Protect Your Science and Its Impact

Be strategic in securing intellectual property rights for the benefit of your patients

by Ronald DePinho, M.D.

As scientists, we are hardwired to communicate our breakthrough discoveries openly and rapidly in order to advance knowledge for the benefit of humanity. While admirable, scientific publications alone do not cure patients. Alleviation of pain and suffering occurs only when such knowledge becomes a commercially viable diagnostic or drug. The realization of the dream to create a new standard of care requires an intellectual property position that establishes ownership of the discovery and claims that preclude others from using the proprietary technology. Investors will not invest the hundreds of millions needed for your biotech start-up to convert your science into an approved drug unless you can protect the commercial potential of your science with secure intellectual property rights.

There is much to know about the laborious process of actually filing for the legal protections offered by the US Patent and Trademark Office and its counterparts abroad. There are many good sources for learning about it, particularly USPTO. For this brief essay, let's look at what it means to be strategic in your approach to securing patents for your discoveries.

What Property is Strategic?

Your intellectual property (IP) consists of the intangible assets created by your scientific discovery, and covers your claim for patents, copyrights, trade secrets, and trademarks.

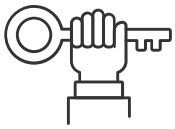
As the inventor of a potentially ground-breaking drug target platform, you may find it dizzying to consider securing ownership rights for all of the possible components of your discovery as embodied in the patent applications claims. On the one hand, you want to draw your ownership boundary line broadly to encompass as much ownership turf as possible in order to enhance your startup's value and to prevent others from claiming market rights from a

similar invention. However, it's important to keep in mind that each of the claims must be backed by real data. An over-reaching patent may not fare well with patent office examiners; and even if you manage to encompass rights to every element of your program, you will be unlikely to summon sufficient focus, time, or money to reduce it to practice in your start-up, thus blocking others from advancing knowledge to address humanity's needs. Additionally, a disorganized or last-minute approach to IP protection will rightfully knock you out of serious consideration by most respected venture investors.

Therefore, focus your efforts on the truly novel elements of your discovery that are critical to differentiating your invention from anything already patented, published, or in development by others. ***Start early*** in your research program (well before you intend to publish your work) to identify what these novel elements will be and to develop a plan and collect the significant data and composition of matter needed to support a strong patent application – and preferably ***multiple related patent protections*** – in the U.S. and key jurisdictions abroad. Each patent application articulates claims that protect an element of your technical invention, such as novel technology or chemical compositions of pharmaceutical drugs. To be patentable, you must be able to demonstrate that each invention is ***clearly different*** from existing technologies to one skilled in the art, i.e., another scientist in your field who would consider it non-obvious. Thus, a patent application must capture ***novel science,*** be written in manner to enable others to repeat your work and be ***useful*** in the medical world.

Not all discoveries warrant the time, effort, and expense of filing for patent protection. Strategic use of trade secret protections alone may be appropriate, for example, if you develop a valuable incremental technology advance in a crowded space. Trade secret protections and strategies will vary based on economic considerations, but at core depend on maintaining strict secrecy over your "secret sauce," which the United States Patent and Trademark Office (USPTO) defines as a "pattern, compilation, program, device, method, technique or process that obtains economic advantage over competitors." Methods of protection include everything from non-disclosure agreements to locking your intellectual property in a physical or encrypted storage space.

For purposes of this brief overview, let's focus on securing patents, which preclude others from encroaching on your discovery through use, manufacture, or sale. Trade secrets may be used as a complement to patent protection as, for example, with Google's strict protection of its search algorithms. But patent protections actually eliminate the need to maintain secrecy, as the inventor must actually provide a detailed and enabling disclosure about the invention. In exchange, patents provide the right, for a specific period of time, to exclude others from practicing the invention.



Can You Own It?

Long before you seek investors for your start-up venture, identify who will own the intellectual property of your target drug platform. Ownership is usually vested in the actual inventor, or joint inventors, of the property. When the research is conducted in an independent community laboratory, incubator, or accelerator, it belongs to the inventor(s). However, academic inventors working in a university laboratory funded at least in part by federal grants typically have no direct intellectual property ownership rights. Ownership of any patents is granted to the institution under the 1980 Bayh-Dole Act, which successfully incentivizes universities to invest in research in order to seek commercialization opportunities and revenues that can further fuel their academic missions of research, education, and patient care.

As an academic researcher, while your contract obligates you to assign all ownership rights as an inventor to your institution, institutions recognize that a patent's value often requires the inventor's engagement in reducing the invention to practice and in collaborating with investors or pharmaceutical entities who seek to generate commercial products enabled by the patent. Typically, academic institutions have a formula that allocates a percentage of future revenues from the patent. The revenue distribution formula varies across institutions with the inventor's share ranging from 25% to 50% and the remainder flowing into the inventor's department and the university at large. The institutional share is justified on the basis of its investment in research infrastructure and the faculty as well as its support of the lawyers and business experts needed to file appropriate IP protections and ultimately work with faculty to secure investments from the private sector.

Most institutions have a Technology Transfer Office (TTO), which has the expertise and processes to review your scientific discovery and seek commercialization opportunities, to determine whether protections can be secured and whether the cost is worth the potential return of filing patents, and to complete the actual applications. When the TTO makes this investment, you will be required to reimburse the institution for some or all of these patent costs when you negotiate invention licensing with the investors in your new company. In licensing the rights of the IP to a start-up, institutions will typically negotiate for an upfront payment plus milestone payments, royalties, and an equity

stake in the company. Institutions typically secure 2-5% of the outstanding shares post-financing with the remainder allocated to Founders (15-20%), management/employees (15-20%) and investors (50-70%).

