Biotechnology Innovation Organization

Biotechnology Entrepreneurship Boot Camp

Presented by:

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#BIO2024 #StandUpForScience

Biotechnology Entrepreneurship Boot Camp

Intellectual Property Mastery

From Fundamentals to Strategic Defense

Intellectual Property Mastery: From Fundamentals to Strategic Defense

Mastering the Essentials

Introduction to IP Basics:
Overview of intellectual property and its importance.

Overview of Different IP Rights:
Understanding patents, trademarks, copyrights, and trade secrets.

Key Patenting Requirements:
Essentials for patent eligibility and protection.

Importance of Confidentiality Agreements:
Role of NDAs and CDAs in protecting IP.

Timing for Filing Patents:
Strategic considerations for when to file.

Guidance on Patent Filing Details:
What needs to be included in your patent applications.

Create Competitive Immunity

Introduction to MyIP Shield™ Pyramid:
Conceptualizing IP strategies using this tool

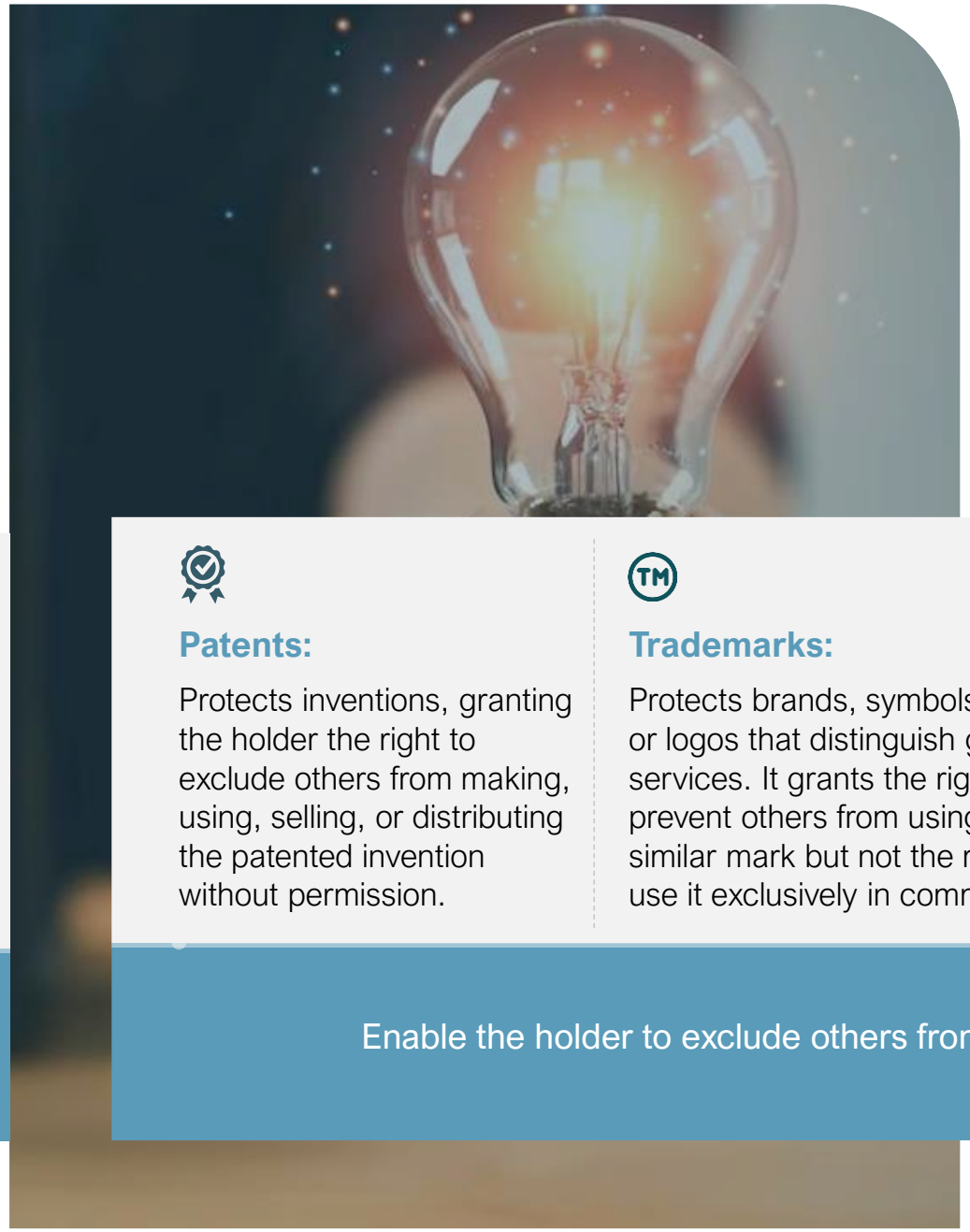
Applying IP Strategically:
How to use IP to gain competitive advantages.

Linking IP Strategy to Business Functions:
Integrating IP with business strategies for market success.

SWOT Analysis of IP:
Assessing strengths, weaknesses, opportunities, and threats related to IP.

Innovative Approaches to Strengthening IP:
Techniques for enhancing IP protection and value.

Assessing Investment Potential of IP Strategies:
Evaluating IP's financial and strategic value.



Types of Intellectual Property Rights and Their Implications

Patents:

Protects inventions, granting the holder the right to exclude others from making, using, selling, or distributing the patented invention without permission.

Trademarks:

Protects brands, symbols, words, or logos that distinguish goods or services. It grants the right to prevent others from using a similar mark but not the right to use it exclusively in commerce.

Copyrights:

Protect the original expression of ideas, such as books, music, artwork, and software. They do not protect the idea itself but rather its expression.

Trade Secrets:

Protects information that is not generally known or reasonably ascertainable, such as formulas, practices, processes, designs, instruments, or patterns.

Enable the holder to exclude others from using the protected IP.

No Right to Exclude: protection is conditional, relying on the secrecy of the information. Disclosure ends its secrecy.

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Other Forms of Exclusivity

12 years	Biologic Exclusivity
7 years	Orphan Drug Exclusivity (ODE)
5 years	New Chemical Entity (NCE) Exclusivity Qualified Infectious Disease Product (QDIP) Exclusivity - (added to any existing exclusivity)
3 years	Clinical Investigation Exclusivity (CIE)
6 months	Pediatric Exclusivity (PED) – (added to any existing exclusivity)
180 days	Generic Drug Exclusivity (GDE)

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Patent Basics

Patent Types

Type of Patent	Description	Duration of Protection	Legal Requirements and Rights	Example in Life Sciences and Medtech
Utility Patents	Protects new and useful processes, machines, manufactures, or compositions of matter, or improvements thereof.	20 years from the filing date, requiring maintenance fees.	Novelty, non-obviousness, usefulness. Grants the right to exclude others from making, using, selling, or importing the invention.	Drug Formulations: Enhancing efficacy or reducing side effects. Medical Devices: Innovative surgical instruments.
Methods Patents	Subset of utility patents that specifically protects new or improved methods or processes.	Same as utility patents: 20 years from the filing date.	Shares the same requirements as utility patents: Novelty, non-obviousness, usefulness. Grants the right to exclude others from using the patented method.	Diagnostic Methods: Processes for disease diagnosis using biochemical techniques. Therapeutic Methods: Surgical techniques or therapy regimens.
Design Patents	Protects the ornamental design of a functional item.	15 years from the grant date (for designs filed on or after May 13, 2015; 14 years if filed before).	Ornamentality, novelty, and non-obviousness. Prevents others from manufacturing, selling, or using a product with the protected design.	Medical Wearable Design: Aesthetic design of a device monitoring patient vital signs.
Plant Patents	Granted to anyone who invents or discovers and asexually reproduces any distinct and new variety of plant.	20 years from the filing date.	Novelty, distinctiveness, and asexual reproduction. Allows the holder to exclude others from asexually reproducing, selling, or using the plant.	Genetically Engineered Plants: Plants modified to produce pharmaceutical compounds.

Patent Terms

Category	Simple Description	Timing	Costs	Details
Standard Term	Standard patent duration	20 years from filing date	Filing fees	Patents typically have a term of 20 years from the filing date of the earliest U.S. or international application to which priority is claimed.
Impact of Provisional Filings	Starts patent clock later	Extends effective term	Lower initial cost	Provisional applications are not counted in the 20-year term, which starts from the filing date of the non-provisional application.
Patent Term Adjustment (PTA)	Compensates for USPTO delays	Adds time beyond 20 years	No direct cost but impacts overall term management	Compensates for USPTO delays in patent examination, potentially extending the term beyond the standard 20 years. Conditions for Extensions: Includes delays caused by the USPTO's failure to meet specific examination deadlines.
FDA-Related Extensions	Extends term due to FDA delays	Up to 5 years extension	No direct cost, dependent on regulatory path	Possible extension due to regulatory review delays for products that require FDA approval. Specific Conditions: Extension not exceeding 14 years from product approval.
Hatch-Waxman Extensions	Compensates for regulatory delays	Up to 5 additional years	No direct cost, significant strategic value	Allows for up to 5 years of additional patent term to compensate for time lost during the FDA regulatory review process. Application: For one patent on one product. Similar Foreign Rights: Major jurisdictions outside the US may offer parallel extensions for regulatory delays.

Provisional:

- After submitting a provisional patent application, you have 12 months to file a corresponding non-provisional patent application. This non-provisional application can claim the benefit of the filing date of the provisional application. This 12-month period allows the inventor to refine the invention, conduct market analysis, or seek funding while retaining the initial filing date provided by the provisional application.
- Possible Lawsuits Against You: While you cannot sue someone based on a provisional application, others could sue you if your activities infringe on their patent rights. This could occur regardless of your provisional filing status if you manufacture, use, or sell an invention that infringes on an active patent.

Patent Requirements & Prior Art

Patent Requirement	U.S. Code Reference	Explanation	Examples of Prior Art
Utility and Non-natural	35 U.S.C. §101	The invention must have practical utility and be a human-made invention or discovery.	N/A
Novelty	35 U.S.C. §102	The invention must be new and not previously known or described in public disclosures.	Scientific articles, theses, public talks, published patents.
Non-obviousness	35 U.S.C. §103	The invention must not be obvious to someone skilled in the field at the time of the invention.	Scientific articles, industry standards, existing patents.
Inventive Step (Rest of World)	Applicable International Laws	Similar to non-obviousness, the invention must represent a non-obvious improvement over existing knowledge.	Same as above, contextual to specific jurisdiction's standards.
Enablement	35 U.S.C. §112	The patent application must enable any person skilled in the art to make and use the invention.	N/A (relates to the content of the patent application itself).
Written Description	35 U.S.C. §112	The patent application must clearly describe the invention to ensure the public understands the invention and its bounds.	N/A (relates to the content of the patent application itself).

