Develop Your IP Pyramid

Solidify Your Competitive Edge

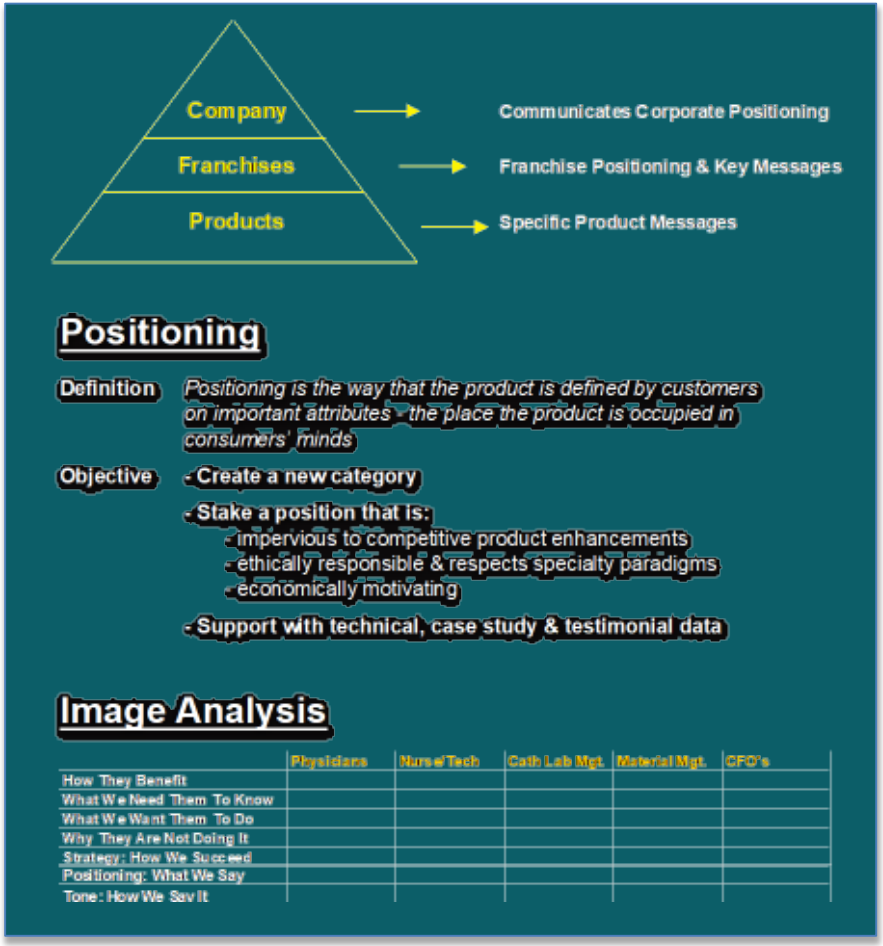
HealthcareData.Center

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



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

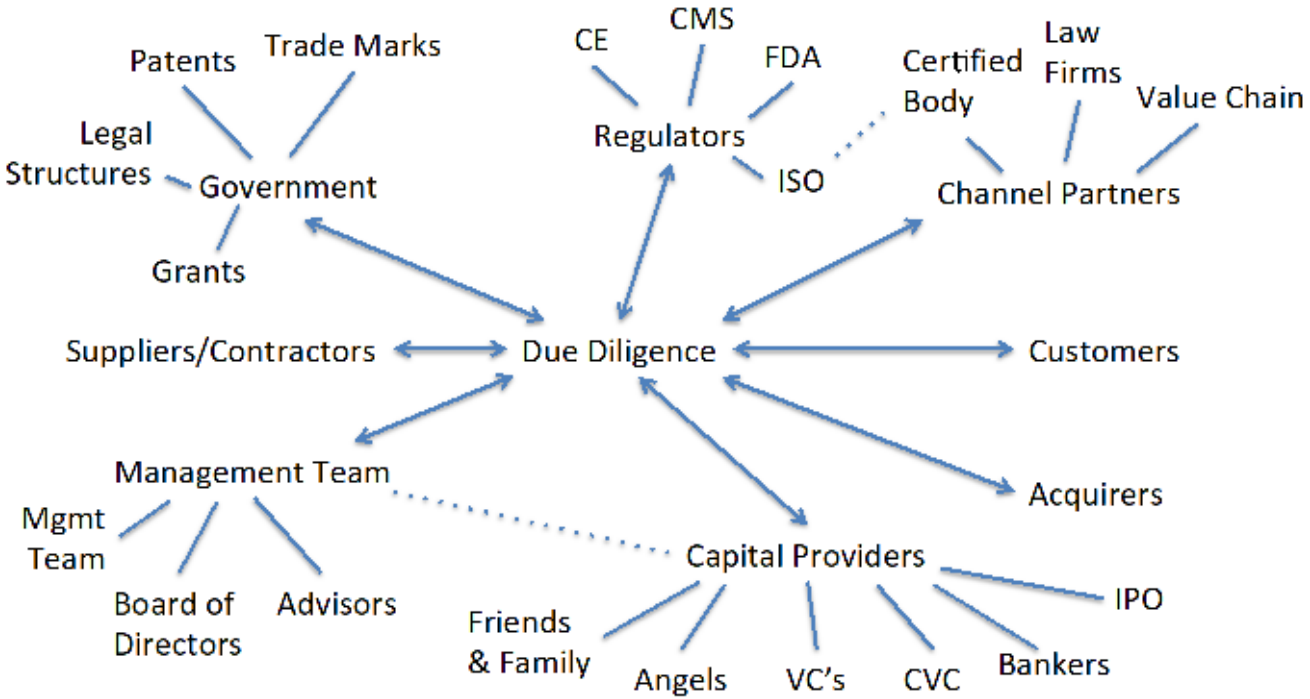


Figure 8.1 Due diligence social network

Proprietary knowledge

- Proprietary knowledge describes the scenario where an individual possesses technical knowledge of the product or the inner workings of a process.
- While in the defense industry, there was an individual who could slice wafer fabrications at a yield that was 20% better than anybody else.
