

IP Portfolio Development: Is Your IP House In Order?

Greg Grissett

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Part 1: Overview of IP and Patents

Part 2: Is Your Revenue Model Protected?

**Part 3: What is your Risk Position
Regarding Competitor Patents?**

Part 1: Overview of IP

Right	What it Protects	Term
Trademarks	Source of goods/services	As long as it is used
Copyrights	Creative Works	Shorter of 95 years from publication or 120 years from creation
Trade Secrets	Valuable Secret Information	As long as it kept secret
Patents	Products, Processes, Devices	20 Years from filing

Patents

Grants Patent Owner the Right to **Prevent Others** From Making, Using, Selling in the U.S. as the Invention **as Claimed** in a Patent.

The Right is Given in Exchange for Disclosure of the Invention

U.S. Patent Claims

–“The name of the game is the claim.”

–Defines scope of rights

–Valid claims are novel and nonobvious over prior art

1. A closure device for sealing a percutaneous puncture in a wall of a body passageway, the closure device comprising:
a deployment body;
a plug configured to engage a surface of the puncture;
a toggle configured to engage an internal surface of the body passageway;
an elongate filament associated with the plug and the toggle;
a locking member disposed along the elongated filament and configured to engage the plug; and
a tamper disposed in the deployment body, the tamper defining a proximal end, a distal end spaced from the proximal end along a longitudinal axis, and at least two lumens that each extend from the proximal end to the distal end along the longitudinal axis,
wherein a first lumen of the at least two lumens is configured to receive a guidewire therethrough and a second lumen of the at least two lumens receives the elongate filament therethrough so as to be slidable along the elongate filament,
wherein the tamper is sized so that a proximal end of the tamper slides entirely out of the deployment body to tamp the locking member against the plug.

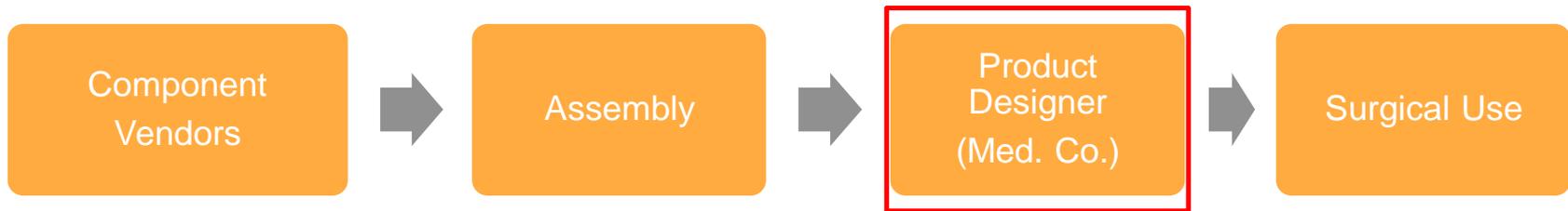
Patents

Patents should cover (**CLAIM**) different aspects of the value chain

Medical device companies should utilize the U.S. patent system to address competitive threats: continuation applications

Part 2: Is Your Revenue Model Protected?