Patent Challenges

Option	Description	Timing	Costs	Grounds for Challenge
USPTO IPR	Post-grant challenge before the USPTO to invalidate a patent based on prior art (existing knowledge) or obviousness (combining existing knowledge in an unoriginal way).	IPRs have a 9-month time limit if filed in response to an infringement suit, but can be filed at any time otherwise.	$30,000 - $500,000	Novelty, Obviousness
USPTO PGR	Post-grant challenge before the USPTO to invalidate a patent based on broadest range of reasons, excluding best mode not being disclosed.	Within 9 months of grant	$30,000 - $400,000	Broadest (most grounds allowed)
EPO Opposition	Formal procedure before the European Patent Office to challenge the validity of a European patent application or patent.	Within 9 months of publication of granted patent	$50,000 - $200,000	Novelty, Obviousness, Enablement, Sufficiency
Litigation	Legal battle in court to challenge the validity or infringement of a patent. Most expensive option.	N/A (not a time-bound option)	Millions of dollars	All grounds for patent invalidity

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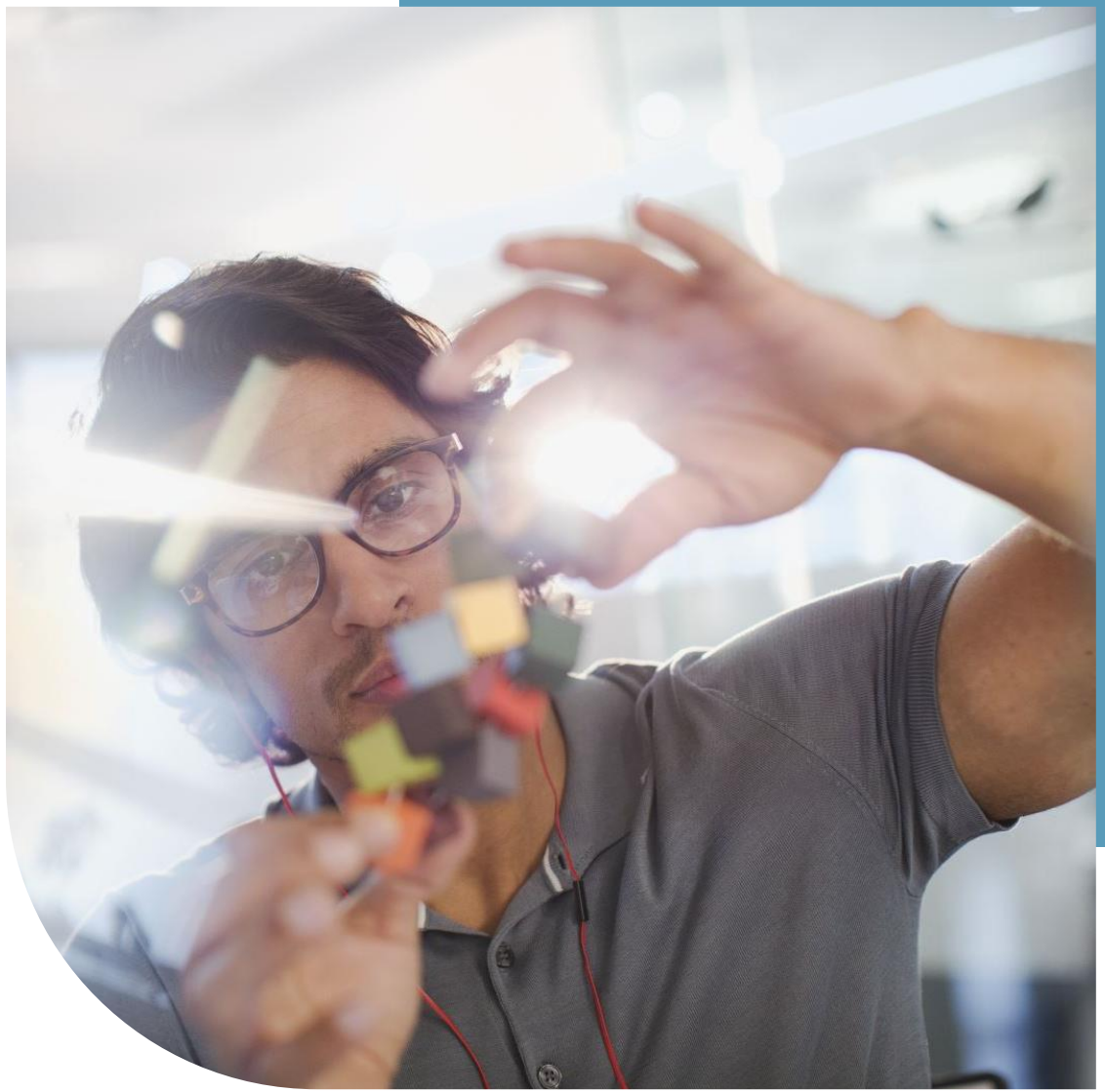
Inventor & Owners

Inventorship

- A patent application **must name the correct inventors**
- A legal determination
- “one of muddiest concepts in the muddy metaphysics of the patent law"
  - Mueller Brass Co. v. Reading Industries, Inc., 352 F.Supp. 1357, 1372 (E.D.Pa. 1972)



Ownership

Ownership resides solely with the named inventor(s), unless there is **an agreement that assigns** the invention to another

Each co-inventor owns **an undivided interest in the entire patent,** irrespective of their level of contribution

A joint inventor who contributed to the invention **of only one claim** has an undivided interest in the whole patent

Critical concept

- Patents can be declared unenforceable if inventorship is not correct
- Rogue inventors don't show up until you are making money

Ownership

Consider in **Every Agreement**

- Employment Agreements
- License Agreements
- University Pitfalls
- Consulting Agreements
- Material Transfer Agreements
- CRO/CMO Agreements

CDA/NDA

Who gets to see your Confidential Information

- Affiliates?
- Consultants?
- Consultants of Affiliates?
- For the “Purpose” of the Agreement

How long is it Confidential

- 5 Years?
- Trade Secrets **should never be allowed** to be disclosed

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Filings

Key Patent Filing Strategies

Criteria	When to File	What to File	Why Consider Provisional Applications	Strategic Considerations
Timing	File before any public disclosures such as presentations, publications, or discussions.	Ensure the invention is sufficiently developed to be described fully and convincingly.	Secures an early filing date, essential for "first to file" rights. Provides additional time for development.	Consider market readiness and potential IP conflicts. Do you have the resources and time today?
Legal Requirements	Prior to any public disclosure to safeguard novelty under patent law.	Complete and detailed descriptions of the invention, operational processes, and the best mode of execution.	Less stringent requirements; does not require formal claims. Protects while still in the development phase.	Align filing strategy with business goals and product development.
Documentation	Ensure all development milestones that might involve disclosure are preceded by filing.	Documentation must meet legal standards for enablement and description as required under 35 U.S.C. § 112.	Allows "Patent Pending" status which can be advantageous in funding and partnership discussions.	Documenting innovation progression is critical for future referencing and legal protection.

Navigating Patent Prosecution and Costs

Filing Costs

- **Provisional Application:** Typically, between $1,500 and $3,000, depending on the complexity.
- **Non-Provisional Application:** The cost can range from $5,000 to $15,000, including attorney fees and USPTO filing fees. The costs increase with the invention's complexity and the application's length.

Examination Costs

- **USPTO Examination Fees:** These are included in the filing fees, but additional charges may occur for excess claims or if the application exceeds certain lengths.
- **Attorney Fees for Responses:** Responding to each office action typically costs between $2,000 and $5,000, depending on the complexity of the issues raised.

Issue and Maintenance Fees

- **Issue Fee:** In the U.S., the fee is approximately $1,000 to $2,000.
- **Maintenance Fees:** In the U.S., they are payable 3.5, 7.5, and 11.5 years after the grant, costing from $800 to $7,400 per fee interval and increasing with time.

International Filing Costs (PCT and National Phase Entry)

- **PCT Application:** Initial filing costs, including international search fees, can range from $4,000 to $6,000.
- **National Phase Entry:** Costs vary by country but typically range from $2,000 to $6,000 per country for filing fees, not including translation or local agent fees.

Translation Costs

- **Required for non-English Speaking Countries:** Can range from $0.10 to $0.25 per word, making extensive specifications particularly expensive.

Patent Agent and Attorney Fees

- **Drafting and Prosecution:** Legal fees can vary widely, but they typically start at $200 per hour for patent agents and $300 per hour for attorneys.

Additional Considerations

- **Annual Renewals in Some Countries:** Vary significantly by country and can be a substantial long-term cost.
- **Enforcement and Litigation:** These are not included in prosecution costs but can be significant if the patent is challenged or infringed upon.

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Patentability & Freedom to Operate

Clearing the Path: Patentability and Ensuring Freedom to Operate

Patentability

Patentability allows them to secure protection for their inventions. Criteria include:

- Novelty: The invention must be new, meaning it has not been previously disclosed or made available to the public.
- Non-obviousness (Inventive Step): The invention must not be obvious to someone with knowledge and experience in the subject area.
- Utility: The invention must be useful.

Freedom to Operate

Freedom to Operate (FTO) FTO ensures that their commercial activities related to those inventions will not infringe on the rights of others.

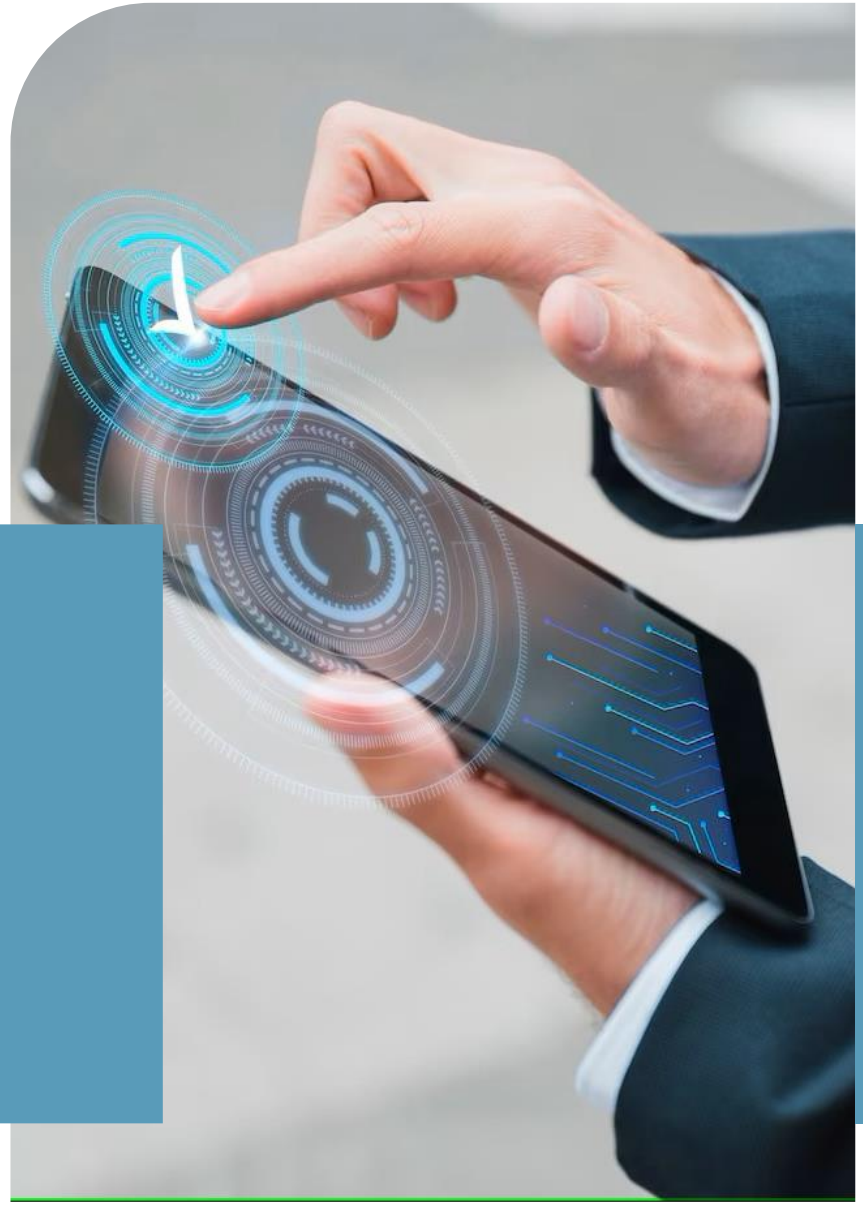
It involves a thorough analysis to identify any active patents under which the intended product or process might fall and assess whether operating in a certain market infringes on existing patents.

An FTO analysis is essential before launching a new product or entering a new market to avoid patent infringement, which can result in costly legal disputes and damages.

Freedom To Operate (FTO)

Do you have FTO?

- FTO is a process, not an event
- What do **you need now**
- What **your investors want to see**



Work Product

- Search Results
- Summary
- **Simple e-mail** (“You’re OK”) or **Formal Letter**

Consider

- What do you expect for your commercial product?
- What patents do you already know about?
- What should be searched?

Addressing FTO Problems

When does the patent expire?

