

Case Study – A Lunch Start-Up

Two faculty members from Coastal Alabama University (CAU), Drs. Lim Lee (asst prof, pharm) and Sheree Hillcrest (prof, mech eng) are involved in a new business collaboration that has advanced beyond their scholarly works in their university departments.

Background: Following Dr. Lee's post-doctoral studies at NIH, he was hired by CAU in 2006. His MD/Ph.D. work at Emory involved investigations on human blood serum to find proteins that were highly correlated with the susceptibility to forming kidney stones. His work eventually led to the discovery of a single protein that was very highly correlated with kidney stone formation. Because of this discovery, Dr. Lee was very competitive in receiving a Post-doc at NIH. At NIH he furthered his studies on finding the gene(s) and promoters for the protein's development and activity. After leaving NIH for CAU, Dr. Lee did find the gene and the promoter for the protein in his lab and quickly found that he could "silence" the protein with a unique therapeutic. The gene sequence, promoter and therapeutic were patented in 2008 by CAU. Dr. Lee has received continuous funding both from NIH and National Kidney Foundation to perfect the activity of the therapeutic and find a delivery system that works more effectively than oral tablets or direct injection.

Dr. Hillcrest, a well known MEMS (micro-electromechanical systems) engineering faculty has a distinguished career developing tiny pumps and osmotic devices important in biomedical fields. Her research has been continuously funded for over 20 years by ARO (Army Research Office) and AMRID (Army Med Research Institute for Infectious Diseases). Dr. Hillcrest's latest tiny osmotic pump uses the kinetic energy of the body to keep the electric pump functioning for years. It was also patented in 2006 by CAU, and has had lots of interest from the CROs (contract research organizations) looking for an alternative drug delivery system for therapeutics typically broken down by digestive enzymes.

Commercialization: At an inventor's recognition luncheon sponsored by CAU in late 2008, Drs. Lee and Hillcrest had the chance to sit at the same table. After a few minutes discussing their inventions, they realized that there was potential for investigating the use of Dr. Hillcrest's MEMS device to deliver the kidney stone therapeutic. The two inventors scheduled a meeting with the CAU Tech Transfer director to discuss the possibilities of commercializing the technology. It was suggested that the inventors consider spinning a company out of the university based one that combined use of both innovations.

As the Lee/Hillcrest business plan was evolving, a local "Angel Investor", Caroline Cody, expressed an interest in forming a company around their innovations, and offered to provide assistance to the inventors to speed the development of an NIH SBIR application. As the self-appointed CEO, she also provided the angel funds for management, incorporation as K-Stone Technologies Corp., and to rent office space at the CAU Tech Park.

Cody negotiated an equity sharing deal with the inventors as founders of K-Stone; Dr. Lee was appointed Medical director; and Dr. Hillcrest was appointed Chief Research Officer. Equity was also provided to CAU in lieu of licensing fees and the "inventors' share" provided to the Research Technology Corporation (RTC) under the terms of the CAU Equity Policy. The technology looked to be so promising that the RTC provided pilot funds to Dr. Hillcrest's lab to

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further her work in miniaturizing a MEMS device that could deliver an annual dose of Dr. Lee's therapeutic.

Continuing their initial successes, both scientists continued to receive competitive funding to advance animal models in their labs at CAU. The animal model successes were so good that additional venture funds were attracted to K-Stone in 2009. An investigator initiated phase I clinical trial was funded by K-Stone with Dr. Lee as the trial physician at CAU Hospital. Also, the NIH SBIR project was funded at K-Stone and a subcontract was written to CAU for Dr. Hillcrest to continue her miniaturization with a graduate student and summer support.

In the process of CAU negotiating with K-Stone for the SBIR subcontract, Dr. Hillcrest submitted an updated COI/COC form as part of her wanting to perform as PI. Upon receipt of the updated COI/COC form, her department head became very uncomfortable in making a ruling as to whether the project was manageable or not with Hillcrest as the PI. The COI/COC issue was elevated to the dean's office, and the dean elevated it to the CAU COI/COC committee for comment and resolution. In the process of reviewing all of the Hillcrest's materials, the University COI/COC committee learned of Dr. Lee's pending application to the IRB for his investigator initiated clinical trial funded by K-Stone. It is not apparent from what Dr. Lee submitted to the IRB that he disclosed his financial interest in K-Stone as its Chief Medical Officer.

COI/COC considerations:

1. COI issues with funding agencies continuing to fund projects.
2. COI/COC issues with K-Stone and SBIR.
3. Open publications.
4. Sarbanes-Oxley—RTC not for profit jeopardized, fire-walled executives?
5. Data safety monitoring—IRB.
6. Coordination of COI issues between campus units (colleges, Tech Trans, Spon Prog, IRB, RTC, etc.)
7. COI management plans—How often? What is monitored and how?
8. Other issues?