NEW YORK STATE SCIENCE & TECHNOLOGY LAW CENTER

THE CAROLINA EXPRESS LICENSE AGREEMENT

WORKING DRAFT 2010

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I always like to put conclusions first. I think the Carolina Express License Agreement (CELA) is an important advance in launching university spin-off companies which, in turn, will stimulate regional economic growth and create new jobs. I would suggest that NYSTAR endorse the CELA and recommend its adoption at universities and research institutions in New York State.

As I read the CELA, the central provisions are the following:

- CELA eligibility
  - Only spin-off companies founded by UNC faculty, staff and students; and
  - Only intellectual property rights owned by UNC.

- CELA execution procedures
  - Required document submissions
    - Detailed business plan;
    - Completed conflict of interest review;
    - Acknowledgement of UNC's rights to IP and contract fee; and
    - Inventor statement regarding student employment, publication of research results and alteration of research direction.
  - Business Plan review committee members: the project manager from the technology transfer office (TTO), a faculty member from the UNC business school, the chair of the founder's/inventor's department, and the director of a non-profit biotech industry association;
  - The TTO and review committee will endeavor to complete the entire process within two weeks.

- CELA management and communications
  - Single points of contact in TTO (project manager) and company (CEO or designee, not faculty founder);
  - TTO project manager assists company in
    - Collecting documents for due diligence;
    - Interfacing between UNC and company;
    - Handling IP matters related to company sponsored research; and
    - Verifying company is in good standing under the license.

- Patent prosecution procedures
  - Patents filed and prosecuted by UNC;
  - PTO correspondence sent to TTO with copy to company;

- Company may communicate with patent counsel directly, but patent counsel may not take action without instructions from TTO;
- Company may not retain patent counsel for other services; and
- TTO will defer to company in patent prosecution decisions so long as there is no conflict with UNC.

- Patent prosecution costs
  - Patent attorney invoices sent directly to UNC;
  - UNC forwards invoices to company for reimbursement on monthly basis; but
  - Company not required to reimburse patent costs until one year after effective date of CELA;
  - Failure to pay invoice amounts is a material breach of CELA; and
  - TTO will honor requests to file new patent applications, if company is not in arrears in reimbursement of patent costs.

- Business plan review criteria
  - Organization plan
    - Type of legal entity;
    - Industry/academic advisors; and
    - Management team.
  - Market opportunity
    - Market needs, size, competitive advantages, barriers to entry;
    - Product development status; and
    - Business model.
  - Risks and Milestones
    - Technical, regulatory, competition risks;
    - Risk levels and variables; and
    - Contingency plans to deal with risks.
  - Development and finance plan
    - Timeline to first commercial sale;
    - Current technical capabilities and future needs;
    - Current facilities and future needs;
    - Partnering and recruitment plans;
    - Budgets and cash flow (operational and capital) for 3-5 years;
    - Current sources of funding, and future funding needs and plans; and
    - Exist strategy for company and investors.
  - Milestones
    - Management team in place by ______;
    - Financing in the amount of ______ by ______;
    - Product development stages
      - Prototype by _____;
      - Testing by _____;
      - Regulatory approvals by _____;
      - Manufacturing or fabrication facilities by _____;
      - Commercial sales by _____.

- CELA payments
    - Running royalties on net sales for clinically-approved (FDA) products = 1.0%;
    - Running royalties on net sales for other products = 2.0%;
    - Sublicensing payments
        - 10% on sublicensing revenue; and
        - 20% on sublicensing royalty revenue.
    - A contract fee of .075% of company fair market value at the time of the first liquidity event (IPO, asset sale, merger or acquisition; and
    - Annual CELA maintenance fees
        - Clinically-approved products = $15K years 3-6 and $30K thereafter; and
        - Other products = $5K years 3-6 and $10K thereafter.

The CELA is a commendable effort to streamline the formation of university spin-off companies by greatly reducing the time and cost of license negotiations. In doing so, UNC clearly prioritizes new company formation and regional economic development over maximizing its licensing revenue. This was a key point in the New York Task Force Report. The requirement of submitting a detailed business plan as part of the CELA procedure is also a good idea. One big problem with faculty founders/inventors is that they often have very little understanding of business and of how to move an invention from the laboratory into the market. The business plan requirement will force faculty founders/inventors to, at least, begin to think about the management, financial, market, regulatory, intellectual property and competition challenges that lie ahead for a new company.

Other provisions of the CELA that I think are also particularly noteworthy include the single point of contact in the TTO to assist the company, the commitment to completing the business plan review within two weeks, the relatively low running royalty rates that can be absorbed by a start-up company without constraining its investment in further R&D and marketing, the one year grace period before paying any patent prosecution costs, and the very reasonable contract fee of .075% of the company's value at the time of the first liquidity event. All of these provisions not only greatly increase the spin-off company's chances of success, they also make the spin-off company a much more attractive investment opportunity for seed-stage and venture investors.

However, I think there are a few shortcomings in the CELA. First, although the CELA can only be used by UNC faculty, staff and students, it is not clear that these folks have the right of first refusal in the event they desire to start a spin-off company and a large, established company also desires to license the technology. Providing a right of first refusal to university faculty, staff and students would definitely move the university further toward an economic development model and away from a revenue maximization model. On the other hand, as noted earlier, faculty, staff and students coming from technical backgrounds may have little understanding of what it takes to build a company. Providing business advisory services, or, ideally, interim management personnel would be extremely helpful to a spin-off company at this early point in time.

Although the one year grace period for paying patent prosecution costs is better than requiring payment of these expenses upfront at the commencement of the CELA, I think there may be many instances in which the spin-off company is unable to reimburse these expenses even after one year. The CELA appears to anticipate this situation by referring to a company that is in a "deferral" period. Patent prosecution costs can pose a major problem for both start-up companies and universities. I don't think there are any easy answers to this problem, but an interesting suggestion was made to me a year or so ago by an entrepreneur who is building a very successful company in New York. The suggestion was for the State to put together a pool of patent law firms that would be willing to provide patent prosecution services to start-up companies at significantly discounted hourly rates, say 50% - 60% of their standard hourly rate. In return, the company would agree to pay their standard hourly rate, plus some interest factor, at the time of the company's first liquidity event. A variation on this arrangement would be for patent firms to discount their hourly rates even more steeply, say 70% - 80%, and take a lien on the patents as a security interest for full payment at standard hourly rates at the first liquidation event.

I have three reservations regarding the acceptance of the CELA at New York State universities and research institutions:

- How many would be willing to accept running royalty rates in the 1% - 2% range?
- How many would be willing to grant licenses to relatively high risk, spin-off companies if relatively low risk, established companies are available to take the licenses?
- How many would be willing to defer recovery of patent costs in licensing spin-off companies if established companies are available to pay the patent costs upfront?

Finally, I would note that even though this is a streamlined, express license agreement, the actual license document is still 29 pages long and full of legal details. For some reason, lawyers are not able to write short, simple, concise contracts.