Innovative Programs in Technology Transfer: An Overview of Cedars-Sinai’s Technology Transfer International Program and Its Complementary Diagnostic Development Unit, 3rd Street Diagnostics

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1. Introduction

Technology transfer offices at nonprofit academic medical centers face many challenges in their mission to protect and commercialize the intellectual property developed at their institutions. To address these challenges and ultimately improve the quality of life for patients around the world, the Technology Transfer Office (TTO) of Cedars-Sinai Medical Center, a California nonprofit public benefit corporation, has initiated two innovative and complementary programs.

The first of these programs is the TTO’s International Program, which focuses on building partnerships with institutions outside the United States to expand technology transfer globally. The program’s goals center on exchanging best practices with its international peer organizations, accessing global markets and identifying opportunities for investments.

In conjunction with the International Program’s technology transfer efforts, the TTO has also initiated a complementary program that harnesses valuable diagnostic technologies from both Cedars-Sinai and its partners to develop such diagnostic assets into commercial products. This diagnostic development unit, otherwise known as 3rd Street Diagnostics, is a direct response to the need for academic institutions, such as Cedars-Sinai and its international partners, to personalize medicine by addressing the commercialization potential of a growing portfolio of biomarker-based diagnostic technologies that may alone not be candidates for typical technology transfer through licensing or spin-off companies.

This article aims to provide an overview of the TTO’s International Program and an analysis of the legal considerations in developing its complementary program, 3rd Street Diagnostics, a commercially-minded diagnostic development unit of Cedars-Sinai.
2. Overview of Technology Transfer at Cedars-Sinai

Established in 1902, Cedars-Sinai is one of the largest nonprofit academic medical centers in the United States, with 886 licensed beds, 2,100 physicians, 3,000 nurses and thousands of other healthcare professionals, staff and volunteers. Cedars-Sinai’s mission is to provide the highest quality patient care, expand scientific and medical knowledge through biomedical research, educate and train healthcare professionals for the future and improve the health status of its community.

Translational research is central to the Cedars-Sinai enterprise, with its scientists and physicians working to accelerate the transfer of medical advances from bench to bedside, so that patients around the world are able to lead healthier and longer lives. Cedars-Sinai’s strong research and academic standing puts it among the top independent hospitals in funding from the National Institutes of Health (NIH) with research expenditures in fiscal year 2016 totaling to $144 million USD. Currently, there are more than 1,500 research projects underway in cardiac care, cancer, digestive health and neurosciences, among other areas.

Through its history, Cedars-Sinai’s commitment to innovative clinical care activities and research has resulted in many discoveries. The Swan-Ganz catheter is one such example. Invented by two doctors at Cedars-Sinai in 1970, it is a pulmonary artery catheter that is still in use today. This extraordinary innovation also represents a missed opportunity for Cedars-Sinai. With no technology transfer office and limited understanding of the market, Cedars-Sinai’s inventors sold their rights to the device to a third party for $10,000 USD. As such, none of the hundreds of millions of dollars in revenue generated by the device made its way back to Cedars-Sinai for the inventors. As a response, Cedars-Sinai developed its Patent and Invention Policy (Patent Policy) and established its TTO to protect and support the commercialization of the Medical Center’s discoveries and technologies. These efforts were immediately rewarded through the TTO’s successful management of its first invention, a method for removing viruses (such as hepatitis) from blood, which generated an annual royalty income of more than $1 million USD per year.

In its current form, the TTO supports the intellectual property (IP) protection and commercialization of the inventions and discoveries from Cedars-Sinai’s researchers and clinicians. In such efforts, the TTO captures new technologies, evaluates whether the technology has enough public or market value to warrant IP protection, secures such IP protection and commercializes the technology through either licensing or the creation of a spin-off company. The TTO currently manages a portfolio of more than 400 diverse technologies, ranging from therapeutics, medical devices, diagnostics and software. In fiscal year 2016 alone, the TTO captured 99 new inventions, signed 10 new licenses to further develop discoveries and generated $30.5 million USD in royalty income, which is subsequently invested back into the Medical Center’s research programs to continue the development of new inventions.

