

SRAI AM Presentation – A. Fong

Tuesday, Oct 29, 2024

Session T509: What Does it Really Take to Go from “Bench to Bedside” – One Small Institution’s Experience

CASE STUDY 2 – MANUFACTURER OF RADIOPHARMACEUTICAL PRODUCTION EQUIPMENT

Background

- On March 31, 2018, after 61 years of operation, the National Research Universal Reactor (NRU) in Chalk River, Ontario, was turned off and decommissioned.
- The NRU was responsible for producing about 40% of the world’s supply of medical isotopes used for diagnosis and cancer therapy, helping more than 76,000 people daily in more than 80 countries.
- The reactor has not produced molybdenum-99, which decays to technetium-99m (Tc-99m), since the fall of 2016. The production method involves the use of highly enriched uranium, which is weapons-grade.
- In the lead up to this event, researchers worldwide were scrambling to find a solution, with governments pouring money into research programs.
- In 2010 and 2012, TRIUMF received federal sponsorship funding from Natural Resources Canada to develop a solution to the impending Tc-99m shortage. The 2012 Contribution Agreement stipulated that TRIUMF (and its research partners) had to repay any “Profits” derived from the technology developed as a result of the federal funding, up to a certain percentage of the total project cost.
- It engaged 3 other research partners (2 universities and 1 cancer agency) to undertake the project and in 2016, the Consortium successfully demonstrated the method to produce Tc-99m from two different medical cyclotrons, without the need to use highly enriched uranium.
- At around the same time, to stave off competition, TRIUMF also established a start-up company, Startup Inc., with the intent of commercializing the technology.
- An inter-institutional agreement among the Consortium members was signed, providing TRIUMF with the right to engage in commercialization activities on their behalf, and contained terms relating to revenue sharing and reporting obligations.
- In parallel, the license agreement was negotiated and signed between the Consortium and Startup Inc., containing terms relating to permitted uses of the technology, IP management, license fees, milestone payments, royalties and equity (Tech A).
- Subsequent to this, a TRIUMF scientist and an engineer developed a device that could be used to produce a different medical isotope. Upon conducting IP diligence, TRIUMF was able to justify to the other Consortium members that the new technology (Tech B) was not dependent on the original technology already licensed to Startup Inc. Thereafter, TRIUMF licensed Tech B to Startup Inc. on similar terms.

- In the intervening time, to get Startup Inc. going, the TRIUMF Lead PI was appointed as the Founding CEO, with a business manager from another consortium member acting as its COO, and 2 TRIUMF engineers left to join the company.
- While all the above was developing, TRIUMF IP counsel was trying to obtain IP assignments from the inventors of Tech A and Tech B. Counsel received assignments from Tech A inventors.
- In 2018, Startup Inc. hired its first full time CEO to take the company forward, to attract investors to finance the company's operations and R&D.
- TRIUMF still had not received assignments from the Tech B inventors.
- In 2021, TRIUMF incorporated as an NFP corporation and replaced the old IP Policy with a new one, mostly to address the ambiguity and to comply with the national security requirements of the new contribution agreement from the Canadian Federal Government.
- Subsequent to the incorporation, one of the former TRIUMF engineers who left to join Startup Inc. contacted the TRIUMF ORS to inquire about share of revenues due to him and his colleague, since he was aware that the company was generating revenues. The TRIUMF CFO started to provide annual reports to these former employees. In 2022, the ORS finally concluded an assignment agreement with these former employees, but it followed the IP Policy that was in effect when they were still TRIUMF employees.
- In 2022, Startup Inc. replaced their CEO with another, and financing activities ramped up. The CEO informed the Consortium in 2023 that the company was trying to get acquired and asked if the Consortium would grant them a grace period to remit the milestone payment that was due. The Consortium agreed but still required staggered payments.
- In early 2024, the Startup Inc. CEO contacted the Consortium and informed us that the deal was getting close to being finalized. A period of 1 month, after push back from the Consortium, was given to review the acquisition documents.
- TRIUMF had to connect with its Auditors and NRCAN to determine if proceeds from sale of shares would be considered "Profit" as defined in the Contribution Agreement. After some back and forth, NRCAN invited TRIUMF to provide them with a proposed response.
- Due to research security obligations, TRIUMF also had to conduct due diligence on the acquiring company, and the result was positive.
- The deal for Startup Inc. was closed in April 2024.

The Issues:

- The question with NRCAN remains to be resolved.
- Due to TRIUMF's IP Policy, the allocation of revenues among the TRIUMF inventors for Tech A are yet to be resolved – they need to agree on what percentage is due to the named inventors and what percentage is due to contributors.

Questions for Discussion:

1. Based on the above scenario, what issues do you see arising from the various engagements?
2. What could TRIUMF have done/put in place that would have avoided the issues/conflicts?