

Navigating Patent Risk and Protecting Your Revenue Model in Medical Devices

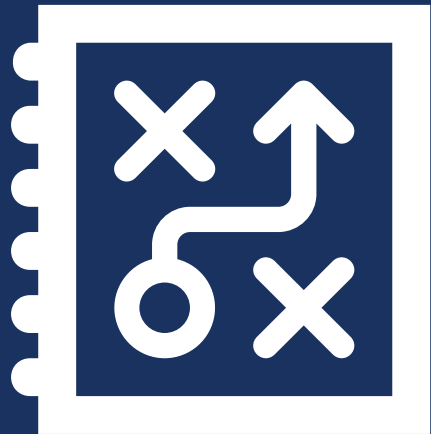
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Agenda

- Part 1: Overview of IP and Patents
- Part 2: Minimizing Patent Infringement Liability Risk
- Part 3: Patent Protection and Your Revenue Model



Overview of IP and Patents

Basic IP Rights

Right	What it Protects	Term	Examples
Patents	Products, Processes, Machines, Compositions	20 Years from filing	Bone plates, testing kits, surgical methods
Trademarks	Source of goods/services	As long as it is used	Brands (Nike, Apple)
Copyrights	Creative Works	95 years from publication/ 120 years from creation	Product Literature, Technique Guides, Software
Trade Secrets	Valuable Secret Information	As long as it is kept secret	Pricing, Customer Lists, CRM Data, Secret Formulas, Etc.

Patent Rights

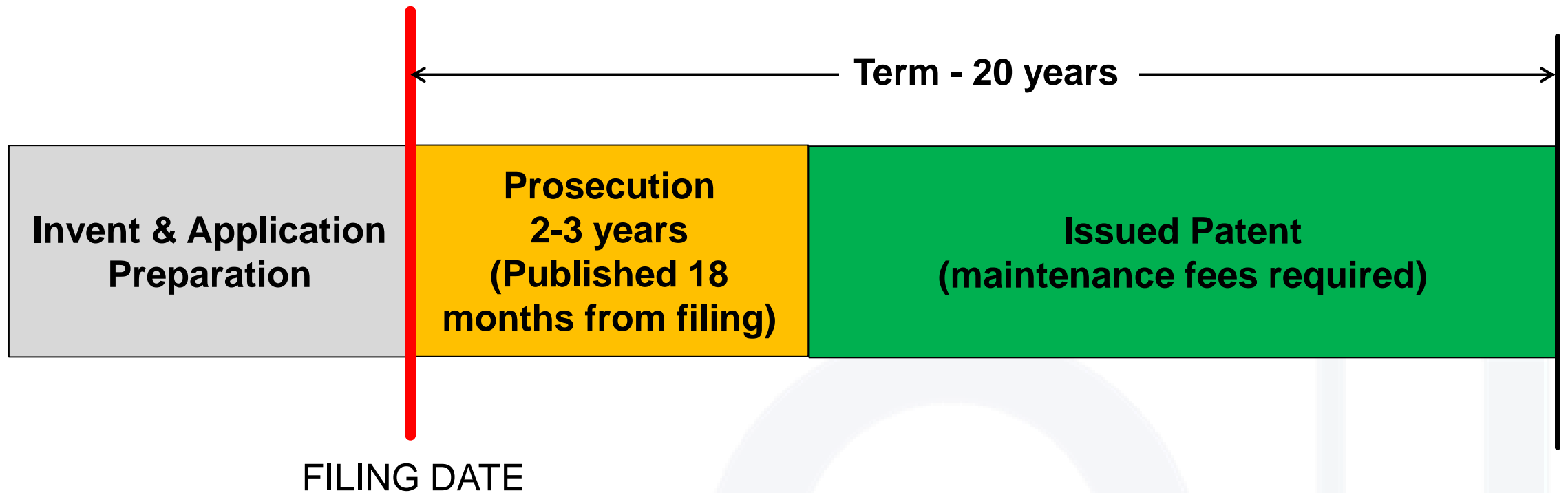
- Patents give patent owners the right to prevent others from **making, using, selling, offering for sale or importing into the U.S.** the invention as claimed in a patent

Patent Claims

- Patent claims define the legal scope of protection
- Claimed invention must be new & non-obvious in view of the prior art, described, enabled, and not (too) abstract

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.

