



Anioplex

Patents in Business: Strategic Considerations

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Devang K. Thakor, PhD, JD
(Call me 出番!)

****Note: this presentation is only for general informational purposes.
Nothing in this presentation should be considered legal or patent advice or opinion.***

Deep tech innovation framework



University Lab

- Foundational patent generation
- Equity
- Royalties/Milestones

Startup

- Translational patent generation
- Patent usage
- Acquisition/licensing
- Value creation

Corporate

- Patent usage
- Externalized innovation
- Pipeline

Business lifecycle: Changing roles of IP



Oncology deals, 2004-2020; Nature Biotechnology volume 39, pages 1048–1054 (2021)

Early stage: fundraising and partnering

Goal

- Breadth to appeal to investors and early partners (“potential” more important than “reality”)

Strategies to consider

- “Patent early, patent broadly”
 - Establish a technology platform early, with a big footprint
 - Establish impact as a “foundational” technology for appeal
- Keep applications pending to preserve breadth
- File as early as possible with minimal invention, keep adding data (maybe only for US?)
- Get narrow claims issued quickly to generate granted IP
 - Get narrow claims issued first, then broaden in continuations
- In-license early when necessary for freedom to operate
- Patent in applicable markets
- Use patent grants for public relations (PR)

Robert Langer: “Patent early, patent broadly:”

- Institute Professor at MIT, pioneer in drug delivery and regenerative medicine
- >1,400 patents, licensed to >250 companies
- Founded >40 companies
- One of 3 scientific founders of Moderna (3.2% stake as of 2020 – Moderna market cap currently \$122B, net worth ~\$3.5b)
- Elements to deep tech venture success:
 - Start early and think big (market-driven, platform tech)
 - Patent early, patent broadly
 - Publish strategically
 - Build the team, and reward its members

Mid stage: licensing and acquisition

Goal

- Actual pipeline that appeals to licensees and acquirers

Strategies to consider

- Ensure that patent claims cover product pipeline
 - Ensure that products that licensees and acquirers want are covered
- In-license when necessary to allow scale-up, expansion of product line, and/or pivot
- Ensure that patents cover markets that licensees and acquirers operate in
- Generate new IP to build on early-stage foundational IP

Late stage: protection

Goal

- **Protect revenue-generating product line from competition**

Strategies to consider

- **Claims broad enough to prevent “workarounds”**
 - **“Build a moat”**
- **Lifecycle management (improvements to extend patent life)**
- **“Picture claims” to minimize invalidation risk**

Take-home message

- **IP plays different roles in different stages of a company's / technology's life**
- **IP strategy should consider the needs of the development stage to maximize the value provided by the IP**

Strategic Consideration

Patent or Trade Secret?

- **Trend: broad, general disclosure (and claims) in patent, keep specific details as trade secret**
- **AIA weakened “best mode” requirement (but best mode still exists!)**
- **Example: Premarin HRT patents issued in 1940s, but Wyeth was still sole supplier in 2009 (>40 years after patents expired!) because nobody else could figure out how to make it.**

IP issues in venture and partnering

- **Partnering and collaboration are often necessary for innovation**
- **However, they can lead to IP issues**

IP issue in collaboration: inventorship

Case

- Dana Farber vs. Ono Pharma et al. (also consider potential US government vs. Moderna litigation)

What happened?

- Dana Farber said that two faculty were inventors on Ono's/Honjo's PD-1 patent
- Ono says that contributions of Dana Farber faculty were too far removed for inventorship
- Federal Circuit says inventorship is to “(1) contribute in some significant manner to the conception or reduction to practice of the invention, (2) make a contribution to the claimed invention that is not insignificant in quality, when that contribution is measured against the dimension of the full invention, and (3) do more than merely explain to the real inventors well-known concepts and/or the current state of the art.
- Not necessary for each joint inventor to individually have conceived the complete invention and have participated in a particular moment of conception!
- Freeman and Wood from Dana Farber added as inventors: “Drs. Freeman and Wood’s work on PD-L1, Dr. Wood’s discovery that the PD-1/PD-L1 interaction inhibits the immune response, and Dr. Freeman’s discovery of PD-L1 expression by human tumors were significant building blocks upon which the ’474 patent is built.”
- Honjo even acknowledged Freeman as a major collaborator in Nobel acceptance speech.

Take-home message

- Consider trying to get all collaborative IP assigned to your company or at least clearly delineate IP ownership
- Consider limiting the work to be done by collaborators
- Consider all contributions when filing patent applications

IP issue when collaborating: confidential information

Case

- Sionyx vs. Hamamatsu Photonics

What happened?

- Sionyx shared CI about “black silicon” with Hamamatsu under NDA. NDA said no use of CI for 7 years, and Sionyx owns all patent rights in and arising from the confidential information.
- Sionyx says Hamamatsu used their CI in Hamamatsu’s later patents.
- Hamamatsu makes procedural arguments, e.g., statute of limitations.
- Federal Circuit says Hamamatsu’s patents are based on CI of Sionyx and not on any CI of Hamamatsu.
- Federal Circuit grants sole ownership of Hamamatsu’s patents in both US and Japan to Sionyx.

Take-home message

- Consider only concluding NDAs when it is absolutely necessary to share CI
- Be careful about IP ownership provisions, including “arising from” (this can be hard)
- Consider isolating internal innovation from external innovation to prevent contamination

IP issue when collaborating: license/sublicense rights

Situation

- Acuitas lipid nanoparticle sublicenses

What happened?

- Tekmira renamed/rebranded as Arbutus. Acuitas was started by a guy who was laid off from Tekmira/Arbutus.
- Arbutus and Acuitas had a cross-licensing deal in 2012 related to Arbutus's pre-2010 lipid nanoparticle technology.
- Acuitas then went and sub-licensed this technology to various players in the mRNA space, including Moderna and BioNTech. However, the terms of their license from Arbutus actually did not allow them to sub-license.
- Arbutus then sued Acuitas to stop them from sub-licensing to others. They got an injunction in 2017, and then Acuitas settled with them in 2018. As part of that settlement, the only sub-licenses allowed to survive were four sub-licenses to Moderna for vaccines, each limited to a specific viral target.

Take-home message

- Understand all relationships and agreements when licensing
- Consider whether to sub-license or to directly license (e.g., BioNTech directly licensed from Arbutus)

IP recent hot topic: written description/enablement

Case

- Juno vs. Kite No. 2020-1758 (Fed. Cir. Aug. 26, 2021) (also see UC vs. Broad interference)

What happened?

- Juno says Kite infringes CAR-T patent, awarded \$1.2b. Kite appeals, argues that Juno patent is invalid for lack of written description.
- Juno patent generally describes an antibody fragment (scFv) that binds to a target, but only discloses two scFVs without disclosing the amino acid sequence of either.
- Federal Circuit finds lack of written description for “any scFv for binding any target” because the patent disclosure does not give “a representative sample of species within, or defining characteristics for, that expansive genus.”
- Juno patent invalidated, jury verdict and damages reversed.

Take-home message

- Consider including a “representative” amount of species to support genus
- Consider establishing structure-function relationship to allow generalization of structural feature
- Consider including “picture” claims (if the product is specifically described in the application)

US patent prosecution insights

- **Use good local/outside counsel with subject matter expertise (not all practitioners are the same!)**
- **Consider the use of functional claims (if structure-function relationship is established)**
- **Ensure that disclosure is complete and comprehensive**
- **Collect appropriate data to support “unexpected results”**
- **Use examiner interviews**
- **Consider the use of AFCP 2.0 rather than after-final responses**
- **Consider the use of pre-appeal brief conferences when stuck**

Thank You!