- Will you even be on the market by then
  - Okay to infringe for research, development and clinical trials

Deep Dive

- Does the Specification support the claims
  - Many changes to patent laws over last 12 years effect older patents
- What is the state of the prior art?
  - How does this affect your own IP?
- Costs

Real Problems

- Is a license available?
- Can you Design Around?
- Patent Challenge ($$$)

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MyIP Shield™

From Fundamentals to Strategic Defense

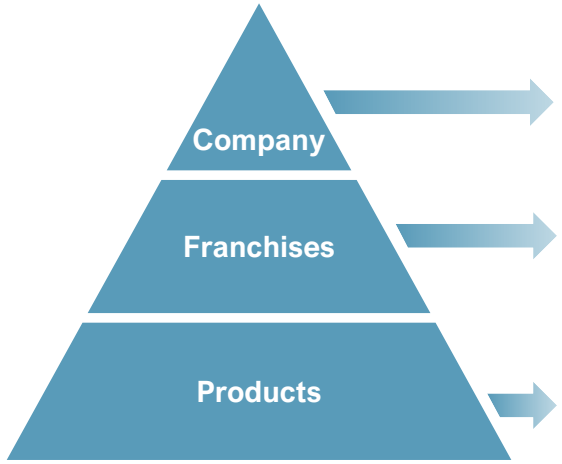
A Startup Company is Designed to be a Temporary Organization

- Its goal is to uncover a business opportunity and apply an unfair advantage.
- An unfair advantage is a combination of:
  - Unique personnel talent;
  - Proprietary relationships;
  - Know-how and assets;
  - Intellectual property: patents, trademarks, copyright, and trade secrets that deliver the scalable business model that is not easily replicated by others.

A Compelling Story Ends in Impervious Positioning

The Investment Pitch

- The venture concept
- The market need
- The product offering
- The market opportunity
- **The unfair advantage**
- The competition
- The business model
- The commercialization plan
- Fundable milestones
- The management team
- The acquirer's needs



Communicates corporate positioning

Franchise positioning & key messages

Specific product messages

Positioning

Definition:
Positioning is the way that the product is defined by customers on important attributes – the place the product is occupied in consumers' minds.

Objective:
- Create a new category
- Stake a position that is:
  - Impervious to competitive product enhancements
  - Ethically responsible & respects specialty paradigms
  - Economically motivating
- Support with technical, case study & testimonial data.

Image Analysis

	Physicians	Nurse/Tech	Cath Lab Mgt.	Material Mgt	CFOs
How they benefit					
What we need them to know					
What we want them to do					
Why they are not doing it					
Strategy: How we succeed					
Positioning: What we say					
Tone: How we say it					

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An Important Note on “Unfair Advantage”

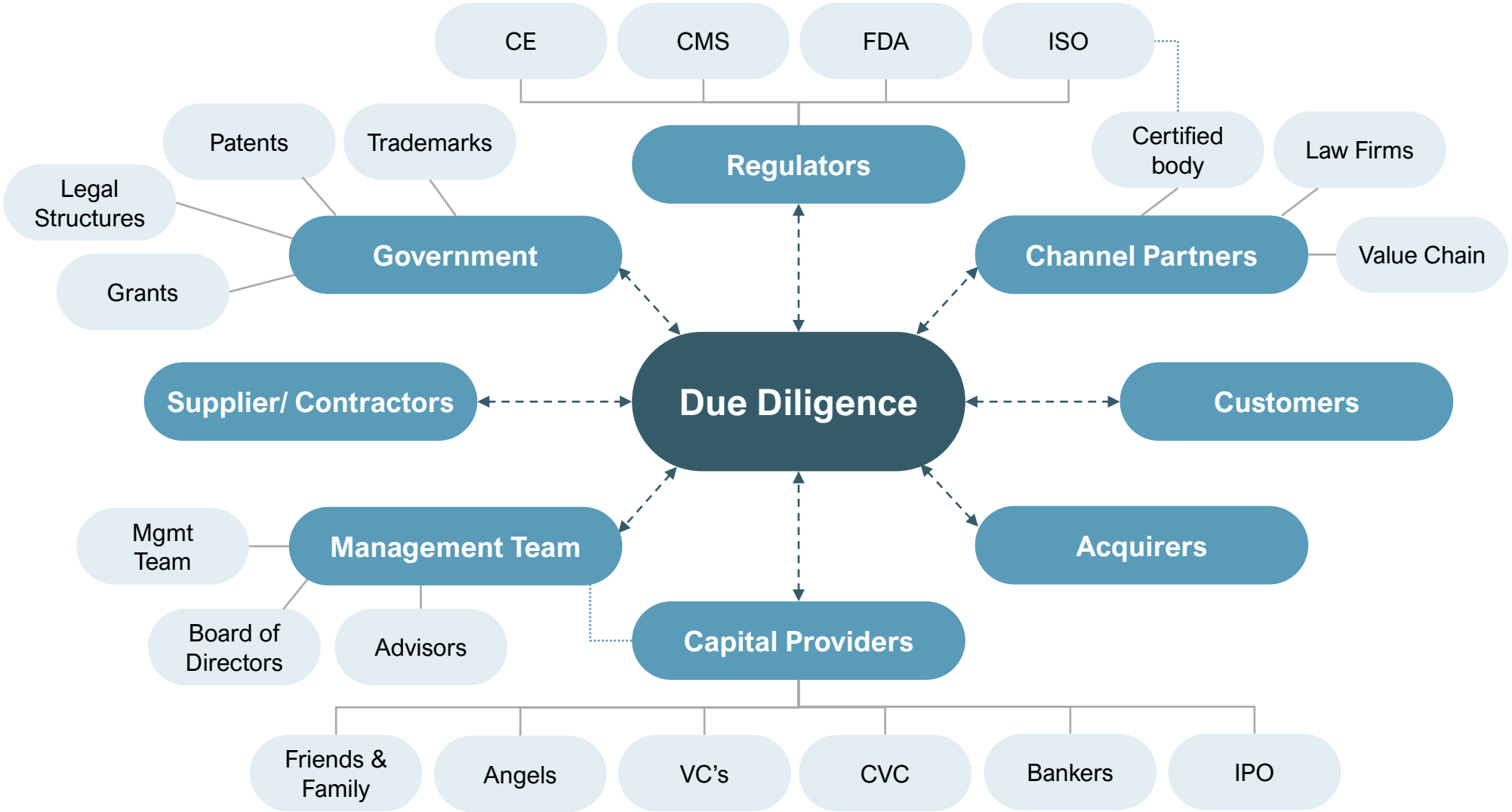
In the startup world, the concept of ‘unfair advantage’ is different than the legal term used by the SEC.

The legal term speaks to the illegal tactics deployed by firms to exclude competition.

This is not the same definition used in the startup, angel, corporate, and venture-capital worlds.

In fact, the term is used to identify the startup’s basis of competition that allows them to compete effectively with larger companies.

Use Proprietary Relationships to Borrow Brand



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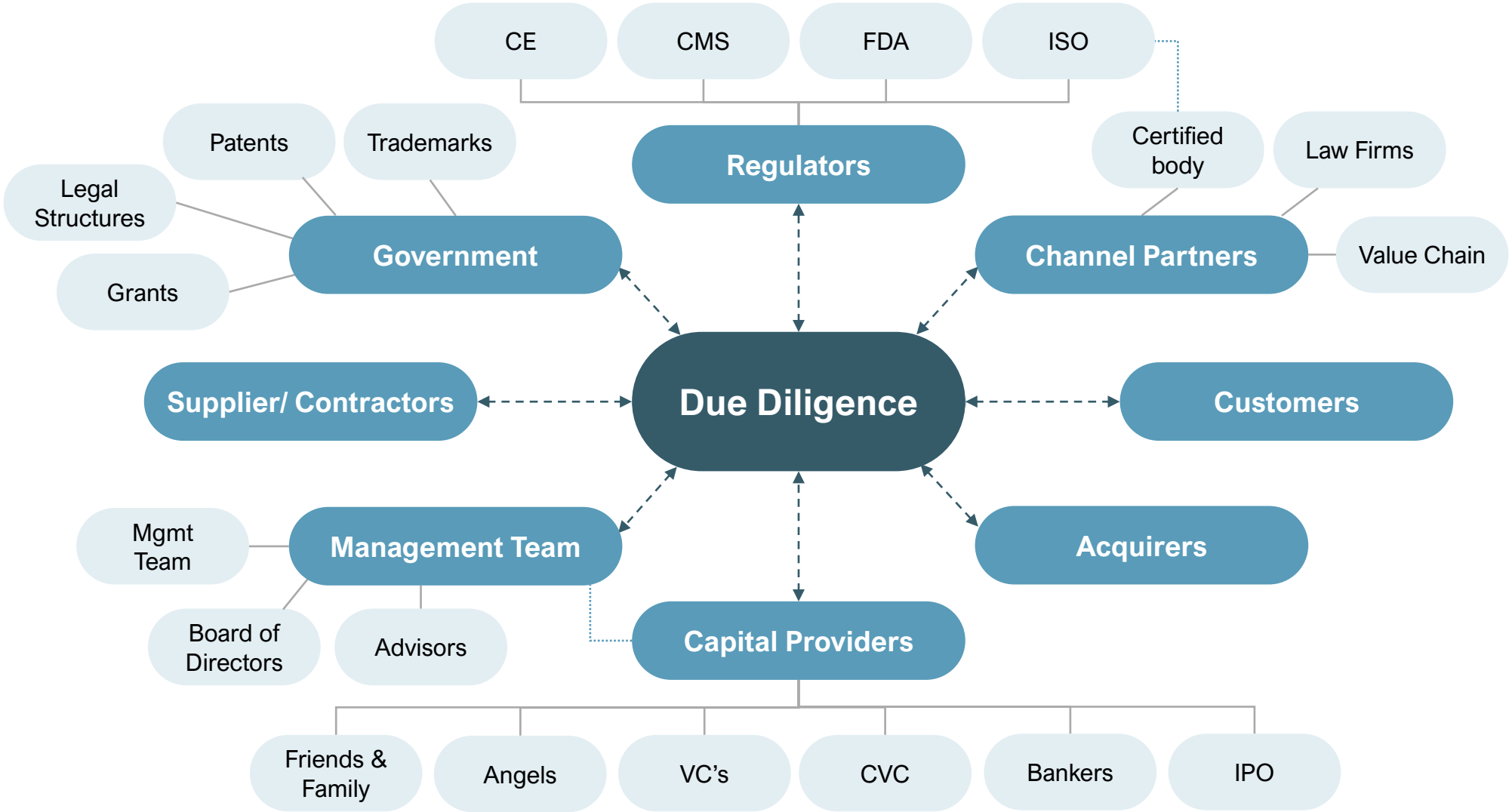
Option with animation flow

Use Proprietary Relationships to Borrow Brand



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Proprietary Knowledge

Proprietary knowledge describes the scenario where an individual possesses technical knowledge of the product or the inner workings of a process.

In the defense industry, there was an individual who could slice wafer fabrications at a yield that was 20% better than anybody else's.

A former executive from a specific industry can de-risk an opportunity by possessing inside information (but the legal kind) about an organization or its industry. An example is Carmell Therapeutics' leadership in BLA.

IP: Patents, Trademarks, Copyright, and Trade Secrets

By far, the most favored unfair advantage is a patent.

A patent may or may not guarantee marketing and sales success.

As important as having a patent sounds, the patent's ultimate value can only be derived by understanding the market size in which it offers exclusivity.

Life sciences is a complex business and understanding a patent's value requires a multilevel analysis.

