



LIFE SCIENCES
PATENTS
FOR STARTUPS

BRYANT LEE

Life Sciences Patents for Startups

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What is the purpose of this book?

This book is a practical guide to patents for startup founders, employees, investors, and advisors. It explains patents for non-lawyers and people who are not experts in patent law. My goal is to help you understand patents and their business uses as fast as possible while keeping any unnecessary legal jargon or theory to a minimum. I assume no prior knowledge so you should be able to get started reading this book right away with no prior preparation.

The core of this book was written to answer the many common questions I have received from my startup clients about patents. The same questions tend to come up over and over again, and it saves me time and my clients time if they know the basics of how patents work before contacting me. For example, a very common question that startups ask me is whether their product can and should be patented. I provide guidance on this topic in chapter one, and I hope that this will help limit the inquiries to me and my office to the patent applications and cases that will benefit from my legal services. I will not file patent applications on inventions that I know cannot be patented or should not be patented since that would only be a waste of your time and money.

In this book, I will focus on life sciences patents. Out of all the different types of startups, life science startups may be the group where patenting is most important. Quite simply, many investors will not consider investing in a life science startup if there is no potential for patent protection. The reason for this is that life sciences startups spend the vast majority of their investment in development of their product, whether it be a drug, compound, or medical device. Once the product is proven, the manufacturing process is relatively inexpensive and straightforward. The startup typically needs to maintain a monopoly in the market, provided by a patent, to sell the product at a high enough price to recoup the investment and make money. Without patent protection, generic competitors can wait until you have proven your product works and simply copy and sell it at such a low price that the startup cannot recoup its development costs.

Not only are patents extremely important in this industry, but the life sciences present unique issues of patent law that are not present in other kinds of patents. For example, there are intricacies related to how far along the inventors need to be and how much they need to know about the invention and how it works before they can obtain patent. Another interesting question that arises for some life sciences products is how different a compound must be from a naturally existing substance before it is patentable. Moreover, there are specific genres of patents that commonly arise in the life sciences, such as patents on diagnostic methods, methods of treatment, pharmaceutical formulations, and compounds or medical devices themselves.

As you read on, I hope you will learn more about patents, particularly in ways that will help your startup achieve its business goals. This book is not legal advice. I can give you information about different aspects of patent law that are likely to affect you, and I will try to anticipate and answer questions that you likely already have. However, different cases can present different

situations, and there is no way for me to know about your unique situation. I cannot provide legal advice until you have told me about your startup and invention and the other full details involved. Therefore, please do not construe anything in this book to be legal advice until you have agreed to hire me, and I have agreed in writing to accept your case.

Who are you and how can you write this book?

My name is Bryant Lee, and I am a patent lawyer who has worked in patent law for my entire legal career. I have helped companies obtain patents, license patents, and assert and defend against patents in lawsuits. After graduating from Harvard Law School, I practiced patent law at Covington & Burling LLP, a large law firm of over 800 lawyers and \$800 million in revenue last year, where the firm billed \$450 per hour for my time. Former U.S. Attorney General Eric Holder now works there. I have represented some of the largest pharmaceutical companies in the world in patent matters, and my patent work has involved small and large molecule drugs, recombinant organisms, statins, sedatives, cancer drugs, nutritional supplements, and many other inventions.

But patent law is not just another field of law to me. I am involved in it because of my background in the sciences and interests in entrepreneurship and building new things. Academically, I have an M.S. from Carnegie Mellon University, where I was a Ph.D. candidate, and a double-degree B.S. from the University of Maryland. I was awarded both an National Science Foundation Graduate Research Fellowship and National Defense Science and Engineering Graduate Fellowship for my scientific work. I am an inventor on twelve patents and have co-authored seven peer-reviewed scientific papers.

My current venture is a new kind of legal service provider, Cognition IP, that offers high quality legal service and uses technology to make our lawyers more efficient. We try to automate routine tasks so our lawyers can focus on practicing law. Many legal tasks involve only routine cutting and pasting, proofreading, or filling out forms, yet are still done by hand at traditional firms. Traditional firms use an hourly billing model that gives them no incentive to be more efficient. Cognition IP uses technology and process management to reduce costs and produce consistent legal work. Of course, all real legal work is done by human lawyers and the entire operation is overseen by lawyers.

I hope that my new venture will help improve the practice of law. That is why I got into technology in the first place, because I believe it can make the world a better place.

