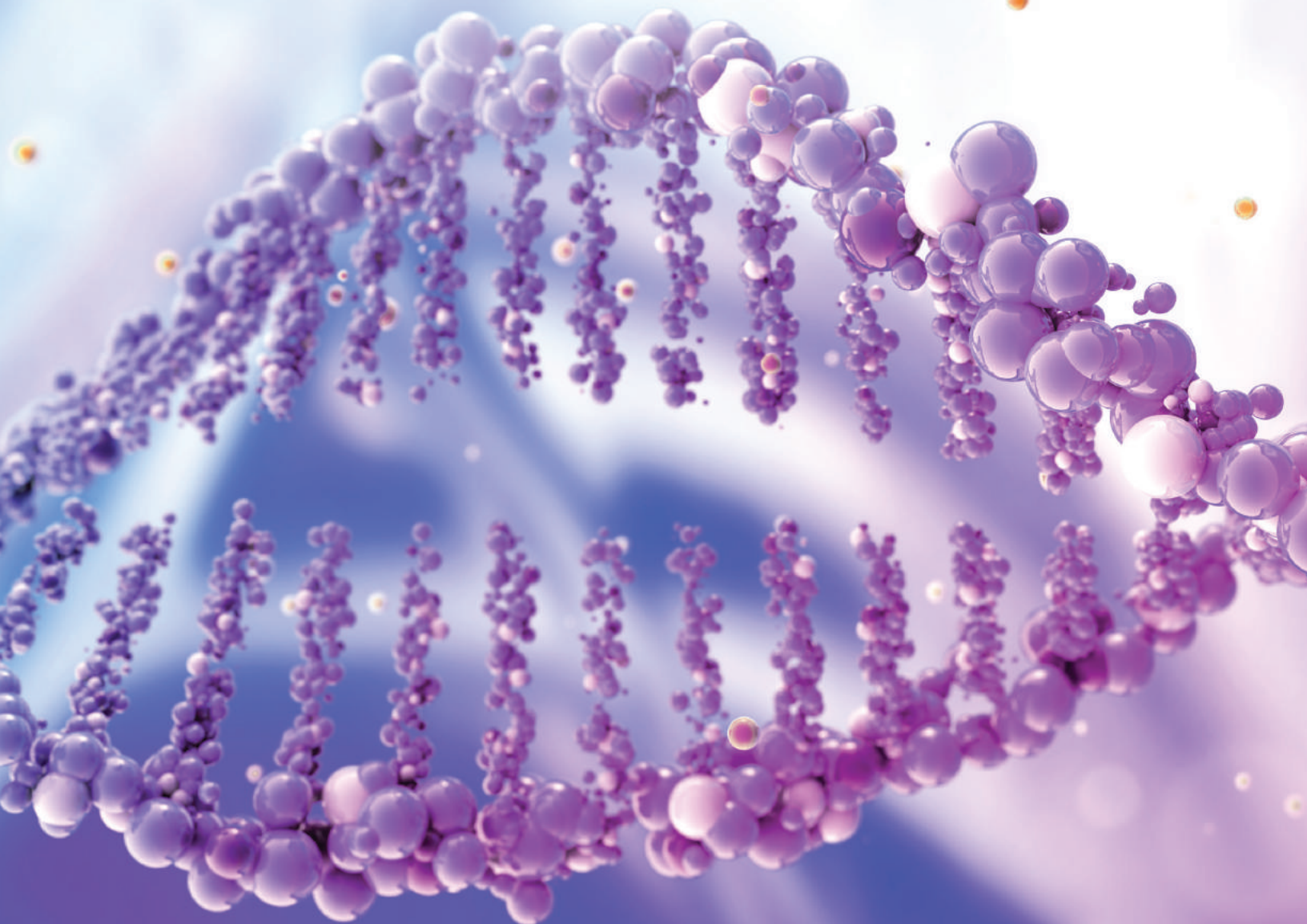




Mount
Sinai

*Innovation
Partners*

Innovation Partners and You **Bringing Mount Sinai discoveries to life**





“AN EXCITING TIME IN NYC FOR THE LIFE SCIENCES”

Dear Innovator,

In my day-to-day, I'm inspired by the promise and quality of our discoveries, how these may touch the lives of patients and their loved ones, and benefit society, communities, and healthcare on a global scale. In addition, the convergence of scientific fields within our community, the growth of the biotechnology and pharma sector, the accelerating pace of discoveries and the importance of intellectual property makes this an opportune time to connect with Mount Sinai Innovation Partners and drive inventions.

