of claims and specification
- 4) Draft summary document with analysis highlights
  - a) If any highly relevant patents are identified, you may need to discuss with client separately (Design around? Full opinion? Other?)
- 5) Consider whether to provide document in writing or summarize it verbally (Zoom is a great option)



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## What does this mean for the Tech Transfer office?

- Should the TTO perform an FTO analysis as part of the licensing process?
- Can the TTO license without having performed an FTO analysis?
- What are the likely pitfalls for
  - the TTO?
  - the licensee?



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## Should the TTO perform an FTO analysis?

- NO
- Not in the TTO's realm of expertise
- Can easily be construed as a warranty of merchantability
- Invalidates the "As Is" nature of most licenses
- Should be understood as a cost of doing business for the licensee
  
- Also, all aspects of a start-up's IP strategy should be revisited regularly
- This operation should be on the start-up as an ongoing matter, not the TTO



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## What if the TTO really, really wants to perform an FTO analysis anyway?

NO

- You can always confer with your General Counsel and Risk Management team
- They will tell you ... NO

(Feel free to review previous slide)



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## Can the TTO license without an FTO analysis?

- Yes, but it helps to understand
  - Why the start-up needs the analysis
  - Why the TTO should not provide that analysis
- But you still need to perform as a reliable licensor of valuable IP
  - Educate your startup team on IP, competitive analysis, and FTO
  - Keep records of your searches and search strategy
  - Maintain a complete file of results and key patent matters and publications
  - Share these with the licensee at as early a stage as is practical
    - Discuss options (e.g., license to blocking IP or collaboration)
  - If outside counsel or a search firm has been involved, make them available to the licensee



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## What are the likely pitfalls for the TTO & the licensee?

- If the TTO provides insufficient detail on the validity of the IP, may lose potential licensees
- If the TTO includes an FTO analysis as part of the licensing process, could expose their institution to litigation
- If the licensee invests in unvetted IP, could end up wasting time and money if IP is invalidated
- If the licensee sinks too much time and money into the FTO analysis, they could also lose time and money by not moving technology forward



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# Thank you for your time



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