Chapter One: Should I get a patent?

The first question that startup clients usually ask me is whether they should patent their product. To answer this question, we must first understand what a patent is. We will start with the question of what things can be patented.

What things can be patented?

There are several different types of intellectual property (IP) in the United States, so it is important to consider whether a patent is the right type of protection for what you are trying to protect.

The term “patent” is commonly used as a short-hand for what is technically known as a *utility patent*. A utility patent is a type of protection to consider for covering the product that your startup sells or the service that you provide. Utility patents cover inventions, which are things that have functionality. In other words, for something to be an invention, it must be able to be used for something. The test for functionality is minimal so even a table is considered to be functional because you can put things on it. Drugs, medical devices, treatments, and supplements can be protected by utility patents because they have utility in curing diseases or improving people’s conditions.

There are two other kinds of patents, *design patents* and *plant patents*, but they are less common than utility patents.¹ Design patents cover how something looks. The design of things like cabinets, automobiles, and computer user interfaces can be covered by design patents. In the life sciences, design patents are sometimes used to protect the design of medical devices. However, design patents are often weaker than utility patents because a competitor can avoid infringing your design patent by offering the same functionality with a different design. For example, if the design patent covers a medical device, then a competitor can develop a medical device that does the same things, but looks different, and not infringe your design patent. Still, design patents are useful in some circumstances. Meanwhile, plant patents cover plants and are probably only relevant if your business is agricultural.

In this book, I will mainly be talking about utility patents and will use the term patent to mean “utility patent” unless otherwise stated.

The three other major types of IP protection are copyright, trademark, and trade secret. While they are not the focus of this book, it is helpful to know what they are and how they would apply to your business.

¹ In 2015, the most recent year that official statistics are available, applicants filed 589,410 utility patent applications, 39,097 design patent applications, and 1,140 plant patent applications in the U.S. U.S. Patent & Trademark Office, “U.S. Patent Statistics Chart Calendar Years 1963–2015,” (https://www.uspto.gov/web/offices/ac/ido/oeip/taf/us_stat.htm).

Copyright protects expression of an idea, but not ideas themselves. It covers things that we would consider to be artistic works like novels, films, paintings, and photographs. However, something need only be expressive and not necessarily what we would call “artistic” to be protectable by copyright. You can use copyright in your business to protect your website, whitepapers, advertisements, blog posts, and the like. It can sometimes be used to cover things like product design and look and feel, much like design patents.

Copyright also covers computer software source code, but the protection is very different from patent protection. Copyright only protects against actual copying by someone else. If someone copied your source code and used it in their product, then that is likely copyright infringement. However, if they only copy your software’s features but implement those features with their own original source code, then that is not copyright infringement.

On the other hand, the U.S. Copyright Office currently does not allow registering a copyright in DNA sequences, even if the DNA sequences are genetically engineered and do not occur in nature.²

Trademark is used to protect brands and company names. The idea behind trademark is to allow companies to uniquely identify the source of goods so that customers will be able to judge quality based on the associated brand or company name. For example, the company named Johnson & Johnson is the only entity that can use that name, and, therefore, consumers know that any product they buy from that brand will have a certain level of quality. Companies that create counterfeit Johnson & Johnson products are committing trademark infringement. In your business, you will likely want to trademark your company name and brand names that you develop.

Trade secret is a way to protect commercially valuable information that is kept secret by a company. This includes things like business information, customer lists, and company strategy. However, trade secret can also be used to protect inventions, such as a secret method of manufacturing a product. Whether to use patent protection or trade secret protection is generally an either-or proposition, you cannot use both. I will discuss how to make the decision between patent and trade secret protection later in this book.

² Christopher Holman, Claes Gustafsson, and Andrew Torrance, “Are Engineered Genetic Sequences Copyrightable?: The U.S. Copyright Office Addresses a Matter of First Impression,” 35 Biotechnology L. Rep. 103 (2016).

Types of Intellectual Property

Patent (Utility Patents) – Inventions that have functionality. Examples: Products, services, pharmaceutical drugs, medical devices, treatments, nutritional supplements.

Design Patent – Designs and look and feel. Examples: Non-functional design of a product, user interfaces.

Plant Patent – Plants.

Copyright – Expression of an idea, but not ideas themselves. Examples: Website, whitepapers, advertisements, blog posts, non-functional design of a product, user interfaces.

