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Subcommittee on Technology and Innovation

Best Practices in Transforming Research into Innovation:
Creative Approaches to the Bayh-Dole Act

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Good morning Chairman Quayle, Ranking Member Edwards, and Members of the Subcommittee. Thank you for the opportunity to appear before you today to provide testimony on the challenging, unpredictable, and oftentimes, rewarding process of moving good ideas from university labs to the marketplace. My name is Catherine Innes and I am the Director of the Office of Technology Development at the University of North Carolina at Chapel Hill. I am responsible for patenting and commercializing promising new inventions arising from our research endeavors. I know the committee is aware that the Bayh-Dole Act encourages universities to license their innovations to small businesses and the Act spurred many universities into developing programs and processes to form and support startup companies. My testimony today focuses on the implementation and success of the Carolina Express License Agreement, which is a 'one-size-fits-all' approach to licensing technologies to UNC startup companies.

Personal Background

I have more than 20 years experience in academic technology transfer at three leading US public institutions: the University of California, the University of Washington and currently, the University of North Carolina at Chapel Hill. I have licensed hundreds of technologies and been involved in licensing transactions with over 100 startup companies.

Genesis of the Carolina Express License Agreement

UNC began very modest technology transfer and commercialization activities shortly after the passage of the Bayh-Dole Act in 1980 but did not actively pursue commercialization and startup formation until the mid '90s. In the boom years that followed, some 20 companies formed, but the rate of new company formation slowed considerably between the years of 2000 and 2008.

In early 2009, UNC began internal discussions among faculty and research administrators on what could be done to stimulate and increase the volume of new companies starting around

UNC technologies and how the process could be streamlined. New company formation plays an important role in regional economic development; but even more importantly, forming a company around an embryonic technology may be the only way to move it forward into commercial applications. Many innovations arising from university research are simply too nascent and pose too many technical risks to be licensable to larger firms until more data on efficacy can be obtained. This is especially true for small molecules, biological therapeutics and other life science technologies which represent nearly 80% of our innovation portfolio. To advance inventions from UNC we need to foster a robust startup pipeline.

Historically, the licensing office at UNC, the Office of Technology Development, was responsive and supportive of startups, but deals tended to become bogged down because faculty founders were unfamiliar with the licensing process and the legal obligations surrounding intellectual property. It was also costly for new companies to pay their business attorneys to negotiate a license with the University and thus the negotiations often dragged on while necessary funds were secured to continue the process.

At Carolina, we wanted to start more companies and help them become sustainable, but we were constrained by limited financial resources and were unable to invest in these ventures. Instead, we focused on finding ways to make the license process faster, easier and more transparent so that the money a company did have could go toward getting the company up and running.

As a first step, a committee comprised of serial entrepreneur faculty members, licensing staff, general counsel and a local venture capitalist reviewed the terms of all of Carolina's previous startups to determine the range of historical royalty, equity, milestone and annual fees, at both the onset of the deal and after the deal had been renegotiated to accommodate institutional investment in the company. The committee concluded that all of our past deals had been very similar by the point of company liquidity and that the University really never had a large equity stake after multiple rounds of dilutive funding.

The committee arrived at a set of financial terms that the stakeholders agreed would be fair to all parties and would not need to be renegotiated for the company to attract financing. The financial return to the University was on the low side, but within our historic norms for early stage life science deals. The next step was to find a way to embed the agreed upon financial terms into a complete contract that all parties would agree to sign. While straightforward in principle, it can take months to negotiate terms to everyone's satisfaction.

We arrived at the final contract after only a few rounds of negotiation. What made the process work so smoothly is that three local law firms that serve as business counsel for most startups in the area agreed to work with us to develop the license. It is important to recognize that by eliminating the need to negotiate a license for each new startup these firms were forfeiting significant revenue they would have otherwise been paid. Their rationale was altruistic in part, but they also recognized that by fostering a larger and more vibrant startup community would generate long term gains that could greatly exceed any short term losses.

Features of the Agreement

The Carolina Express License is an *option* for all startups with a UNC faculty, student or staff founder if we approve of the company's management team and business plan. The same financial terms are offered to all, regardless of the technology, and the financial terms in this agreement represent the best deal available from the University.

Key license provisions include:

- No upfront license fees;
- Six month delay in obligation to begin repayment of patent costs;
- Optional payment plan to spread patent cost reimbursement over four years;
- A 1% royalty on products requiring Food and Drug Administration approval based upon human clinical trials;
- A 2% royalty on all other products;
- A cash payout to UNC equal to 0.75 percent of the company's fair market value at the time of a merger, stock sale, asset sale or initial public offering; and
- Provisions to make products available on a humanitarian basis in developing countries.

The agreement does *not* include provisions granting UNC equity in the company or milestone fees. The committee found that while most universities' start-up deals have equity provisions in lieu of cash upfront fees, it is difficult for the University to manage equity and by the time a liquidation event occurs, the University typically only holds a small amount of equity in the company. One venture capital firm analyzed historical transactions and found that on average, a university has .6% equity in their startup companies at a liquidity event. UNC arrived at the payout value and royalty terms through an analysis of our previous transactions.

The first version of the Carolina Express License provided a one year deferment for repayment of incurred patent costs. We anticipated that the companies would be able to raise sufficient funds during the first year to repay outstanding patent costs by the first anniversary of the license, but this objective proved to be overly ambitious. Many companies have had to request an extended payment schedule, which the University has granted. In the current version of the Carolina Express License companies are required to begin monthly payments towards patent costs after six months. If they are unable to pay outstanding costs in full by the end of the first year, the University will offer an extended repayment schedule in exchange for increased payout percentage.

