

Putting Together the Pieces for a Successful Medical Device Company

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About the Author



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Karl Klassen has extensive experience managing the intellectual property (IP) portfolios of emerging companies and international corporations. He regularly counsels both national and international corporations in patent strategies, freedom-to-operate analyses, and other IP due diligence and patent licensing. Karl works with inventors to monetize patent assets and develop IP portfolios

focused on interconnected devices, commercial Internet of Things (IoT) software, and IoT ecosystems.

In the medical device industry, Karl has particular experience with respiratory technology (e.g., intrabronchial valves and intrabronchial catheters), aesthetic treatments, photodynamic therapy, energy-emitting catheters (e.g., radiofrequency catheters, light emitting catheters), cardiac technology, spinal technology, and tissue processing and imaging equipment. He also has extensive experience in a variety of other technologies, including aerospace technology, injection molding, semiconductor processing equipment, and micro-electro-mechanical systems.

I. Introduction

Innovating medical device technologies, founding a startup, and building a company can take you on an exciting and challenging journey. At different stages in the journey, entrepreneurs' attention will be focused on specific objectives, including inventing, raising funds, hiring employees, and developing products. In the fast-paced startup environment, it is difficult to be mindful of how day-to-day activities affect intellectual property (IP) rights, even though IP rights are often core assets. At each stage of the journey, IP rights come into play. By maximizing these rights, startups can attract potential investors, increase valuations, streamline diligence, and lay the foundation for either company growth or a successful exit.

The complex interplay between a startup's business activities and management of its intellectual property, if ignored, can lead to significant and avoidable missteps. These missteps can materially affect the company's intellectual property and lead to loss of funding opportunities, decreased

valuations, and litigation, as well as jeopardize the future of the company. For example, publicly disclosing your technology at a medical device conference may be an effective way to expand your network and create more opportunities for raising capital. However, if you disclosed the technology before filing a patent application, your well-intentioned promotional efforts may affect your ability to obtain patent protection. During the life of a startup, the startup's IP portfolio (e.g., filed patent applications, issued patents, trade secrets, other IP assets), formal agreements, and past activities are often investigated and analyzed numerous times. This chapter introduces IP rights and provides tools for identifying common IP pitfalls, preparing for IP due diligence, and effectively developing and managing your intellectual property.

The intended audience of this chapter includes early-stage medical device entrepreneurs, physicians, and engineers who are not IP experts but who want to understand IP rights, learn strategies to protect their proprietary technology, and avoid common pitfalls in the early stages of the startup life cycle.

II. Intellectual Property

Well-thought-out and comprehensive IP strategies are critical to medical device startups. The IP portfolio of a startup should provide competitive positional advantages by blocking other companies. During the early stages, startups are susceptible to foreseeable IP pitfalls, including failing to establish ownership of a core technology, relying on poorly drafted patent applications, and failing to identify and address freedom-to-operate risk (i.e., infringing on a competitor's patent). Ideally, early-stage entrepreneurs should work closely with patent counsel; however, in reality, they may have budgetary constraints, especially in the pre-seed and seed financing stages when they have limited capital or uncertainty about whether sufficient capital can be raised. Awareness of how day-to-day activities can affect IP rights is critical because a single misstep can have devastating long-term effects. Even after the startup hires good patent counsel who understand its budgetary constraints and business objectives, entrepreneurs' continued IP vigilance, with guidance by patent counsel, can further strengthen the company's IP position.

The term *intellectual property* broadly refers to patent, trade secret, and trademark rights for protecting intangible assets from unauthorized use.

Patents and patent applications are often the most important IP asset of medical device startups; however, medical device startups invariably have additional IP assets that should not be ignored. For example, if you sketched a concept on a piece of paper, you have copyright protection under state law. If you federally registered the sketch, you have copyright protection under federal law. Data (e.g., bench test data, clinical data), customer lists, and proprietary manufacturing techniques can be kept as trade secrets. Inventions can be kept as trade secrets before patent applications publish or, if non-publication requests are filed, before issuance of the patents. Understanding the advantages and disadvantages of different types of intellectual property is fundamental. This chapter explores some of the issues specific to putting together the pieces of your company. It primarily focuses on U.S. patent rights but will also touch on patent rights in foreign countries.