Trademark – Brands and company names.

Trade Secret – Commercially valuable information that is kept secret. Examples: Business information, customer lists, company strategy, secret inventions.

What is a patent?

Now that we know that a patent covers inventions, it's important to understand what a patent is. A patent gives you the power to prevent other people from using an invention—in other words, it can be described as a legal monopoly given to you by the government. From a business perspective, it is easy to see that having a monopoly on an invention helps you drive more demand for your product and keep prices high. If your customers cannot buy your product from a competitor, then they must buy it from you.

Patents have a limited lifetime. Currently, they expire 20 years from when they were first filed.³ After a patent expires, anyone is free to use the technology in a patent.

The product where it is easiest to see the effects of patents is pharmaceutical drugs. When a pharmaceutical company develops a new drug, they will almost always have a patent on it. During the lifetime of the patent, the company has a monopoly on the sale of this drug and can charge high prices. However, once the patent expires, other companies can make generic versions of the drug that are simply copies of what the innovator pharmaceutical company invented. The ingredients in a drug are usually inexpensive, so drugs are cheap to produce—it is only the original research needed to discover a drug that is expensive. As a result, generic drugs often sell for 10x or 100x less than the original drug. These generic competitors significantly weaken customer demand for the original drug. Therefore, most of the money that pharmaceutical companies make on drug development comes from the time when they have patent protection or some other legal mechanism for maintaining a monopoly in the marketplace.

There is an additional detail to cover in that, since a legal change in 2006, patents do not always give you the power to absolutely prevent others from using your invention. Instead, you

³ More specifically, they expire 20 years from the filing date of the first non-provisional U.S. or Patent Cooperation Treaty (PCT) application to which priority is claimed.

might be awarded monetary compensation. There is a legal test developed by courts to decide whether you either get to use your patent to (1) prevent someone from using your product, as was historically the case, or (2) obtain a monetary recovery in exchange for someone else using your invention. The latter option can be thought of as similar to a compulsory license, where someone can use your patented invention if they want but they have to pay you a royalty fee. Obtaining a royalty on the use of your invention might not be as good as being able to stop others from using your invention completely, but it can provide a sizeable monetary recovery in the right circumstances.

The legal test for determining whether you can obtain a court order to prevent others from using your invention, or are instead entitled to royalties, is based on complex legal language. However, one of the key factors is whether the company owning the patent produces the patented product, and it is their direct competitor that is infringing the patent by creating a copycat product.⁴ In this case, the probability that you, as the patent holder, will be able to stop your competitor from producing a copycat product is higher. However, if your company does not produce a product covered by your patent or is not a direct competitor with the company using your patented invention, then the probability that you will be able to stop the infringer is lower. You would still be able to collect a royalty fee though.

Life sciences patents tend to be relatively stronger than other kinds of patents in that they tend to be more likely to let you obtain a court order to stop infringers, as opposed to just a compulsory license. The reason for this is that life science patent lawsuits tend to involve two companies that both produce products and are actually competitors, plus the patent often covers the core aspects of the product. For a pharmaceutical drug that your company sells, you would likely be able to use your patent to obtain a court order stopping competitors from selling the same drug.

In summary, a patent gives you the power to either stop others from using your invention or at least collect a royalty from them for using it. To close out, let's consider a couple of things that patents *are not*.

A patent does not give you the power to make something. In the highly regulated space of pharmaceuticals and medical devices, your permission to make something will come from the Food and Drug Administration (FDA), which is entirely separate administrative process, or whatever other regulatory agency regulates your type of product. Also, you can be prevented from making a product if other companies have a patent on what you make. If there is no regulation controlling

⁴ The applicable case is *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391 (2006), which states that a company must show the following to obtain an order to stop a patent infringer: “(1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction.”

your product and no patents owned by other companies on it, then you are generally free to make whatever product you wish and do not need to get permission by obtaining a patent.

This second point is important to consider: the fact that you have a patent on your product does not mean that other companies might not own patents on other aspects of your product that could prevent you from selling it. A product can be covered by multiple patents, and different patents might cover different features of the product. Even though you have patents on some parts of the product, other companies might still own patents on other parts of the product. The process of determining whether other companies have patents on your product is known as *freedom to operate* (FTO) and is distinct from the process of obtaining a patent. If you want to make sure that you can make a product without being sued by other companies for patent infringement, then you can hire an attorney to do a search for existing patents and provide a freedom to operate opinion.