Overview of Patent Process



Patent Rights: Protection vs Risk Avoidance

Patentability: Obtaining Patents

Focused on the invention and technology in view of requirements for obtaining patents

Is invention novel and non-obvious over the prior art?

≠

Freedom-to-Operate: Avoiding Patents

Focused on solely on what you will sell and receive \$ for

Does the product infringe a valid claim of a U.S. Patent?



Minimizing Patent Risk

Minimizing Patent Risk: Why? Patent Rights-- Revisited

- Patent owners have the right to **prevent others** from **making, using, selling, offering for sale or importing into the U.S.** the invention **as claimed in a patent**

Minimizing Patent Risk: Why? Patent Infringement Liability

- Complaint of infringement of a claim of a U.S. patent filed in Federal District Court
- Judicial determination that the product literally or equivalently infringes at least one claim of a U.S. patent
- Failure by the defendant to prove the patent claim is not valid or that patent is not enforceable
- Ascertainable and available sales (damages) during the relevant time period

Patent Risks

- Money damages (reasonable royalty or lost profits)
- Triple Damages?
- Attorney's Fees?
- Injunction
- Defense costs
- Reputational harm
- Lost opportunities

Minimizing Patent Risk

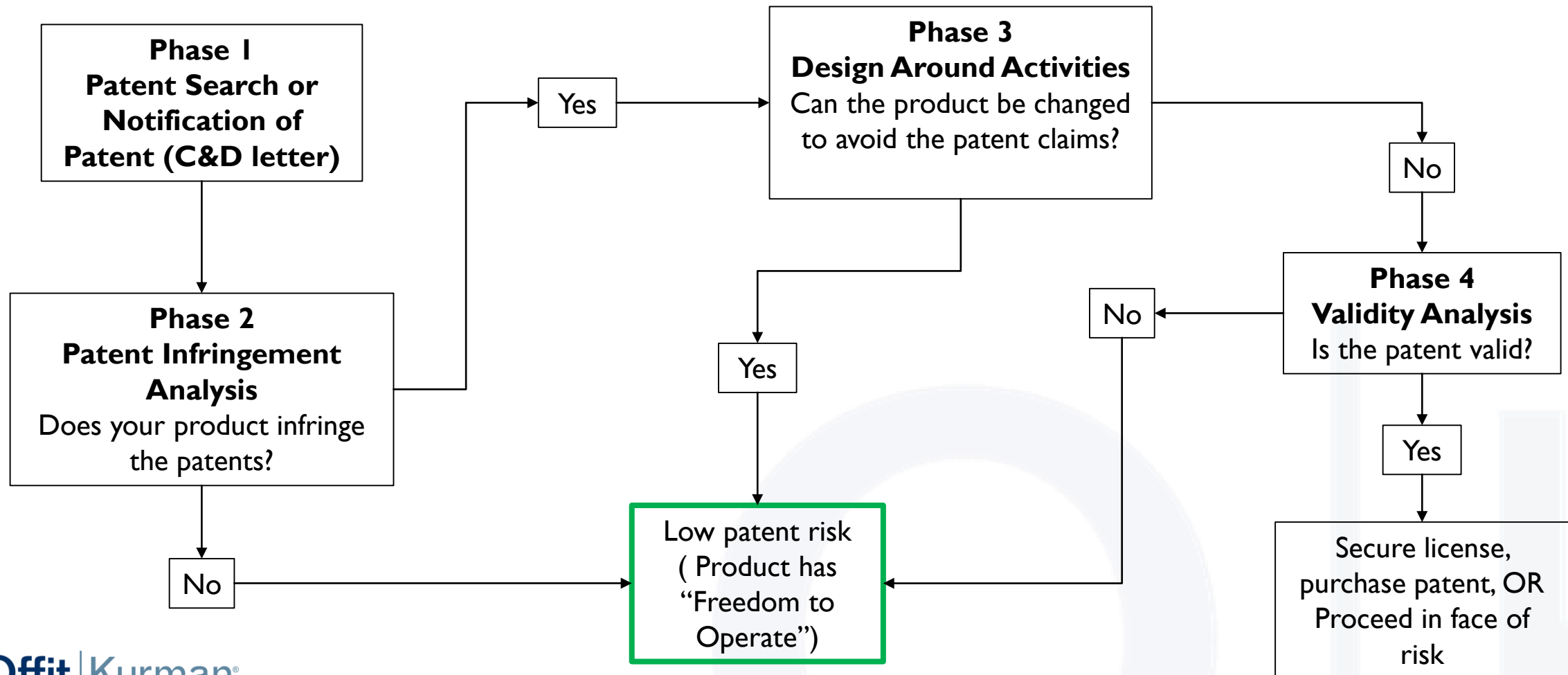
What is a Freedom to Operate (FTO) Study?

