Why Protecting Intellectual Property Rights is Important to Startups

Real Case Studies

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HOW TO START A START-UP

by Anna Vital

live in the future, ahead of your time
what is missing in the world?
write it down and bounce ideas around
make a prototype
show the prototype to 100 people

launch - let everyone know you have made something
look for funding and build version one at the same time
register your C-corp, split equity
find a co-founder
iterate on the prototype until it makes sense

1,000
get to 1,000 users
grow 5% a week (hard, but proven possible)
keep growing for another 4 years, and at that rate you will reach 25 million users

launch again (after iterating) launch until users stay (AirBnB launched 3 times)

SUCCESS

https://blog.adioma.com/how-to-start-a-startup-infographic/
Intellectual Property (IP)
Physical Assets vs Intangible Assets

• Physical Assets
  – Physical object: land, building, equipment, etc.
  – Limited availability: limited number of people may use at the same time

• Intangible Assets
  – Have monetary value but no physical substance: e.g., software, brand recognition, goodwill (商譽)
  – Creations of one’s mind: e.g., ideas, songs, writings
  – Unlimited availability: one can use without preventing others from using
IP Rights

• Intellectual Property
  – Intangible
  – Creations of one’s mind: e.g. ideas, songs, writings

• Exclusive Rights

• Four Main Types
  – Patent (invention)
  – Trademark (product/service identifier)
  – Copyright (artistic/literary work)
  – Trade secret (know-how)
Patents Protect Inventions

- **Exclusive rights** in exchange for **full disclosure** of the invention

- **Patent owner** has the **right to exclude** others from **making, using, selling, importing** and **offering to sell** the patented product for a set period of time

- In the US, patents are granted by the **Government**, but policed by the **Applicant**

US patent ribbon copy
From R&D to commercialization

- High risk business
  - Huge capital & running cost
  - High failure rate
  - Long development time
  - Competitors
Why Intellectual Property Rights (IPRs)?

• Protection
  – Prevent undesired/disagreeable exploitation by others

• Business development
  – Freedom to operate, minimize risk of infringement
  – IP portfolio → technology transfer, generate revenue
  – Sustain or expand R&D → commercialization
Drug Approval Process in U.S.

0  2  4  6  8  10  12  14  16  18  20  22  24  26  28  30
YEARS

R&D

Discovery
Preclinical testing
Investigational Drug Application (IND)
Phase I: safety & dosage (20-80 healthy subjects)
Phase II: Efficacy & side effects (100-300 patients)
Phase III: Monitor adverse effects (1000-5000 patients)

Patents

File US application
File foreign applications
Grant of US application

New Drug Application (NDA)
FDA reviews NDA
FDA approves NDA
Post marketing testing

Hatch-Waxman Extension

Patent Term 20 years

http://www.oblon.com/Pub/Gifs/hatchwaxgraphlarge.jpg
Drugs – Regulatory & Market Exclusivity

• 10-15 years from laboratory to patients

• Market Exclusivity
  – Patent term – 20 years
  – Patent term extension for drugs – max 5 years
  – Data exclusivity (藥品市場獨佔期) – 5 years after drug approval
Expiry of Exclusive Right

- **Plavix® (clopidogrel bisulfate)**
  - Antiplatelet agent - prevents blood clots in heart attack
  - Marketed worldwide in nearly 110 countries
  - Top or second best-selling drug for years

- **May 17, 2012**
  - US Patent expired
  - FDA approved generic versions of Plavix

http://articles.mercola.com/sites/articles/archive/2012/10/10/plavix-health-risks.aspx
What Happened to Retail Sales?

![Graph showing sales decline after patent expiration.]

**Patent expired in May (~Q2)**

- ↓ 40% in Q2 to 935 millions
- ↓ 96% in Q3 to 64 millions
- ↓ 97% in Q4 to 49 millions

http://www.drugs.com/stats/plavix
http://www.reuters.com/article/2012/10/24/us-bristolmyers-results-idUSBRE89N0NL20121024
IPRs – International Aspect & Timing

- IPRs are *territorial* in nature. Time is of the essence.

- **Paris Convention**
  - Right to claim the priority of a prior application within 6 (TM/industrial designs) or 12 months (patents/utility models) (177 regions)

- **Patent Cooperation Treaty (PCT)**
  - One PCT application → reserve right to file applications in up to 152 regions
  - File, prosecute, grant and maintain *independently* in each region of interest

- **Madrid System**
  - One *existing* TM application → simultaneously seek registration in up to 115 regions
  - Save costs & procedures for individual national filings
  - No protection if, during the first 5 years, the initial TM application is finally withdrawn, refused, or the registered TM is cancelled
PCT – International & National Stage

“Priority Application”

PCT Application

Publication

National Entry

18 months

12 months

30 or 31 months

United States

Japan

Europe

Up to 152 Regions

☑️ Buy time/delay filing

☑️ Preserve priority date

Note: Countries/regions that are not members to the PCT are not covered by the PCT scheme, e.g. Taiwan, Argentina
Inventorship

• Determination of Inventorship
  – Conception of the invention or the inventive idea is established when “the invention is made sufficiently clear to enable one skilled in the art to reduce it to practice without the exercise of extensive experimentation or the exercise of inventive skill”

• Different than Ownership

• Different than authorship on scientific publication

• In the US, false inventorship with deceptive intent may render a patent unenforceable
Ownership

• Determination of ownership: the right of the patent
• Ownership is transferrable, and owners stand to sue against infringement
• HKU IP policy
Intellectual Property Rights Policy

Understanding and protecting Intellectual Property Rights (IPR) is important in order to avoid potential disputes when engaging in research and writing. HKU’s Intellectual Property Rights Policy—approved by the Council in June 2011—sets out the University’s policy on IPR for works produced at the University by staff, students and visitors of HKU.