The MyIP Shield℠ is an Analysis Technique

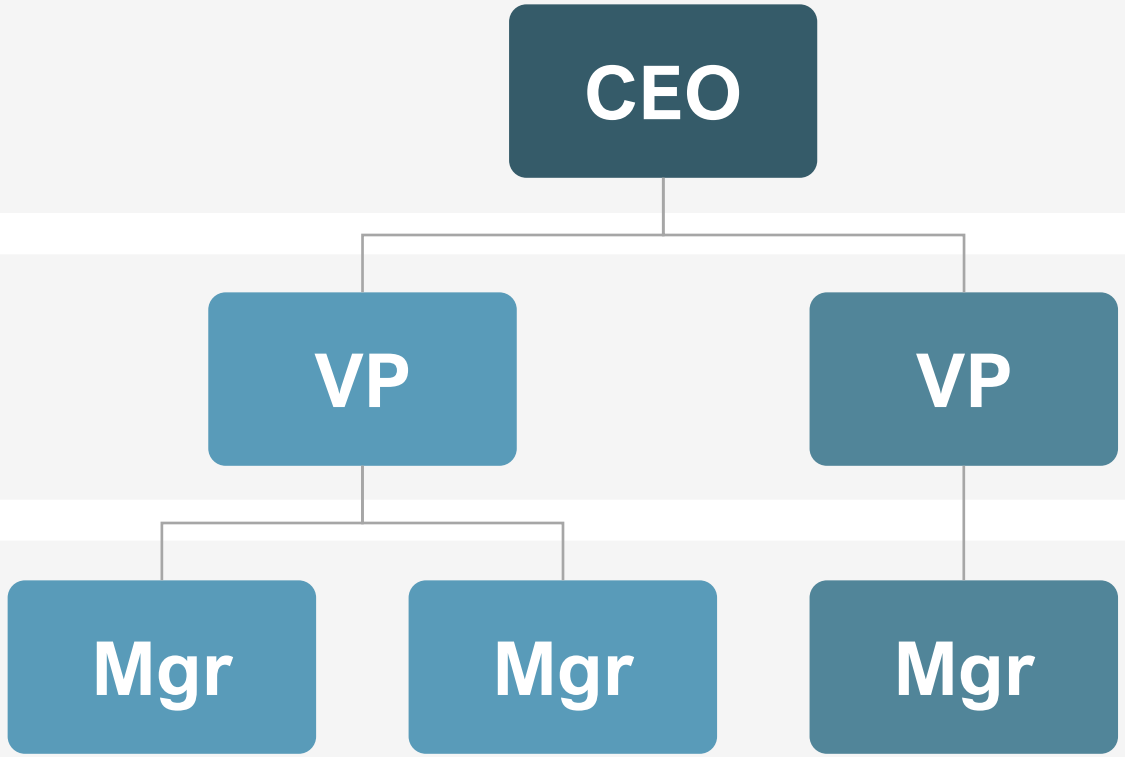
- It looks at both the market and the patent landscape.
- You are trying to determine if the company's IP allows them to Stake not take a position that is "impervious to competitive advancement".℠
- Startups most likely see their intellectual property as a basis for expressing their unfair advantage to investors; however, the ability to have a patent does not necessarily create an exclusive market position.
- The goal is to understand if the exclusivity matches the desired results.
- What you are trying to uncover is the reason the patent exists (the problem you are solving), and then ask yourself if the patent is the only path to achieving that goal.

Let's Conceptualize this for Moment...

Market

Segments

Attributes



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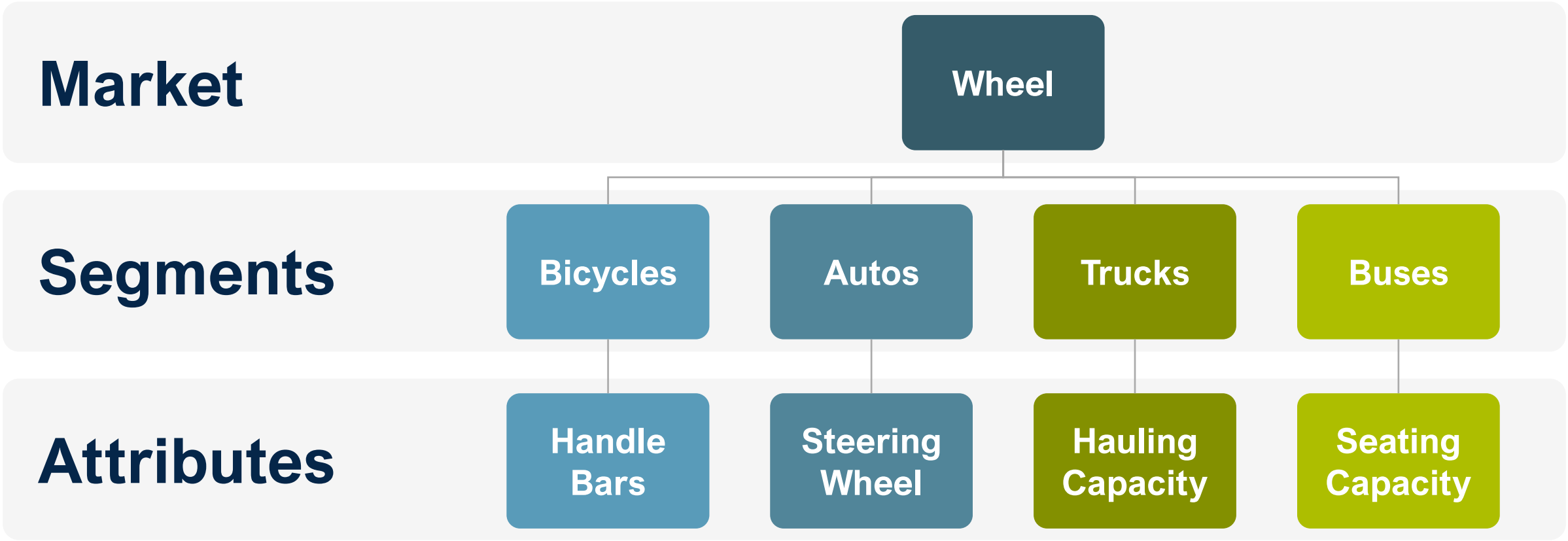
An Extreme Example Might be Illustrative

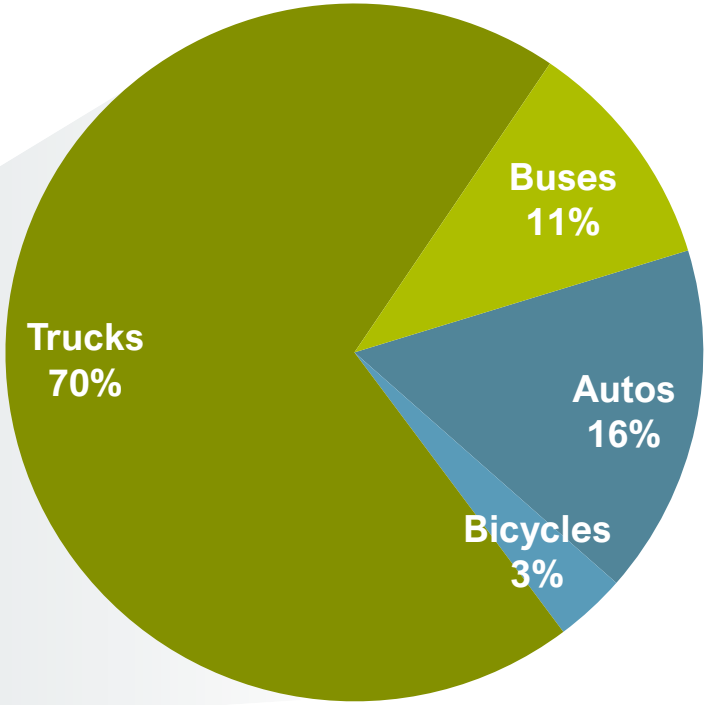
Picture an organizational chart where the problem is the need to create the ability to transport people long distances over land.

- Immediately we think of bicycles, automobiles, trucks and buses.
- Imagine for a moment that you have the exclusive right to patent the wheel.
- **Clearly, this exclusivity would be very valuable.**

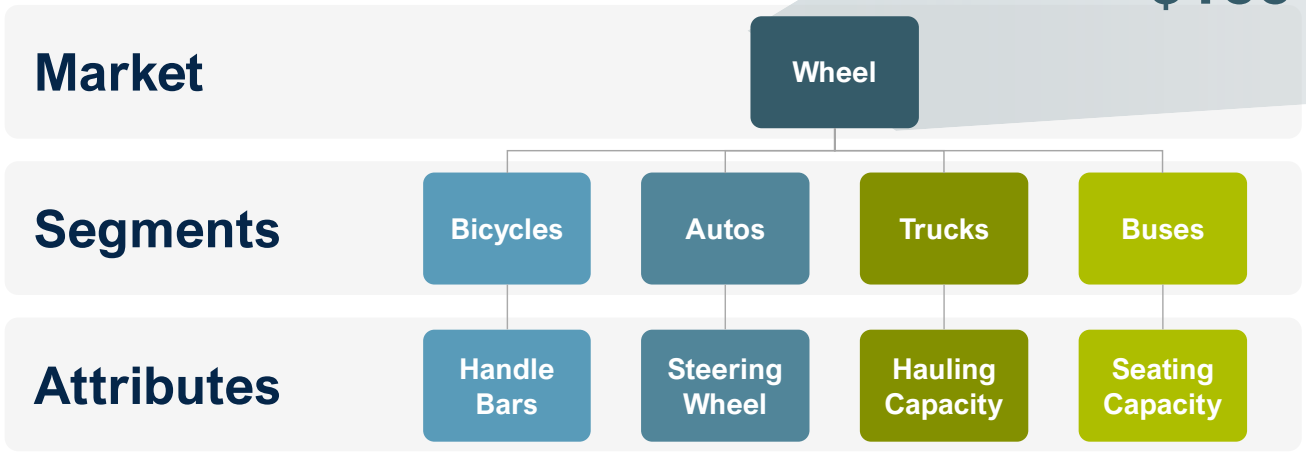
The Patent Owner May Think of the Market This Way…



The Wheel Gets Monetized



Revenue today is $185 Billion(*)



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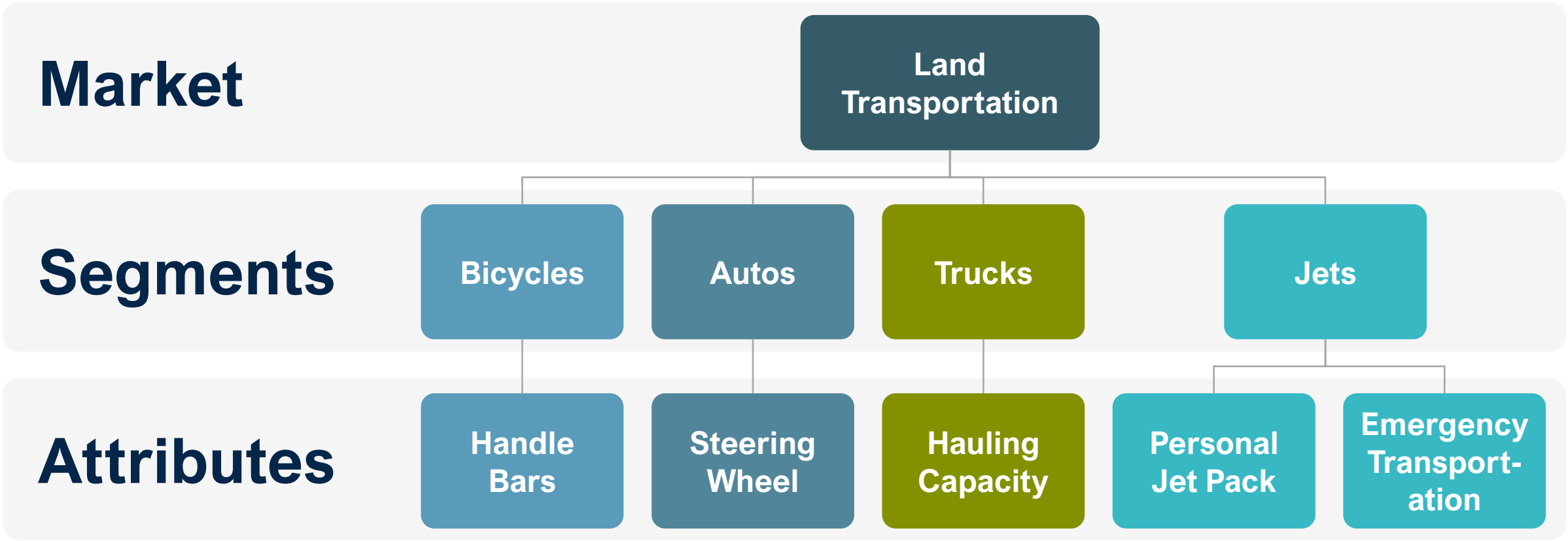
An Extreme Example Might be Illustrative

However, over time, perhaps a jetpack technology would become inexpensive and deployed to obtain a piece of the wheel market. Assuming all costs, safety factors and other considerations were equal; it would not be unreasonable to expect that a subset of people would prefer the jetpack technology.