New York City, with its 1.6 billion in annual research funding, is well positioned to be a hub for innovation in the life sciences, and recently, city and state commitments to economic development include plans to inject significant capital to fund a broad array of infrastructure that will help fertilize and grow this environment. NYC's life sciences community has become more visible and united in its cause, developing a network of advisors and mentors necessary to train the next generation of entrepreneurs.

Mount Sinai innovators and entrepreneurs are poised to take advantage of the growing momentum within this ecosystem. Mount Sinai Innovation Partners is here to help bring your discoveries and inventions to life. We look forward to embarking on this exciting journey with you.

Sincerely,

Erik Lium

Senior Vice President
Mount Sinai Innovation Partners

HOW THIS INNOVATION GUIDE WORKS

Mount Sinai Innovation Partners (MSIP) drives the real-world application and commercialization of Mount Sinai discoveries and inventions, and the development of research collaborations with industry. In partnership with you, our aim is to translate discoveries and inventions into healthcare products and services that benefit patients and society. MSIP is accountable for the full spectrum of commercialization activities required to bring Mount Sinai innovations to life.

This guide provides readers with six steps for innovating in healthcare. You will also learn about the journey of two Mount Sinai innovators who have launched companies through their technologies.



Yiannis Ioannou

PhD, Professor of Genetics and Genomics

Yiannis Ioannou, PhD, Professor, Genetics and Genomics, has worked at Mount Sinai for 21 years with a focus on lysosomal storage diseases, a set of diseases which are difficult to treat and can cause severe neurodegenerative effects. His research led to the creation of drug-like compounds that are able to cross the blood-brain barrier and may serve as the foundation for new therapies in the field of lysosomal storage diseases.

Children diagnosed with lysosomal storage disease are asymptomatic for the first four to five years and only survive for approximately 10 years. With the guidance of MSIP, Dr. Ioannou has started a company that leverages his technology in the creation of therapeutic compounds for these lysosomal storage diseases.



Ya-El Mandel-Portnoy

PhD, CEO and Founder of Cardea Sciences

While completing her PhD at the Icahn School of Medicine at Mount Sinai, Ya-El Mandel-Portnoy, PhD, launched Cardea Sciences in response to the critical, unmet medical needs of patients with Atrial Fibrillation (AFib)—the most common cardiac arrhythmia. The condition costs the United States an estimated \$26 billion annually.

Dr. Mandel-Portnoy's technology aims to help patients and care providers better manage AFib in an outpatient setting by measuring pulse deficit—the difference in the heart rate between key areas in the body—and segmenting AFib patients based on the magnitude of their pulse deficit.

STEP 1: DISCOVER YOUR MOTIVATION

At Mount Sinai, we share one common motivation: to benefit patients and society on a global scale. There are many other motivations for innovating, but the overarching concern for patients is crucial in developing your discoveries. It will also carry you through the lengthy and complex process of commercialization, since not all discoveries may be appropriate for patenting or commercialization.

“ *It's always great when you know you have something novel, which opens up new avenues of investigation. It's one thing to do basic research, but when you can take those discoveries and see them through to the clinic where they can benefit patients, that's extremely rewarding.* ”

—Dr. Ioannou

STEP 2: CONNECT WITH MSIP

Who we are

MSIP is your partner in navigating the universe of healthcare commercialization to advance commercially-relevant translational discoveries. Let's begin the journey together, and you'll benefit from:

- One-on-one collaboration with an MSIP commercialization professional in your area of expertise
- A tailored approach that will increase the market value for your discovery
- Business networking and connections to commercial partners for licensing and investment
- Educational materials and opportunities to advance your knowledge of innovation, intellectual property, commercialization, and entrepreneurship

“ *It's extremely important to disclose. In accordance with the Bayh-Dole Act, the intellectual property of a discovery made within Mount Sinai belongs to Mount Sinai. That is simply the law. Additionally, filing a patent is an expensive proposition. Once you disclose, and MSIP has assessed that your discovery is ready for filing, MSIP will cover those costs. MSIP are the experts in assessing whether a technology is patentable. They will guide you through tasks or experiments that will lead to your technology being patent ready.* ”

—Dr. Ioannou

“ *Upon disclosure, your technology may be amorphous. Early on, you may have a very broad concept. Disclosing to MSIP helps to flesh out ideas. They will ask questions that explore market potential: who is going to buy or pay for this technology or service. Since most of us have limited business experience, these conversations are essential to help navigate your thoughts through the commercialization process.* ”

