From Concept to Company: Building Strong Foundations for Medtech Innovation

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Monday, November 10, 2025

- **Objective:**
  Outline the steps YOU can take to bring a concept to market using the Chrysalis Process including practical, real-world examples

Introduction

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Founder and Managing Partner

Brendon Pittman
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- **Key Takeaways:**
  1. Clients often begin projects without a structured method
  2. There is a lack of comprehensive knowledge and viewpoints
  3. Clients frequently lack the time and concentration needed

Why a Disciplined Approach?

✓Phase Zero process

✓Foundation of successful projects

✓Systematically addressing unmet medical needs

PHASE ZERO: SETTING UP FOR SUCCESS

PHASE ONE: STRUCTURING FOR SUCCESS

PHASE TWO: BUSINESS BLUEPRINT

PHASE THREE: SECURE FUNDING AND PLAN FOR LAUNCH

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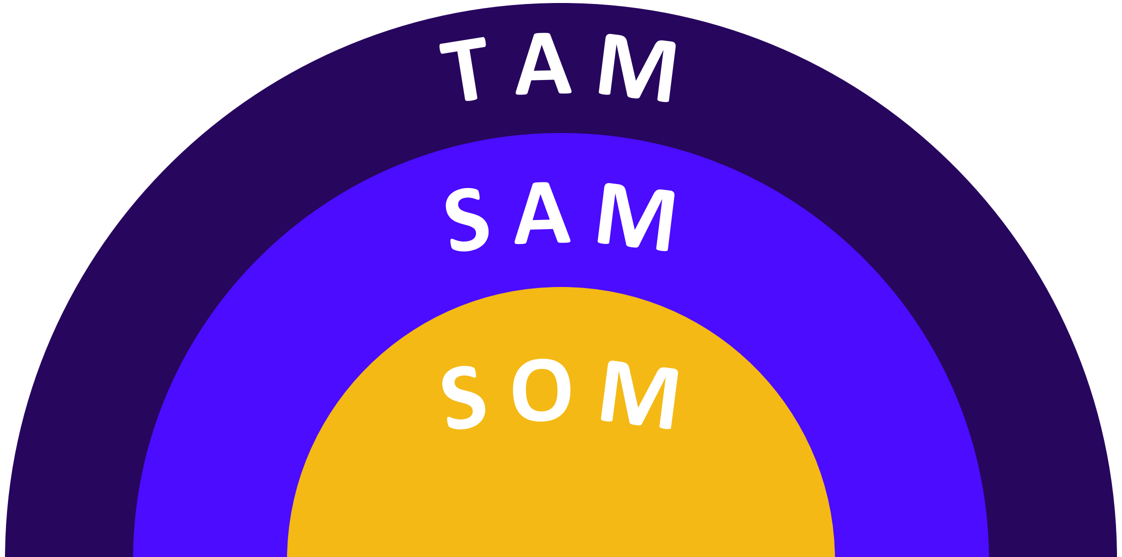
Is there an **unmet clinical need**?

Whether it's a sketch on a napkin, a provisional patent, or prototype, have you defined and substantiated the unmet need?

Is there a **market**?

- ✓Have you calculated the disease cascade and continuum of care?
- ✓Have you determined Prevalence and incidence?
- ✓What is the Total Addressable Market (TAM), Serviceable Addressable Market (SAM), and Serviceable Obtainable Market (SOM)?



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How do you develop the **right solution**?

✓Human-centered design

✓Meeting the needs of patients and HCP's

✓Innovation and collaboration

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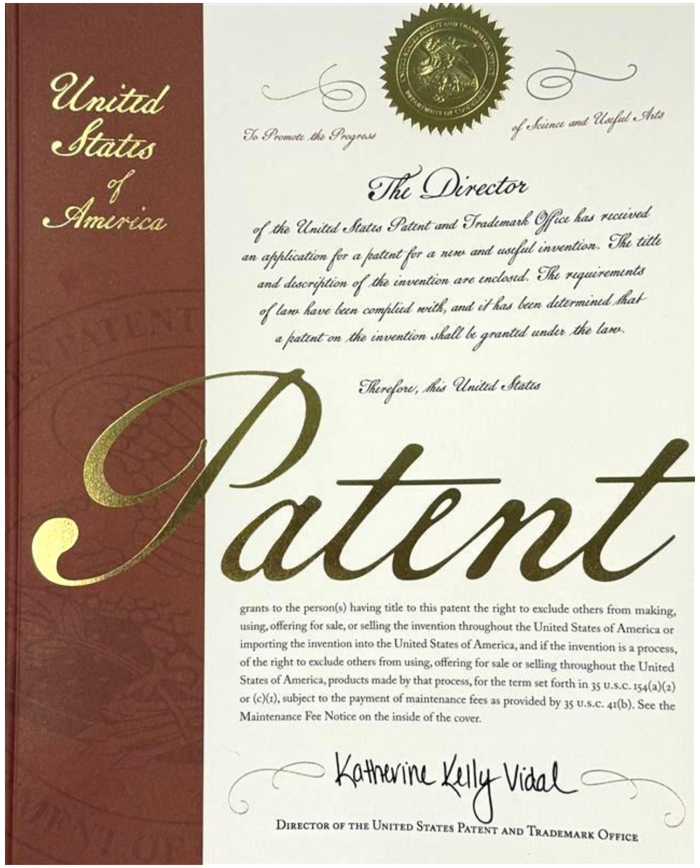
How do you develop an effective **IP strategy**?

