

# Building an IP Pyramid impervious to competitive advancement

14<sup>th</sup> Annual Biotechnology  
Entrepreneurship Boot Camp

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# Having a patent can cause false confidence

- ▶ A patent excludes others from replicating an approach
- ▶ A patent (approach) may not create an exclusive market position
- ▶ True exclusivity is creating a position impervious to competitive advancement
- ▶ A patent's ultimate value is exclusivity to a market position
- ▶ The extent of exclusivity determines if you own the category or a segment within a category

Hank Safferstein

# The Concept

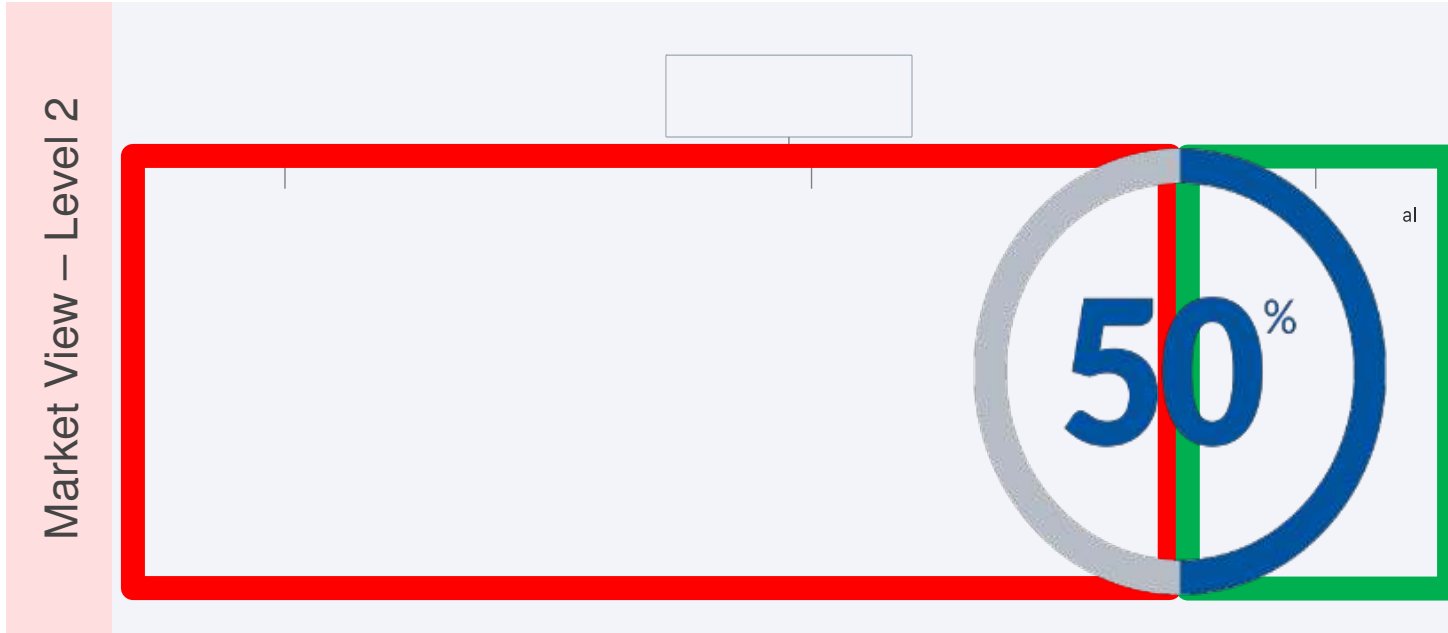
# An Intellectual Property Pyramid™ affirms confidence

- ▶ The goal of the Intellectual Property Pyramid (IPP) is to understand the exclusivity a patent provides matched with the desired result of the product's market positioning
- ▶ What you are trying to understand is the reason the patent exists (the problem it's solving) and then ask yourself if your patent is the only path to achieving that goal
- ▶ Being enamored with a particular technical approach can inhibit technologists and marketers from working together to create the broadest market protection possible