- Search or identification and analysis of relevant patents to determine a risk of patent infringement liability attaching to a company for its commercial marketing of a product or service in the United States
- Compares **commercial product** to claims in a relevant U.S. Patent or Published Patent Application
- May included an assessment of validity of relevant and high risk patent claim

Minimizing Patent Risk: Outcomes of an FTO Study?

- Business tool to evaluate risk of product launch and/or product development pathway
- Legal tool to limit damages in response to a willful infringement allegation
- Results can be used to disprove an inducement infringement theory
- Investors and strategic partners want freedom-to-operate

How to Conduct a Freedom to Operate Study



Phase 1 Search and Identify Relevant Patents

- Hire search firm to compile relevant patents and published patent applications
- Designate a person with patent searching proficiency to compile/search patents
- Monitor key competitors and inventors for new patents and new patent publications
- Learn of patent via C&D letter or invitation to license letter
- Conduct preliminary analysis to weed out irrelevant patents, expired patents, or abandoned patent applications

Phase 2 of FTO: Direct Infringement Analysis -- Products

Claim 1

A medical 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, and
- E) a controller.

Product B Includes

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

Product A literally infringes claim 1 – No Freedom to Operate

Product B does not literally infringe claim 1 – Is there Freedom to Operate?

Phase 2 of FTO: Direct Infringement Analysis for Patented Methods

Method Claim 1: A surgical method, comprising:

- A) making an incision,
- B) inserting a grey implant through the incision, and
- C) attaching the implant to a target tissue.

Med Device Co sells and delivers to the healthcare provider a grey implant, sutures, and anchors.

No *Direct* Infringement by Med Device Co

Phase 2 of FTO: Inducement Infringement Analysis – Methods

- Inducement Infringement occurs when A) one party induces or encourages another to infringe a patent claim and B) that party had knowledge that the induced acts constitute infringement (35 U.S.C. § 271(b), *Global-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754 (2011))
- Can a medical device company induce a healthcare provider to infringe a surgical method?
Maybe

Phase 2 of FTO: Inducement Infringement Analysis

Method Claim 1: A surgical method, comprising:

- A) making an incision,
- B) inserting a grey implant through the incision, and
- C) attaching the implant to a target tissue.

Med Device Co sells and delivers to the health care provider a grey implant, sutures, and anchors AND encourage surgeons to perform steps via technique guides and training

**Possible Inducement Infringement
by Med Device Co**

Phase 3 of FTO: Design Around

Claim 1

A medical 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, and
- E) a controller.

Modified Product A Includes:

- A) a **blue** widget,
- ~~B) a grey gizmo,~~
- C) a first actuator,
- D) a second actuator, and
- E) a controller.