A. Patents

Historically, the United States has taken an expansive view on subject matter that qualifies for patent protection. The U.S. patent statutes broadly state, “Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.”¹ A broad “anything under the sun that is made by man” guideline was generally applied by the courts in the 1980s; thus, diagnostic technology, surgical procedures, software, and other types of technology that are often unpatentable in foreign countries are patent-eligible in the United States.² In 2014, the U.S. Supreme Court narrowed the scope of patent-eligible subject matter by setting forth a two-step analysis for determining whether claims are directed to patent-ineligible laws of nature, natural phenomena, or abstract ideas.³ Diagnostic technology that informs physicians on well-understood, routine, conventional activity in which they previously engaged is not patent-eligible subject matter.⁴ Patent eligibility is a “murky morass” of jurisprudence; reasonable minds can differ on whether a claimed invention is directed to, for example, an abstract idea.⁵ Since *Alice*, the patent ineligibility of abstract ideas has resulted in a sea

¹ 35 U.S.C. § 101.

² See *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980).

³ *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 134 S. Ct. 2347, 2354, 110 U.S.P.Q. 2d 1976, 1980 (2014).

⁴ *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289 (2012).

⁵ *MySpace, Inc. v. GraphOn Corp.*, 672 F.3d 1250, 1260 (Fed. Cir. 2012).

change, especially for computer-related technologies. The first step of the patent-eligible analysis is determining whether the claims are directed at an abstract idea.⁶ If so, the second step is determining whether there is “significantly more” in the claimed invention or if the “inventive concept” “transform[s]” the invention into patent-eligible subject matter so that the claims do not cover only the abstract idea itself.⁷ The courts, the U.S. Patent and Trademark Office (USPTO), and the medical device industry have struggled with this sea change in patent-eligible subject matter. Even so, the medical device industry in the United States continues to rely heavily on U.S. patent rights while the patent eligibility landscape evolves.

Patent rights are interwoven into the fabric of the medical device industry. A patent grants the owner the right to exclude others from making, selling, or using a patented invention for a limited period of time. If there is no patent protection for a product, competitors are allowed to reverse-engineer the product, then develop and commercialize a competing knockoff product. The competitor could then flood the market with the knockoff product. If the knockoff product requires approval from the U.S. Food and Drug Administration (FDA), the competitor could design knockoff products that are similar enough to the FDA-approved non-patented product to meet the “substantially similar” standard for 510(k) FDA regulatory clearance, thus streamlining regulatory clearance. Thus, patents are valuation drivers, especially for companies without FDA-approved products, customer loyalty, or other significant positional advantages.

The U.S. patent system has both utility patents and design patents. Utility patents protect new and useful processes, machines, manufactures, or compositions of matter, as well as a new and useful improvement thereof.⁸ This broad list covers technology ranging from implants to surgical procedures. Therefore, medical device companies focus their patenting efforts on obtaining utility patents to protect the medical devices, functionality of their technology, surgical procedures, methods of using the medical devices (e.g., surgical techniques), diagnostic technology, and proprietary manufacturing techniques.

Although utility patents often provide the broadest protection, design patents can play a role in protecting the appearance of technology. The Patent Act provides that “[w]hoever invents any new, original and ornamental design for an article of manufacture may obtain a patent therefor,

⁶ *Alice*, 134 S. Ct. at 2355.

⁷ *Id.* (quoting *Mayo*, 132 S. Ct. at 1294, 1297).

⁸ 35 U.S.C. § 101.

subject to the conditions and requirements of this title.”⁹ Design patents are limited to (a) the ornamental design for (b) an article of manufacture; to avoid doubt, the Patent Act states that “[t]he provisions of this title relating to patents for inventions shall apply to patents for designs, except as otherwise provided.”¹⁰ Because the value of medical device technology is based on its utility more than its appearance, design patents often do not play a significant role in the early stages. However, as the technology matures and a product nears commercialization, design patents may come into play; they are frequently used to protect graphical interfaces, ergonomically designed handpieces, delivery instruments, and disposable components (which may be difficult to protect with utility patents) to block competitors from selling confusingly similar knockoff products.