- A former executive from a specific industry can de-risk an opportunity by possessing inside information (but the legal kind) of an organization or its industry. Example, Carmell Therapeutics leadership in BLA

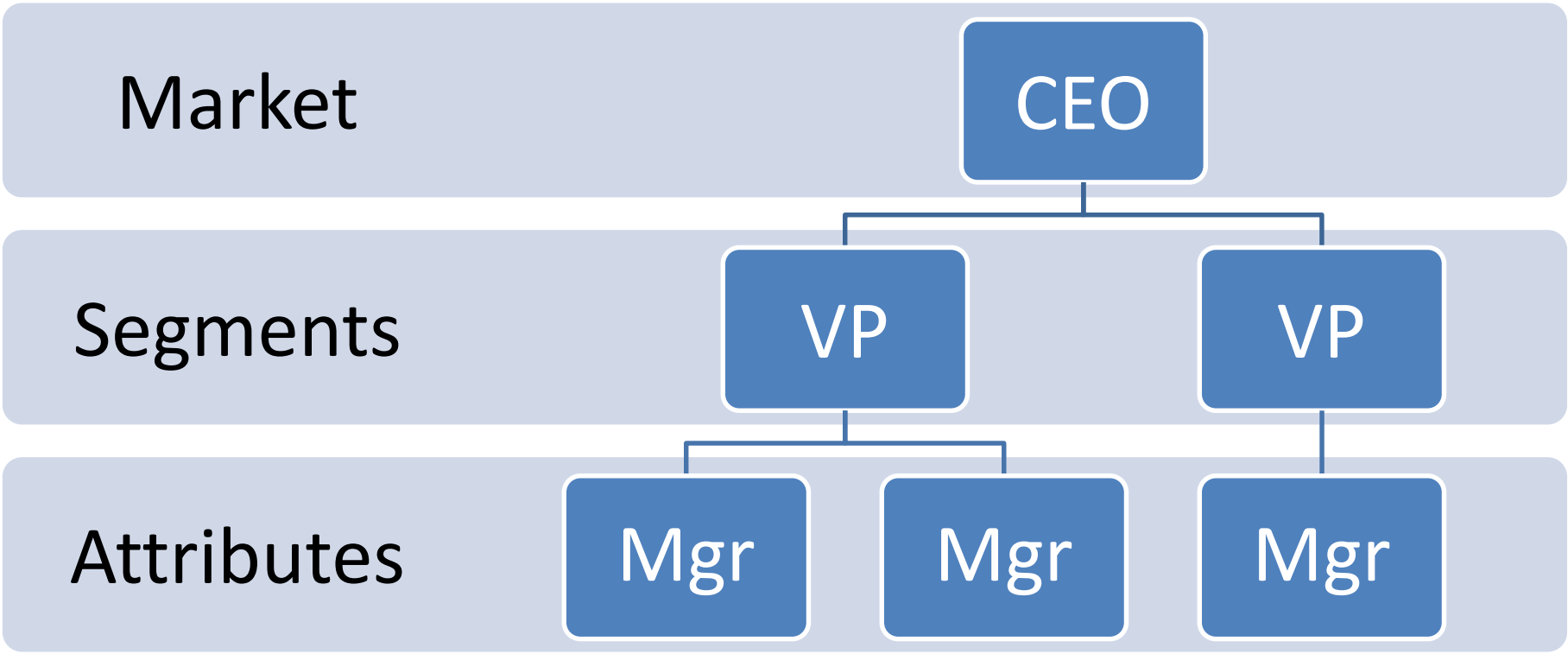
IP: patents, trademarks, copyright, and trade secrets

- **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 Intellectual Property Pyramid SM (IPP) 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 take a position that is "impervious to competitive advancement"SM
- Startups most likely see their intellectual property as a basis of 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