Checking that you have freedom to operate is an important consideration for many life sciences companies. Because so much investment must be made to develop the product and life sciences patents have a higher chance of being able to completely block a product (instead of simply providing a compulsory license), it is typically a good idea to make sure you have freedom to operate before developing a life sciences product.

A patent is also *not* an award or endorsement from the government of your product. You can advertise the fact that you have obtained a patent, but the government's grant of a patent is not a statement about the usefulness or quality of your invention. When it examines your patent application, the government does not test your invention or evaluate whether it does what you say it does. The government's evaluation criteria are aimed more at whether it ought to grant you a legal monopoly to your invention. There is little danger to the government if it grants you a legal monopoly on an invention that is not very useful, which is why this is not a major evaluation criterion.

Having covered what a patent is, we'll turn to the question of whether you should apply for a patent.

Should I patent my invention?

If you want to prevent your competitors from using a new invention that you have come up with, then you are right to consider obtaining a patent. In the life sciences, you often need to be able to prevent competitors from using your invention in order to make money. Therefore, patenting often makes sense.

A patent is only as valuable as the invention. If the invention you've come up with is groundbreaking and has huge customer demand, then a patent could easily be very valuable. However, if your invention is only a minor feature or is not attractive to customers, then the value of a patent is probably less.

In the life sciences, in the early days of the company, you often do not know if your invention will be valuable or not because it is unclear if the product will be effective and safe to use. However, it will typically still make sense to consider patenting early on because, if the product succeeds, the multiplicative value that the patent adds could be very great. Without a patent, the value of your company could be much lower. The potential for large returns due to patent exclusivity is also very important for attracting investors and convincing them to invest.

There are also three specific situations that apply to startups, where patenting can make a lot of sense: (1) attracting investor interest (2) protecting the idea before disclosing it to potential partners or investors and (3) preventing patent lawsuits against your company.

Investment

In the life sciences, having patent applications is typically very important for being able to obtain investment. Most of the risk and expense for life sciences startups is in the development of their drug or medical device. Once the product is proven to be effective and safe, manufacturing is relatively inexpensive. Moreover, other than the core product itself, there are typically few other differentiators between products in the market (for example, you probably cannot differentiate based on design the way that Apple does with computers or based on customer service the way that Zappos does with shoes). Therefore, without patent protection, a generic company could wait until your startup successfully develops the product and then copy and sell it for much less. This occurrence would drive prices down so low that your startup would probably not be able to recoup the cost of product development.

For this reason, many investors will insist on patent protection before they will invest in a startup in the life sciences. In the early stages, they will typically want to see that you have filed patent applications. Once your company gets closer to market, investors may want to see that some of your patent applications have been successfully granted and become issued patents.

In addition, many investors will insist on a freedom to operate analysis performed by a lawyer to make sure that your product is not already covered by another company's patents, which could keep your product off the market.

Therefore, you will probably want to seriously consider patenting in order to be able to attract the investment that you would need to build your company.

Disclosure to potential partners and investors

Startups often need to disclose their ideas to potential partners and investors, and startup clients often want to know if they need to file a patent application beforehand. Filing a patent application can provide useful protection in this situation, though it is not always necessary. A less expensive tool for protecting yourself in this situation is a non-disclosure agreement (NDA). Your attorney can prepare a form NDA for you very inexpensively, or you can obtain a free NDA online

that you fill out yourself from highly reputable firms like WilmerHale or Cooley.⁵ However, NDAs do not always provide as much protection as patents, which I will explain in more detail below.

Also, some investors are not willing to sign NDAs. Most investors will not go out and purposely try to take your idea, but if a different founder comes along with the same idea, they do not want to have signed an NDA that prevents them from investing.

Companies that are interested in partnering with you should generally be willing to sign an NDA, especially if they operate in a similar space as you. If another company refuses to sign an NDA, be aware that they may be able to use what you disclose to them without repercussions.

For these reasons, if your potential partner or investor will not sign an NDA, then you might want to protect yourself by filing a patent application. Having a patent application on file will mean that you are first in line. Even if your potential partner or investor tries to patent the same thing later on, you have priority over them.

Also, you may want to consider filing for a patent even when your potential partners or investors do sign NDAs because NDAs do not always provide the best protection. An NDA does not spell out exactly what your inventions are, unlike a patent which states exactly what inventions you own. Therefore, in a later dispute, it is harder to prove that someone else took what belonged to you.