—Dr. Mandel-Portnoy

How it happens

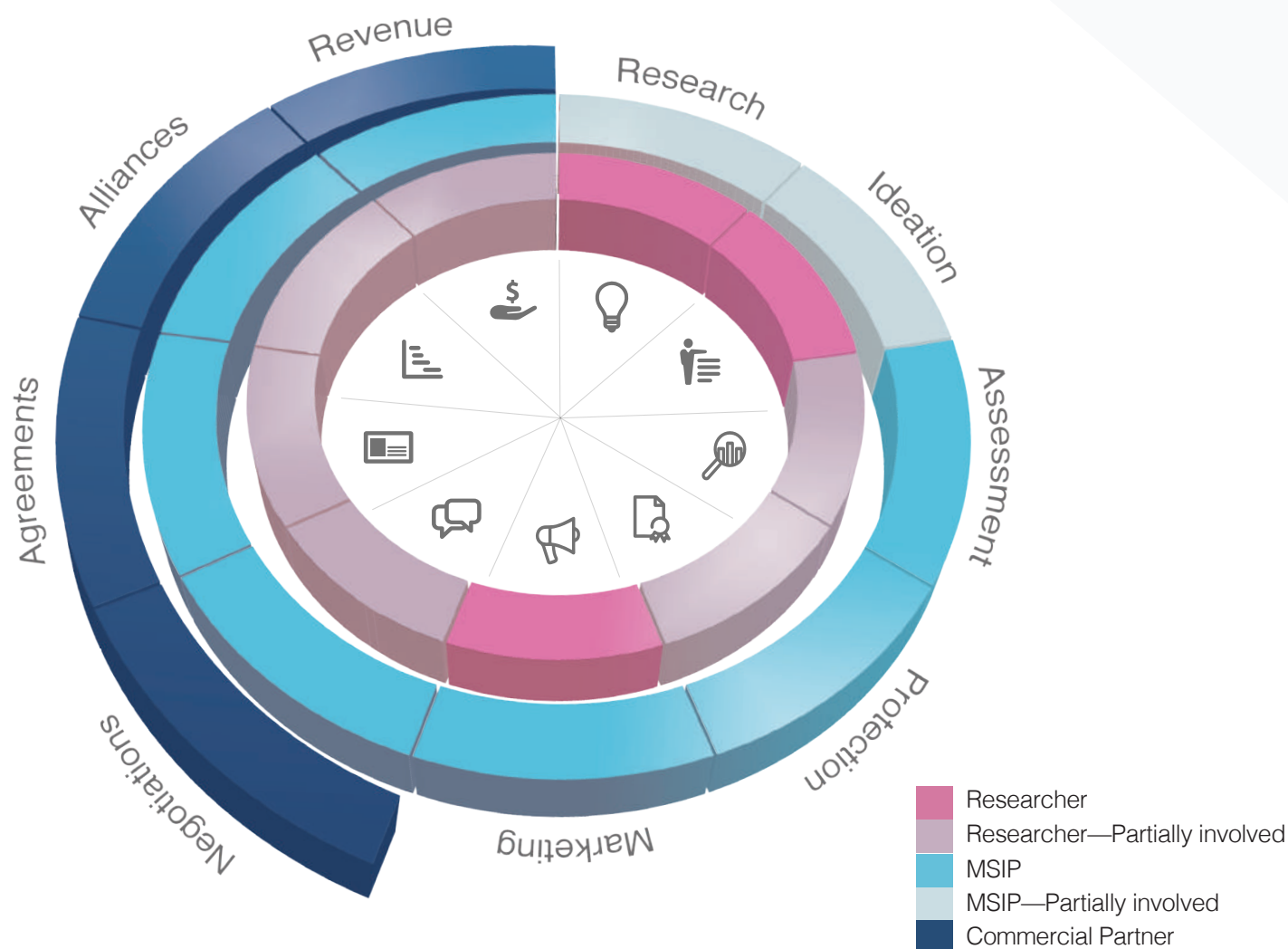
MSIP is your partner in technology development and commercialization. We ensure that technologies developed from these discoveries are advanced and find the best home, at existing companies or new companies created specifically for a technology (startups).