Patents in the Medical Device Value Chain

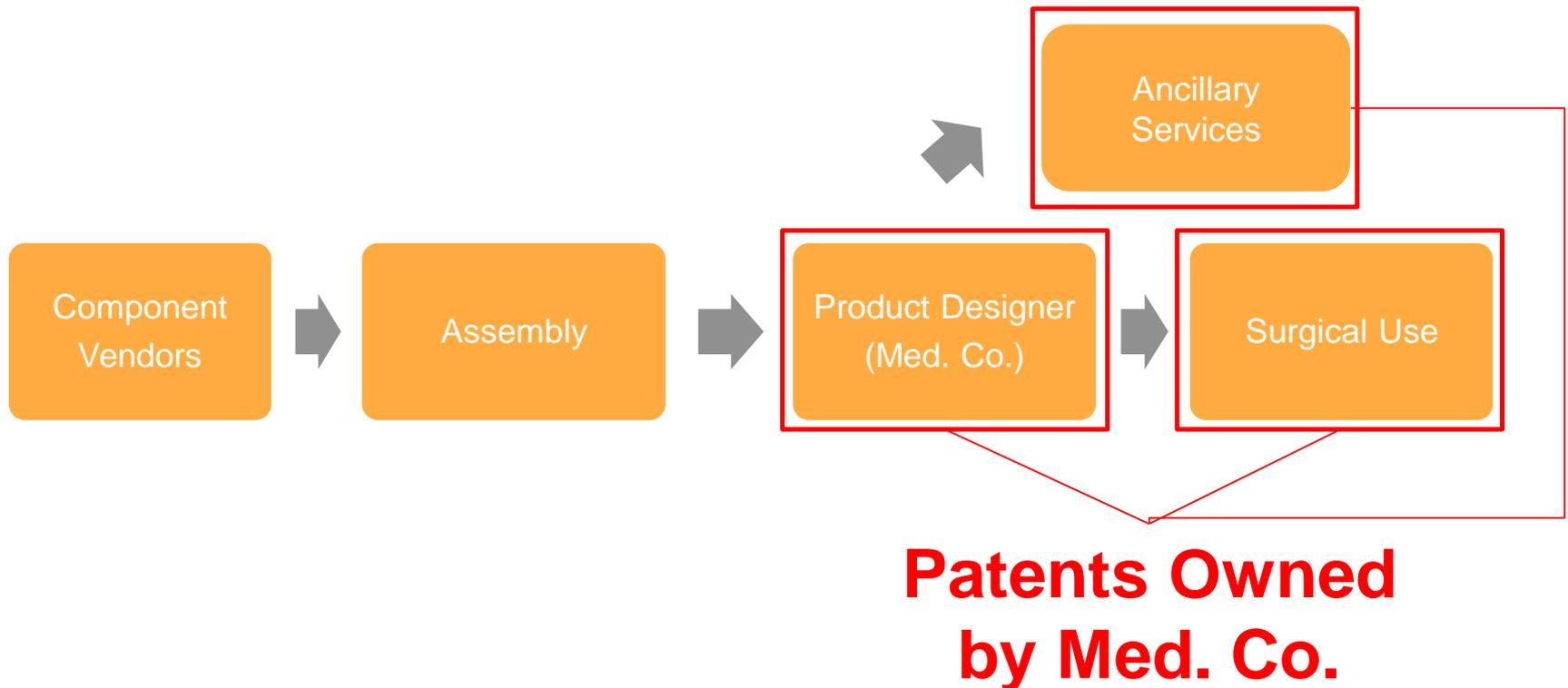


**Patents Owned
by Med. Co.**

Can your customer buy from a 3rd party?

Not Without Permission from Med. Co.