Importantly, patents do not grant the owner the right to make, use, or sell the invention. A startup that is able to patent its technology may be surprised that it can be blocked by another company’s patents because patentability and freedom to operate are separate and distinct concepts. In some instances, a patent that impairs freedom to operate by blocking aspects of the startup’s technology may also affect patentability; however, in other instances, it may not.

It is important for a startup to identify and monitor expansive patent portfolios that could potentially block it. If the startup’s attempts to commercialize its technology infringe on a competitor’s patents, that competitor can seek an injunction blocking the startup. It is particularly devastating when the competitor’s patents block foundational technology, resulting in the startup’s cost for redesigning its technology being prohibitively high or the startup being unable to engineer a non-infringing competitive product. The value of medical device patents is evidenced by the number of significant exits by startups without commercialized FDA-approved products.¹¹

⁹ *Id.* § 171(a).

¹⁰ *Id.* § 171(b).

¹¹ Press Release, Medtronic, *Medtronic Completes Acquisition of Ardian* (Jan. 13, 2011), <http://newsroom.medtronic.com/phoenix.zhtml?c=251324&p=irol-newsArticle&ID=1770617>; Press Release, Boston Scientific, *Boston Scientific to Acquire Vessix Vascular, Inc.* (Nov. 8, 2012), <http://news.bostonscientific.com/2012-11-08-Boston-Scientific-to-Acquire-Vessix-Vascular-Inc>; Press Release, Edwards Lifesciences, *Edwards Lifesciences Enters into Agreement to Acquire CardiAQ* (July 10, 2015), <http://www.edwards.com/ns20150710>; Press Release, Medtronic, *Medtronic to Acquire Twelve, Inc., Developer of Transcatheter Mitral Valve Replacement Device* (Aug. 25, 2015), <http://newsroom.medtronic.com/phoenix.zhtml?c=251324&p=irol-newsArticle&ID=2081800>; Press Release, Edwards Lifesciences, *Edwards Lifesciences Completes Acquisition of Valtech Cardio* (Jan. 23, 2017), <http://www.edwards.com/ns20170123>.

Medical Device Exits Without Commercialized FDA-Approved Products

- \$800 million acquisition of Ardian, Inc. (2011)
- \$125 million acquisition of Vessix Vascular, Inc. (2012)
- \$350 million acquisition of CardiAQ Valve Technologies, Inc. (2015)
- \$458 million acquisition of Twelve, Inc. (2015)
- \$340 million acquisition of Valtech Cardio Ltd. (2017)

When startups are in a race with competitors that are expanding their reach into new technology areas, patent assets can be key drivers for acquisitions. In recent years, public medical device companies have aggressively acquired startups (typically venture-backed startups) to expand their product lines to stay competitive. For example, medical device companies looked to startups backed by highly regarded investors to acquire catheter-based aortic heart valve replacement technology for treating valve stenosis and valve regurgitation. With market successes of aortic valve therapies, startups recognized the need for mitral valve therapies, so they innovated transcatheter mitral valve replacement (TMVR) technology and developed patent portfolios. Large medical device companies eventually sought to expand their heart valve product lines by pursuing TMVR technology via strategic acquisitions. For example, Abbott acquired TMVR developer Tendyne for up to \$250 million and also secured an option in Cephea Valve Technologies.¹² Edwards Lifesciences Corporation (Edwards) and Medtronic plc (Medtronic) are heart valve manufacturers that were involved in global patent litigation against one another. After they reached an agreement ending a litigation dispute involving atrial heart valves, Edwards acquired TMVR developer CardiAQ Valve Technologies, Inc. (CardiAQ); shortly thereafter, Medtronic followed up by acquiring venture-backed TMVR developer Twelve, Inc.¹³ After this flurry of activity, Boston Scientific Corporation (Boston) pursued

¹² Press Release, Abbott, *Abbott Completes Acquisition of Tendyne Holdings, Inc.* (Sept. 2, 2015), <http://abbott.mediaroom.com/2015-09-02-Abbott-Completes-Acquisition-of-Tendyne-Holdings-Inc>.