✓Plan before you execute. You may only get one chance!

- Patent applications publish after 18 months
- Filing a patent application initiates an expense timeline. Missteps can result in a loss of rights
- Early filing is important, but business plan must account for funding IP expenses



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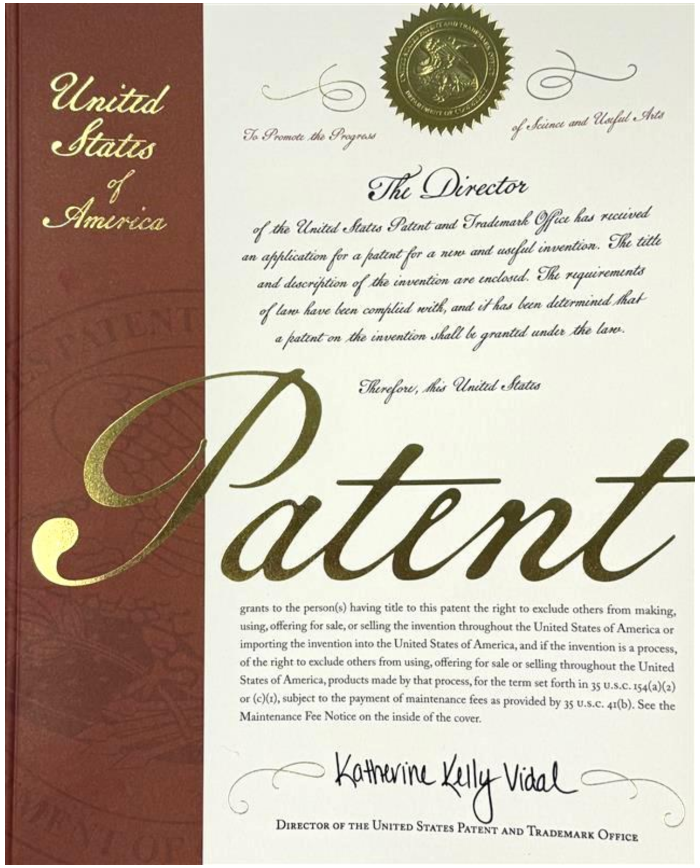
How do you develop an effective **IP strategy**?

✓Intellectual Property Rights:

- Patents
  - Utility
    - Provisional
    - Non-Provisional
  - Design
- Copyright
- Trademarks
- Trade Secrets



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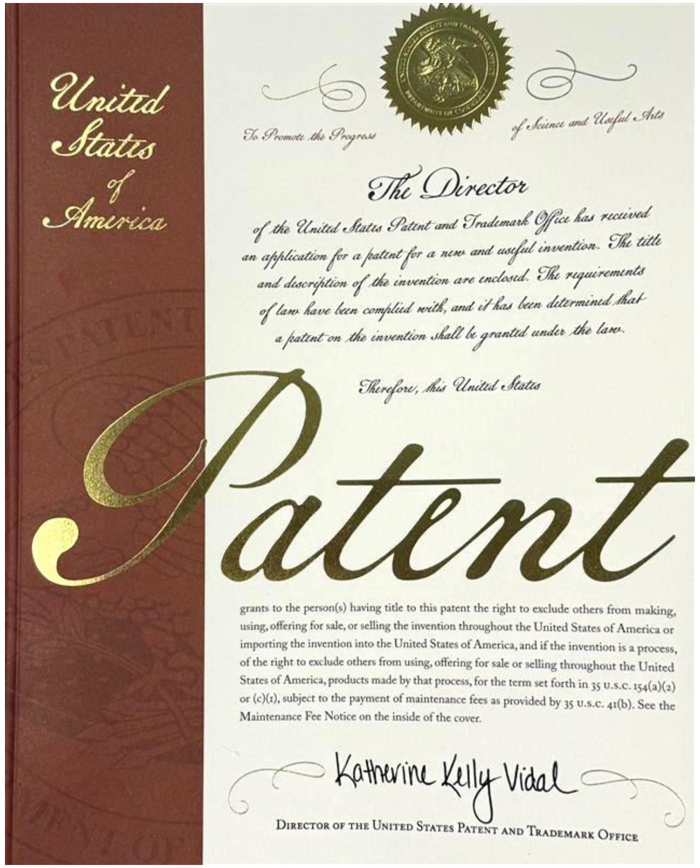
How do you develop an effective **IP strategy**?

✓ Other IP Considerations

- Confidentiality
  - Keep it secret
  - Use a non-disclosure agreement
- IP Ownership
  - Keep development inhouse
  - Define in employment agreements
  - Specify in development agreements
- Competitive landscape
  - Conduct prior art analysis
  - Consider freedom to operate



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What is your **FDA strategy**?