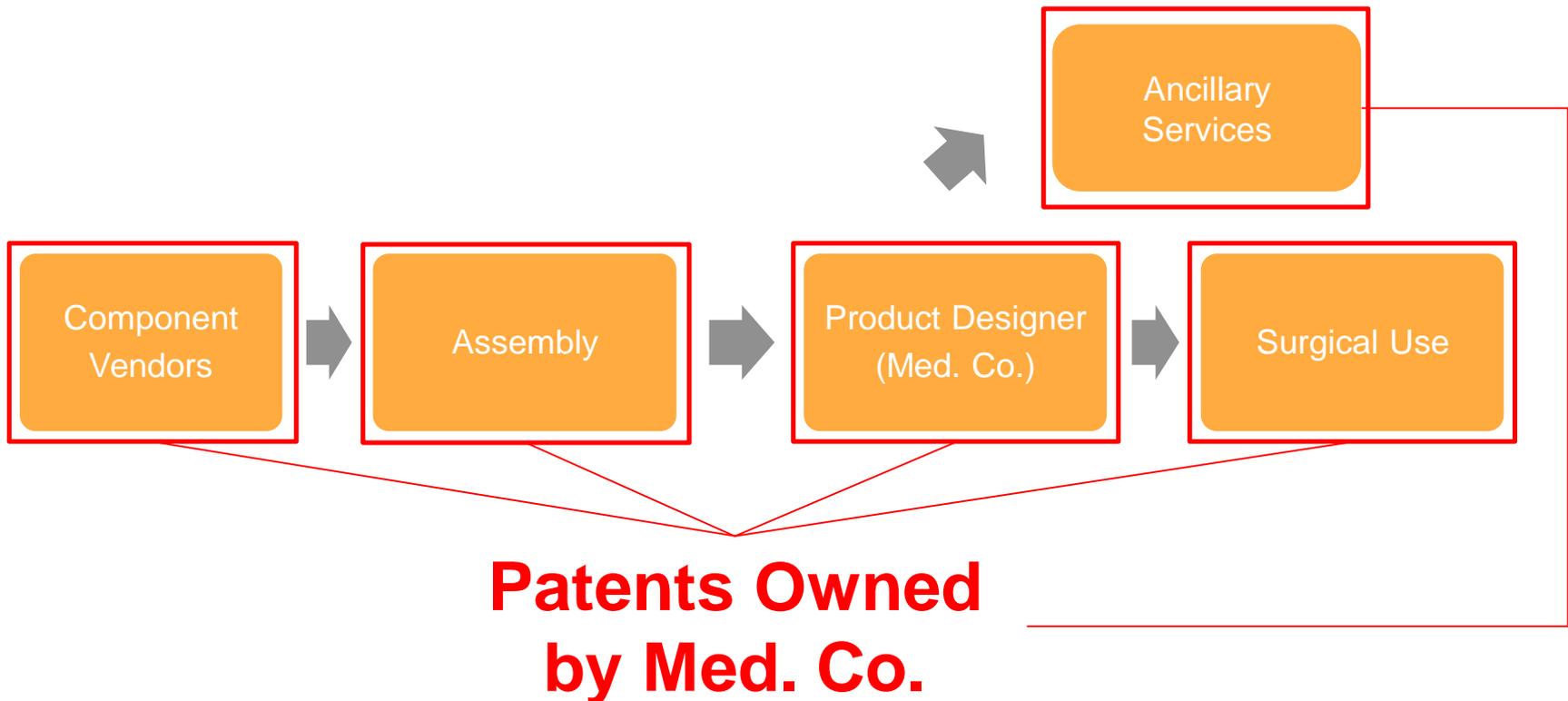
Patents in the Medical Device Value Chain



