

Non-Profit Technology Transfer

Non-Profit Technology Transfer — Helping Institutions Protect and Commercialize Inventions

Many of the world's most important innovations began as research discoveries in universities, hospitals, research institutes, and government agencies. The **non-profit research** sector continues to fuel the growth of scientific breakthroughs leading to life-enhancing products and services.

The experienced <u>IP attorneys</u> of Marshall, Gerstein & Borun LLP evaluate, protect, and advise on the strategic transfers of research institutions around the world, while navigating contractual and statutory restraints and other issues related to IP in this highly complex environment.

Ranked among the "World's Leading Patent Professionals" and "The World's Leading IP Patent and Technology Licensing Lawyers," "Virtually no other lawyers in the country know as much about university licensing and tech transfer" - IAM Patent 1000

Decades of experience

Marshall Gerstein has been driving the dialogue on IP issues on behalf of non-profit clients all along. Early in our history, we represented the Board of Trustees of the University of Illinois before the U.S. Supreme Court in *Blonder Tongue Laboratories, Inc. v. University of Ill. Foundation*, 402 U.S. 313 (1971). Today, we provide ongoing counsel to more than 75 non-profit institutions across the full spectrum of IP matters.

In-house technology transfer experience

Our team includes former technology transfer managers at non-profit institutions, who have first-hand knowledge of the issues and priorities of institutions, their corporate collaborators, and individual researchers and academics. We also understand the technologies and scientific principles that underlie new inventions and products, and are sensitive to the timelines and budgetary constraints that affect our clients' research activities.

Multidisciplinary approach to asset protection

Our patent prosecution team is skilled in all key disciplines of science and engineering and regularly evaluates invention disclosures, prosecutes meaningful claims, and develops broad-based portfolio management strategies. Our **trademark attorneys** help non-profits protect their reputations and leverage IP assets, and we handle clearance, registration, licensing, monitoring, and enforcement of **trademark** rights. Our **copyright** practice is skilled in the strategic use of copyrights, including in the software arena and with regard to ownership and use issues. Trade secrets are no longer irrelevant to non-profit technology transfer. We are sensitive to the research mission and its balance with special circumstances.

Effective negotiators focused on the end game

At Marshall Gerstein, we develop sophisticated licensing and transaction strategies, stay abreast of rapidly changing legal issues, and create enforceable agreements for each unique <u>IP transaction</u>. Having sat on all sides of the negotiating table, and given our deep experience representing non-profit organizations, we deliver creative yet practical solutions that help align and achieve our clients' long-term goals. We regularly negotiate funding, collaborations, IP acquisitions, and provide opinions on policy interpretations.

Strategically resolving disputes

In pursuing a client's objectives, our attorneys often recommend arbitration, mediation, or other forms of alternative dispute resolution (ADR) as the best way to address a dispute. We work with our clients to develop a course of action



based on the importance of the matter, the economics of litigation versus using ADR, and the probability of the outcome. At times, disputes cannot be resolved through ADR. These matters are handled by attorneys who possess significant courtroom experience and have a strong record of success in intellectual property and contract formation and litigation.

Committed to advances in the industry

Our attorneys are thought leaders, authoring articles on technology transfer and IP issues in journals such as *Intellectual Property Magazine, Managing Intellectual Property,* and *InsideCounsel.* Frequently invited to teach around the world, Marshall Gerstein contributes at conferences by the Association of University Technology Managers (AUTM), Biotechnology Industry Organization (BIO), Licensing Executives Society International (LESI), American Intellectual Property Law Association (AIPLA), Global Healthcare Innovation Agreement Accelerator (GHIAA), and American Chemical Society (ACS).

Representative matters

- Gene Therapy Requires Multifaceted Licensing Strategy
 - Salk Institute for Biological Studies and Juan Carlos Izpisúa Belmonte sought the counsel of Marshall Gerstein on a licensing strategy for a technology platform for gene therapy. The technology platform allows for genes to activate without creating breaks in the genetic code that may result in unwanted mutations. Salk's technology platform has proved to treat models of diabetes, muscular dystrophy and acute kidney disease and could be applied to more cell types and organs to treat a wider range of human diseases and age-related conditions. Marshall Gerstein executed a portfolio licensing strategy which offered the best way to ensure development of all the potential applications. Marshall Gerstein collaborated with Salk's in-house technology transfer team and their general counsel's office to construct the portfolio licensing strategy.
 - Vanderbilt University Partners with Lundbeck to Develop Schizophrenia Therapeutics

Vanderbilt University, one of the top 10 most innovative universities in the world, developed compounds that represent a new approach to treating schizophrenia. Announced in January, Vanderbilt University signed separate licensing and research collaboration agreements with Lundbeck, a global pharmaceutical company. Vanderbilt was supported in the negotiation by Marshall Gerstein's IP Transactions team, who is a strategic transaction advisor to the University. The collaboration formed by the agreements will speed the development of a new class of potentially promising treatments for schizophrenia's cognitive deficits and negative symptoms which go largely unaddressed by existing medications. A selected drug candidate is expected to be ready for transition into clinical development by 2020. Vanderbilt receives upfront and success-based payments in addition to royalties on global sales of products developed under the collaboration. This novel approach is also being explored as a potential treatment for behavioral disturbances in Alzheimer's disease and other neuropsychiatric disorders.

Enabling Technology Development to Heal Those Who Protect Us

The Non-Profit Technology Transfer team led the drafting and negotiation efforts to finalize 60 subcontracts for the Institute for Regenerative Medicine at the Wake Forest School of Medicine as part of the effort to initiate the second phase of the Armed Forces Institute of Regenerative Medicine (AFIRM). A consortium of more than 30 academic institutions and industry partners, AFIRM is focused on applying regenerative medicine to battlefield injuries. Wake Forest Institute for Regenerative Medicine was selected to lead the second phase of the federally funded program. Nearly 200 patients received treatment with technologies developed under the first phase of the AFIRM program, including the first double hand transplant in the United States, face transplantation, and innovative treatments for scar reduction and burns.



