

Case Study for COC/FCOI

University Spin-Out — *USA Diagnostics*

During December 2008, a provisional patent was filed on a new diagnostic method and genetic marker to test for prostate cancer. The diagnostic and new methodology for a test kit was disclosed by two Mitchell Cancer Institute inventors and one Washington University inventor (hereinafter referred to as P-Test). The invention was determined to be owned by USA but with multiple university inventors. From December 2008 to present, all indications were favorable that the diagnostic procedure using the unique marker is likely to outperform the present-day PSA test currently administered to millions of American males to monitor the onset of prostate cancer.

After a marketing study was completed in September of 2009 and an operability study demonstrated that there were no other patents to be considered in commercialization, USA was approached by angel investors to execute an option to license P-Test exclusively to a start-up company named USA Diagnostics. As a condition of the license, USA is to go forward with patenting P-Test, and in lieu of patent costs, own a small percentage of USA Diagnostics.

USA Diagnostics knows that additional R&D will have to be conducted on P-Test, as well as initiate additional human diagnostic studies. USA Diagnostics will be submitting an SBIR phase I proposal to NIH with significant funds to come back to MCI. The USA inventors have been offered founders shares for USA Diagnostics and to serve as Chief Research Officer and Chief Medical Officer. The WashU inventor has not been asked to serve as an officer in USA Diagnostics.

The University is filing the patent application in December 2009, is taking equity in USA Diagnostics, and has received notification that one of its inventors will choose to negotiate founders' shares, and the other will take his share of royalties earned by the university. Additionally, the University is leasing limited space in MCI to house USA Diagnostics during the critical phase of R&D development of P-Test.

The USA inventors received an ROI award in November 2009 to work on perfecting the P-Test marker for placement on a diagnostic "chip." Additionally, the USA RTC is interested in investing in USA Diagnostics as an additional source of funds for a share in P-Test.

- What are the issues of COI/COC that the University needs to monitor?
- What has to happen in the conduct of the ROI to ensure COI is appropriately managed?
- What has to happen if the SBIR grant is successful?
- How does MCI monitor where inventions are taking place (e.g. university vs. company)?
- What concerns does the University have for RTC investment in University technology companies?