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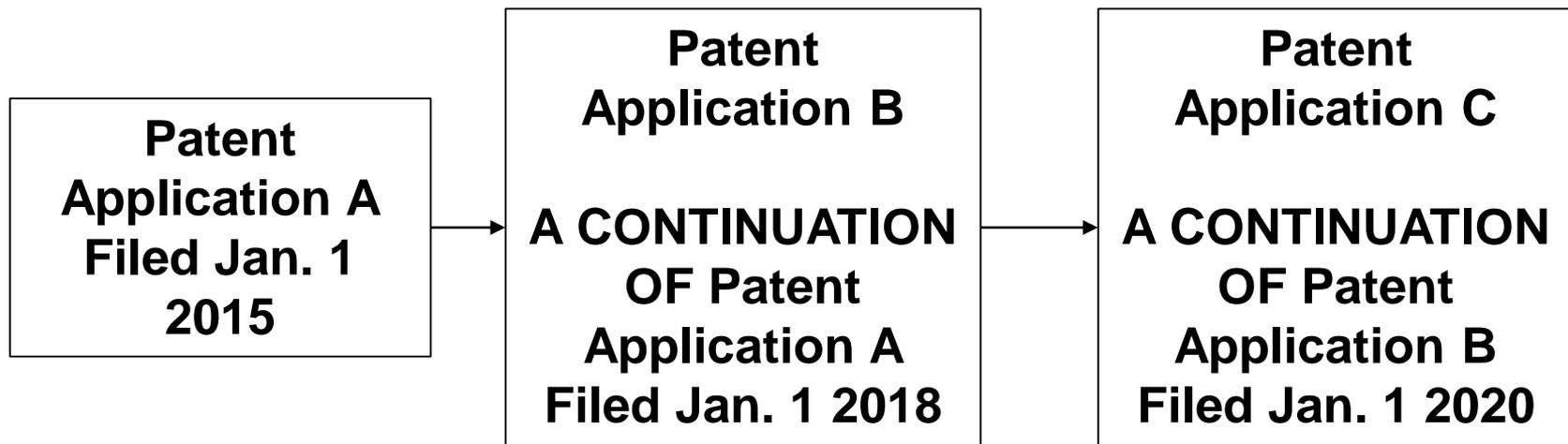
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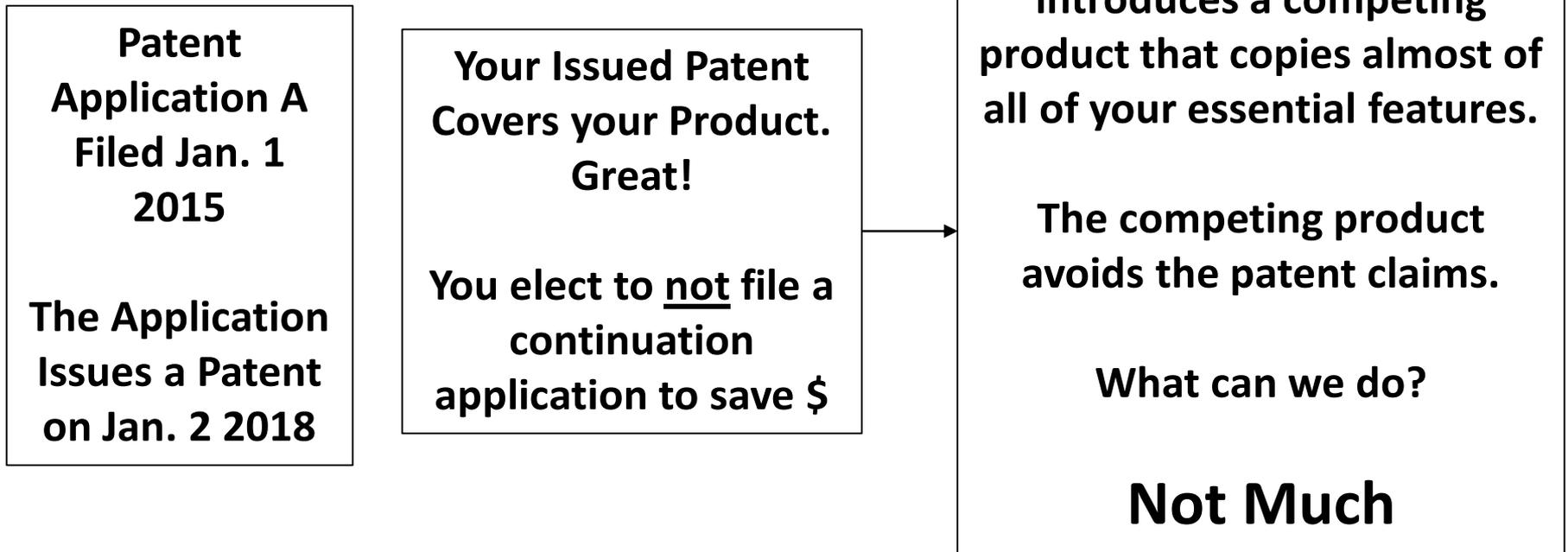
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Using the Patent System to React to the Market: Continuations