¹³ Press Release, Edwards Lifesciences, *Edwards Lifesciences Enters into Agreement to Acquire CardiAQ* (July 10, 2015), <http://www.edwards.com/ns20150710>; Press Release, Medtronic, *Medtronic Settles Global Patent Litigation with Edwards Lifesciences* (May 20, 2014), <http://newsroom.medtronic.com/phoenix.zhtml?c=251324&p=irol-newsArticle&ID=1932573>.

TMVR technology by securing a \$200 million option from MValve Technologies and then acquired assets from Neovasc Inc.¹⁴

Acquisitions have also spurred the development of denervation technology. Medtronic acquired renal denervation pioneer Ardian, Inc. (Ardian) for \$800 million in 2011.¹⁵ The next year, Boston acquired Vessix Vascular, Inc. for \$125 million to expand its reach into the denervation market.¹⁶ Since the Ardian acquisition, new startups have entered the renal denervation market and have aggressively pursued their own IP positions.

This trend of large medical device companies competing to acquire technologies and patent portfolios developed by startups is likely to continue in the coming years because the current survival of the strongest angel/capital funding model weeds out weak startups. The crown jewels in successful startup patent portfolios are well-drafted early patent filings disclosing numerous embodiments and with supporting broad claims (see Figure 1-1).

Patent portfolios need to be strategically cultivated—typically over many years—to lay the foundation for a successful exit. A haphazard IP strategy with a single patent filing (or even a handful of patent filings) may not be sufficient to establish an early filing date for core concepts or protection for further developments. Companies that fail to develop IP assets may be unable to attract potential acquirers. Even if they become an acquisition target, they may struggle to survive due diligence, much less achieve a suitable valuation.

B. Trade Secrets

Trade secrets are confidential and valuable business information, such as information regarding manufacturing processes (e.g., heat treatment

¹⁴ Press Release, Boston Scientific, *Boston Scientific Closes Acquisition of Advanced Biological Tissue Capabilities and Acquires Common Shares of Neovasc, Inc.* (Dec. 13, 2016), <http://news.bostonscientific.com/2016-12-13-Boston-Scientific-Closes-Acquisition-of-Advanced-Biological-Tissue-Capabilities-and-Acquires-Common-Shares-of-Neovasc-Inc>; *Boston Scientific announces \$200M option to purchase Israeli transcatheter mitral valve player*, FIERCEBIOTECH (Oct. 8, 2015, 11:17 AM), <http://www.fiercebiotech.com/medical-devices/boston-scientific-announces-200m-option-to-purchase-israeli-transcatheter-mitral>.

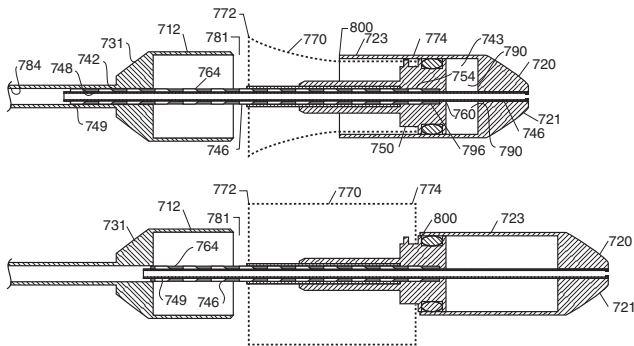
¹⁵ Press Release, Medtronic, *Medtronic Completes Acquisition of Ardian* (Jan. 13, 2011), <http://newsroom.medtronic.com/phoenix.zhtml?c=251324&p=irol-newsArticle&ID=1770617>.

¹⁶ Press Release, Boston Scientific, *Boston Scientific to Acquire Vessix Vascular, Inc.* (Nov. 8, 2012), <http://news.bostonscientific.com/2012-11-08-Boston-Scientific-to-Acquire-Vessix-Vascular-Inc>.

FIGURE 1-1 Twelve, Inc.'s Early U.S. App. No. 13/781, 504 (U.S. Pat. No. 9,579,198) was Filed Prior to the Medtronic Acquisition and Contains More Than 80 Figures Illustrating Numerous Embodiments of Twelve's Technology.