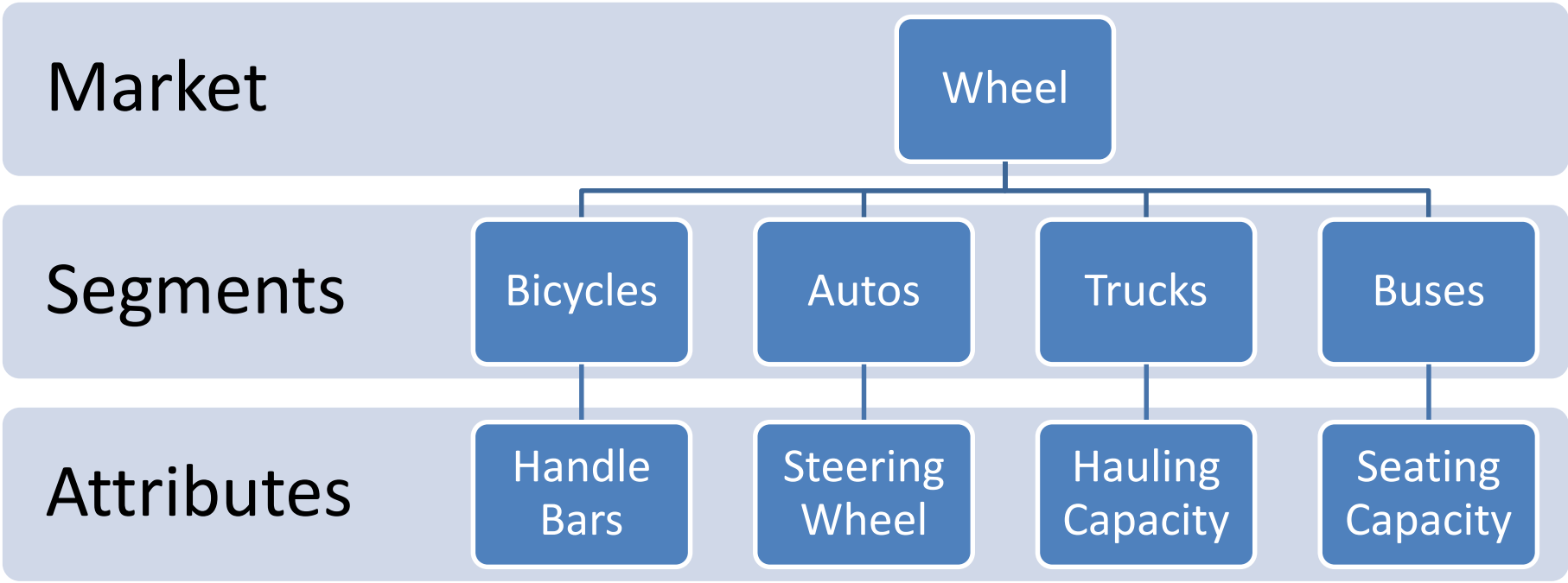
Let’s conceptualize for a moment



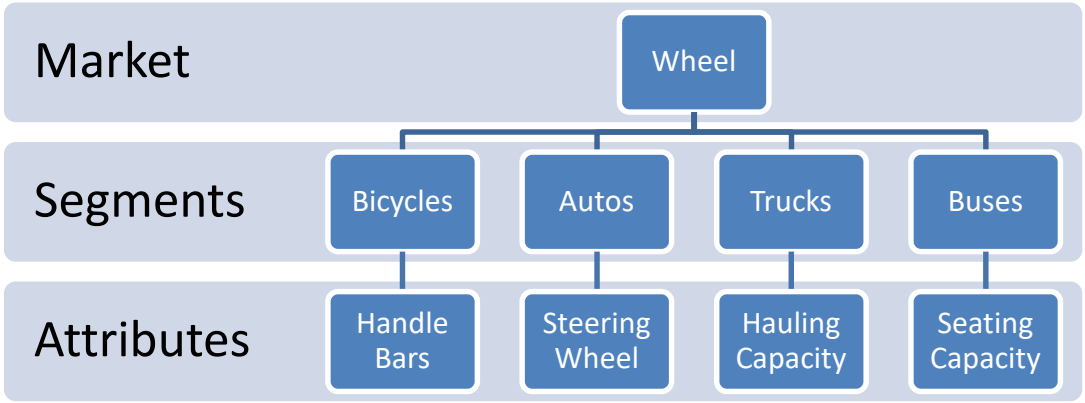
An extreme example might be illustrative

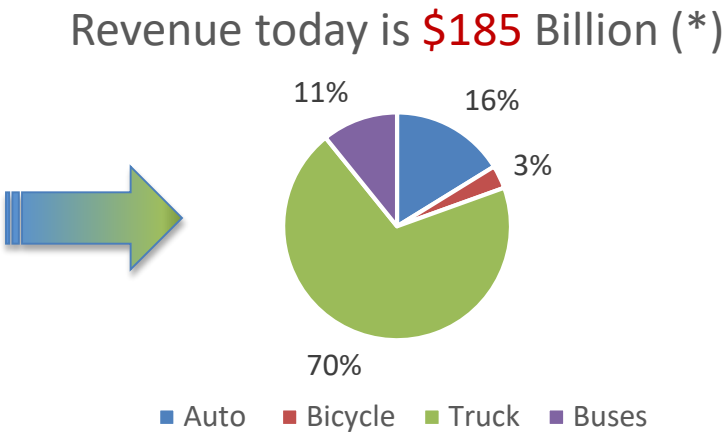
- Picture an organizational chart with the problem that you are seeking to solve is the need to create the ability to transport people long distances over land
- Immediately we think of bicycles, automobiles, trucks and buses
- Imagine for a moment that you have the exclusive right to patent the wheel
- Clearly, this exclusivity would be very valuable

