
Timeline Of A Startup: The Role Of Intellectual Property From Idea To Commercialization

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Key Points

- During the evolution of your company, from startup through technology development/early commercialization to mature company, you will develop and leverage many business assets, one of which is intellectual property
 - During the evolution of your business, the role of IP also evolves:
 - Startup: IP provides the option to take a risk
 - Technology development/early commercialization: IP protects the company as the technology and markets mature
 - Mature company: IP protects gross profit
 - The right to exclude is important, but the freedom to operate your business is essential!
 - You should secure IP to get your business started and help make it profitable
 - You need to avoid other's IP because it can put you out of business
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In the evolution of your company from startup through technology development/early commercialization to mature company, you will be developing and leveraging a variety of business assets, one of which is intellectual property.

The Business Assets Of Your Biotech Startup

- The founders' vision
 - Of a large market with an unmet need and an idea for a new product to fill that need
 - The founders' sweat
 - Their commitment to personally turn that dream into a reality
 - Promising, new technology
 - That you will develop into a breakthrough product
 - Startup and follow-on capital
 - To finance the execution of the business plan
 - Intellectual property
 - Assures investors you have the right to mine the technology area
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The Business Assets Of The Development Stage Company

- Research and Development Team
 - Proof of concept for technology
 - “Productizing” the technology
 - Sales and Marketing
 - Identifying promising markets for technology
 - Strengths and weaknesses of the technology are becoming apparent.
 - Identifying applications where the technology has large added value
 - Capital
 - Which you are spending down to support development and commercialization
 - Intellectual Property
 - Protects the company’s exclusive right against others to develop and commercialize the technology
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The Business Assets Of The Mature Company

- Operations
 - Makes the product with highest quality and lowest cost
 - Sales and Marketing Team
 - Creates demand for the product
 - Distribution channels
 - Gets the product to customers
 - Quest Diagnostics – has a lab near you!
 - Intellectual property
 - Protects market share and profit margin = gross profit
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The Role Of Intellectual Property
Changes As The Company Evolves
From Startup Through Technology
Validation To Mature Company

In The Startup, IP Protects The Investor's Option To Take A Risk

- Risk: The variance in possible outcomes
 - Downside risk: Technology fails and company goes out of business
 - Upside risk: Technology succeeds in the market
 - The greater the range of uncertainty in outcome, the greater the risk
 - Starting a biotechnology company involves RISK, because you don't know at the outset whether the technology will succeed or fail
 - Investors are people willing to bear a risk
 - i.e., both the upside risk and the downside risk
 - By excluding others from the technology, intellectual property protects the upside risk from being shared with those who do not also share the downside risk
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Ciphergen: A Tale Of Two Technologies