# An upstream solution without downstream intervention would obsolete existing categories

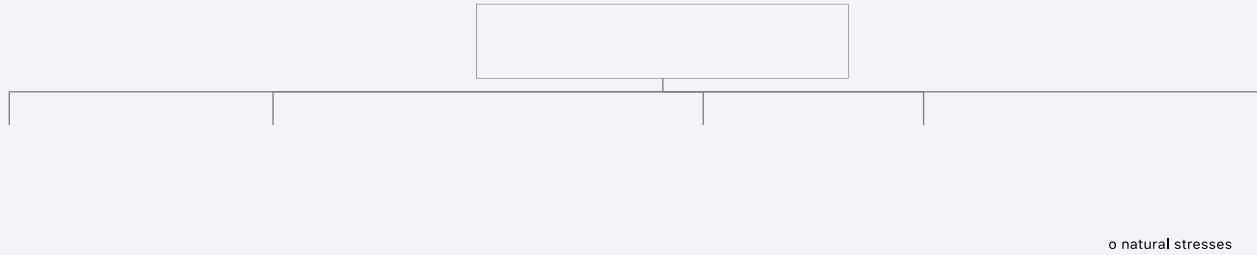


# A partial upstream solution would only shift share



# Five market requirements embody the promise

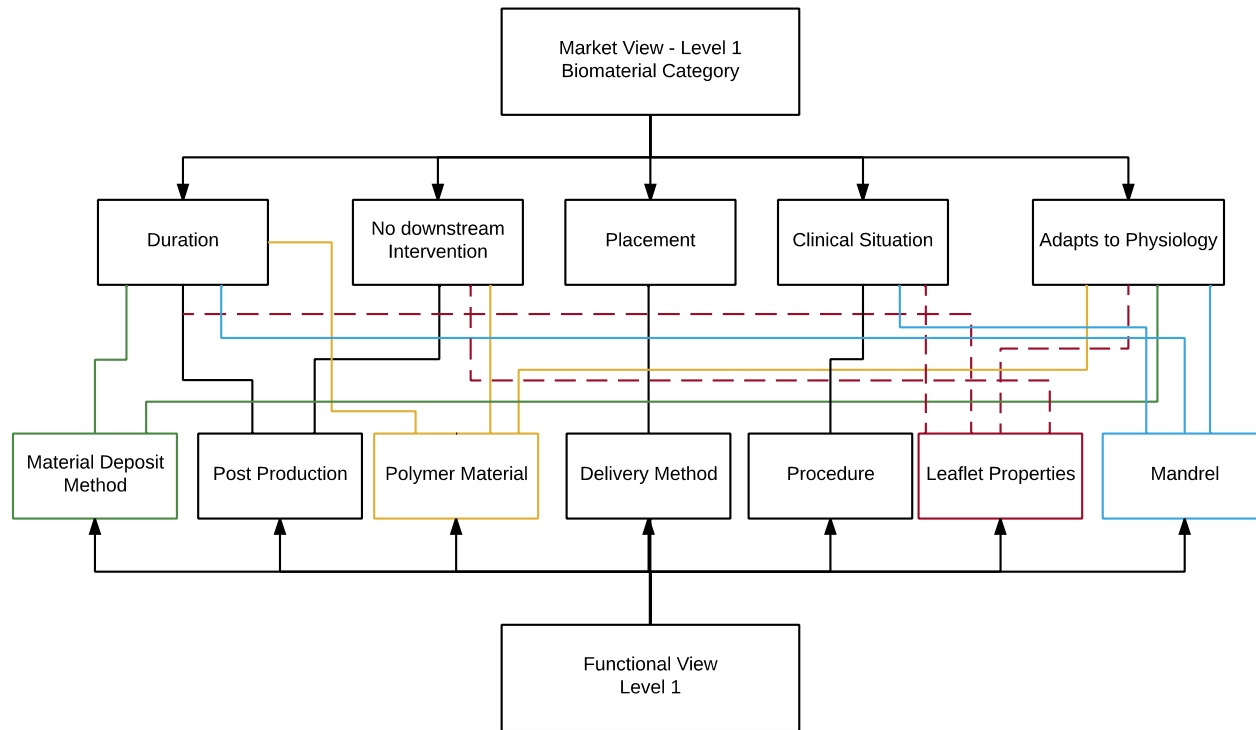
## Market View – Level 1



# The promise must be converted to function



Translation into  