3. Overview of Cedars-Sinai’s International Program

Cedars-Sinai’s TTO has long recognized that it increases its opportunities to bring innovative medical solutions to patients around the world by forming partnerships with researchers and institutions internationally. The International Program first originated in 2000 through Cedars-Sinai’s research collaborations with Central and Eastern European hospitals and academic research institutions. As part of Cedars-Sinai’s charitable mission of education, the program provided operational support, education and strategic direction for the biotechnology research and development activities of these Central and Eastern European institutions.
From its origins as a technology transfer educational program in Eastern Europe, the International Program has matured into a full-fledged division of the TTO with an expanded network of 50 active partners from around the globe, including those in Australia, Hong Kong, Singapore, Spain, South Korea, the United Kingdom and Uruguay. Through innovative partnership models, the scope of the International Program has grown beyond education and adds accessing global markets, finding resources to develop technologies and identifying opportunities for investment to its expanding list of goals. Through international collaboration, the TTO’s International Program aims to work together with its international partners to develop and enhance each other’s technology transfer efforts with the common goal of maximizing technologies for the benefit of patients worldwide.

One of the key benefits of the TTO’s international activities is the ability to access the intellectual property portfolio assets of its international partners. The TTO has received unique inventions and discoveries including novel drugs, medical devices and diagnostics in areas that complement Cedars-Sinai’s IP portfolio. Having access to these technologies enhances Cedars-Sinai’s IP portfolio beyond its own research enterprise and can result in collaboration projects where Cedars-Sinai works with its partners to create packages of technologies to increase commercial viability, assist its partners in marketing the technologies in the United States or provide Cedars-Sinai with opportunities to invest in or co-develop a technology.

One specific area in which the TTO’s international partners have been uniformly contributing technologies to supplement Cedars-Sinai’s intellectual property portfolio has been in the area of diagnostic technologies. This flow of diagnostic technologies from the TTO’s international partners came about at the same time as the emergence of another innovative program within Cedars-Sinai’s TTO—3rd Street Diagnostics—a commercially focused diagnostic development unit of Cedars-Sinai. The TTO’s establishment of 3rd Street Diagnostics and its complementary activity with the TTO’s International Program has led to unique and interesting challenges for the TTO’s in-house counsel team to consider.

### 4. Overview of 3rd Street Diagnostics

3rd Street Diagnostics is a diagnostic business unit within Cedars-Sinai that will be developing and commercializing diagnostic, prognostic, and other personalized medicine tests. With the current market push towards personalized medicine (which has received renewed attention from patients, healthcare providers, scientists and diagnostic and pharmaceutical companies in efforts to make healthcare costs more sustainable and improve treatment outcomes), the need for the commercialization of personalized medicine tests is strong.

Playing a critical role in personalized medicine, biomarkers are biological measurements that can be used to predict risk of disease, to enable early detection of disease, to improve treatment selection and to monitor the outcome of therapeutic interventions. Academic medical centers, like Cedars-Sinai and many of its international partners, play a pivotal role in biomarker discoveries and validation. In addition, these academic institutions assist in the development and adoption of diagnostic tests through their translational and clinical research capabilities, implementation of research, and education of health professionals and the public.

As previously mentioned, translational research is a core part of Cedars-Sinai’s mission as a nonprofit academic medical center, and as such, it strives to maximize its technologies for the benefit of society. However, while promising biomarker discoveries and related new inventions are being developed at academic institutions such as Cedars-


Sinai and its international partners, such technologies on their own may not be candidates for typical technology transfer through licensing or spin-off companies due to challenges these diagnostics technologies face with respect to patent protection or market conditions. To address these concerns, Cedars-Sinai and its TTO developed 3rd Street Diagnostics, a diagnostic development unit of Cedars-Sinai, that will evaluate, in-license, commercially develop and market innovative diagnostic tests and services based on these discoveries and related new inventions to maximize the value of these technology assets for patients worldwide.