✓ How will FDA regulate your product?
  - Device, drug, biologic, combo product? None of these?
- What “class” is your device, I, II, or III?
- Isa a 510(k), De Novo, or PMA required? Or is the device waived or not a device at all?
- How much time and money do you need?
- Do you have a quality management system (Part 820)?
- Where do you start?

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What is your **reimbursement strategy**?

- ✓ Does adequate coding, coverage, and payment already exist?
- ✓ Do you have a new product?
- ✓ Who will pay for your product and/or service?

Is **clinical evidence** needed for every product?

✓What evidence is needed?

✓Animal, Cadaver, Human requirements based on regulatory path

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- **Why Chrysalis Incubator?:**
  1. Set you on the right path
  2. Multifunctional expertise
  3. Empowerment

Thank You

Insights into our disciplined approach and expertise at Chrysalis Incubator

Visit www.chrysalisincubator.com for more information

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Questions

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Appendix

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What will investors look for?

Carefully crafted strategies

Robust pitch deck

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How do you **finalize** the concept/product?

- ✓Rapid prototyping
- ✓Robust IP Strategy
  - o Confidentiality and ownership considerations
  - o Patentability analysis and landscape analysis
  - o Contracts/agreements and IP protection
- ✓HCP input

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Marketing Strategy

✓Identify target audience

✓Model market opportunity

✓Ensure market validation

✓Crafting compelling value proposition

✓Developing marketing claims

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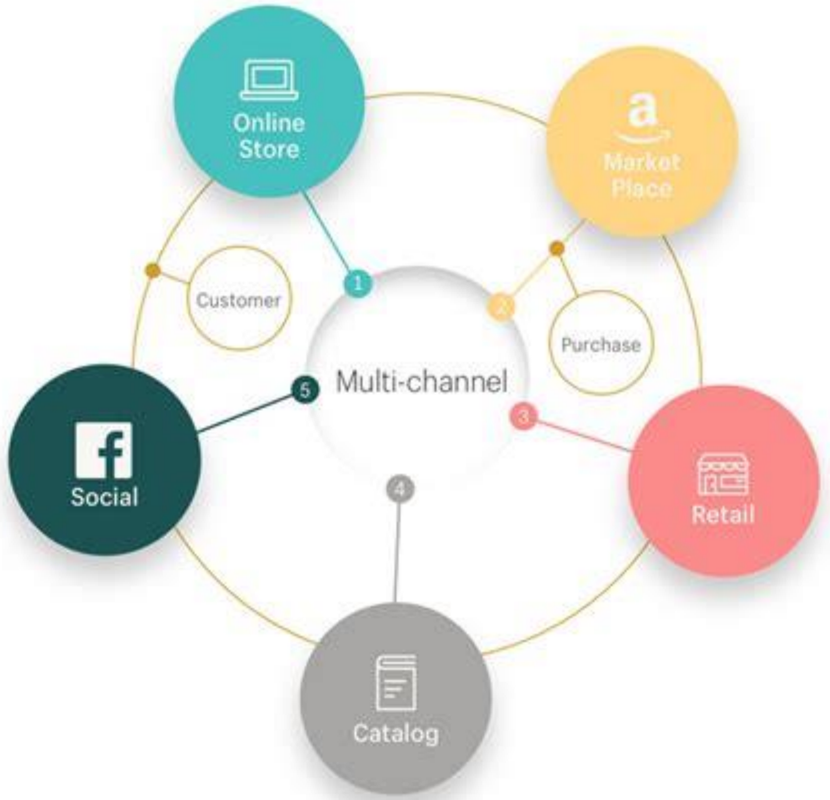
Sales and Distribution Strategy

✓Selecting distribution channels

✓Complying with legal and regulatory requirements

✓Maximize market penetration via multi-channel strategies



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Competitive Advantage Strategy

✓Identifying competitors' offerings

✓Developing competitive positioning

✓Creating FDA cleared messaging

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Reimbursement

- ✓Do you have a new product?
- ✓Or is it like something that already exists?
- ✓If your product is new, how will it be paid for?
- ✓Who will pay for your product and/or service?
- ✓Does adequate coding, coverage, and payment already exist?
- ✓that the world has never seen for which you will have to forge a new pathway to reimbursement?

Conclusion

- ✓ Thank you for joining us today!
- ✓ Insights into our disciplined approach and expertise at Chrysalis Incubator
- ✓ Visit www.chrysalisincubator.com for more information

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R&D Strategy

✓Human-centered design

✓Meeting the needs of patients and healthcare providers

✓Innovation and collaboration

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Clinical Strategy

✓Integrated clinical evidence strategy

✓Aligning clinical strategies with regulatory requirements

✓Managing risks through systematic planning

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Intellectual Property (IP) Strategy

✓Keep it secret

✓Consult with an IP attorney

✓Consider patent protection

✓Ensure you own it

✓Consider landscape and freedom to operate analysis

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Questions

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