Functional View – Level 1





# Bring creditability to your investor pitch

Internal

Strengthen

Investigate Weaknesses

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Expand Opportunities

Remove Threats

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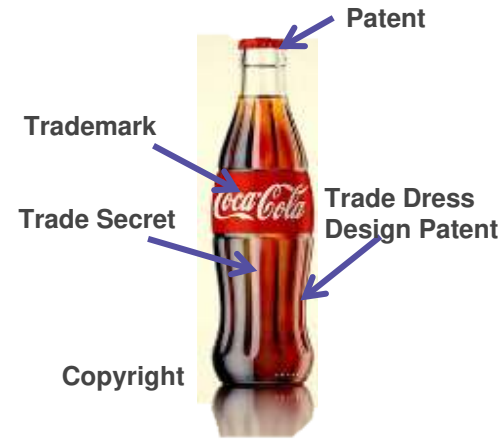
External

Raymond A. Miller

# The Execution

# Main types of IP

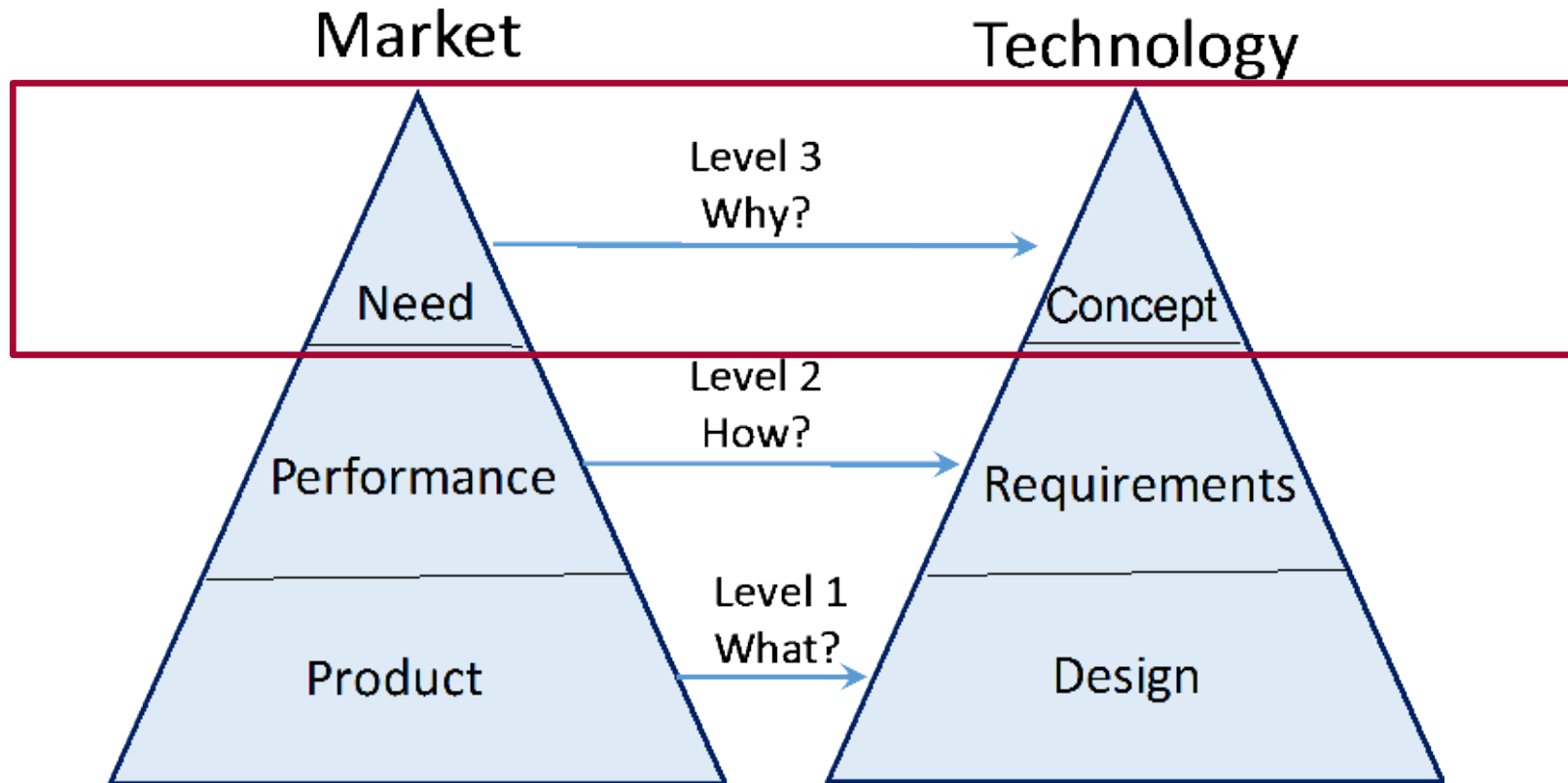
- ▶ Patent: novel, non-obvious and useful processes, products, or ornamental design
- ▶ Trademark: Name, design, symbol, word(s) or other source identifier of goods or services
- ▶ Copyright: original work of authorship fixed in a tangible medium
- ▶ Trade Secret: Information kept confidential which has commercial value due to its secrecy