<p>(12) United States Patent Deem et al.</p>	<p>(10) Patent No.: US 9,579,198 B2 (45) Date of Patent: Feb. 28, 2017</p>																																										
<p>(54) HYDRAULIC DELIVERY SYSTEMS FOR PROSTHETIC HEART VALVE DEVICES AND ASSOCIATED METHODS</p>																																											
<p>USPC 623/1.46 See application file for complete search history.</p>																																											
<p>(71) Applicant: Twelve, Inc., Menlo Park, CA (US)</p> <p>(72) Inventors: Mark Deem, Mountain View, CA (US); Hanson Gifford, III, Woodside, CA (US); John Morris, San Francisco, CA (US); Matt McLean, San Francisco, CA (US); Michael Luna, San Jose, CA (US)</p> <p>(73) Assignee: Twelve, Inc., Menlo Park, CA (US)</p> <p>(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 405 days.</p> <p>(21) Appl. No.: 13/781,504</p> <p>(22) Filed: Feb. 28, 2013</p> <p>(65) Prior Publication Data US 2013/0231735 A1 Sep. 5, 2013</p> <p>Related U.S. Application Data</p> <p>(60) Provisional application No. 61/605,699, filed on Mar. 1, 2012, provisional application No. 61/760,399, filed on Feb. 4, 2013.</p> <p>(51) Int. Cl. A61F 2/24 (2006.01) A61F 2/95 (2013.01) A61F 2/00 (2006.01)</p> <p>(52) U.S. Cl. CPC A61F 2/243 (2013.01); A61F 2/2436 (2013.01); A61F 2/95 (2013.01); A61B 50/30 (2016.02); A61F 2/0095 (2013.01)</p> <p>(58) Field of Classification Search CPC A61F 2/2436; A61F 2/243; A61F 2/95; A61F 2/0095; A61B 50/30</p>	<p>(56) References Cited</p> <p>U.S. PATENT DOCUMENTS</p> <table border="0"> <tr><td>3,526,219</td><td>A</td><td>9/1970</td><td>Balamuth</td></tr> <tr><td>3,565,062</td><td>A</td><td>2/1971</td><td>Kuris</td></tr> <tr><td>3,589,363</td><td>A</td><td>6/1971</td><td>Banko et al.</td></tr> <tr><td>3,667,474</td><td>A</td><td>6/1972</td><td>Lapkin et al.</td></tr> <tr><td>3,823,717</td><td>A</td><td>7/1974</td><td>Pohlman et al.</td></tr> <tr><td>3,861,391</td><td>A</td><td>1/1975</td><td>Antonevich et al.</td></tr> <tr><td>3,896,811</td><td>A</td><td>7/1975</td><td>Storz</td></tr> <tr><td>4,042,979</td><td>A</td><td>8/1977</td><td>Angell</td></tr> <tr><td>4,188,952</td><td>A</td><td>2/1980</td><td>Loschilov et al.</td></tr> </table> <p>(Continued)</p> <p>FOREIGN PATENT DOCUMENTS</p> <table border="0"> <tr><td>CN</td><td>1440261</td><td>9/2003</td></tr> <tr><td>CN</td><td>101076290</td><td>11/2007</td></tr> </table> <p>(Continued)</p> <p>OTHER PUBLICATIONS</p> <p>US 9,265,606, 02/2016, Buchbinder et al. (withdrawn)</p> <p>(Continued)</p> <p><i>Primary Examiner</i> — Richard Louis</p> <p>(57) ABSTRACT</p> <p>Systems, apparatuses, and methods for treating native heart valves are disclosed herein. A system for delivering a prosthetic device into a heart of a patient includes an elongated catheter body and a delivery capsule. The delivery capsule can be hydraulically driven to deploy at least a portion of a prosthetic heart valve device. The delivery capsule can release the prosthetic heart valve device at a desired treatment site in a patient.</p> <p>9 Claims, 63 Drawing Sheets</p>	3,526,219	A	9/1970	Balamuth	3,565,062	A	2/1971	Kuris	3,589,363	A	6/1971	Banko et al.	3,667,474	A	6/1972	Lapkin et al.	3,823,717	A	7/1974	Pohlman et al.	3,861,391	A	1/1975	Antonevich et al.	3,896,811	A	7/1975	Storz	4,042,979	A	8/1977	Angell	4,188,952	A	2/1980	Loschilov et al.	CN	1440261	9/2003	CN	101076290	11/2007
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processes), prototyping information, engineering drawings, or financial, business, scientific, technical, economic, or engineering information.¹⁷ Trade secrets have economic value, whether actual or potential; they cannot be generally known to, or readily ascertainable through proper means by, another person who can obtain economic value from the disclosure or use of the confidential information.¹⁸ Competitors are free to reverse-engineer trade secrets, so aspects of technology that can be reverse-engineered should be protected by patents. Additionally, reasonable steps must be taken to control access to and distribution of trade secret information. A trade secret remains valid and enforceable as long as it is kept secret.