Product A literally infringes claim 1 – No Freedom to Operate

Modified Product A does not literally infringe claim 1 – Freedom to Operate

Phase 4 of FTO: Validity

Claim 1

A medical device comprising:

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

Does the prior art render the claim invalid?

Is the claim enabled?

Is written description violated?

Etc...

If the claim is invalid, there is lower risk (even if infringement is present)

If claim is valid, consider license, purchase, or proceed in view of risk

Minimizing Patent Risk: FTO study results

- Confidence in risk position relative to 3rd party patents
- Non-infringement and invalidity opinions can be used to disprove willful infringement allegation
- Favorable non-infringement opinions can mitigate risk of inducement infringement... by proving that defendant did not have actual knowledge of the patent or that they had a good faith belief it was not inducing infringement
- Invalidity opinions can form the bases to cancel patents at the U.S. Patent Office (via Inter Partes Review and/or ex parte reexaminations)

What can you do with the results of an FTO study?

- Designing around a 3rd party patent can generate new patents and help block 3rd parties from implementing the design around
- Patent risk mitigation attracts capital and can streamline due diligence*

Minimizing Patent Risk: When do you conduct an FTO study?

- Timing is driven by key commercial milestones and external events--the earlier the better
- After product/service is relatively concrete (concepts are hard to clear)
- Ideally before:
 - significant capital outlay
 - filing of PMA or 510(k)
 - significant design changes
 - selling the product in the U.S.
- In response to receiving a cease & desist letter or a patent notification/invitation to license letter



Is Your Revenue Model Protected?

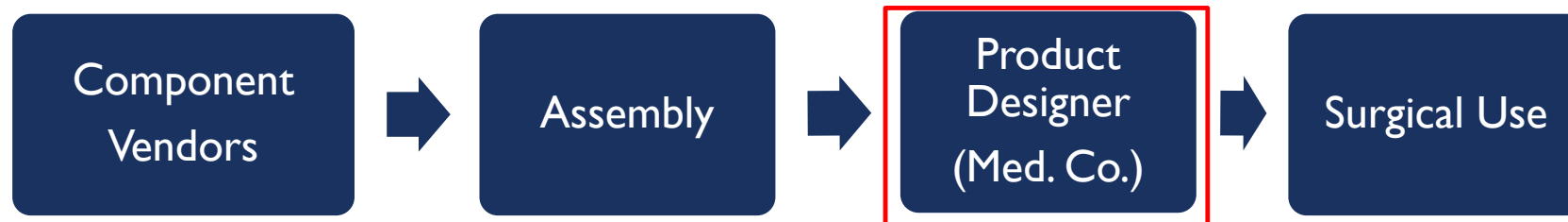
Patent Strategy: Protecting Revenue

- Patents should cover (CLAIM) the revenue generating product or service
- If possible, the patent should also cover (CLAIM) different aspects of the value chain
- Medical device companies should utilize the U.S. patent system to address competitive threats: continuation applications

Patent Strategy: Protecting Revenue

- Patents claims should focus on what product or service your company is selling for which it generates invoices for
- If the patent claims do not cover what is “in the package” the patent claims do not cover the revenue model
- If the business sells implants (but not sutures or anchors), then claims should focus on implants
- If the business is service based (e.g. diagnostic testing method/POC), the claims should focus on the services provided to paying customers