Helping Clients Feed the World

We represented NUtech Ventures, a client of the Firm, and Bayer CropScience AG in negotiating and executing a collaboration license and germplasm transfer agreement that focused on wheat improvement. The agreement also included provisions for an endowed professorship at the University of Nebraska-Lincoln (UNL), support for UNL research and education programs, support for UNL's first Presidential chair named for the Nebraska Wheat Growers, and plans for Bayer to establish its first North American wheat-breeding station near Lincoln. Marshall Gerstein is privileged to have worked side-by-side with NUtech Ventures, UNL, world-renowned UNL wheat breeder, P. Stephen Baenziger, and Bayer to draft and negotiate this expansive agreement that facilitates this wheat-breeding research partnership.

Completed 75 Clinical Trial Agreements in Less than Two Months

A major hospital medical center and research institution turned to Marshall Gerstein with its large backlog of clinical trial agreements. In less than two months, the IP Transactions team turned around 75 drug or medical device clinical trial agreements. Protecting the interests of the client without a protracted negotiation was balanced with the need to propose terms that the pharmaceutical or medical device company would be able to accept. Often characterized as "high-anxiety contracting," these types of negotiations are particularly challenging because there is so much at stake, including the significant financial investment in the trials, liability issues, and the need to navigate stringent regulatory requirements.

Unique Public and Private Partnership to Advance Stem Cell Research

Marshall Gerstein structured and negotiated a highly unusual multi-year relationship between a private hospital and research institute and a state university medical system so a world-renowned expert in gene therapy, tissue engineering, and regenerative medicine could serve as a full-time tenured professor at the university and chief scientific officer of the private research institute. Many agreements, policies, and procedures had to be created to implement the vision of one lab in two locations that capitalizes on the university's infrastructure for basic research and the private hospital and the research institute's clinical research environment. With decades of experience in non-profit technology transfer organizational management, Marshall Gerstein's team was well positioned to advise on the legal constraints of state universities, Bayh-Dole requirements, and best practices to draft policies on IP and tangible material transfer, management committee governance documents, and the many other agreements to implement a joint technology transfer infrastructure.

Ensuring Access to Cancer-Preventing Medications

On behalf of Loyola University of Chicago, Marshall Gerstein prosecuted and obtained <u>patents</u> around the world covering Cervarix® (Human papillomavirus bivalent vaccine, recombinant), which protects against Type 16 and Type 18 of the HPV virus that causes 70 percent of cervical cancers. The vaccine was invented at Loyola, and the Firm represented Loyola when its ownership was unsuccessfully challenged by MediGene AG. The Firm also renegotiated Loyola's license with GlaxoSmithKline, which now manufactures and sells Cervarix® (Human papillomavirus bivalent vaccine, recombinant). This long-term client relationship is sustained by combining the skill and experience of the Firm's patent prosecutors, attorneys, and IP transactions attorneys.

Client Successes

Nanotechnology

Northwestern University licensed a patent portfolio of technologies from the laboratory of Chad A. Mirkin to launch AuraSense LLC., a biotechnology company founded to pursue the unique therapeutic potential of engineered nanoparticles.



Founded in 1851, Northwestern University is one of the premier U.S. institutions of research and higher learning. In 2010's fiscal year, Northwestern was awarded research grant funding of \$557.3 million.

Marshall, Gerstein & Borun LLP has been handling Northwestern's patent portfolio of inventions from Chad Mirkin's laboratory since 2005. Professor Chad Mirkin is recognized as a world leader in the research and application of nanotechnology. Currently, Dr. Mirkin is the most-cited chemist in the world, and he is the most-cited nanomedicine researcher in the world. Among other awards, Professor Mirkin is the first in the Midwest and the 10th in the world to be elected to all three branches of the National Academies, in 2009 he won the prestigious Lemelson-MIT Prize which recognizes outstanding inventors, and is named to the U.S. President's Council of Advisors on Science and Technology. Professor Mirkin is the Director of the International Institute for Nanotechnology.

For more than a year, we led the Northwestern University team in negotiating this portfolio license agreement to launch Professor Mirkin's third start-up company, AuraSense LLC. The company has gone on to license additional inventions from Northwestern and develop the technology. AuraSense plans to develop this nanoparticle technology for transfection of genetic material into cells to regulate protein expression, therapeutics to mimic HDL or "good" cholesterol, and to study and quantify intracellular agents and corresponding phenomena, including genetic and small molecule activity in live cells.

Gene Therapy Requires Multifaceted Licensing Strategy

Salk Institute for Biological Studies and <u>Juan Carlos Izpisúa Belmonte</u>, one of TIME magazine's "50 Most Influential <u>People in Health Care"</u> sought the counsel of Marshall Gerstein on a licensing strategy for a technology platform for gene therapy. The technology platform allows for genes to activate without creating breaks in the genetic code that may result in unwanted mutations. Salk's technology platform has proved to treat models of diabetes, muscular dystrophy and acute kidney disease and could be applied to more cell types and organs to treat a wider range of human diseases and age-related conditions. Marshall Gerstein executed a portfolio licensing strategy which offered the best way to ensure development of all the potential applications. Marshall Gerstein collaborated with Salk's in-house technology transfer team and their general counsel's office to construct the portfolio licensing strategy.

To learn more about Juan Carlos Izpisúa Belmonte, see MIT Technology Review's article highlighting his work at Salk Institute for Biological Studies.