The patent owner may think of the market this way



The wheel gets monetized

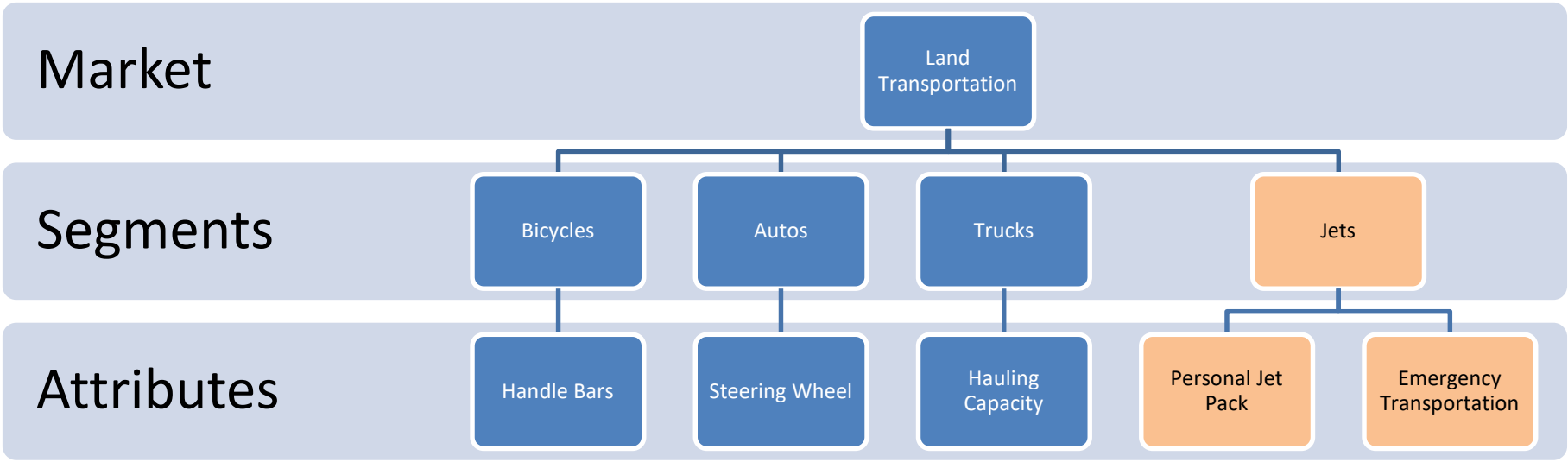




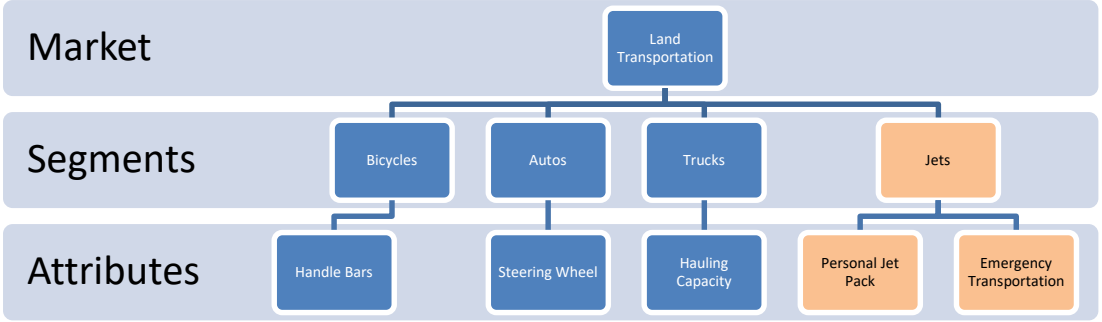
An extreme example might be illustrative.

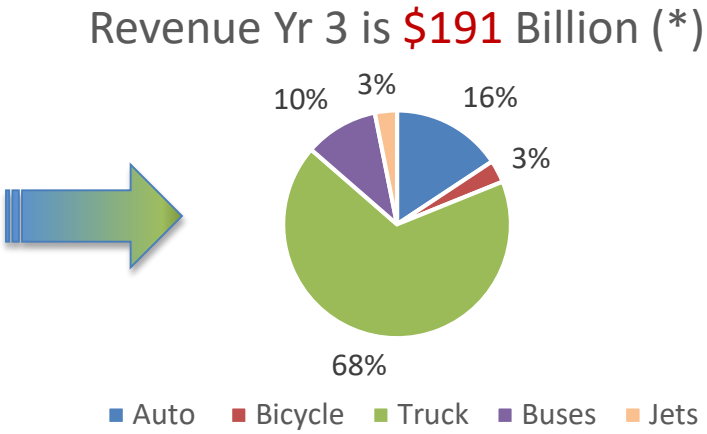
- However, over time, perhaps a jetpack technology would become inexpensive and deployed to obtain a piece of the wheel market. Assuming all costs, safety factors and other considerations were equal; it would not be unreasonable to expect that a subset of people would prefer the jetpack technology.
-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