This is made possible through the Bayh-Dole Act. Enacted in 1980, the Bayh-Dole Act allowed academic institutions to become very active agents of innovation; it is credited with stimulating interest in tech transfer activities and generating increased research, commercialization, educational opportunities, and economic development in the United States. As a result, all discoveries from the Mount Sinai Health System go through MSIP in order to comply with this law. Universities and other non-profit institutions began to have ownership rights to discoveries resulting from federally funded research, provided certain obligations were met, and led to the creation of technology development and commercialization offices. Obligations include making efforts to appropriately protect and commercialize discoveries, submit progress reports to funding agencies, give preference to small businesses that demonstrate sufficient capability, provide for substantial manufacturing for U.S. sales, and incentivize inventor participation.

Our collaboration begins with a discussion. Contact your MSIP representative and fill out a Technology Disclosure: a written description of your invention or development that is provided to MSIP. The Disclosure should list all collaborators, sources of support, and all information necessary for MSIP to evaluate whether an investment should be made to pursue protection, marketing, and commercialization activities. Both federal and state laws assert that the employer, in this case Mount Sinai, owns the work product of its employees. In addition, investors interested in your technology require that the work product or intellectual property is protected.

STEP 3: ENGAGE IN THE CYCLE OF COMMERCIALIZATION

The life-cycle of commercialization includes multiple critical stages where inventor(s), MSIP, and a commercial partner participate in the cycle, starting with Research (listed below).



RESEARCH

From complex biology to genomics and artificial intelligence, Mount Sinai supports diverse fields of research. The table below outlines the five most common classes of technologies being pursued at Mount Sinai.

Academic vs. Commercialization Research

- Academic research: to publish a research article.
- Commercialization research: to advance the technology or asset that can be developed into a product or service. MSIP will help guide experiments to make the technology more attractive to potential licensing partners. For example, if a drug candidate is the focus of the technology, it is important to ensure that toxicology profiles are created, especially if it will be targeted for clinical trials at a later stage.

| | |
|-------------------------|---|
| Therapeutic | e.g., Fabrazyme First ever treatment for Fabry disease |
| Diagnostic | e.g., Recombinant human tissue factor Point-of-care monitoring of anticoagulation therapy |
| Medical Device | e.g., Physio II for mitral valve repair Surgery more efficient |
| Research Reagent | e.g., LX-2 Human Hepatic Stellate Cell Line Used to study liver fibrosis |
| Digital Health | e.g., RxUniverse Doctors prescribing medical apps to patients |



COMMERCIAL IDEATION

Engage with MSIP and start the ideation process with our team to explore the commercialization potential of your discovery. Contact us or submit a Technology Disclosure on our website. A Technology Disclosure is a written description of your discovery or invention and should list collaborators, sources of support, and all information necessary to progress to the next stage.



TECHNOLOGY ASSESSMENT

MSIP examines the commercial potential of discoveries or inventions and evaluates whether it will enter the cycle of commercialization. If your discovery has potential, MSIP develops a strategy to enhance its commercial value. This assessment is performed in collaboration with inventors, intellectual property attorneys, advisors, industry experts, and entrepreneurs-in-residence.



PATENTING AND LEGAL PROTECTION

If MSIP determines that a technology should be patented, we will involve expert legal counsel in the appropriate field to pursue patent protection. Mount Sinai will also utilize copyright or trademarks to commercialize associated inventions or works of authorship when applicable, but keep in mind that not all intellectual property requires legal protection.



MARKETING

Through its extensive network, MSIP identifies potential licensees and/or research collaborators (companies, entrepreneurs, and investors) to bring your discovery to market and employs best practices to create commercial partnerships.

MSIP engages potential licensees and/or research collaborators to determine the best possible arrangement and path to market. In order to find the best licensing partners for your technology, it is most effective to look at your existing networks. These may be folks that have been interested in your research in the past who perhaps are connected with a possible licensing partner.

Think of your network as a potential pool of licensing partners, and MSIP will discuss which of your connections might look like an attractive partner to approach. In addition, faculty publications, presentations, or academic expertise may result in third-party licensing interest.



NEGOTIATIONS AND DUE DILIGENCE

Marketing often results in one or more third-parties requesting in-depth information regarding a technology or potential research program. Providing this information requires the completion of a confidentiality agreement to protect Mount Sinai's information. Potential partners will present a commercialization strategy and negotiate the terms of the license with MSIP. MSIP also engages potential licensees and/or research collaborators to determine the best possible arrangement and path to market.



LICENSING AND CONTRACTING

When a prospective licensee and/or research collaborator is ready to move forward, MSIP shapes the transaction (a license for an invention and/or a sponsored research agreement) to reflect the negotiated business terms. When an agreement is signed by both parties, the licensee may begin to develop the invention and/or research collaborations between Mount Sinai and the partner commences. Compensation varies and may involve fixed fees, milestone fees, royalties, equity, and other forms of consideration. Compensation is shared with inventors in accordance with policy.