The full text of the Carolina Express License is available on our website at http://otd.unc.edu/starting_a_company.php#CaroExLic

Implementation, Supporters and Critics

Our model was unique when first implemented because it offered the same set of terms to all startups. Many licensing professionals felt that their deals were too dissimilar to offer the same

financial terms to all or that the university should receive greater returns from its licenses. These are relevant points and questions each institution should ask in considering the implementation of a standard licensing program. The value of standard licenses is they can be put in place quickly with minimal negotiation. However, for multiple parties to agree to use the standard terms the university will likely have to offer favorable financial terms and pose no unreasonable restrictions or liabilities. If the objective is to maximize financial returns to the university a standard license is not going to be helpful.

Many licensing professionals are surprised to learn that the startup companies are willing to accept a license agreement without negotiation. The important element in our case is that the agreement is non-negotiable because it has already been negotiated. By working with the local law firms that represent nearly all of our emerging startup companies we were able to reach agreement on a set of terms that each law firm would recommend to its clients without hesitation. Without the law firms' willingness to partner with UNC on this endeavor we likely would not have been able to arrive at a standard agreement. In areas where startup companies use dozens of law firms to represent them rather than two or three, it might be very difficult to find a set of terms that all firms would accept.

It is also essential to consider whether or not you have a set of transactions that are inherently similar. UNC is predominantly licensing very early stage life science technologies and the Express License royalty terms reflect those of our past deals in this sector. We have used this license for non-life science technologies and were willing to accept that our returns for these may be lower than if we negotiated a license for each specific deal. In recent years, a number of universities and institutions around the country that have implemented standard licensing programs and several, including the NIH, that have implemented programs similar to the Carolina Express License.

Results to date

In the two and a half years since program inception, UNC has launched 19 startup companies around intellectual property; all but three used the Carolina Express License. The vast majority, 79%, of these companies have formed around life science technologies.

Prior to implementation of the Express License, we were starting 3 companies per year, on average. For the past two and a half years we have started 7-8 companies per year, more than doubling our historical average. At this time, all 16 Carolina Express companies are still in existence, though most are struggling with fundraising. One of our companies has attracted institutional seed funding and several others have received loans from the regional small business development entities, or leveraged the SBIR and STTR programs.

Summary

We have learned through this process that most of our companies are having trouble finding sufficient funding to support payment for patent costs so the University must carry expenses

for three or four years rather than the one year we originally anticipated. This is straining our internal resources, but we believe starting companies is important and we must continue to find new ways to support this effort.

UNC has invested in a program called Carolina KickStart to improve the probability of successfully commercializing the intellectual property developed at UNC faculty by assisting faculty in the business planning process, building liaisons with industry, identifying stage-appropriate funding, educating faculty about the commercialization process, and incubating companies spinning out of UNC. Carolina KickStart is part of the NC Translational and Clinical Sciences (NC TraCS) Institute, the academic home of the NIH Clinical and Translational Science Awards (CTSA) at UNC.

In addition, UNC has launched the Innovate@Carolina Campaign to implement the next generation of cross-campus entrepreneurship initiatives. The $125 million campaign seeks to make Carolina a world leader in launching university-born ideas for the good of society. Key initiatives of the campaign include: seed funding for the most promising innovations on campus; entrepreneurs-in-residence to mentor and counsel students and faculty involved in entrepreneurial ventures; Innovation Professorships; a student Innovation Hub; an Innovation Scholars Program; and the expansion of the Carolina KickStart program among other initiatives.

I strongly believe that a standard licensing program can work for universities, particularly for licenses to university startups. For these programs to be successful, the university must be willing to settle for a fair deal rather than the most lucrative deal and establish criteria for when the standards can be used and when they cannot. It is essential for the university to gain the support and buy-in of those negotiating on behalf of the startups as they must be willing to forfeit payment for negotiating multiple deals with the university for the benefit of the program and the opportunity for a greater volume of business in the future.

Thank you, again, Mr. Chairman and Subcommittee Members for the opportunity to appear before you today. I stand ready to answer any questions you may have.

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Catherine Innes joined UNC in 2005 and manages the 13 member Office of Technology Development at UNC Chapel Hill and is responsible for all aspects of managing and licensing the intellectual property owned by the University. Prior to this role, Catherine spent 14 years in the technology transfer offices at the University of Washington and the University of California. She has a BS in Industrial Engineering and Operations Research from the University of California at Berkeley and spent ten years in business development and engineering roles in aerospace and computer industries before joining the field of academic technology transfer.

Catherine currently serves on the Contracts and Intellectual Property Committee for the Council on Government Relations (COGR) and has previously served on the board of trustees for the Association of University Technology Managers (AUTM) as Vice President for Communications. She is also active in the Biotechnology Industry Organization (BIO) and is a member of the Licensing Executive Society (LES). She is a frequent speaker on intellectual property management and licensing issues at conferences and events throughout the country and internationally.

Her publications include: *AUTM Educational Series No. 4: Copyright Protection of Software, Multimedia and Other Works: and Author's Guide,* with Charles C. Valauskas; *AUTM Educational Series No. 5: Development and Deployment of Digital Works in Universities: A Guide for Authors and Licensing Officers,* with Charles C. Valauskas; and *AUTM Educational Series No. 6: Academic Technology Transfer: Driving Public Use of University Research Results,* with Howard Bremer and Christopher McKinney.