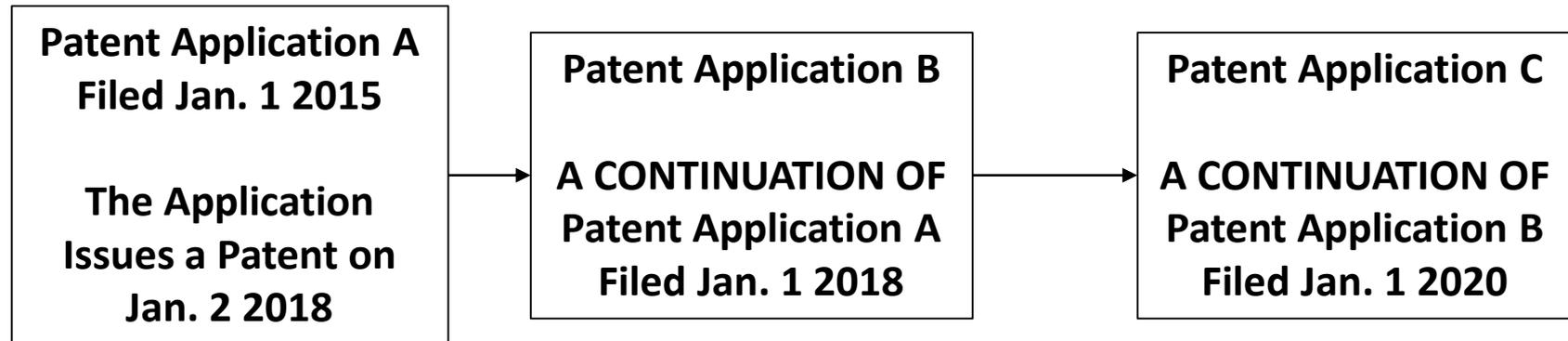


Continuation/Divisional patents have the Same Technical Description but Have Different Claims (Device vs Method vs Composition)

Using the Patent System to React to the Market: Continuations



Using the Patent System to React to the Market: Continuations



Your Issued Patent Covers your Product. Great!

This time you chose to file a continuation application and keep the family alive.

2 years later a competitor introduces a competing product that copies almost of all of the essential features of your product. The competing product avoids the patent claims. What do we do?

We draft claims to cover the competing product in Application B and/or C. **The competitor now has patent infringement risk and calls you for a license.**

How do patents impact top line, bottom line, and capital?

1. Patents on core technology protects the revenue model - protects top and bottom line
2. Continuation patents limit encroachment - protects top line
3. Robust patent coverage attracts capital

**Protect as much of the value chain
as you can**

**Make use of continuations to react
to the market**

Part 3: Avoiding IP Infringement

You develop a product and are close to market release. You have not conducted a patent search to assess your risk of infringement. What do you do?