- This example points out that the wheel was a solution for a problem. The root problem remains unchanged.
- However, have we adequately defined the problem?
- The wheel created and validated the market and yet, at some point in time, jetpack technology may garner a profitable piece of that market, or perhaps even grow it.

What Problem are you Seeking to Solve?



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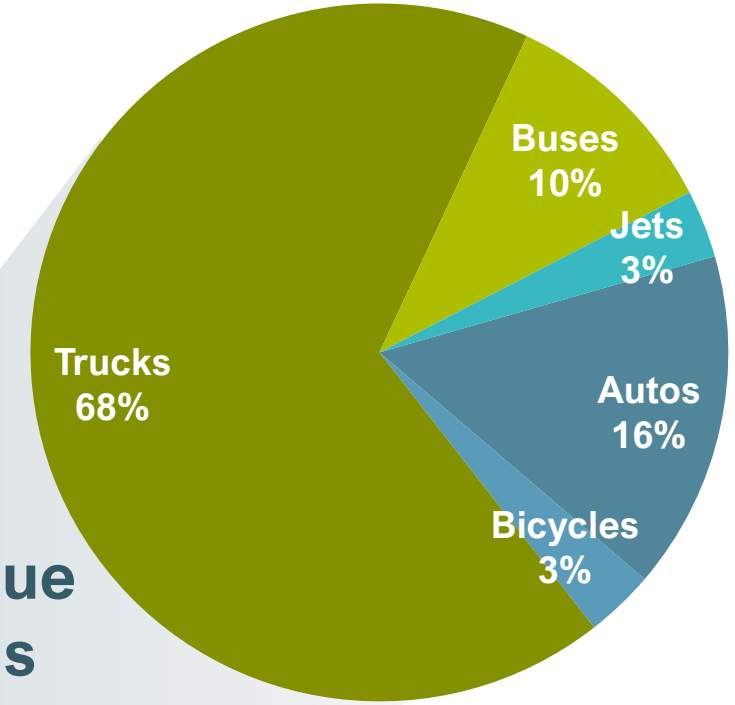
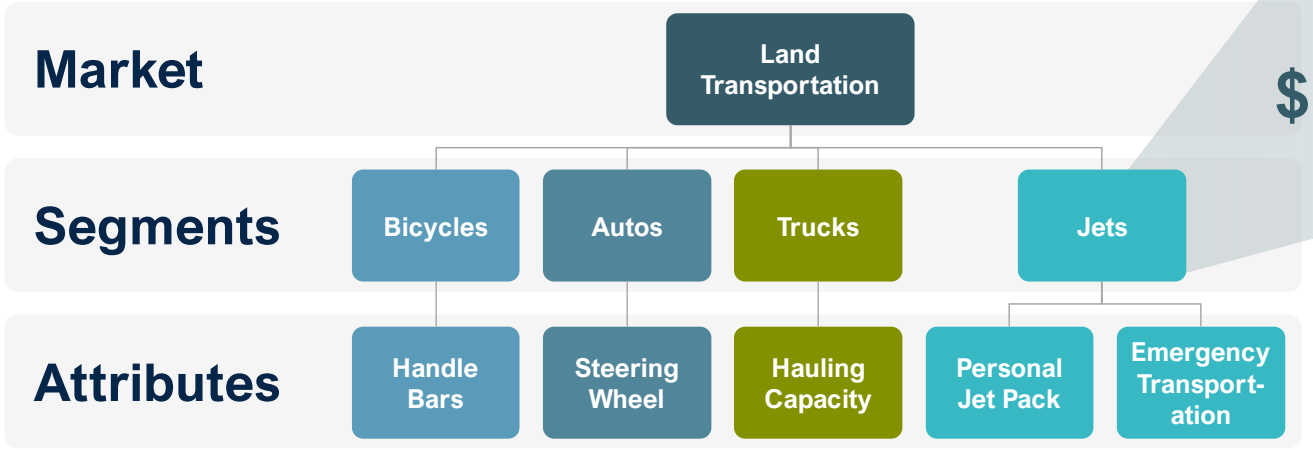
Should you Look at the Problem Differently?



Revenue Yr 3 is $191 Billion(*)



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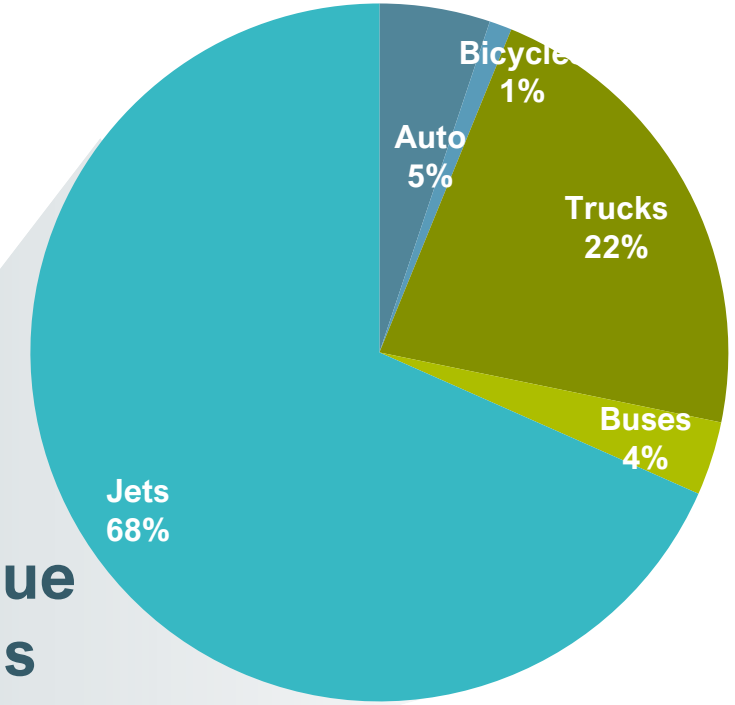
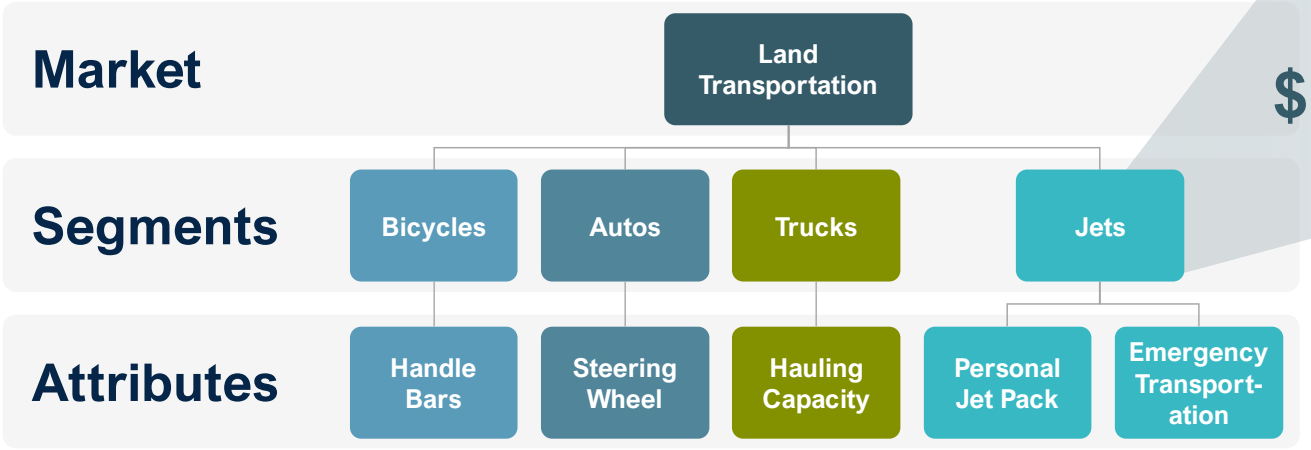
Should you Look at the Problem Differently?



Revenue
Yr 6 is
$585 Billion(*)



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We’re Trying to Establish a Marketing Framework that the Intellectual Property is Attempting to Support

This connection is frequently overlooked by the startup, as evidenced by venture capitalists who say, “that seems like a technology in search of a problem."

What they are referring to is a situation where the patent has been issued, but it does not solve a meaningful market problem.

If we are solving an important problem, our success invites others into the marketplace, and our ability to hold competitors out longer has a tremendous impact on ROI.

How do we determine if the patent is solving an important market problem?

Can the technology create a franchise or product category?

Does the patent allow for:

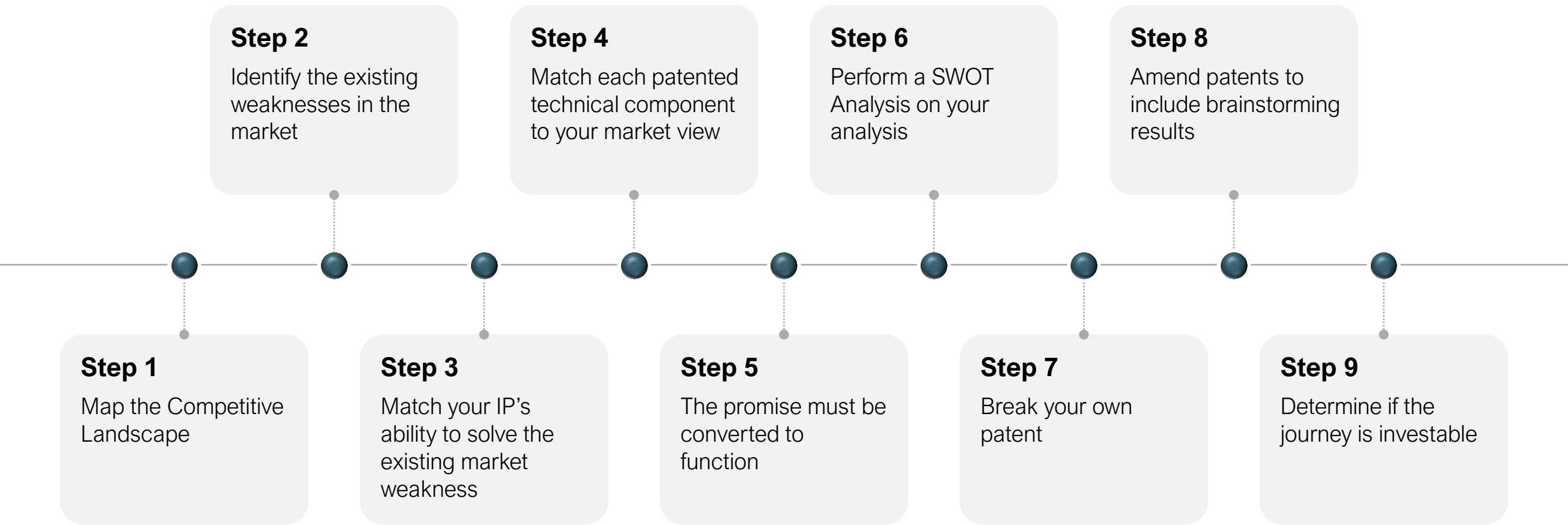
- A position that is impervious to competitive advancement?
- A clinically responsible positioning?
- Economic return for the user?

Is there a specific class for a patient clinical situation that the patent would be the obvious answer?

- Is there outcome evidence?

How can this patent be built upon over time, to evolve, to go the distance as other players attempt to enter the market?

Steps to Perform an Intellectual Pyramid Analysis?