Patent Strategy: Securing Coverage in the Medical Device Value Chain

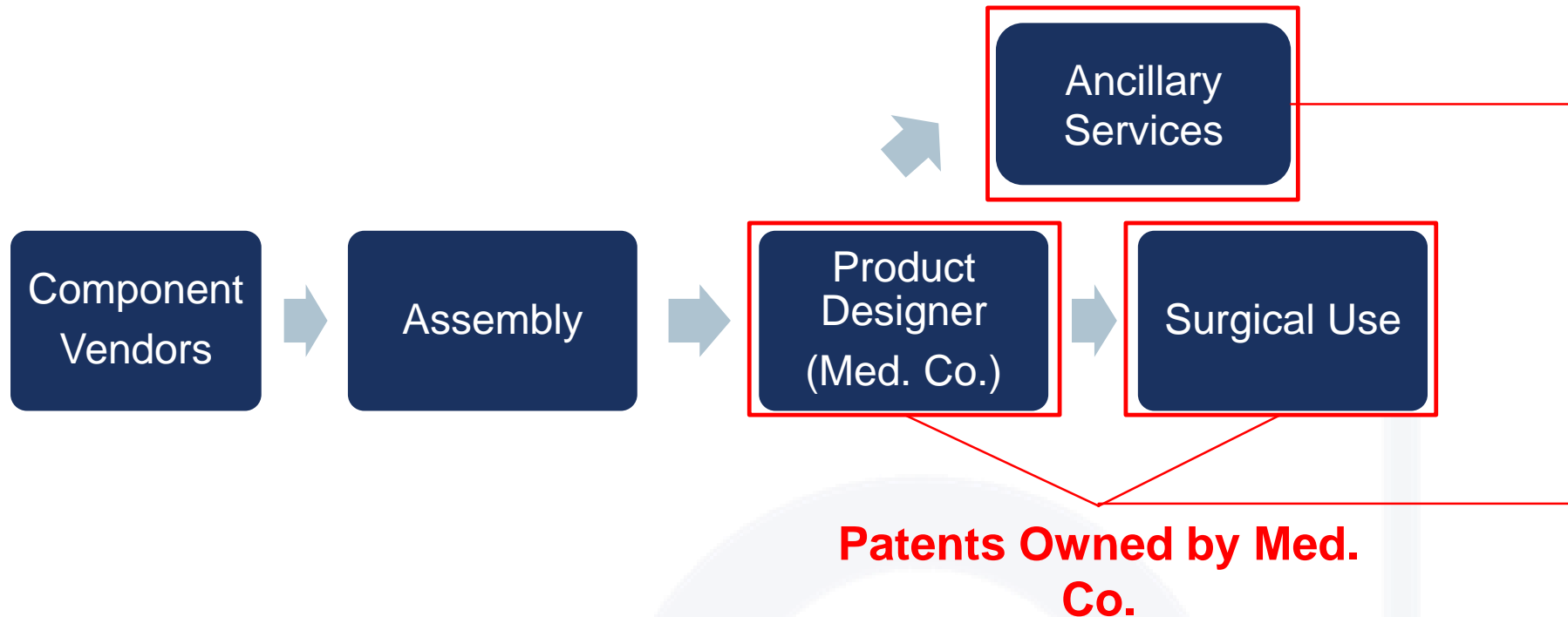


Patents Owned by Med. Co.

Can your customer buy from a 3rd party?