When you enter into a partnership with another company, your inventions can easily leak over into their organization and end up being used by them. Quite commonly engineers will use the best solution available without necessarily inquiring into who owns it, so unless you have a patent clearly showing that the invention belongs to you, then your ideas could end being used by and sometimes even have ownership claimed by someone else. For these reasons, a patent provides an additional, stronger layer of protection over an NDA.

Once you start publicly disclosing your product to other people, it is best to file patent applications relatively quickly on any inventions that you plan to protect with a patent. The U.S. has a rule that you cannot file a patent application on an invention that you have publicly disclosed more than one year ago. This is a strict rule so you need to be very careful that you file your patent applications within one year of publicly disclosing your invention. If you have another person sign an NDA before you disclose your invention to them, then generally this is considered private and *not* a public disclosure that would cause the one-year clock to start running. However, many disclosures that in casual conversation we would call “private” are considered by the law to be public disclosures, so the safest thing to do is file your patent applications within one year of any disclosures.

⁵ The WilmerHale and Cooley document generators are available at <https://launch.wilmerhale.com/build/document-generator/> and <https://www.cooleygo.com/documents/index-document-generators/>.

Another reason to file quickly is that the United States uses a “first to file” system where the first person to file a patent application on an invention is the one who is entitled to the patent. This creates a risk that after you disclose your invention someone else could potentially file a patent on a minor variation and get a patent before you. Legally, someone else is not supposed to be able to obtain a patent on the exact idea they got from you, but it may be possible for them to change your idea slightly and obtain a patent. Their patent may then prevent you from patenting your own original idea.

Preventing patent lawsuits against your company

Another very good reason for obtaining patents is to prevent lawsuits against your company. The reason this works is because your patents create a threat that you will countersue a company that sues you. The threat of a countersuit ends up deterring many companies that would otherwise sue your company for patent infringement.

This use of patents can be very valuable because it can allow your company to operate in areas where it might otherwise be shut out by existing patents. By having your own patents, you can sometimes minimize the risk of patent lawsuits even if your company is infringing other patents.

For this strategy to be effective, your company would need to have patents that other companies are infringing. Deterrence is only effective when other companies know you can sue them for patent infringement. To develop a set of patents for deterrence, you will probably need a detailed strategic analysis of what your competitors are making so you would know what they are potentially infringing.

Also, this strategy does not work against companies that do not make products. There are some companies that make a business of just filing patent lawsuits, who are often referred to as *patent trolls*. Patent lawsuits can be so lucrative that this is a viable business model now. These companies cannot be deterred by your patents because they do not make anything that would infringe your patents. A different set of strategies is needed to defeat lawsuits from these companies.

Can I patent my invention?

The next question after whether you *should* patent your product is whether you *can* patent your product. In this section, I discuss factors that will determine whether the U.S. Patent & Trademark Office will grant you a patent for your invention.

First, it is okay if your invention is just at the idea stage. You are not required to have a prototype or model. All you need to do is be able to describe your invention completely so that an engineer or scientist can read your description and build it. In legal parlance, you need to write your description for a person of “ordinary skill” in your field to be able to make the invention.

Statistically, the odds of obtaining a patent are good. A recent study found that between 55% to almost 70% of patent applications are allowed to become issued patents by the U.S. Patent

& Trademark Office.⁶ The range accounts for different ways the study authors counted patent issuance versus non-issuance. While these numbers are high, this does not mean that all of these issued patents are highly valuable. Some companies are able to obtain large numbers of patents by keeping the legal coverage of their patents narrow (in other words, the monopoly granted by each patent covers a small number of potential products). This increases the chances that the patents will be granted but decreases their value. Patents that cover fundamental technology might be more difficult to obtain. Patents on drugs and medical devices are granted at a slightly lower rate than other patents.⁷

There are three major criteria that your invention must meet for it to be patentable. Your idea must be (1) new, (2) not obvious, and (3) not a natural law or abstract idea.

Novelty

Novelty is the requirement that your invention be new. In other words, no one else can have done this before.