Because the TTO does not have the infrastructure or capability to operationalize 3rd Street Diagnostics on its own, the unit intends to perform all test development with an affiliated contract research organisation that has Clinical Laboratory Improvement Amendments (CLIA) and College of American Pathologists (CAP) certified labs. Initially, 3rd Street Diagnostics aims to develop tests in the areas of oncology, gastroenterology and rare disorders based on validated biomarker discoveries, primarily focusing on utilizing deoxyribonucleic acid (DNA) sequencing, ribonucleic acid (RNA) expression, single and multiplex protein based assays and cell based tests as technologies to develop these diagnostic tests. 3rd Street Diagnostics sources its diagnostic product candidates not only from Cedars-Sinai’s own IP portfolio, but also from those of its international partners who face the same challenges in commercializing diagnostic technologies. Ultimately, 3rd Street Diagnostics intends to sell and distribute diagnostic test kits and services in the United States and foreign markets through distributors and strategic collaboration with qualified international labs and the TTO’s international partners.

5. Legal Considerations for 3rd Street Diagnostics

Setting up 3rd Street Diagnostics required Cedars-Sinai’s TTO and its legal team to transition from operating as a department with traditional academic technology transfer concerns and begin thinking more commercially. As such, the TTO and its legal team needed to address the legal considerations and documentation that 3rd Street Diagnostics would require in order to become a fully operating business unit of Cedars-Sinai. These considerations included how to brand the diagnostic development unit, how to engage consultants and development partners, how to interact with the TTO’s international partners and how to funnel new diagnostic technologies into 3rd Street’s development pipeline.

5.1 Establishing 3rd Street Diagnostics and Building Its Brand

A. Choosing a Name

A core component of any new business endeavor is its name and brand. Once the TTO made the final decision to initiate a diagnostics development unit, the question arose of what to name it. The name needed to be identifiable, distinct and recognizable, but also general enough to be relatable and easily memorable. Thoughts were given towards having the unit’s name connect with Cedars-Sinai’s name and brand in some way, but ultimately, since the diagnostic development unit is intended to be a commercially facing entity, it seemed best to give the unit its own separate identity. Thinking of possible connections to the TTO that are not overtly connected to Cedars-Sinai, the TTO thought of 3rd Street Diagnostics, as the TTO is located on 3rd Street in Los Angeles, California.

Subsequently, the TTO’s legal team ran a thorough trademark search using the Trademark Electronic Search System of the United States Patent & Trademark Office (USPTO) to determine whether any entity had registered the name “3rd Street” in connection with a diagnostics company. With no results relating to 3rd Street and diagnostics on the USPTO’s trademark database, the TTO’s legal team then investigated whether there were any potential companies at all that could be using the name 3rd Street
in connection with diagnostics. Using publicly available search engines, the TTO found no such results, affirming its decision to move forward in titling the TTO’s diagnostic development unit as 3rd Street Diagnostics.

**B. Establishing a Fictitious Business**

Having 3rd Street’s name chosen, the TTO then began its next steps to formally establish 3rd Street Diagnostics as a business unit of Cedars-Sinai. To do so, it needed to register 3rd Street Diagnostics as a fictitious business, also known as a DBA. In California, any person or company doing business for profit under a fictitious name must register as a fictitious business with the state in order to protect those dealing with individuals or partnerships doing business under fictitious names. By requiring businesses operating under fictitious names to register with the state, those doing business with such fictitious businesses have transparency in knowing the identities of persons doing business under fictitious names.¹

There are also benefits for the registrant to formally register a fictitious business name. In California, filing a fictitious business name gives the registrant the “exclusive right to use as a trade name the fictitious name, as well as any confusingly similar trade name, in the county in which the statement is filed, if the registrant is the first to file such a statement containing the fictitious business name in that county, and is actually engaged in a trade or business utilizing such fictitious business name or a confusingly similar name in that county”.² As such, in filing 3rd Street Diagnostics as a fictitious business name, Cedars-Sinai and its TTO would have the exclusive right to use 3rd Street Diagnostics as a trade name in Los Angeles County, California.

