

Patients, Chemists *and* Patenting Professionals JOIN UP

By Randolph Fillmore



Photography: Ray Reyes

PARTNERSHIP AIMS TO FIND COMPOUNDS THAT INHIBIT CANCER CELLS

“We all know that a goal in cancer research is to move discovery from the ‘bench to the bedside,’ but today’s efforts at drug discovery are more likely to start at the bedside where patients donate tissue for research carried out at the scientist’s bench.”

~ Moffitt medicinal chemist Nicholas Lawrence, Ph.D.

“The long and winding road ...” is a familiar lyrical statement about love, life and waiting recorded by The Beatles almost 50 years ago. But that lyric could also apply to the long and circuitous route traveled by Moffitt scientists to bring new and effective cancer drugs to the patient’s bedside. Uncountable hours are spent in the laboratory learning new things by testing huge libraries of compounds on cancer cells to observe their effects.

Getting a patent for a compound that may be the foundation for a new cancer drug begins in the medicinal chemist’s laboratory. After “proof of concept” has been established through a variety of experiments and once a real discovery has been made — but long before the clinical trials of a new drug begin — the “long and winding road” from discovery to the patient’s bedside begins with the patenting process.

When a Moffitt scientist makes a “disclosure” to Moffitt’s Office of Innovation and Industry Alliances on the discovery, the Innovation Office initiates a complicated and exacting process that culminates in the patent application. Fortunately, Moffitt has a team of professionals who guide a promising discovery along its patenting and commercialization journey from the “bench to the bedside.”

INVENTIONS MUST BE PATENTABLE AND MARKETABLE

“Before filing a patent application, we need to make sure that the new discovery is patentable and marketable,” explains Praba Soundararajan, Ph.D., a registered patent agent in Moffitt’s Innovation Office. He is responsible for assisting in patenting Moffitt’s intellectual property. “Some inventions may be patentable but not marketable, or marketable but not patentable. At the beginning of the patenting process, we determine how new and different an invention may be in light of prior patents.”

It may take many years for a discovery to finally find its way to the clinic as a new drug, Dr. Soundararajan explains. Once the “newness” and the claims about the discovery have been hammered out, the Innovation Office files a patent application at the U.S. Patent and Trademark Office in Washington, D.C., where the patenting process may take several more years.

Since Moffitt’s Innovation Office was established in 2003, Moffitt has had 445 disclosures, filed 332 patent applications and received 53 patents. In recent years, the rate at which Moffitt scientists make disclosures and receive patents has escalated.

Dr. Soundararajan, who hails from Pondicherry, India, the same city from which the movie “The Life of Pi” originated, earned his Ph.D. in neuroscience from Dalhousie University in Halifax, Canada. He began his career as a stem cell scientist investigating the disease mechanisms of amyotrophic lateral sclerosis (ALS), often called “Lou Gehrig’s disease.” A few years ago, he made the career-changing decision to become a registered patent agent, which required taking intensive courses and passing a rigorous examination. As a U.S. Patent and Trademark Office registered patent agent, he came to Moffitt in 2014.

After a scientist achieves a breakthrough in the lab, is the long wait for the patenting process to be completed a little frustrating?

“Yes,” says Moffitt medicinal chemist Nicholas Lawrence, Ph.D. “But we are well positioned at Moffitt to have a high chance of not only getting a patent on our discoveries, but also getting the discovery to the clinic and to the patient’s bedside. The process of delivery for new medicines is slow. There’s a lot of testing to ensure that drugs are safe and work well. This simply takes time.”



Dr. Lawrence, originally from the West Sussex city of Chichester, England, received his Ph.D. in organic chemistry from Cambridge University. Before coming to Moffitt in 2004 and joining Moffitt’s Drug Discovery Department, he worked with scientists at The Paterson Institute for Cancer Research, part of the University of Manchester in England. His wife, Harshani Lawrence, Ph.D., also was recruited in 2004 and serves as staff scientist in the Chemical Biology Core facility at Moffitt.

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Medicinal chemists at Moffitt work closely with their biologist colleagues who identify proteins related to the mechanisms of cancer development. Once these proteins are identified, the chemists begin looking for compounds that can inhibit cancer cell growth, which may involve discovering and defining complicated biological pathways and genetic “switches” related to cancer.

PATIENCE, KNOWLEDGE AND LUCK

To discover compounds that are active against the mechanisms of cancer, medicinal chemists and their colleagues need patience, perseverance and knowledge, along with a dose of luck, Dr. Nicholas Lawrence says. In the search for compounds that inhibit cancer cell development and growth, scientists test thousands of compounds against established cell lines of cancer to determine their effect, if any.

While the success of the drug discovery scientist includes an element of luck, the work of the patent agent is more like detective work, says Dr. Soundararajan.

“Preparing a patent application is more like the work of a Sherlock Holmes,” he says with a smile. “Whether we are investigating the possibility of patenting a drug, a diagnostic, a medical device or intellectual property, we have to thoroughly search through what is already out there to confirm that our find is unique.”

WITH PERSEVERANCE, HOWEVER, THE DISCOVERIES ARE MADE.

For example, Dr. Lawrence focuses much of his work on developing new anti-cancer agents that can be targeted to inhibit cancer cells. Among his recent investigations is work aimed at finding compounds that inhibit the activation of STAT3, an important regulator of many biological processes.

“STAT3 is a signal transducer. It’s like a protein switch that can turn on cancer cell growth and is implicated in a great number of different kinds of cancers,” Dr. Lawrence explains. “We developed, along with our co-workers in Moffitt’s Drug Discovery Department, a compound that can inhibit STAT3 activation, and the compound was patented in 2012.”

The best outcome is that a compound receives patent approval and that Moffitt’s Innovation Office finds industry partners to license and develop the compound into a drug. With help from the Innovation Office, Moffitt’s patented compound that successfully inhibited STAT3 in laboratory experiments will be licensed to a pharmaceutical company. Then the company will further work with the compound to develop a therapy that can move the discovery into clinical trials to show safety and efficacy.

Another Moffitt-patented, highly potent, multi-targeting inhibitor developed in Dr. Lawrence’s lab recently was licensed to Aptose Biosciences for developing a new therapeutic for



PRABA SOUNDARARAJAN, PH.D.

targeting underlying mechanisms of cancer. The small molecule agent originally developed by a team of Moffitt scientists inhibits a protein family that targets both genes and specific enzymes that regulate cancer cell growth.

PATIENTS ARE THE ACTIVE PARTNERS

The medicinal chemists and the patenting pros do not work alone. Moffitt patients are active participants in finding tomorrow’s successful cancer treatments, Dr. Lawrence notes.

“Without patients donating tissue samples, a lot of this work could not be done,” Dr. Lawrence says. “We hear a lot about the ‘bench to bedside’ path for a discovery that becomes a new therapy, but there is also a ‘bedside to bench’ pathway by which patient tissue donation becomes critical to our success. Our research has become circular. It’s a loop.”

On weekends, Dr. Lawrence enjoys cycling in Hillsborough County’s Flatwoods Park, known for its own long, seven-mile, paved loop road. As he glides under the Florida sun through the palms and pines on his classic 1990 Raleigh 14-speed, does he think about the patients, small molecules, mechanisms of cancer and the latest technologies to inhibit the disease?

“Of course,” he says. 🎧