Early-stage entrepreneurs with budgetary constraints often rely on trade secret protection due to the cost of preparing and filing patent applications. Reliance on trade secret protection carries risk: Once a trade secret is disclosed publicly, trade secret protection is lost forever. In addition, it is difficult to detect misappropriation of trade secrets because a rogue employee, a disgruntled partner, or anyone else with access to trade secrets can often easily copy electronic files (e.g., customer lists, test data, CAD files), access physical records, or capture images using a smartphone and then remove the information from a company's premises. The misappropriated information may ultimately reach a competitor that may utilize the misappropriated information without the rightful owner's knowledge. For example, if the trade secret is a proprietary heat treatment for setting shapes of memory material, such as Nitinol, it may be difficult to detect a competitor that is using misappropriated information in its heat treatment processes.

C. Trademarks

Trademarks can be used to identify goods sold by startups to prevent confusion in the marketplace. They typically play a lesser role for early-stage medical device companies without commercialized products. Because the timeframe for developing and releasing Class II and Class III products can be fairly long and acquirers often rebrand, trademarks take a backseat to patent protection. Trademarks become more important as the technology

¹⁷ See Defend Trade Secrets Act of 2016, Pub. L. No. 114-153, 130 Stat. 376 (codified as amended at 18 U.S.C. §§ 1831–1839).

¹⁸ 18 U.S.C. § 1839(b)(3)(B).

nears commercialization because trademarks can be used to avoid customer confusion. When choosing a company name, it is important to do some research to help avoid trademark infringement or domain name problems. A company may be at risk of infringing another company's trademark if the mark causes confusion among customers in the marketplace. A starting point can be performing trademark searches using search engines (e.g., Google), USPTO's Trademark Electronic Search System, and Secretary of State corporate or limited liability company records in the states where the startup will do business. A trademark attorney can perform a professional search and issue a clearance opinion to clear any trademarks before release of the products.

D. Copyrights

Copyrights protect original works of authorship, including drawings, design sketches, computer software, and architecture.¹⁹ Works created by an individual have protection for the life of the author, plus 70 years.²⁰ Works created anonymously, pseudonymously, or for hire have protection for 95 years from the date of publication or 120 years from the date of creation, whichever is less; thus, the duration of copyrights is much longer than the duration of patent protection.²¹ A medical system may include commercially significant features suitable for copyright protection. For example, copyrights can be used to protect software (e.g., software that controls operation of instruments, imaging equipment, or other computer-controlled equipment), user interfaces, and other artistic features.

III. Protecting Your IP Rights

A theme throughout this chapter is that protecting IP rights requires identifying activities that will put your IP rights at risk and taking steps to protect your IP rights. Table 1-1 lists various activities and associated IP risks.

Once you identify IP risks, you will be faced with choices about whether or not to put IP rights potentially at risk and can take steps to maximize your IP rights. A successful patent strategy is based on

¹⁹ 17 U.S.C. § 102(a).

²⁰ *Id.* § 302(a).

²¹ *Id.* § 302(c).