Filing patent applications is an expensive and lengthy process. Each as-filed application establishes a priority date for determining prior art, so that subsequent competitive applications are not likely to be patentable unless they are novel and non-obvious over what came before them. You will also need to file foreign patent applications, particularly in first-world markets such as Europe and Japan. Several options are available. Perhaps the most common is filing a Patent Cooperation Treaty (PCT) application, an international treaty with more than 150 contracting countries, which enables you to file in multiple countries with a single application. The PCT application can now be submitted through USPTO, which streamlines the process considerably.

Each patent application will take months to prepare and can cost thousands of dollars, so conduct a careful competitive review and cost-benefit analysis as part of your early planning process for each element of the invention that you consider core, to determine if you can obtain sufficient return in the longer term. For those that you consider having enough strategic potential, you can buy yourself an extra year of protection with a relatively inexpensive provisional patent application, which establishes your priority filing date, giving you first dibs over everyone else and enabling you to label your invention as "Patent Pending" while you continue your research and prepare your non-provisional patent applications.

Maintain Strict Confidentiality

Because only non-obvious inventions can win patent protection, you must protect the uniqueness of your science by avoiding disclosure – verbal, written or electronic – by you or your colleagues to others not involved with the patent. Until your patent application publishes approximately 18 months from its earliest priority date, avoid presentation of the invention in public and be circumspect in conversations with potential recruits, partners, and investors. If you wish to communicate to a third party in order to commercialize your invention, your institution should establish non-disclosure agreements that prohibit anyone from disclosing the invention. Collaborators or partners should enter material transfer agreements that lay out very specifically the ownership rights or uses for any inventions in your platform now or in the future. Every company employee, contractor, and collaborator involved in the ultimate commercialization of your research program should be required to sign an invention agreement assigning to you or your company full ownership of any inventions they develop in the course of employment.

Also, you should carefully consider the optimal time to publicly disclose any information yourself. Plan a conservative timeline for when and what you will say, show, or publish through seminar or conference presentations, peer-reviewed papers, recruiting interviews, or even in negotiations with investors. Patent protection is precluded on inventions that are publicly disclosed. Public disclosure is any communication that is deemed to meet one of more of the following considerations:

- Documented to be known or in use by anyone other than the inventor prior to the date of invention,
- Patented or described in a printed or electronically available publication anywhere in the US or abroad prior to the date of invention by the inventor,
- In public use in the US more than one year prior to the patent application filing date, and/or
- On sale in the US more than one year prior to the filing date of the patent application.

This can be a very grey area, as existing case rulings are often contradictory and hard to understand. A poster presentation may constitute printed matter and so preclude your invention from receiving patent application approval. An oral presentation without slides or handouts is not printed material but is still a public disclosure. Anything with slides or other visual treatments, even those appearing only temporarily, is likely to be deemed published material. Finally, patents can be torpedoed by pre-print servers or online versions of journal articles which constitute public disclosures. Thus, the best course of action is to file patent applications before any submissions.

Clearly, a patent attorney should be part of your early strategic planning evaluations to research existing patents, to help you determine if you can establish a protective boundary around your invention, and to help you create ironclad confidentiality, employee invention assignments, material transfer, and nondisclosure agreements. *An upcoming article will address this: "Professional Advisors: When, Who, How Much, How to Manage: Contracts Needed."*

The Race to be First

To be viable, your science must be replicable; and being replicable, it is vulnerable to others claiming ownership first. Legitimate research programs can get caught in a race to establish ownership rights for new science discoveries. Claiming trademark

protection for your name, logo, and visual representations of your company's identity can only protect those visuals. Copyright protection only establishes your ownership of original writings.

It's also possible that you will encounter theft, counterfeiting, or piracy. Theft of intellectual property costs U.S. businesses billions of dollars and hundreds of thousands of jobs per year. Certain countries are notorious for intellectual property violations, so business engagements should be conducted by those skilled in those jurisdictions.

Patents help companies recoup research and development costs and exist to incentivize original research in companies and institutions. Whether your research is an improvement on existing technology or a unique drug target, develop a protection strategy and step by step plan as early as possible.

Don't wait to the last minute! Make intellectual property protection a key part of your research strategy and maintain such efforts as you transition to your business. If you determine that you have a truly unique platform with key assets that are likely to establish a profitable marketplace, pursue the broadest boundaries you can.

Prove to potential backers of your startup that their investment will be secure and will return value to shareholders — and ultimately to patients — in the form of new medicines. ■

For an overview for academic researchers of starting a biotechnology company, see:
Entrepreneurship: Fundamentals for Academics Starting a Biotech Company

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Dr. Ronald DePinho is an internationally renowned physician-scientist who has made significant scientific discoveries in the fields of cancer and aging. An innovator in translational research, healthcare leadership, entrepreneurship, patient advocacy, and public health collaboration, he is passionate about ending suffering for patients and their families through the dissemination of exceptional cancer care for all, promoting disease prevention, and developing breakthrough therapies. Former president of MD Anderson Cancer Center, Ron is holds the Harry Graves Burkhart III Distinguished University Chair in Cancer Biology and is an MD Anderson faculty member in the Department of Cell Biology, where he leads a 20-person research lab pushing the frontiers of science. He has launched several new biotech companies that are developing critical drugs for patients in need and is building a global collaboration framework to better coordinate efforts across the many diverse stakeholders in the cancer community to accelerate progress in the prevention and treatment of cancer in many countries.