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Step 1: Map Competitive Landscape

The first step is to determine the opportunity and risk of the market you are deciding to enter. Identify the scope, structure and size of the market to validate its IP protection.

This starts with gathering and mapping the competitive landscape.

This analysis shows that there are two major categories and two ways to deliver the valves.

	Global		Category			Clinical Approach		
	US	OUS	Description	US	OUS	Description	US	OUS
Total 39	25	14	Repair	14	4	Surgical	11	1
			Replace	11	10	Transcatheter	14	13
Repair 18	14	4	Repair Products	13	4	Surgical	7	1
			Biomaterial	1	0	Transcatheter	7	3
Replace 21	11	10	Tissue	10	9	Surgical	4	0
			Mechanical	0	0	Transcatheter	7	10
			Biomaterial	1	1			

This is an example of an inventory of the global prosthetic valve market.

Step 2: Identify Existing Market Weaknesses

To assess the competitive landscape, startups should search patent literature for issued or pending patents.

Investigate regulatory websites for clinical trials that are underway, recently approved or recently completed.

Search databases that contain venture capital and corporate venture capital investments (such as Venture Source or Pitchbook) in your space to identify companies that have received funding in your market segment.

Although there are different delivery methods, they don't solve downstream issues associated with valves

Existing Weakness		
Mechanical	Tissue	Common
• Valve Noise • Suboptimal hemodynamics • Clots → Blood Thinners • Lifetime 15-20 years	• Calcification Issues • Longevity • Lifetime 7-15 years	• Endocarditis, Infection • Inability to remodel with changes in patient anatomy • Inability to adapt to natural stresses in the body • Post-op valve dissection, dislodgement • Surgical Complications

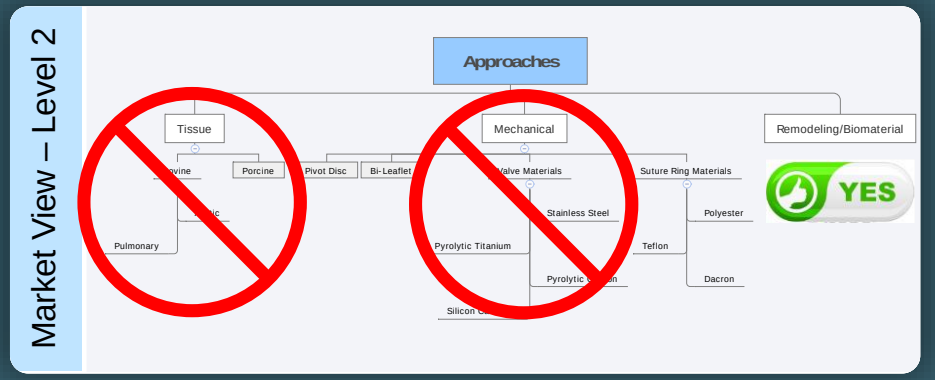
This is an example of an inventory of the global prosthetic valve market.

Step 3:
Match your IP's Ability to Solve the Existing Market Weakness

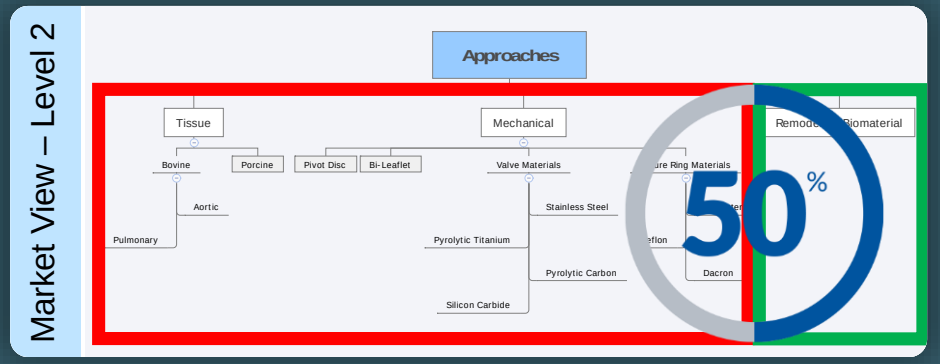
Utilizing the market view information
from step 2, we have defined the perfect solution.

- A lifetime placement
- No long-term medications to maintain effectiveness or mitigate complications
- Adapts to natural stresses in the body
- Remodels with changes to patient anatomy
- Supports both surgical and transcatheter placement
- Replaces native valve
- Repairs previously-treated valves

An upstream solution without downstream intervention would obsolete existing categories



A partial upstream solutions would only shift share



This is an example of an inventory of the global prosthetic valve market.

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Step 4:
Match Each Patented Technical Component to your Market View

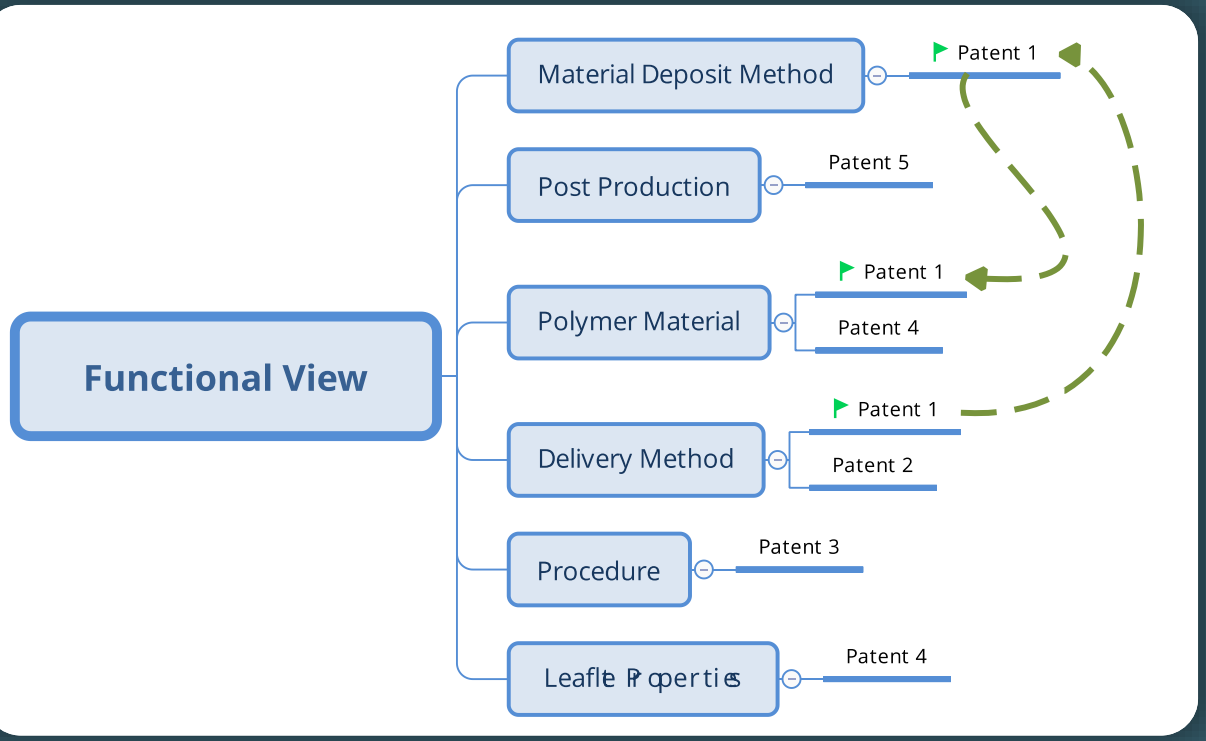
The purpose of a functional view is to create the hierarchy of the technical components embodied in your patent to each market view outcome/need.

At the end of this exercise, each component of the technology would be matched to a market need.

For example, in the analysis of a “Bio”-valve, its intent is to replace a non-functioning heart valve.

Its material function would be to draw appropriate cells to mimic a natural heart value. Subordinate to this would be detailed IP around such matters as the exact material, how the material would be formed, and the properties of the individual leaflets. Another top function would be how to deliver the valve to its proper location non-surgically.

Gather each patent’s detail and roll it up to a functional view.



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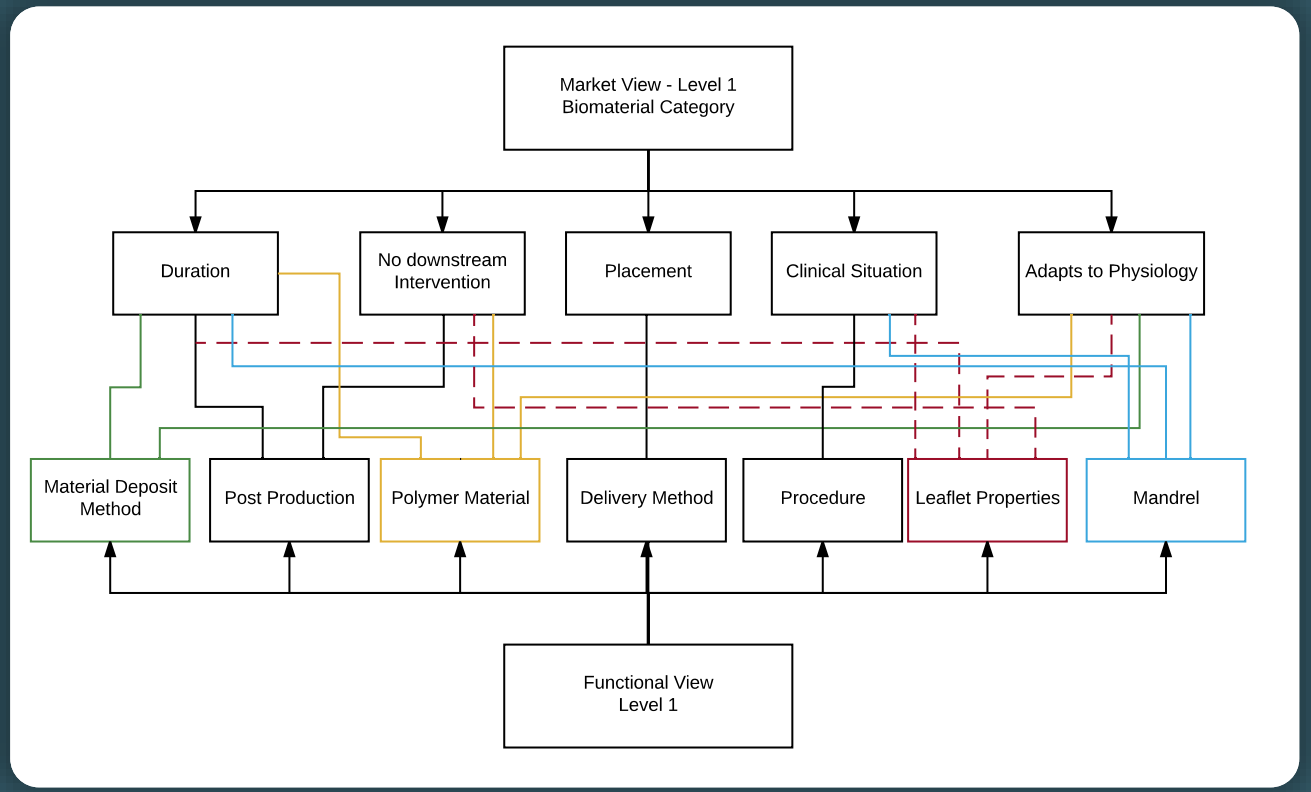
Step 5:
The Promise must be Converted to Function

Notice that there are multiple lines drawn between individual boxes between the functional view and the market view. This is because a particular functional view component may contribute to multiple market view components.

Unfortunately, due to the proprietary nature of such analyses, we can only provide a market summary here.

Summarize Step 3 and Step 4 into a map that matches the market view to the functional view.