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4. Overview

4.1 The key provisions of this Policy regarding Intellectual Property Rights of Staff, Students and Visitors are summarised below:

4.1.1 Staff

(a) The University shall own all Intellectual Property Rights in works generated by Staff in the course of their employment with the University.

(b) However, the University will normally only enforce such rights under a limited set of circumstances, including where the work was generated using a substantial use of University resources or personnel, where the work is an Institutional Work, or where the work is subject to an agreement signed by the Staff which requires the Staff to assign rights to the University or a third party.

(c) Intellectual Property Rights in works generated by Staff in the course of an exchange with another institution shall be dealt with by the mutual agreement of the two institutions in accordance with their respective Intellectual Property Rights policies. It is recommended that a formal agreement regarding Intellectual Property Rights is entered into between the two institutions as early as possible.
Ownership vs. Inventorship: Board of Regents v. Taborsky: Background

• Petr Tabosky:
  – Undergraduate chemistry and biology student at University of South Florida (USF)
  – Worked as student assistant in 1987 on project sponsored by Florida Progress Corporation (FPC) to determine if bacteria could clean clinoptilolite so that it could be reused in wastewater treatment

• Dr. Robert Carnahan
  – Dean of Research at USF overseeing the project

• After the FPC project ended, Taborsky ask Carnahan for permission to continue research on his own in hope of using it as his Master’s thesis
Ownership vs. Inventorship: Board of Regents v. Taborsky: Background

- Petr Tabosky discovered that superheating clinoptilolite to 850°C greatly enhanced its ability to absorb ammonium which is completely different from the FPC project but of potential value to FPC.

- Showed his results to Carnahan who told him “This could be worth millions” but USF was entitled to his work (Shop rights).

- In contrary, his patent attorney told him since the work is outside the scope of the FPC project it should belong to him.

- FPC offered Taborsky a job and first inventor on patent application but Taborsky was not content that the company could fire him at will.

- Tabosky therefore filed and obtained 3 US Patents 5,082,813, 5,162,276 and 5,304,365.

- Dr. Robert Carnahan left several intimidating messages on Tabosky’s answering machine demanding him to turn over his lab notebooks to USF and threatening criminal prosecution*

- Due to this pressure from Carnahan and USF, Tabosky took all his notes and notebooks and fled without even taking his final exam.

*Based on Tabosky’s account.

- What do you think would result?
Ownership vs. Inventorship: Board of Regents v. Taborsky

- Dr. Carnahan swore in a criminal affidavit that Tabosky had stolen 32 trade secrets from USF
- Tabosky was convicted of second degree grand theft and theft of trade secrets
- Sentenced to 1 year house arrest and 15 years of probation
- After patents were issued to Tabosky, USF filed additional criminal charges contending Tabosky of violating his probation by pursuing his ownership rights
- Judge told him to sign over his first patent to USF within 10 days or go to jail.
- Tabosky refused and sentenced to 3.5 years in prison
- After losing appeals, he served his sentence in 1995
- He spent two months in a maximum security state prison before transferring to a minimum security work release center and was also placed on a chain gang for part of his sentence

https://prospect.org/sites/default/files/styles/thumbnail/public/chaingangap95112101533_1.jpg?itok=CdYaf4Fd
Inventor’s Award

Whether an inventor (or a joint inventor) is named as assignee (patent owner) or not, the inventor may still be awarded by

• Sharing in the final return, if any, from subsequent commercialization of the invention via university/company policies

• Recognition through publications and presentations
Best Practices of Patent Application

• Designated personnel, “Chief IP Officer”
  – Good Communication Skills
• Do not solely rely on external counsel and attorneys
• Employment Agreement
  – Are employee inventors obligated to assign inventions to the startup company
• NDA and Confidentiality Terms
  – Sign NDA with counterparties before disclosing the invention
Startup IP Protection (Example #1)

• Entity established in 2018
• US patent application filed March 2019, allowed September 2019, and issued October 2019
• Two short-term HK patents granted in Nov 2019
• Multiple patent applications pending, including PCT
• Negotiating with potential business collaborators in several countries
• More inventions in pipeline
Startup IP Protection (Example #2)

• Research on functional nerves innervating the wall of arteries and catheters
• Over 20 patents issued in US, EP, CN, AU, SG, CA, JP, IL, KR, RU, ZA,
• Over 20 applications pending in above countries, including PCT
• Received multiple rounds of $$
• From $300K initial investment to over $300M value
Startup IP Protection (Example #3)

• Method to increase and re-introduce a specific type of cell extracted from a subject’s body for therapeutic purpose

• Ex vivo therapy

• Franchise business?
THANK YOU!

Any Questions?