TABLE 1-1 Various activities and associated intellectual property (IP) risks

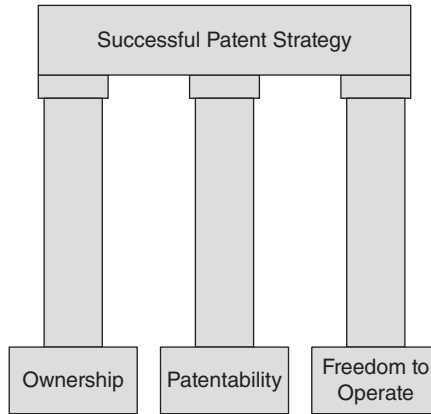
Activity	IP risks	Steps to protect IP
Inventing	<ul style="list-style-type: none"> • Startup not owning early developed inventions 	<ul style="list-style-type: none"> • Use agreements (e.g., founder agreements) to establish ownership of inventions by founders
	<ul style="list-style-type: none"> • Former or current employer having rights in early inventions 	<ul style="list-style-type: none"> • Study agreements with your employer (e.g., employment agreements, consulting agreements, other work-related agreements) <ul style="list-style-type: none"> ◦ If agreements are in place, understand what IP is owned, or potentially owned, by your employer • Consider the impact of state and federal laws addressing ownership of copyrights and patents • Evaluate employer's potential ownership based on <ul style="list-style-type: none"> (1) claim that the invention relates directly to the business of your employer or to the employer's actual or demonstrably anticipated research or development, or (2) claim that the invention results from any work performed by you for your employer • Do not use your employer's equipment, supplies, facilities, or trade secret information • Invent on your own time outside of employment hours
Disclosing IP to third parties	<ul style="list-style-type: none"> • Your disclosure could qualify as prior art that affects your ability to obtain patents • Third party using your invention 	<ul style="list-style-type: none"> • File patent applications before disclosing technology to third parties • Limit disclosures to third parties to what has been disclosed in patent applications • Use nondisclosure agreements to prevent public disclosures and use of your technology by third parties • Keep records about confidential information provided to third parties

Collaborating with third parties	<ul style="list-style-type: none"> • Third party having rights in IP 	<ul style="list-style-type: none"> • Obtain agreements addressing IP <ul style="list-style-type: none"> ○ Consultants should execute consulting agreements ○ Partners should execute joint development agreements ○ Address ownership of IP, including future inventions
Building a team	<ul style="list-style-type: none"> • Entanglement with third-party IP 	<ul style="list-style-type: none"> • Evaluate work history of potential hires to identify potential IP baggage • Perform due diligence on any IP baggage, including <ul style="list-style-type: none"> ○ Former employers' potential rights, including noncompete obligations ○ Confidentiality obligations (e.g., a well-known physician consultant may have obligations with multiple companies) ○ IP owned by potential hires (e.g., highly regarded consultants may have patents in your space)
	<ul style="list-style-type: none"> • Company failing to own IP 	<ul style="list-style-type: none"> • Use agreements for your company's ownership of IP (e.g., employment agreements that contain assignment of future inventions clause, obligations to transfer IP, founder agreements) • Inventors should execute formal assignments for patent applications • Record assignments for patent applications • Comply with state law requirements for establishing IP ownership

ownership of inventions, patentability of inventions, and freedom to operate (see Figure 1-2).

A. Early-Stage Inventing

This section is primarily focused on how to avoid ownership pitfalls at the early stages in the life cycle of a startup. Under U.S. patent law, inventors own inventions absent an agreement, such as employment agreements,

FIGURE 1-2 Successful Patent Strategy.

consulting agreements, or development agreements, which often have IP provisions addressing ownership of inventions. Whether an employer owns an invention often turns on specific language, so a detailed and thorough review of your agreements and IP provisions addressing inventions should be performed prior to inventing. In the pre-formation stage, it may be helpful to keep your full-time job to maintain your personal cash flow. You may, however, be at risk of entangling your startup with your current employer. Your employer may have an ownership interest in inventions made during the term of your employment and inventions that relate directly to your employer's business or actual or demonstrable participative research or development. You should study your employment documents, such as employment agreements and employee handbooks, to determine how to avoid IP entanglements with your employer. If you are a physician, researcher, or scientist working at a teaching hospital, your employment agreement may include IP assignment provisions establishing that the hospital owns all of your inventions during and associated with your employment. A university affiliated with a teaching hospital may also have an ownership interest in the inventions. Nonteaching hospitals often do not have such IP assignment provisions. If you are an engineer employed by a medical device company, *any* of your medical-related inventions—even on your own time—may be owned by, or arguably owned by, your employer.