**5.2 Consulting Agreements**

Because the TTO does not have the expertise, equipment and facilities to fully operationalize 3rd Street Diagnostics within Cedars-Sinai itself, 3rd Street Diagnostics currently relies on working with external consultants to enable it to assess, develop and market diagnostic product candidates. The TTO engages these consultants through fee-for-service consulting arrangements in which 3rd Street Diagnostics retains any and all intellectual property rights to a consultant’s work product. To date, these consultants consist of strategy experts, commercialization specialists, reimbursement professionals, and most importantly, a contract research organisation (CRO) that specializes in diagnostic technologies and contains its own CLIA/CAP certified laboratories.

3rd Street Diagnostics works with its CRO in two separate phases. The first phase focuses on product gap assessments, and in the second phase, 3rd Street Diagnostics works with the CRO to develop a product development plan, which includes a budget, timelines and an analysis of the other required resources for the diagnostic product development for the selected diagnostic technology.

During the first phase of the engagement with the CRO, 3rd Street Diagnostics works with the CRO on a periodic basis to review and assess the diagnostic technologies and their commercial viability. This assessment involves an analysis of scientific rationale, validation data, market size/segment, patent protection, regulatory concerns and reimbursement factors. These technologies may be from Cedars-Sinai’s own intellectual property portfolio or from those of its international partners. Currently, there are roughly a dozen diagnostic technologies that are being assessed as diagnostic product candidates,

² Id. § 14411
with approximately half of those technologies coming from the TTO’s International Program and its international partners.

If, after completing the first phase assessment, 3rd Street Diagnostics finds that a certain technology has potential to become a diagnostic product candidate, 3rd Street then engages with the CRO to collaboratively develop a product development plan, which includes a detailed analysis of the technology and provides an evaluation and recommendation regarding the specific technology’s methodology, process and market opportunities, including whether there are any potential competing technologies. The detailed analysis of the technology further provides a detailed development and commercialization proposal for the diagnostic technology, including without limitation, a budget, timeline and material requirements for the development of the technology to CLIA standards.

While 3rd Street’s consulting agreements typically contain standard terms and conditions that would be found in any template consulting agreement, due to the nature of 3rd Street’s relationship with its international partners, the consulting agreement with 3rd Street’s CRO does contain specific provisions to protect the interests of both 3rd Street and its international partners. First, 3rd Street requires the CRO to maintain the confidentiality of not only its own intellectual property, but also that of its international partners. Second, to protect its pipeline of diagnostic technologies provided by its international partners, 3rd Street requires the CRO to acknowledge Cedars-Sinai’s proprietary business relationships with its international partners and agree not to utilize any technologies for the organisation’s direct private benefit without 3rd Street’s express written consent. 3rd Street also asks that the CRO avoids engaging in any business involving the diagnostic technologies provided by 3rd Street in competition with 3rd Street or Cedars-Sinai’s business interest, in order to prevent any disruption with 3rd Street’s business relationship with the TTO’s international partners.

5.3. Confidentiality Agreements

As discussed, several of the diagnostic product candidates reviewed by 3rd Street Diagnostics come from the TTO’s International Program and its international partner institutions. The manner in which these diagnostic technologies are shared with 3rd Street Diagnostics for review are through confidentiality agreements. This is because confidentiality agreements are fairly standard agreements with uniform standard terms and conditions regardless of industry, type of entity or where such entity may be geographically located. These confidentiality agreements tend to have a broad scope to cover multiple facets of the relationship between Cedars-Sinai and the partner institution, including the exchange of technologies between the institutions for 3rd Street Diagnostics. These agreements also have a longer duration of five to seven years, in contrast to the TTO’s standard one-year term length for its confidentiality agreements with potential licensees. In addition, because 3rd Street Diagnostics relies on consultants to assess and develop its diagnostic product candidates, it is crucial that 3rd Street has the flexibility to provide the confidential information of the TTO’s international partners to 3rd Street’s consultants, provided that such consultants are bound by similar covenants of confidentiality. Going one step further, in its confidentiality agreements with international partners, 3rd Street will often incorporate a provision that allows it to share an international partner’s technologies with another international partner to leave open the possibility of technology co-development with multiple international partners should the opportunity arise. Incorporating these concepts into its confidentiality agreements with the TTO’s international partners creates an open working relationship to facilitate 3rd Street’s goals to maximize these technologies commercially.
5.4. Options & Licensing