ALLIANCE MANAGEMENT

After an agreement is signed, MSIP works with all parties to ensure that the program relationship proceeds effectively and is managed well from a business perspective. Achieving milestones is critical to maintain our relationship with licensing partners and may affect revenues.



FUNDING AND REVENUE

The path to revenue and/or funding varies depending on the nature of the discovery, the market it is addressing, the discovery's stage of development and/or scope of the research. Revenue received pursuant to a license agreement is shared with inventors as defined in Mount Sinai's Intellectual Property (IP) Policy and funding received pursuant to a sponsored research agreement is used to support projects, as agreed upon with the industry sponsor. Under the Terms of Agreement, the commercialization partner provides regular progress reports to the Icahn School of Medicine at Mount Sinai on its commercialization activities.

STEP 4: EXPLORE COMMERCIAL OPTIONS

Discoveries may be commercialized through licensing to existing companies or to new companies created specifically for a technology (startups). In some cases, the most effective strategy is licensing a technology to an established, larger company. In other cases, it may be to develop a startup and pursue licensing from Mount Sinai. Many factors influence the choice of strategy, and MSIP will review these with you. In all cases, it is essential for us to collaborate closely because of the lengthy and complex process of commercialization.

“ *Deciding on whether you want to embark on a startup requires deep soul-searching, since it is a lengthy process. Over 90 percent of startups fail, so you need to be motivated and passionate about your technology. Ask yourself the following questions. Are you the best person to take this to market? Is another colleague in the lab a better fit because you would like to keep your position? Is it best to license the technology to another company?* ”

—Dr. Mandel-Portnoy

“ *First off, you will need a patent. A startup is time-consuming. You really need to be motivated to do your day job, basic research, and manage your group. Additionally, you need to put in all hours necessary in order to start the company. When bringing a startup into fruition, you actively participate in the company's structure and recruitment. It is also your responsibility to explore all available funding opportunities. The MSIP folks have all the appropriate experience to help through every aspect of this process.* ”

—Dr. Ioannou

Considerations for Startups

- Business and development plan: a plan for executing how the startup is going to work. This is best created by the people who are responsible for accomplishing the plan.
- Management team: the CEO and other advisors who are typically experienced entrepreneurs. A management team with strong and credible leaders will be an asset to the startup.
- Diligence requirements: ensures that the management team has established a key set of achievable milestones and their timeline until market launch.
- Funding sources: there are a few options
 1. Angel Investors are high-net-worth individuals, willing to invest in earlier stages with smaller amounts than venture capital firms in exchange for equity. They can take passive or active roles, and have a longer investment horizon.
 2. Venture Capital—provides millions of dollars in capital. They provide more equity, exercise control, and typically provide experienced management talent. Venture capitalists invest in several rounds of funding as part of a larger consortium of investors.
 3. Government grants—Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR).

When working with the commercialization office on a possible startup, some financial considerations are needed for the following: upfront fees, milestones, minimum annual royalties, annual maintenance fees, royalties on sales, equity, sublicense revenue sharing, past patent cost reimbursement, and ongoing patent-reimbursement fees.



STEP 5: SHARE THE BENEFITS

In collaboration with MSIP, your efforts to advance and commercialize your discoveries have the potential to revolutionize healthcare and improve the lives of patients worldwide.

Mount Sinai's revenue distribution from license fees, royalties, and equity is one of the most generous for inventors in the tristate area. Per the Mount Sinai IP Policy, all revenue—minus any unreimbursed patenting and legal or other out-of-pocket expenses—are shared with inventors. Typically, the distribution of royalty income is shared among Mount Sinai, the inventor, and the inventor's department. Below is a graphic outlining this distribution.

Licensing Revenue* Distributions:



Legend:

- Mount Sinai
- Inventor(s)
- Inventor(s) Dept./Institute

*Adjusted royalty income
= gross income less Mount Sinai
out-of-pocket expenses specific to
the licensed technology

Is your bright idea the next breakthrough in healthcare?

Share your 'eureka!' moment with us and start your journey today.



BRING YOUR DISCOVERIES TO LIFE

Connect with MSIP and
find your representative

MSIPInfo@mssm.edu

(212) 659-9680

Learn more with
MSIP's Innovation Guide

ip.mountsinai.org

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