When researching whether your invention is new, you have to consider nearly every kind of public information including other patents, publications, publicly used or known products, and products being sold or that were sold. A common misconception among startups is that the fact that an invention has not been patented before means that they can patent it. This is not true. A prior use, publication, or sale of the invention anywhere will prevent you from obtaining a patent. Doing a thorough search of what inventions were previously known or used is an important part of the patent process and is something you should probably use an attorney or professional patent searcher for. This is what is called a *patentability search* because you are doing a search to determine if your invention is patentable.

It is important to do a search that is more thorough than just going to the store and seeing if they sell your invention or not. There are many products that are sold or have been sold and, for one reason or another, are not available in mainstream stores in the U.S. Keep in mind that a public use or sale anywhere in the world, at any time, will prevent you from obtaining a patent.

Also, there are many patents and scientific journal articles that describe advanced or speculative technologies that are not found in stores. Large companies often file patents on technologies that they might use in the future, even if they are several years away from commercialization. Scientific journal articles can cover technologies that are even more advanced and far from commercialization.

⁶ Michael Carley, Deepak Hegde, and Alan Marc, “What is the Probability of Receiving a U.S. Patent?” 17 Yale J.L. & Tech. 203, 210 (2015). Another study found that approximately 75% of all patent applications result in at least one patent. Mark Lemley and Bhaven N. Sampat, “Is the Patent Office a Rubber Stamp?” 58 Emory L.J. 181, 182 (2008).

⁷ Carley, 17 Yale J.L. & Tech. at 213.

It is highly recommended that you hire a lawyer or professional patent searcher to perform the patentability search. Searching requires specialized skills, and if you do it yourself, there is a large risk that you will miss something. However, you can do a first pass search yourself as an initial filter. If you find that someone else has made your invention before, then you do not need to pursue your patent application further. If you do not find prior references to your invention, then you can proceed to seek professional assistance from a lawyer.

To do a first pass patentability search yourself, I would suggest the following steps, which are in order of simplest to more complex.

1. Perform a search for your invention on common search engines like Google. Make sure to use a variety of different words that could describe your invention.
2. Perform a search on Google Scholar and other databases of scientific articles that you may have access to. Again, be sure to use a variety of words that someone might use to describe your invention.
3. Perform a search on Google Patents (<https://patents.google.com/>), which includes U.S. patents and many worldwide patents. The search interface to Google Patents uses natural language search queries so that searching is much like using Google. Natural language queries are user-friendly but make it harder to focus your search than the structured search queries that the tools below provide.
4. Next search the U.S. Patent & Trademark online databases of patents and patent applications. These are available with PatFT for patents and AppFT for patent applications (<http://patft.uspto.gov/>). The Advanced Search option for each of these databases allows the use of structured search queries that are more precise than queries you can enter on Google Patents.
5. If none of the above searches turned up your invention, then I suggest going to a Patent and Trademark Resource Center (PTRC) where you can use the Examiner Assisted Search Tool (EAST) that Patent Examiners use. Patent Examiners use EAST to search for prior patents and patent applications when they review your patent application. This is a high-powered tool that allows more sophisticated searches than the U.S. Patent & Trademark Office's online databases. There is at least one PTRC in every state, and you can find their locations on the patent office website (<https://www.uspto.gov/learning-and-resources/support-centers/patent-and-trademark-resource-centers-ptrc/ptrc-locations>). PTRCs are public facilities and are free to use.
6. Finally, make sure to hire a patent lawyer or professional patent searcher to do a thorough search.

Lastly, with the novelty requirement, there is a related limitation that is worth mentioning: an invention that you have used or publicly disclosed more than 1 year in the past is no longer considered to be “new.” That is, your own use, disclosure, or sale of your invention will be

considered by the U.S. Patent & Trademark Office to prevent you from patenting your invention. So be careful not to miss the one-year deadline.

Non-obviousness

Closely related to the requirement of novelty is the requirement that an invention be non-obvious. The question is whether your invention would be obvious to a person having ordinary skill in the field of your invention at the time you filed the patent application.⁸ If so, then the invention is not patentable.

The way that obviousness is examined by Patent Examiners at the United States Patent & Trademark Office is whether someone could take prior references and piece them together to make your invention. By “references” I mean the same things that are considered for novelty purposes, in other words nearly every kind of public information including other patents, publications, publicly used or known products, and products being sold or that were sold. For this reason, your patentability search should not just be a search for inventions that are identical to yours but also any inventions that might be similar.