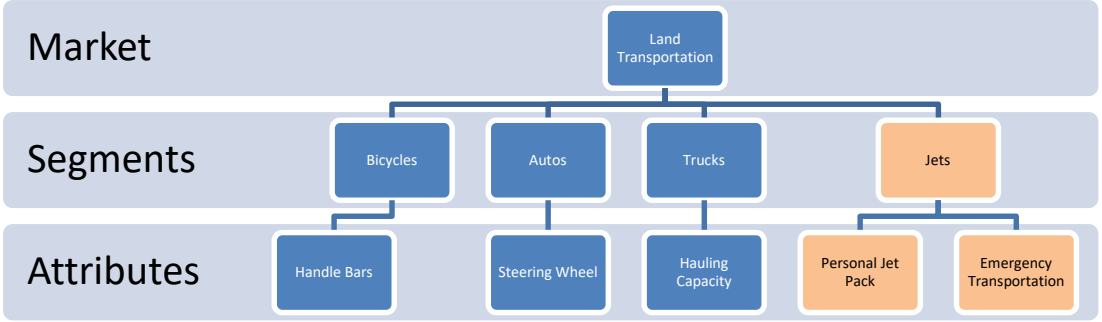


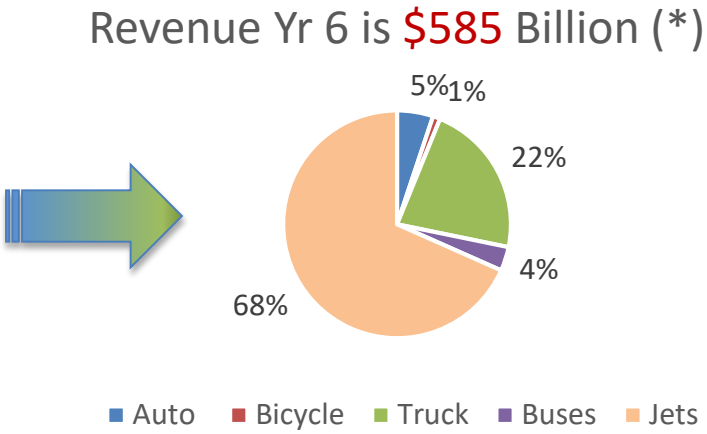
Should you look at the problem differently?





What about now?





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 is 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.
- Importantly, 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?

- Step 1 – Map the Competitive Landscape
- Step 2 – Identify the existing weaknesses in the market
- Step 3 – Match your IP's ability to solve the existing market weakness
- Step 4 – Match each patented technical component to your market view
- Step 5 – The promise must be converted to function
- Step 6 – Perform a SWOT Analysis on your analysis
- Step 7 – Break your own patent
- Step 8 – Amend patents to include brainstorming results
- Step 9 – Determine if the journey is investable

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

Step 1 – Map Competitive Landscape

	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			

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

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

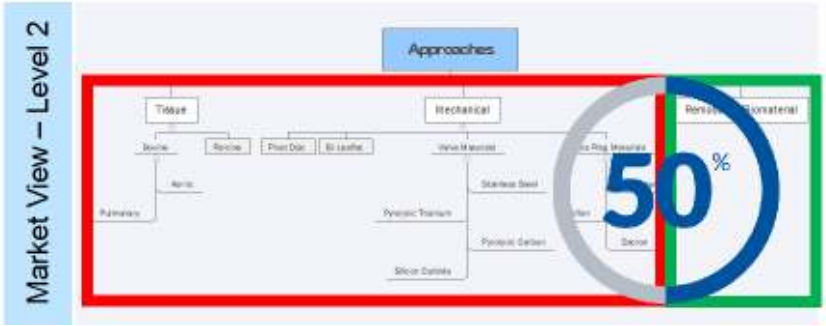
Step 2 – Identify Existing Market Weaknesses

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

- 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.

An upstream solution without downstream intervention would obsolete existing categories

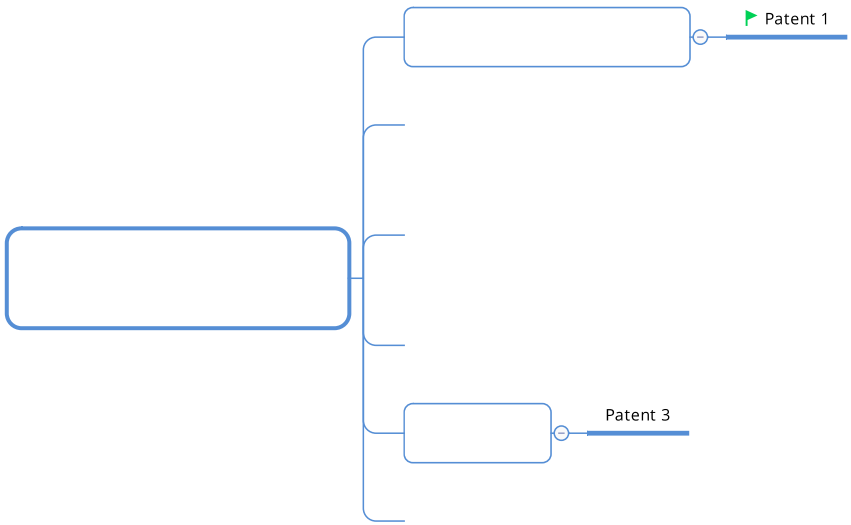
A partial upstream solution would only shift share