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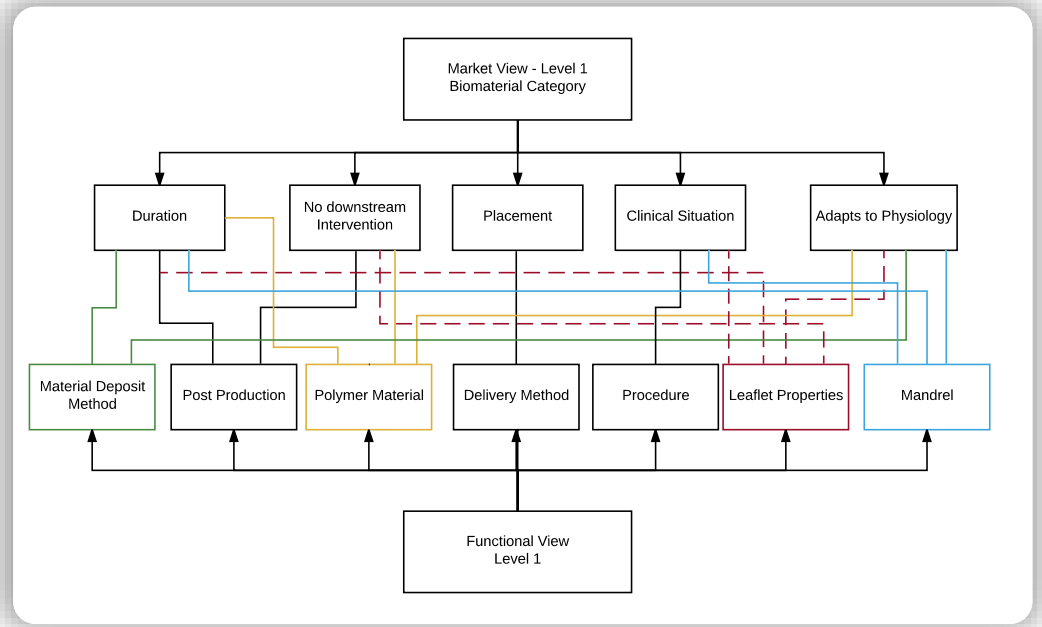
Step 5: (Cont'd) Aligning Clinical & IP could Provide Competitive Entry Barriers



Consider using your IP to erect regulatory impediments to slow down the competition

		Functional View					
Market View		Material Deposition Method	Post Production	Polymer Material	Delivery Method	Procedure	Leaflet Properties
	Duration				Intersect R/IP		
	No Downstream Intervention	Intersect R/IP					
	Placement						Intersect R/IP
	Clinical Situation			Intersect R/IP			
	Adapts to Physiology					Intersect R/IP	

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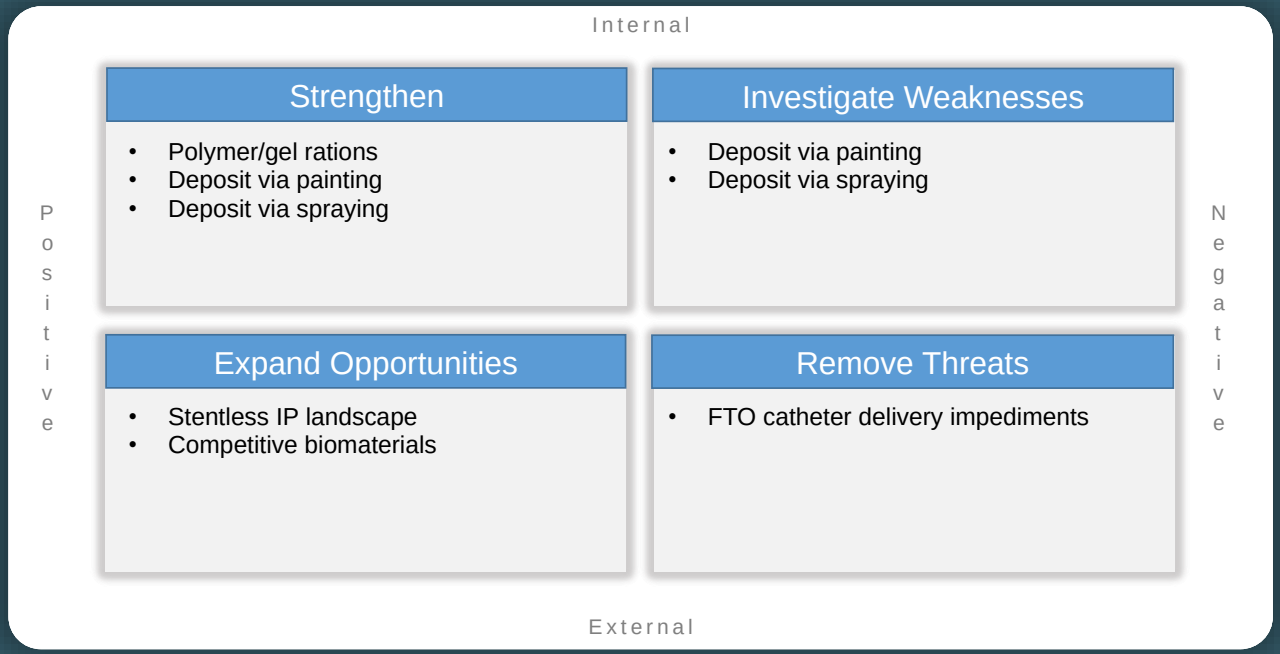
Step 6: Perform a SWOT Analysis

At this point, reviewing your analysis and identifying obvious areas for improvement and omissions would be prudent.

For example, if a material was being deposited onto the leaflet by dipping it in a polymer solution, had you thought about painting or spraying it on?

If that is plausible, you should add it to your patent because if you do not capture this path to market in your patent, you just gave your competition an opportunity to enter the market.

If you were an investor, how would you look at the competitive IP landscape?



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Step 7:
Break Your Own Patent

This is one of the most difficult parts for a startup company's technology team to do, however, it is a vital step.

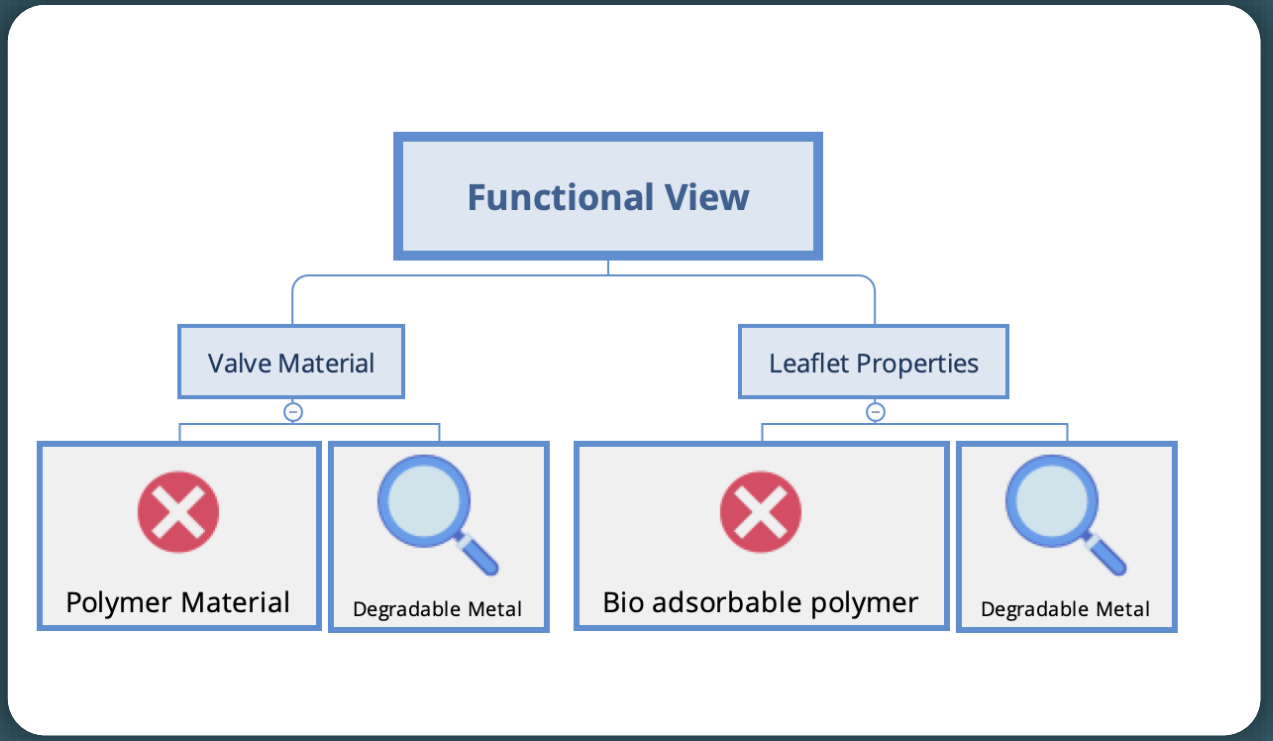
Take your existing patents, and any conceived improvements from Step 6, and take it away from your technical team.

Have them go back to the market view (Step 2) and brainstorm solutions to achieve create new IP (Step 3).

Do not inhibit your brainstorm by the constrains of today's technology.

For example, in this analysis, we assumed that the material for a Bio-Valve is a polymer.

Could it be a degradable metal?



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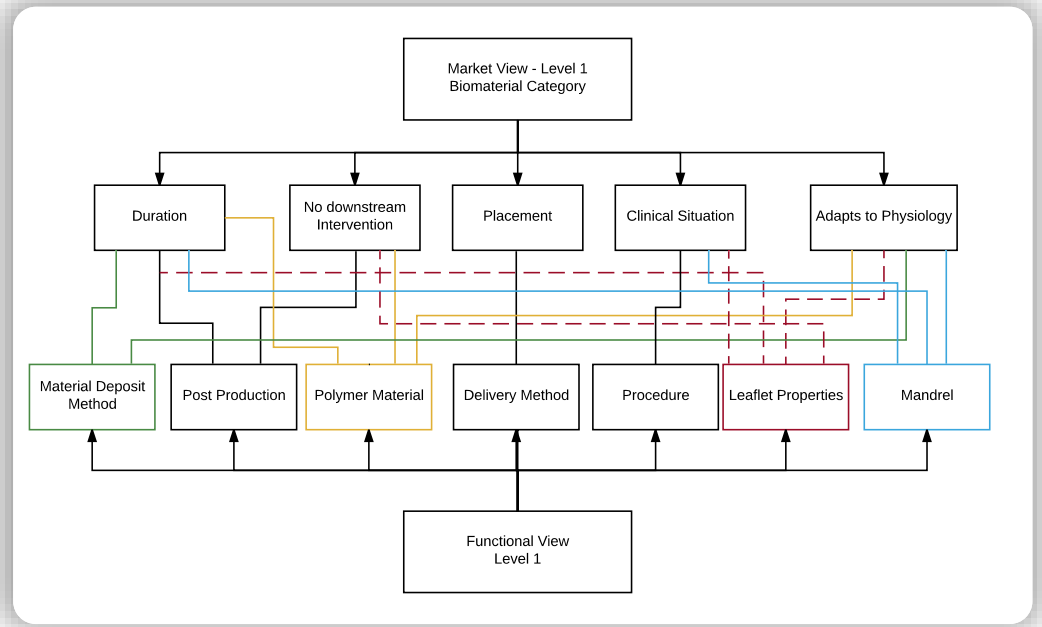
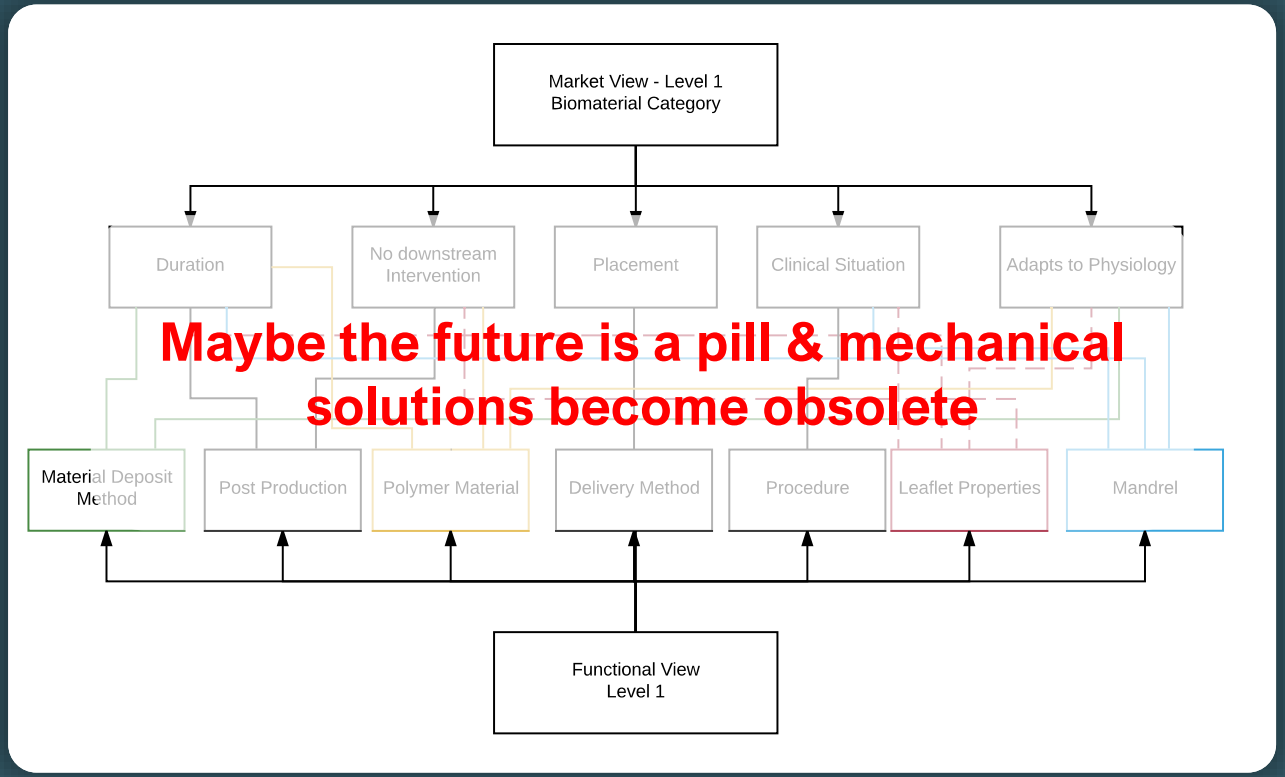
Step 7: (Cont'd) Break Your Own Patent