# Trade Secrets

- ▶ Information that is not disclosed outside of an obligation of confidentiality
  - Formula, recipe, or manufacturing process
  - Software source code
  - Business information (sales data, market intelligence)
  - Customer lists
- ▶ Has commercial value due to its secret nature

# Align market need & technology concept



# Common Problems with IP development

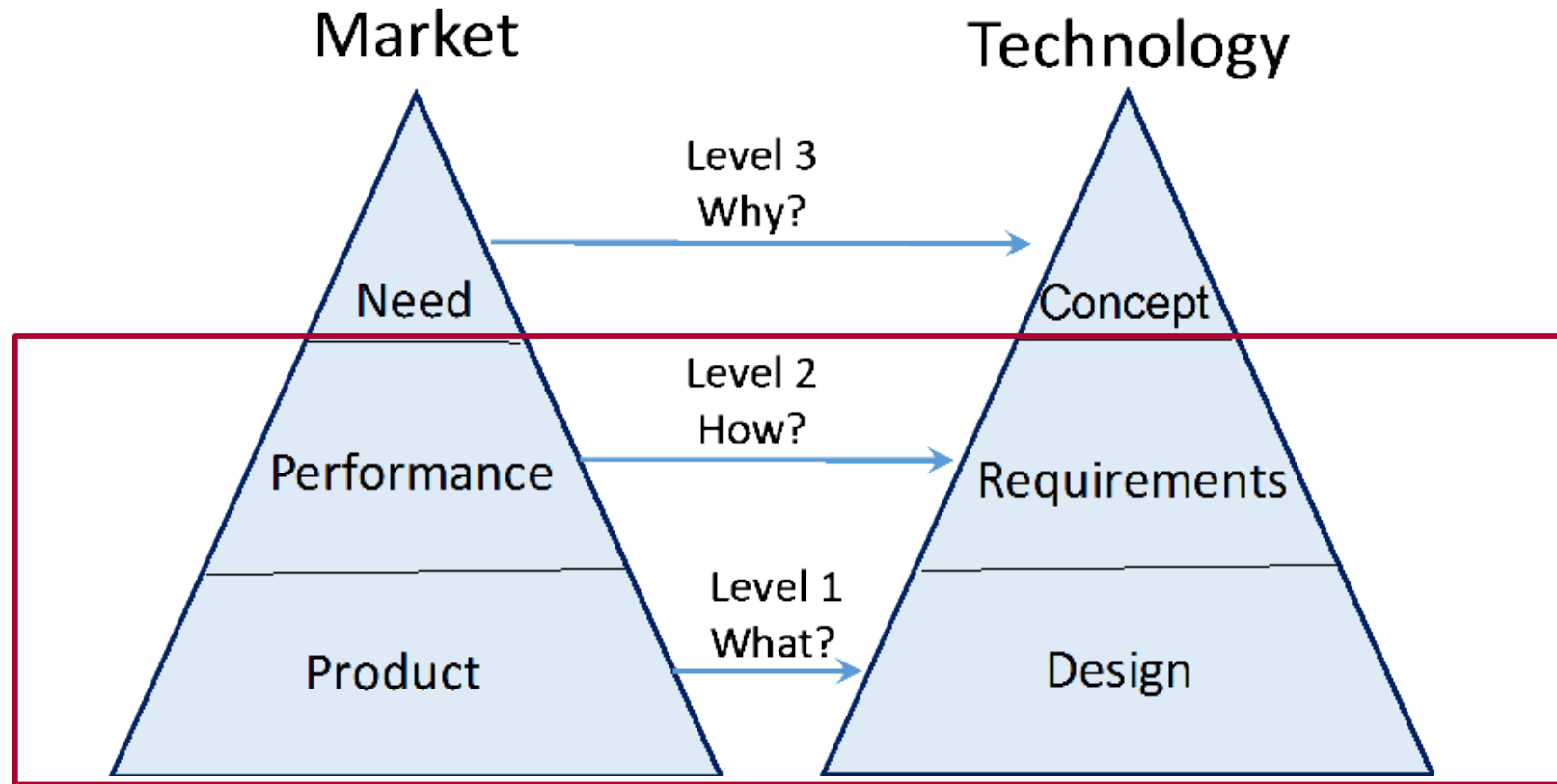
## ▶ Lack of **market alignment**

- Product elements not mapped to market needs and requirements

# Common Problems & Missed with IP development

- ▶ **IP Inventory** unknown or not mapped out
  - Company unaware of complete picture of IP portfolio
  - Lack of recognition for other forms of IP (trademarks, copyrights, trade secrets)
  - No mapping and inventory procedures in place
  - IP is often most significant component of valuation for start ups and development stage companies