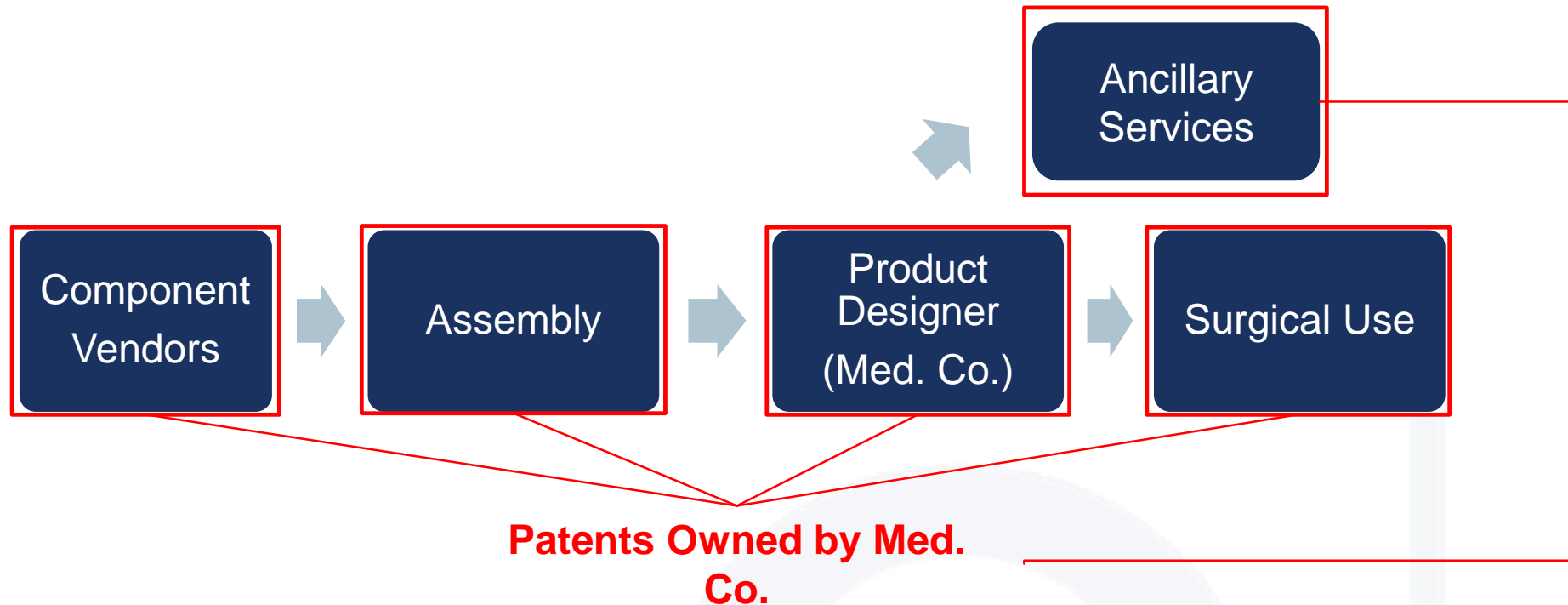
Not Without Permission from Med. Co.

Patent Strategy: Securing Coverage in the Medical Device Value Chain



Can your customer buy from a 3rd party?
Not Without Permission from Med. Co.

Patent Strategy: Securing Coverage in the Medical Device Value Chain



Can your customer buy from a 3rd party?
Can the customer have the device made by 3rd party?
Not Without Permission from Med. Co.

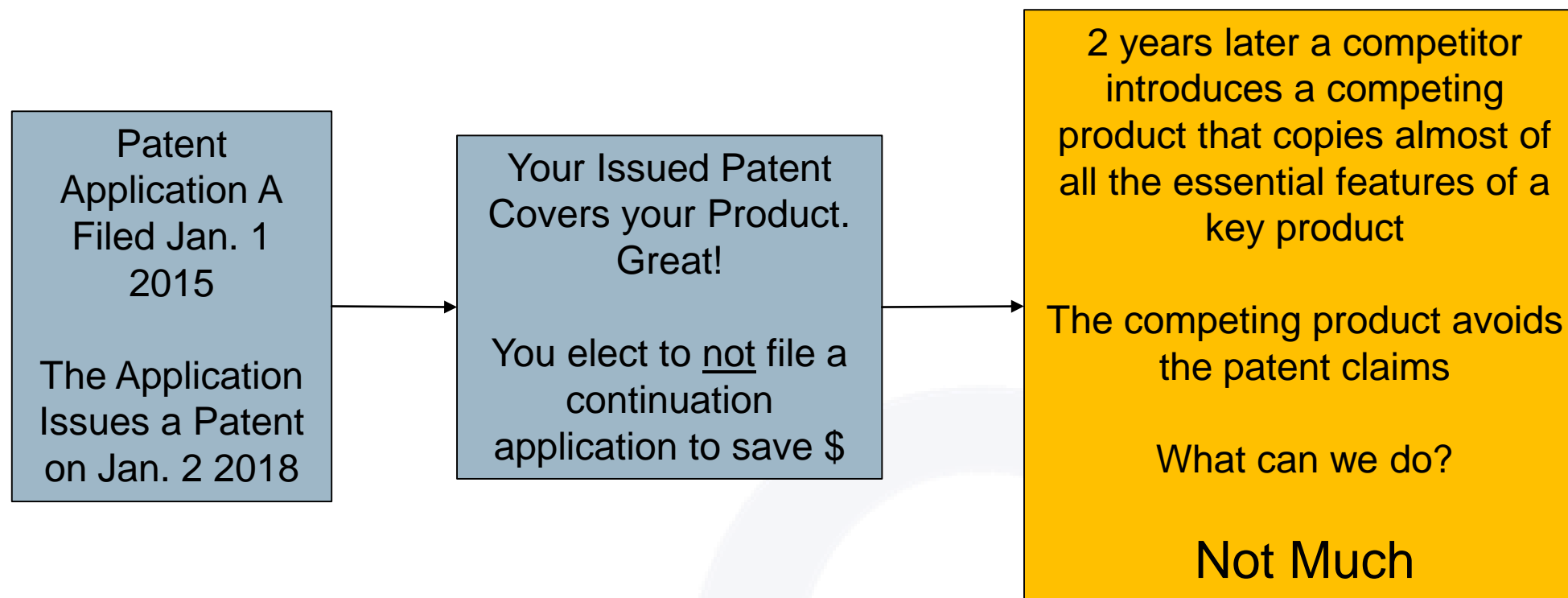
Patent Strategy: Using the Patent System to React to the Market--Continuations