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

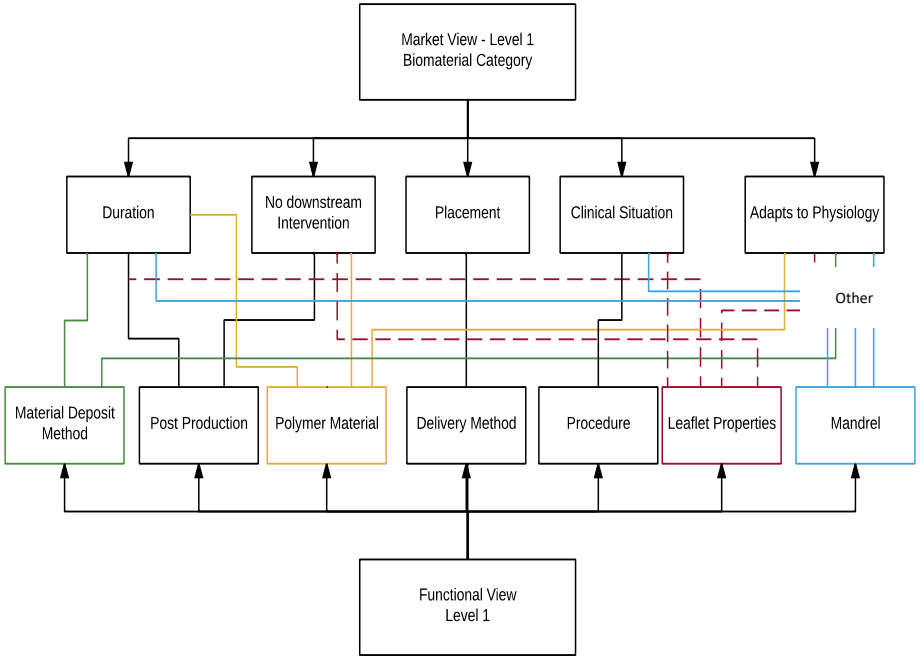
Gather each patent's detail and roll it up to a functional view.



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.

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

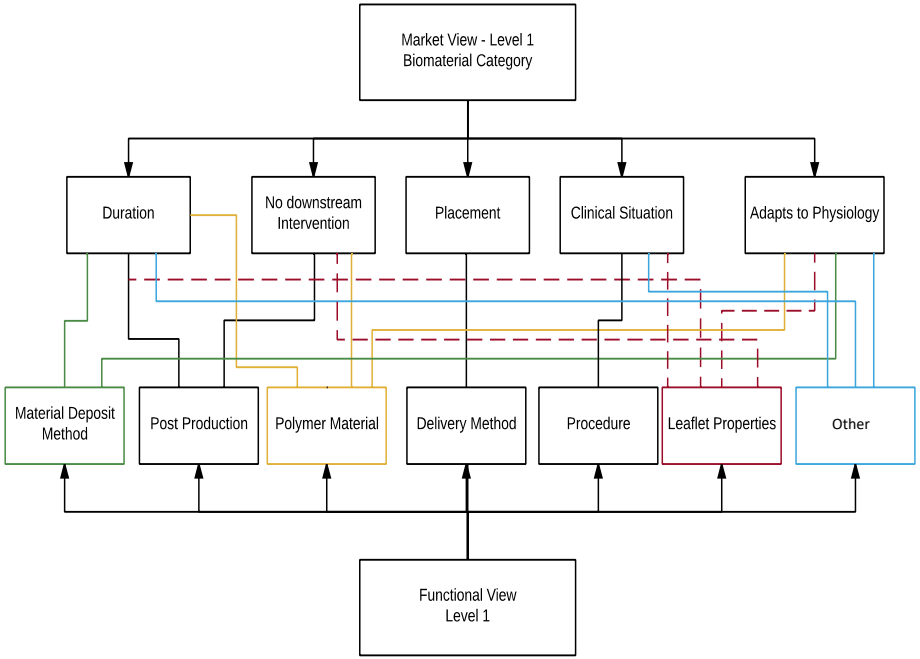


Step 5 – The Promise must be converted to function

- 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.