Also don't be constrained by your product category, in this case, a medical device, perhaps the future is a pill.



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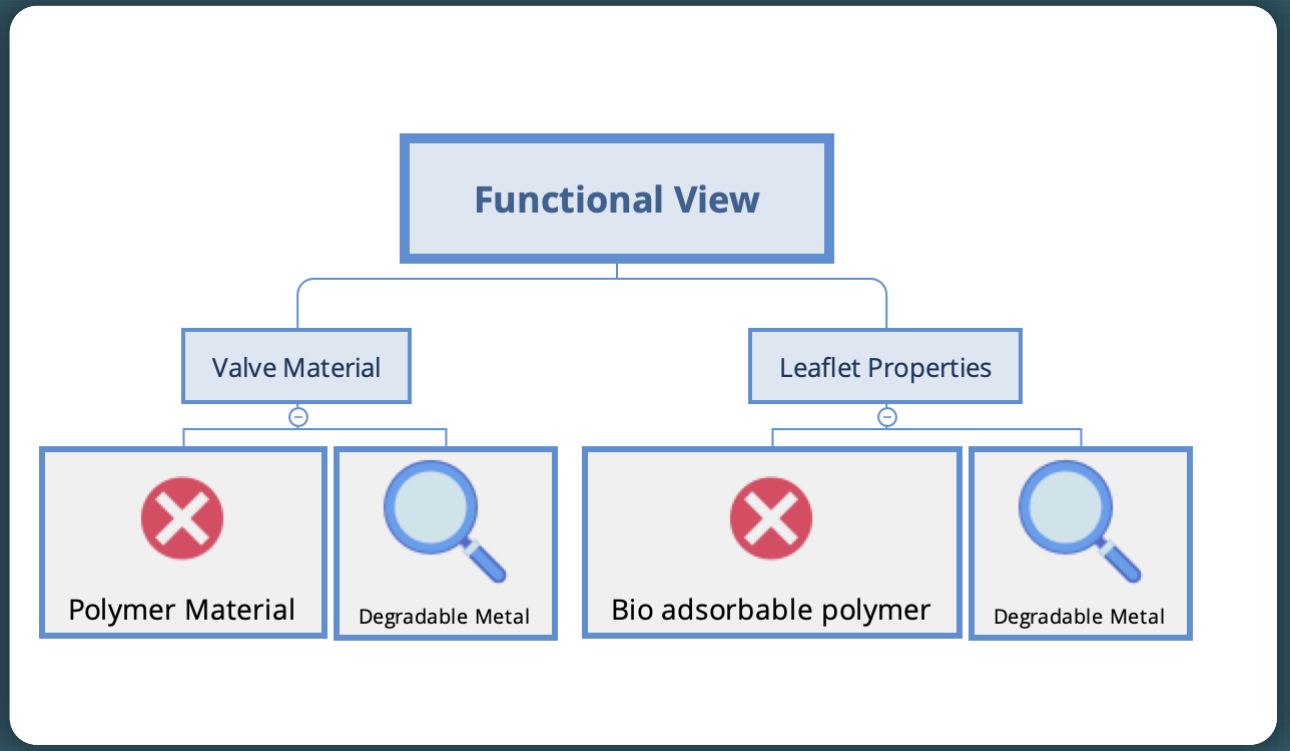
Step 8: Amend Patents to Include Brainstorm

Step 7 will avail opportunities to improve your existing position or identify patents in other markets that might be used to enter your market once you created it.

If you develop a billion-dollar market, you can be sure that someone will find that material and bring it to your market.

For example, a degradable metal might exist in a non-medical market that may be able to be used in the human body.



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Step 9: Determine if Your Journey is Investable

So, how far are you from solving the existing market's weaknesses? If you cannot solve all the existing weaknesses in the market, is your product a significant advancement over existing solutions?

This is a crucial question. If your product doesn't address all the market's weaknesses, it's vital to discern whether your technology represents a small step forward or a game-changing leap.

If your technology is an incremental improvement, it will most likely not gain market traction over existing market players or attract investors to your startup.

If this is the case, you should not pursue a start-up or develop a new IP that makes a monumental leap.

Monumental leap or incremental improvement? First to market, last to market?

Entry Schedule Fact Book

Date

Competitive Entry Schedule or Drug Trial

Company	Competitive Platform	Year 1				Year 2				Year 3				Year 4			
		Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Company 1	Product A																
	Product B																
Company 2	Product C																
	Product D																
Company 3	Product E																
	Product F																
Company 4	Product G																
	Product H																
Company 5	Product I																
	Product J																

Legend:
C = Clinical Trial Begins
D = Regulatory Submission
R = Ruglatory Approval
L = Launch

Figure 18.2 Entry Schedule Fact Book

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The Ability to Articulate Unfair Advantage can be the Difference Between Obtaining Funding and Not

- Unfair advantage has numerous components; however, IP represents the largest percentage of a startup's valuation.
- Intellectual property that is not matched to the problem may result in a partial solution or leave technical pathways open for others to gain access once the market is developed.
- The MyIP Shield™ Analysis:
  - maps for investors an understanding of risk & reward
  - it validates the novelty of the products approach
  - ensures a future market position is not easily displaced by competitive advancement

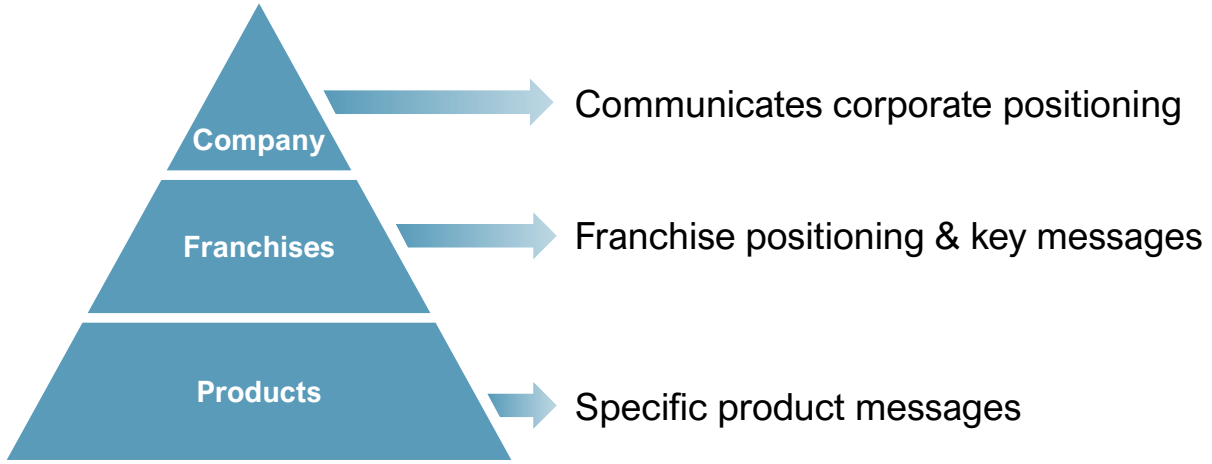
To Obtain Funding, the Ability to Articulate Unfair Advantage in Your Story is Required

IP that is not matched to the problem may result in a partial solution

MyIP Shield ensures you are not leaving technical pathways open for others to gain access once the market is developed.

The MyIP Shield Analysis is a tool to build your story:

- It maps for investors an understanding of risk & reward
- It validates the product's approach & market framework
- It ensures a future market position is not easily displaced by competitive advancement



Positioning

Definition:
Positioning is the way that the product is defined by customers on important attributes – the place the product is occupied in consumers' minds.

Objective:
- Create a new category
- Stake a position that is:
  - Impervious to competitive product enhancements
  - Ethically responsible & respects specialty paradigms
  - Economically motivating
- Support with technical, case study & testimonial data.

Image Analysis

	Physicians	Nurse/Tech	Cath Lab Mgt.	Material Mgt	CFOs
How they benefit					
What we need them to know					
What we want them to do					
Why they are not doing it					
Strategy: How we succeed					
Positioning: What we say					
Tone: How we say it					

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Preparing for your Pitch

Integrating IP into Your Investor Pitch: Strategy and Impact

IP Role in Strategy

Intellectual Property not only secures your innovations but also significantly impacts your funding strategy. Effective communication of your IP strategy is essential for gaining investor confidence and securing necessary capital.

IP Protection as a Competitive Edge

Effective IP management secures exclusive rights to innovative technologies, creating barriers to entry that constitute a significant unfair advantage in the marketplace most favored by investors.

Budget and IP Management

Accurately forecast the financial needs for your IP filings and maintenance. Ensure investors understand the importance of these investments in protecting the business's core assets.

Anticipate Legal Challenges

Plan and raise funds for potential IP litigation before it occurs. Presenting a well-considered legal defense budget to investors can prevent financial strain and avoid the necessity for a down round of funding due to unforeseen legal challenges.

Commercialization and IP Milestones

Align IP milestones with key product development stages. For example, initial patent applications should precede market testing phases to ensure protection prior to any public disclosure.

Crafting a Winning Investor Pitch with IP

Effective Communication of IP Value.

"In your pitch, clearly articulate how your IP rights protect the business, enhance market exclusivity, and increase potential returns on investment.

Illustrating IP's Financial Impact

Demonstrate how strategic IP management contributes to the business's financial health, from fostering innovation to mitigating risks and defending against competitive threats. Utility patent should increase revenue, methods decrease COGS.

Using IP as a Foundation for Market Entry

Explain to potential investors how your IP strategy is not just about legal protection but is a deliberate part of your go-to-market strategy, aiming to maximize market penetration and profitability

Evolve your IP Strategy

Encourage proactive development of IP strategies that resonate with your business goals. Consider how your unique IP can attract investment and drive business success. Evolve for distance from competitive threat.


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Questions