After assessing and evaluating the commercial opportunity of the diagnostic technologies in its portfolio, in the event that 3rd Street Diagnostics determines that it desires to pursue the product development of a diagnostic technology from one of its international partners, 3rd Street’s goal is to exclusively license such diagnostic technology from its international partner.

To date, 3rd Street has expressed interest in a couple diagnostic product candidates—one being an internal Cedars-Sinai technology and the other being an external technology from one of the TTO’s international partners in Europe—with both in the field of oncology. While 3rd Street does not require a license to develop its own internal technologies owned by Cedars-Sinai, it does require a license to commercially develop the technologies of its international partners. For this particular technology from a European partner, 3rd Street Diagnostics successfully executed an exclusive option for an exclusive license to such diagnostic technology. Taking an exclusive option to the technology before executing an exclusive license allows 3rd Street to secure the rights in the technology, while also providing it with some flexibility in being able to continue further evaluating the technology’s market potential without being obligated to commercially maximize the technology, as would often be required under any standard academic license. Executing an option also allows 3rd Street to ask the international partner institution to perform further research with its support to validate the technology to solidify its commercial potential, which in turn allows the international partner and its inventors to continue research activities with respect to the technology in collaboration with 3rd Street.

Unlike other commercial entities, 3rd Street sees licensing or optioning a technology as an opportunity for partnership between 3rd Street Diagnostics and its international partner. Although 3rd Street takes the commercial lead in developing the diagnostic asset, it encourages its international partner to remain actively involved in the technology’s development, whether it be through working closely with the inventors or conducting joint research efforts with respect to the technology. Having such a collaborative relationship with its licensor international partner helps to ensure the technology’s success and the international partner’s participation in such success.

6. Conclusion

As exemplified by its International Program and 3rd Street Diagnostics, Cedars-Sinai, fueled by its charitable mission, aims to find creative and innovative paths to maximize the value of its technologies for the benefit of society.

Looking to the future, Cedars-Sinai anticipates that the efforts of the International Program will continue to expand into finding new ways to enhance the value of technology through international collaboration, including through its role in supporting the efforts of 3rd Street Diagnostics.

These dynamic initiatives provide the TTO’s legal team with unique and interesting opportunities to challenge itself beyond standard academic licensing, including developing technology co-development models with an international partner, having to think like a licensee when in-licensing an international partner’s diagnostic asset, or, in the event that 3rd Street Diagnostics is able to get a product on the market, thinking about distributor and strategic partnership agreements with international labs to produce diagnostic products.

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Cedars-Sinai is one of the largest nonprofit academic medical centers in the United States with 886 licensed beds, 2,100 physicians, 3,000 nurses and thousands of other healthcare professionals and staff. Cedars-Sinai has evolved to meet the healthcare needs of one of the most diverse regions in the world, continually setting new standards in quality and innovation in patient care, research, teaching and community service. Clinical programs range from primary care for preventing, diagnosing and treating common conditions to specialized treatments for rare, complex and advanced illnesses. Renown for transforming healthcare for the benefit of its patients, Cedars-Sinai is a leader in the clinical care and research of heart disease, cancer and brain disorders, among other areas. Pioneering research achievements include using cardiac stem cells to repair damaged hearts, developing minimally invasive surgical techniques and discovering new types of drugs to target cancer more precisely.