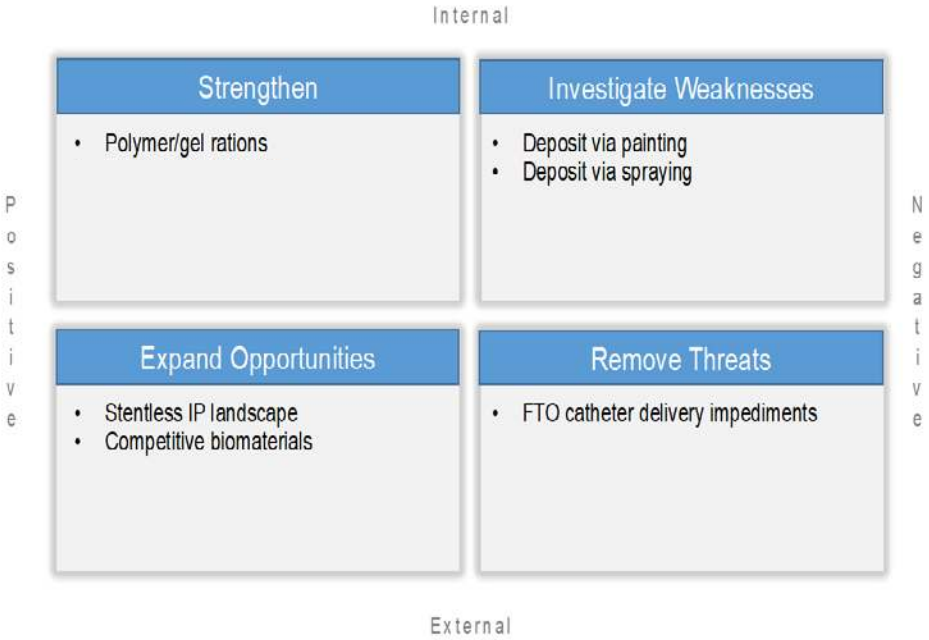
Consider using your IP to erect regulatory impediments to slow down the competition

Step 5 – Aligning clinical and IP could provide competitive entry barriers



Market View	Functional 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	

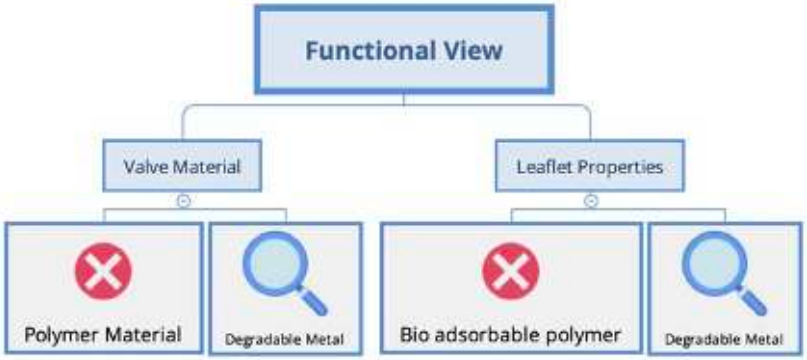
If you were an investor, how would you look at the competitive IP landscape?



Step 6 – Perform a SWOT Analysis

- At this point, it would be prudent to look at your analysis and look for obvious areas of improvement. You are looking for obvious omissions.
- 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 was plausible, you should add to your patent because you just gave your competition an opportunity to enter the market if you do not capture this path to market in your patent.

For example, in this analysis we made the assumption that the material for a Bio-Valve is a polymer. Could it be a degradable metal?