Freedom to Operate (FTO) study

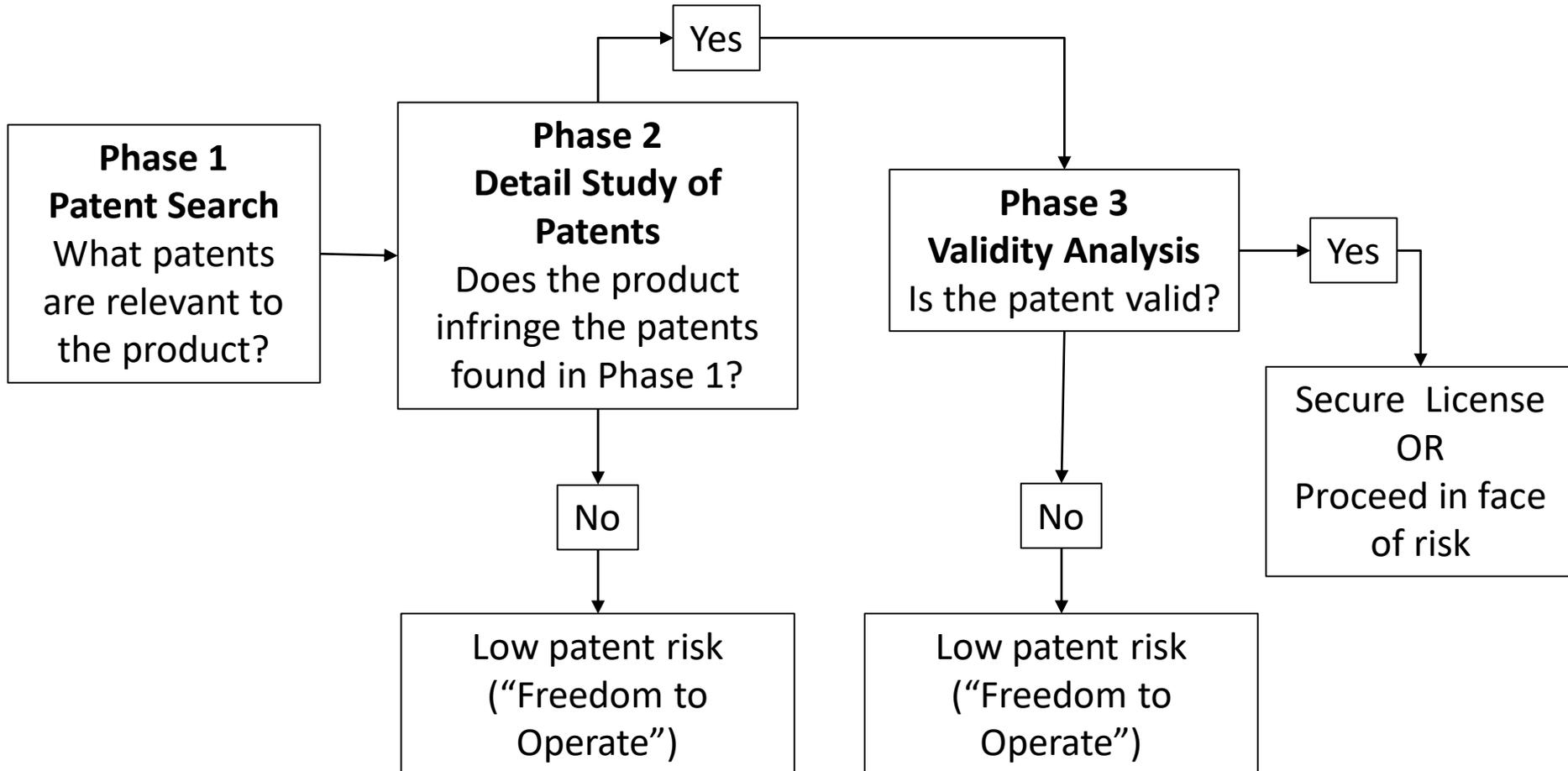
Search and analysis of relevant patents to determine a risk of patent infringement for marketing a product or service in the United States

Compares **commercial product** to claims in a relevant U.S. patent

Why Conduct an FTO study?

1. Business tool to evaluate risk of product launch and/or product development pathway
2. Legal tool to limit damages in response to a willful infringement allegation
3. Investors want freedom-to-operate

Freedom-to-Operate Patent Study



Phase 1 of FTO

Claim 1

A device comprising:

- A) a brown widget,
- B) a grey gizmo,
- C) an actuator, and
- E) a controller.