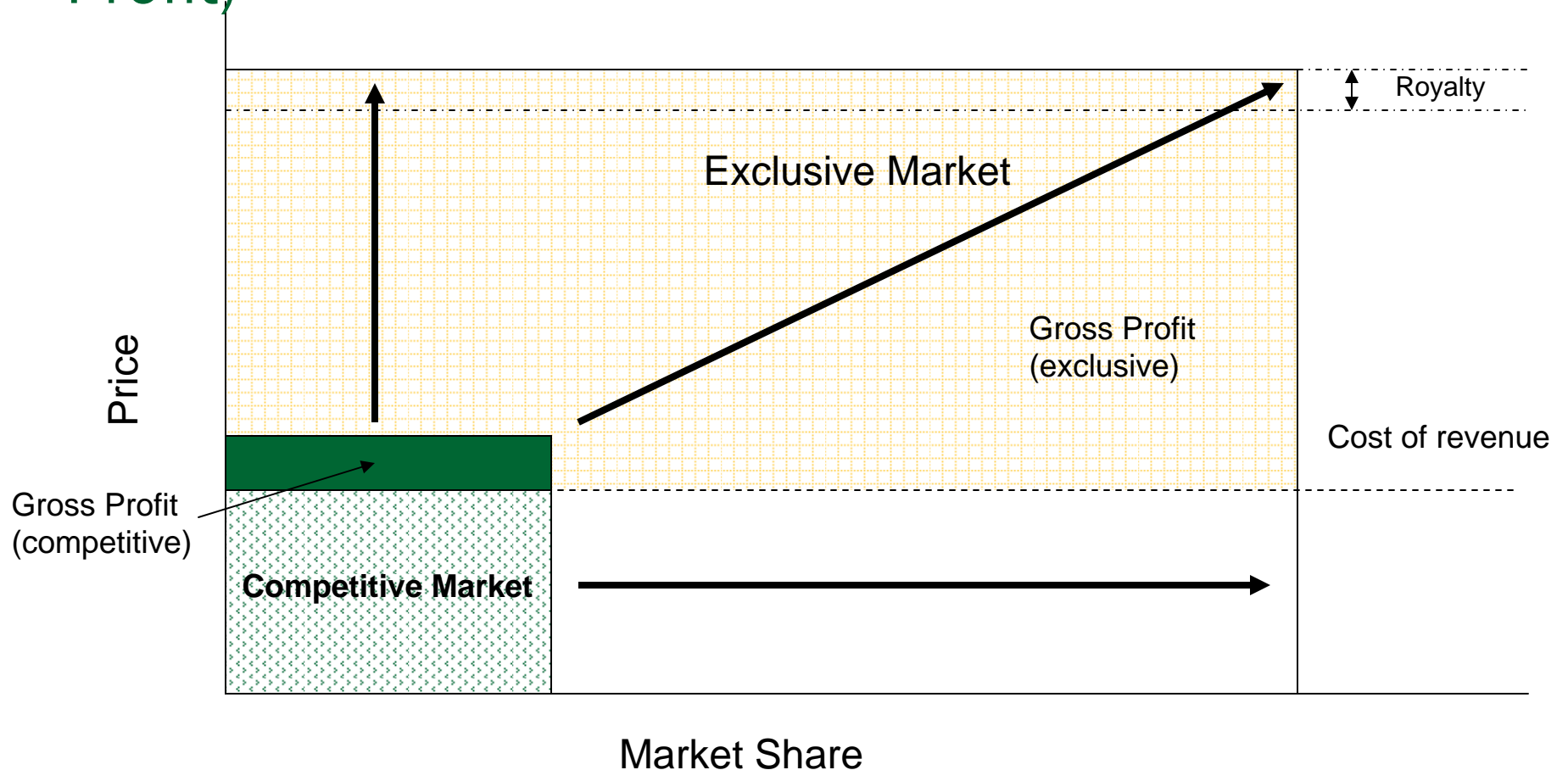
- Founded in 1994 with a mission to bring mass spectrometry to the benchtop of the protein biologist
 - First technology: Protein Ladder Sequencing
 - In-licensed from The Rockefeller University and Scripps Institute
 - Protein ladder sequencing was not a market success.
 - Second technology: SELDI
 - In-licensed from Baylor College of Medicine/MAS in 1997
 - Ciphergen has developed SELDI into a successful technology for biomarker discovery
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In The Technology
Development/Early
Commercialization Phase, IP
Protects The Company From
Competition While The Company
Develops Markets For The
Technology

Affymetrix: Competition And Success In The DNA Array Market

- While Affy established its market position ...
 - Early defined markets according to Affy's prospectus
 - Genetic mapping
 - High-throughput screening
 - Gene expression monitoring
 - Polymorphism screening
 - Ultimate market advantage
 - Gene expression monitoring
 - SNP detection
 - ... intellectual property staved off early competitors
 - Incyte/Synteni
 - HySeq
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In The Mature Company, Intellectual Property Protects Market Share and Product Margin (Gross Profit)



The exclusionary power of intellectual property allows both an increase in price and an increase in market share. This results in an increase in gross profits. Royalty payments decrease gross profit.

Generic And Proprietary Drugs

Indication: Arthritis

	Wal-proxen naproxen (Walgreen's)	Aleve naproxen (Bayer)	Vioxx rofecoxib (Merck)
Amount	100 pills 220 mg/pill	100 pills 220 mg/pill	100 pills 25 mg/pill
Cost	\$6.99	\$10.49	\$337.39
Daily dose	2-3 pills	2-3 pills	1 pill
Cost per day	14¢-21¢	21¢-32¢	\$3.37

The trademark increases the value of pill by 50%
The patent increases the value of the pill by 5000%.

The right to exclude others with
your patents is powerful.

But the freedom to operate your
business is essential!

Confirm both early on.

Confirm Your Control Of Core Intellectual Property Assets

- Is your invention patentable?
 - Have your attorneys do a prior art search
 - Trace the chain of title
 - Does the inventor own it, or is he or she obligated to assign to someone else?
 - Assignment is the surest form of control of IP
 - Because you control what you own
 - Licenses always involve risk
 - Licensor and licensee may disagree about the scope of a license
 - Loss of a license can be disastrous
 - Lack of control of IP can scuttle a financing deal or even wipe out a company
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Confirm Your Freedom To Operate

- Freedom-to-operate is an often overlooked side of intellectual property
 - People tend to be more interested in acquiring IP
 - The primary purpose of a business is to stay in business
 - Infringement of a third party patent can put you out of business
 - Have your patent attorneys perform a patent clearance on
 - The product you intend to commercialize
 - The method of making the product
 - Review clearance opinions periodically, as products and methods can change between conception and execution
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