However, Patent Examiners are not allowed to say that your invention is obvious by taking a bunch of unrelated references and combining them for no reason. Instead, they must also provide a reason, or “motivation,” that a person of ordinary skill in the field of the invention would combine pre-existing references in a way that leads to your invention. Patent Examiners have some leeway in the reasons they can use to find inventions to be obvious. In fact, the U.S. Patent & Trademark Office provides to its Examiners a number of standard reasons for combining references such as “Combining prior art elements according to known methods to yield predictable results,” “Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results,” and “Obvious to try – choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success.”⁹ As you can see, an invention that merely consists of two separately well-known features that are combined in a way that would be apparent to an ordinarily skilled person in the field has a good chance of being rejected by the patent office.

Nonetheless, this does not mean that an invention that is made of a combination of pre-existing parts will be denied protection. On some level, almost every invention is a combination of previously known features because every invention builds on the past. Moreover, the U.S. Patent & Trademark Office allows between 55% to almost 70% of patent applications to become patents,¹⁰ so clearly Patent Examiners find many patent applications submitted to the patent office to be non-obvious.

⁸ 35 U.S.C. 103.

⁹ Manual of Patent Examining Procedure § 2143.

¹⁰ Michael Carley, Deepak Hegde, and Alan Marc, “What is the Probability of Receiving a U.S. Patent?” 17 Yale J.L. & Tech. 203, 210 (2015).

It's hard to predict whether the U.S. Patent & Trademark Office will consider an invention to be obvious or not. An experienced patent lawyer who files many patent applications in a particular technology area will often have some sense of what the patent office will allow to be patented. However, it's never totally certain because obviousness is a bit subjective and varies between different Patent Examiners.

One factor that pretty consistently affects whether your invention will be considered non-obvious is the number of different references that the Patent Examiner must combine to find all the features of your invention. Legally, Patent Examiners can combine as many references as they want.¹¹ In practice, though, Patent Examiners tend to lean more towards allowing a patent to be granted when they must combine three or four or more references to argue that your invention is obvious. Many Patent Examiners just seem to feel a bit silly when they must use so many different references to argue that this invention was “obvious” in the past.

If the invention is due to an unexpected or surprising result, then that also makes a stronger case for patentability. The combination of two previously known compounds in a way that leads to an unexpected effect is more likely to be patentable than an invention that combines two previously known compounds in a way that simply results in the combination having the same effects as the two compounds would have individually. The less predictable the outcome of the combination is, the more likely a patent can be obtained.

Companies that have released a product using the patented invention can also use the commercial success of the product as evidence that the invention was not obvious.¹² The reasoning is that, if the invention was obvious, then someone else would have done it already and reaped the financial rewards. Commercial success essentially indicates pent up demand. To use this argument, however, you must provide evidence that your patented invention was responsible for the commercial success of the product. If the commercial success was based on other unpatented features of the product, or on business factors like marketing, then the commercial success argument cannot be used. In addition to commercial success, other factors that can be used to support non-obviousness include winning awards, positive media attention, the fact that competitors have copied your product, other people having previously tried to make the invention and failing, and extensive licensing of the patent.

Not a natural law or abstract idea

Finally, an invention must not be a natural law or substance or abstract idea to be patentable. This criteria is much less commonly used as a grounds of rejection by the patent office than the prior two, and most patent applications will not have an issue in this area.

¹¹ Manual of Patent Examining Procedure § 2145(V).

¹² Manual of Patent Examining Procedure § 2145.

Under U.S. law, a naturally occurring substance cannot be patented. For example, patents cannot be obtained on a naturally occurring DNA sequence, such as the DNA sequences for the BRCA1 or BRCA2 genes that are correlated with an increased risk of breast and ovarian cancer.¹³ However, a synthetically created cDNA sequence that is related to a natural DNA sequence but has had its non-coding sequences removed *is* patentable.¹⁴

A similar principle prevents the patenting of natural laws, which can be thought of as naturally occurring relationships. For example, patent applications for diagnostic methods that simply detect the levels of a metabolite and determine the right dosage of a particular drug based on the detected levels are at risk for being rejected as an attempt to patent a natural law, namely the relationship between metabolite and dosage.¹⁵

Lastly, the requirement that the invention not be an abstract idea most typically only comes into play in the life sciences for inventions involving software or business methods. The requirement to not be abstract essentially requires that the invention be a concrete advance and not an abstract concept. For example, a patent application for the general concept of storing paper medical records electronically would likely have an abstract idea problem. Factors that would tend to cause a patent application to be found to be abstract include (1) if the invention can be performed entirely in the human mind or with just a pen and paper, (2) if the invention is very similar to an activity that has long been performed by humans, or (3) if the invention is simply to do something on a computer in the exact same way that it was previously done but by hand.