Product A Includes

- A) a brown widget,
- B) a grey gizmo,
- C) a first actuator,
- D) a second actuator,
- E) a controller

Product B Includes

- A) a brown widget,
- B) **a black gizmo**,
- C) a first actuator,
- D) a second actuator,
- E) a controller

Product A infringes claim 1 – No Freedom to Operate

Product B does not infringe claim 1 – Freedom to Operate

Patent Litigation

Patent infringement liability attaches when one makes, uses, sells what is CLAIMED in a valid and enforceable patent

Remedies: Damages, Injunction, Attorney Fees (sometimes)

Willful infringement triples damages awards

Patent Lawsuits are Expensive

- \$2.5 million when more than \$25 million is at stake

- \$750K when less than \$1 million is at stake

How does an FTO study impact top line, bottom line, and capital?

1. Avoiding infringement avoids unexpected costs – protects bottom line
2. Designing around a patent can generate new IP – protects top and bottom line
3. Risk mitigation attracts capital

Conduct FTO Study at the Right Time

After initial product conception but before large capital outlay

When you make substantial product changes

Patentability -- Obtaining Patents	Freedom-to-Operate -- Avoiding Patents
Is the invention as claimed novel and non-obvious over the prior art?	Focused on solely on what you will sell and receive \$ for
The prior art = publications or patents available or sales before the filing date	Does the product infringe a valid claim of a U.S. Patent?

Questions?

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- New Co. develops a health monitor with a new sensor module that can obtain physiological characteristics that far exceeds data currently obtained by sensor modules on the market. The device includes a communication system that increases data transfer rates. The new device does the work of three different devices and results in far superior data sets. Marketing calls it “newdevice.” The device has an ergonomic shape with sleek design features.
- Developing the new device used a new coding scheme developed in house that is robust and intuitive.
- The new coding scheme can create software used to operate the sensor module.
- The new coding scheme includes open source software that was implemented to make it work as intended.
- The software uses a compilation of physiological data obtained by New Co. over the last 20 years that others do not generally have.

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Intellectual Property - Due Diligence Inquiry	
A	A list of all intellectual property rights owned by the Business (e.g., patents, copyrights, trademarks, trade names, service marks, etc., including any applications therefore), any agreements, licenses or other documentation related thereto and the expiration dates thereof, and a description of any interest in the intellectual property rights held by senior management or major stockholders. Include (i) a description of the product, device, process, service or business covered by any such rights, and (ii) the name of the registered or other owner of such rights.
B	A checklist, with attachments summarizing and documenting that each issued or pending patent has assignments from the inventors to the Business
C	A list of all persons who participate in development and/or maintenance of products of the business, including all agreements related to assignments of inventions, copyrights, know-how, etc.
D	A list of all intellectual property rights licensed to or from the Business, including, without limitation, any agreements, licenses or other documentation related thereto and the expiration dates thereof.
E	A listing of all previously prepared non-infringement, infringement opinions, including disclosure of any oral opinions
F	Summary listing of all issued and pending patents, indicating each patent matter's applicability/non-applicability to the currently planned commercial products
G	A list of all know-how, trade secrets, technology, technical information and computer software owned or licensed by or to the Company or subsidiary
H	A listing of: <ul style="list-style-type: none"> a. Known competitors developing or selling similar products to the business; b. Known third parties owning patent matters relating to similar products or methods of use; and c. Any known patent matters, not licensed or assigned to the business, that relate to products of the business

The Two Issues in Technology Heavy Capital Transactions:

1. Is the technology covered?
2. What are 3rd Party IP Risks? What is the plan to address those risks?

2. Are There any 3rd party IP Risks?

Freedom-to-Operate (FTO) Studies: If your company sells a product, would that product infringe a valid 3rd party IP right, e.g. a patent?

In other words, is your investor buying a patent infringement lawsuit?

• New Co. develops a health monitor with a new sensor module that can obtain physiological characteristics that far exceeds data currently obtainable from other modules on the market. The device includes a communication module that significantly increases data transfer rates. The new device does the work of three different devices and results in far superior data sets. Marketing calls it “newdevice.”
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 - ©
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