When hiring employees or consultants, it is important that employment agreements and consulting agreements address IP ownership.

Startups often encounter problems when they do not pay enough attention to IP ownership provisions, including whether there is an automatic assignment of future inventions.

Case Analysis: Agree to Assign Versus Hereby Assign

A research fellow at Stanford University executed a “Copyright and Patent Agreement” that included the phrase “I agree to assign,” which obligated the research fellow to assign future inventions to Stanford University. The research fellow then visited Cetus Corp. (Cetus). Cetus required that the research fellow execute a “Visitors Confidentiality Agreement” that stated that the research fellow “do[es] hereby assign” to Cetus inventions made “as a consequence of” visiting Cetus. When Stanford University later filed a patent application directed to an invention, Cetus’s equitable title based on the “hereby assign” phrase converted to legal title by operation of laws, so Cetus was the owner of the research fellow’s inventions.

Bd. of Trustees of Leland Stanford Junior Univ. v. Roche Molecular, 563 U.S. 776 (2011).

A startup can maintain a collection of employment documents, consulting documents, and other documents that address the confidentiality of the startup’s technology and ownership of intellectual property. Every employee and consultant should be required to keep the startup’s proprietary information confidential, both during employment and after employment. In addition, they should be required to sign agreements establishing that the startup, not the employee or consultant, owns any inventions or other intellectual property that is developed during the term of employment and that is related to the startup’s business.

Given that provisions may be subject to scrutiny by investors and potential acquirers, agreements should state that inventors presently assign all inventions, including future inventions, to the company using broad language, such as that the inventor “hereby does assign” all inventions. Inventors should execute formal assignments (e.g., a patent assignment) at the time of the invention or soon thereafter; the assignments can be recorded at the USPTO.

The company’s inventors should be cautious about executing any third-party agreements touching upon IP ownership. A seemingly innocuous confidentiality agreement may include strongly worded IP provisions that result in the third party having an ownership interest in the company’s inventors’ inventions. Signing an agreement without studying and understanding the provisions that address intellectual property can carry significant risk.

B. Disclosing Intellectual Property to Third Parties

Checklist for Making Disclosures to Third Parties

1. File patent application before making a disclosure to any third party.
 2. Use confidentiality agreements.
 3. Review your disclosure materials to confirm that proprietary information is disclosed in patent filing(s).
 4. Label materials as “confidential.”
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Entrepreneurs love talking about their technology and its potential benefits, but they often lose sight of how their promotion activities may qualify as “prior art” capable of affecting their ability to obtain patent protection. Whether a disclosure qualifies as a “public” disclosure (which itself qualifies as prior art that can be cited against your later-filed application) varies between countries and may be a fact-intensive analysis. Your disclosure may lead to a third-party prior art event in which the third party intentionally or unintentionally publicly discloses your proprietary information before you file a patent application.

i. Your Own Activity Can Destroy Your Ability to Obtain a Patent

Prior art that can be used to prevent patenting or invalidate an issued patent includes printed publications, public use, offers for sale, or other public disclosures occurring before your application’s effective filing date. Disclosing your technology outside of a confidentiality agreement can seriously affect your ability to procure foreign patent protection because most commercially relevant foreign countries require “absolute novelty” (commonly referred to as “strict novelty”). Under the stringent “absolute novelty” standard, any public disclosure of your invention before filing a patent application may prevent patenting, regardless of the party responsible for the prior art activity. If you publicly disclose your technology at a conference, you may have destroyed your ability to obtain foreign patent protection, which in turn may lead to investors not investing in your company and the inability to block competitors in significant foreign medical device markets.

Patent laws of the United States are more forgiving than those of many foreign countries. The United States permits certain exceptions to what constitutes prior art because it has a one-year disclosure grace period. If you disclose your technology at a conference or other public setting, you