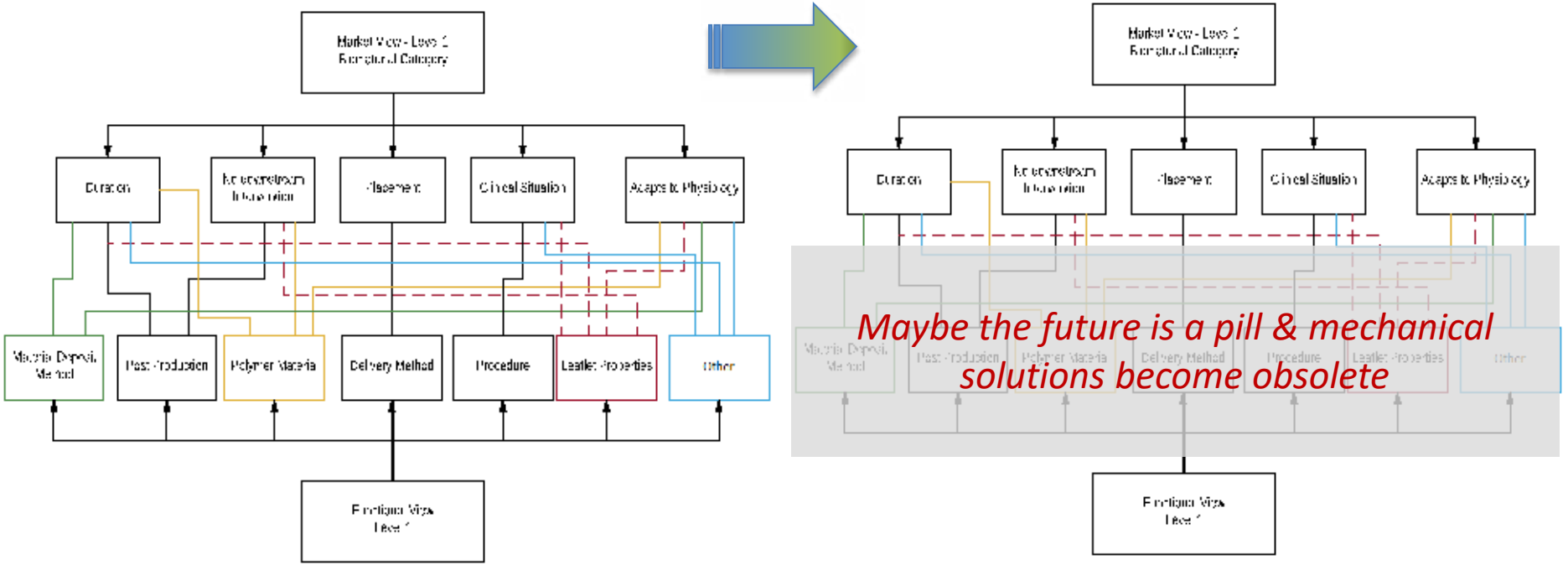


Step 7 – Break your own patent

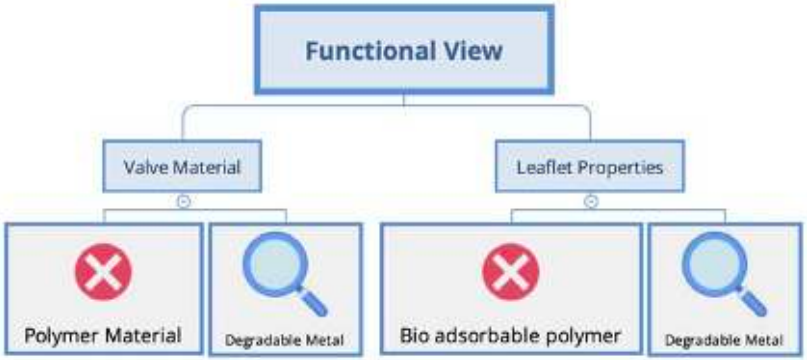
- This is one of the most difficult parts for a startup company's technology team to do, however, it is a vital step.
- Take your existing patents, and any conceived improvements from Step 6, and take it away from your technical team.
- Have them go back to the market view (Step 2) and brainstorm solutions to achieve create new IP (Step 3).
- Do not inhibit your brainstorm by the constrains of today's technology.

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

Step 7 – Break your own patent



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

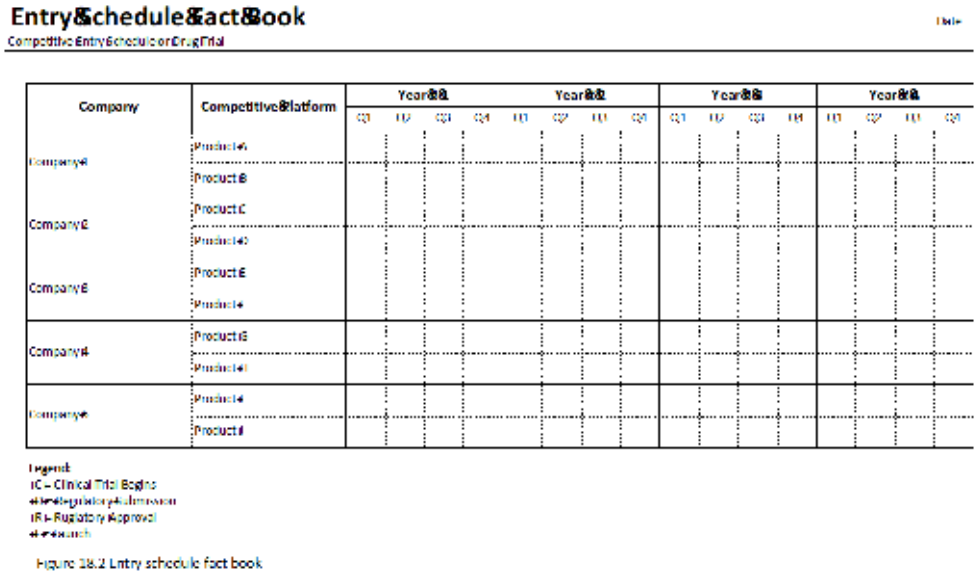


Step 8 – Amend patents to include brainstorm

- Step 7 will avail opportunities to either improve your existing position or identify patents that exist in other markets that might be used to enter your market once you created it.
- You can be sure if you develop a billion-dollar market, someone is going to find that material and bring it into your market.

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

Step 9 – Determine if your journey is investable


Entry Schedule Fact Book

Competitive Entry Schedule on 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 A	Product A																
	Product B																
Company B	Product C																
	Product D																
Company C	Product E																
	Product F																
Company D	Product G																
	Product H																
Company E	Product I																
	Product J																

Legend:
IC – Clinical Trial Begins
RS – Regulatory Submission
IR – Regulatory Approval
R – Launch

Figure 28.2 Entry schedule fact book

- So how far away from solving the existing markets weaknesses are you? If you are not able to solve all the existing weaknesses in the market, is your product a significant advancement over existing solutions?
- This is an important question because if you are not solving all the existing weaknesses in the market, you need to determine if your technology is an incremental improvement or a monumental leap?
- If you're technology is an incremental improvement, it is most likely not going to gain market traction over existing market players nor attract investors to your startup.
- If this is the case, you should not pursue a start-up or develop new IP that makes a monumental leap.

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 startups valuation.
- Intellectual property that is not matched to the problem may result in a partial solution, or may leave technical pathways open for others to gain access once the market is developed.
- The IP Pyramid 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
- IPP ensures you are not leaving technical pathways open for others to gain access once the market is developed.
- The IPP 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