# How to go avoid or leverage product drift

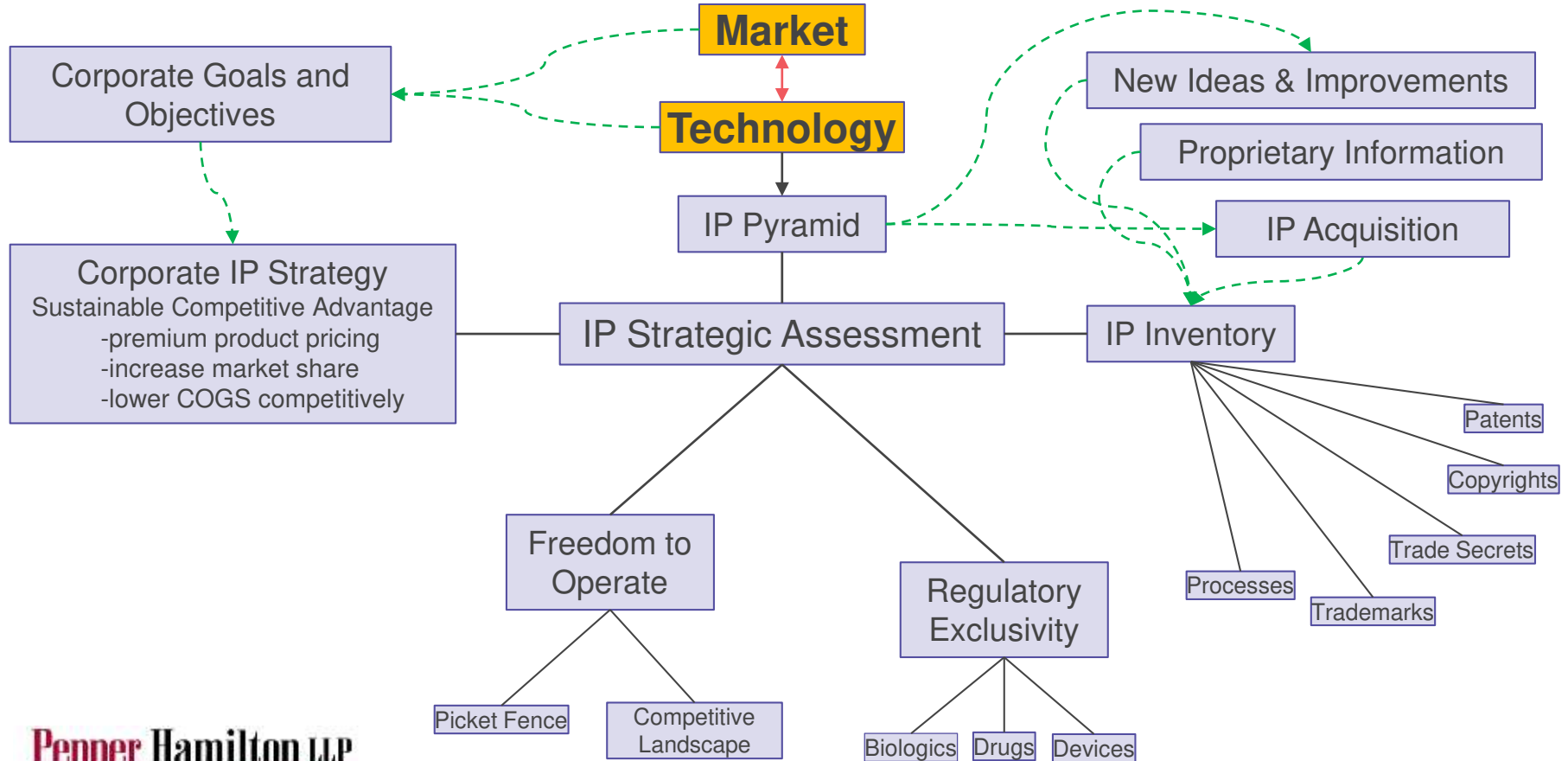




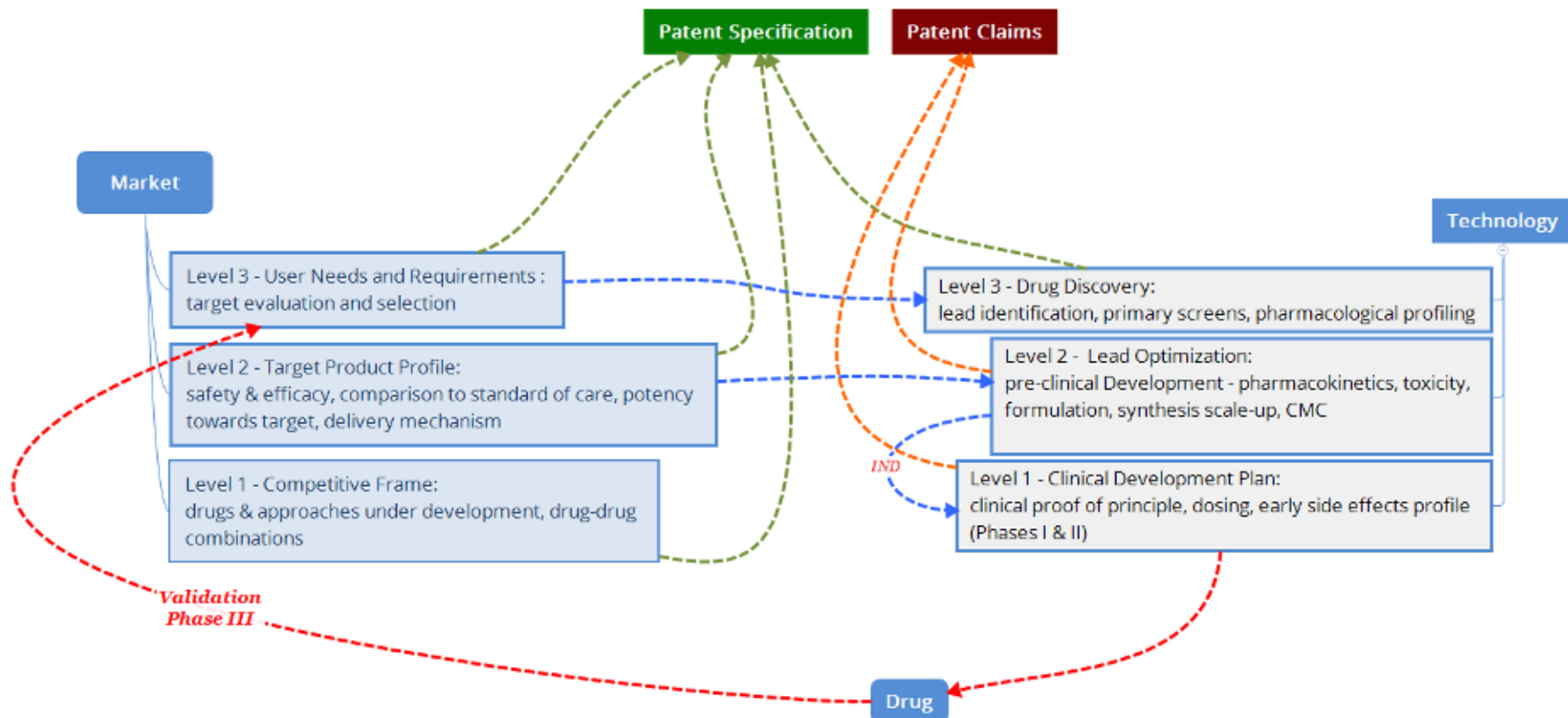
# Problems & Missed Opportunity with IP development

- ▶ **Product drift** during development and claim mapping – commonly bad, sometimes good
  - Patent claims does not track product evolution and final product
  - Freedom to operate (FTO) often over emphasized because of product drift
  - Product elements not mapped to patent claims resulting in patents that don't cover products
  - Or a great drift idea does not flow back up into a patent claim

# The IP Strategic Assessment



# IP Pyramid – Drugs & Biologics



# Potentially “Counter-Intuitive” IP Thinking

- ▶ **IP should not drive therapy** – but therapy should be tracked in the patent claims
- ▶ Regulatory Exclusivity without **any** patent coverage **does** provide an opportunity for ROI
- ▶ **Patent Term Extension** (PTE) for time in clinical trials while patent is issued
- ▶ **Freedom to Operate** is often **over-emphasized**
- ▶ **Grant of a patent** should be viewed as a **milestone, not a golden ticket** –vigilance is needed

# Every Product Has a Story

- ▶ Traditional views of having a simple COM patent with a 14 year life upon launch is very rare (e.g. statins)
- ▶ Don't be afraid to challenge FDA (e.g. Amarin's redefined NCE)
- ▶ FTO risk worth taking in HepC market for Pharmasset / Gilead's Sovaldi®
- ▶ A drug / device PTE permitted sufficient time for ROI for ProGEL®
- ▶ A “failed” clinical trial provided opportunity for Acorda to capture IP on walking speed and bolster Ampyra®.



Combining a wide-angle perspective with close attention to detail, Pepper Hamilton provides a gilt-edged patent prosecution service – especially in the life sciences, where it has in-depth industry insight. The Pennsylvania squad also excels on tech-related agreements; it has handled many rounds of private financing for innovators.”

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