- Continuation/divisional patents have the same technical description but have different claims (device vs method vs composition)

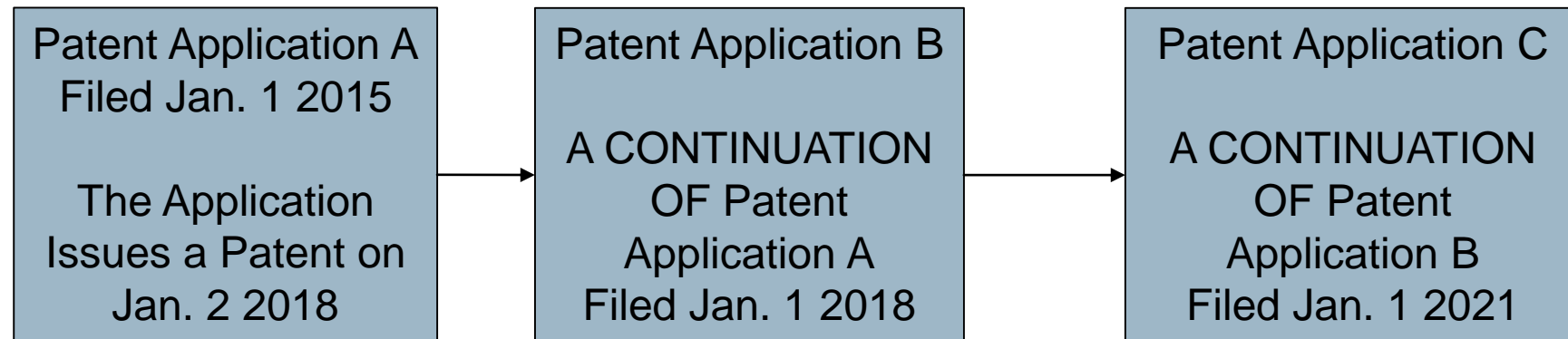


- Can file continuations indefinitely until patent term expires

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 continuation applications 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?

Draft claims to cover the competing product in Application B and/or C. **The competitor now has patent infringement risk and your business now has a response if the competitor sues you for patent infringement**

Effective Patent Strategy: Final Thoughts

- Minimize patent risk by conducting FTO studies at the right time
- Develop and procure patents on core technology that protects the revenue model--protects top and bottom line
- Whenever possible, secure coverage along the entire value chain--protects the supply chain
- Continuation patents limit encroachment by competitors--protects top line
- Robust patent coverage and low patent risk attracts capital and provide commercial flexibility

Questions?



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