Trade secret alternative

In deciding whether you should seek a patent, it is worthwhile to consider an alternative form of legal protection that may be possible for your invention, namely trade secret. Unlike patent, obtaining a trade secret does not require submitting an application to the government and going through an approval process. Instead, trade secret is effectively a layer of legal protection on top of your own efforts to keep an invention secret. Basically, the way trade secret works is this: if you keep an invention secret, and make reasonable efforts to ensure it stays secret, then someone stealing your invention from you would be illegal and you could sue them to stop them from using the invention.

Trade secret protection can apply not just to inventions but to many kinds of valuable business information such as business plans, customer lists, supplier lists, marketing information, and so on. There are three basic requirements for trade secret law to apply: (1) the information must be secret, (2) you must make reasonable efforts to preserve its secrecy, and (3) the information must be specific (not general knowledge) and be commercially valuable.

¹³ *Assoc. for Molecular Pathology v. Myriad Genetics*, 133 S. Ct. 2107, 2111–12 (2013).

¹⁴ *Id.* at 2119.

¹⁵ *Mayo Collaborative Services v. Prometheus Labs.*, 132 S. Ct. 1289, 1293–94 (2012).

The protection that trade secret gives you is different from that of patent law. Trade secret does not give you a monopoly on an invention the way that a patent does. Instead, what trade secret provides is protection from someone else *misappropriating* the invention from you. Roughly speaking, misappropriation occurs when someone does a wrongful act, and the most common types of misappropriation are (1) industrial espionage and (2) acquiring an invention when there is a duty not to disclose. Industrial espionage includes things like stealing documents from your workplace, hacking into your computer system, or bribing your employees. In terms of acquiring inventions when there is a duty not to disclose, this can occur, for example, if a competitor poses as a potential business partner and you disclose your inventions to them under an NDA. If the competitor then uses those inventions in their business, that is a potential misappropriation. Similarly, if your competitor gets your inventions from your former employees who are still under an NDA agreement, then that is also a potential misappropriation.

By contrast, reverse engineering a product is not misappropriation and neither is copying a product's features. Independently inventing a product is also not a misappropriation.

Another difference with patent law is that trade secret protection lasts forever, so long as you continue to meet the requirements—including keeping the information a secret.

Let's now consider what types of inventions might be best protected by trade secret versus patent law. First, any invention that is public would not be possible to protect with trade secret law because it is not secret. Drugs and medical devices that go through the FDA approval process will generally become public after FDA approval is granted. The active ingredients of a drug, and the mechanism of operation of a medical device will generally become public information. Therefore, trade secret protection will not work for these types of inventions.

Second, if your product can be easily reverse engineered, have its features copied, or can be independently invented, then trade secret protection is probably not a good choice. Trade secret law would not protect you from any of these methods that competitors could use to obtain your invention. This aspect of trade secret law also makes it a bad choice for most drugs and medical devices because many of these products are easy for competitors to reverse engineer through a chemical analysis or product teardown.

Trade secret law may be a good choice, however, for an invention that operates behind the scenes, can be kept secret, and is not easy to reverse engineer, copy the features of, or independently invent. One possible place where life sciences companies could use trade secret protection is for processes that occur internally to the company and are not exposed to customers. For example, a company like 23andMe, which does DNA analysis of samples provided by consumers and presents results in a web interface, could use trade secret to protect the procedures and tools that it uses internally to analyze the samples.

Trade secret makes a lot of sense for technologies that are rapidly changing and where technology would likely become obsolete before patents could be obtained from the patent office.

In the case of 23andMe, it would probably still be better for it to patent any foundational innovations in DNA testing and analysis, but it might make sense to use trade secret to protect incremental innovations that are rapidly changing, like a new way of storing samples or transferring them so that the analysis could be completed faster.

In sum, trade secret is an important type of legal protection to consider for your inventions. However, it often does not apply well to life sciences inventions because many life sciences products have their ingredients or features made public through the FDA approval process and because the products are often easy to reverse engineer. Trade secret may be a good choice for hidden features of a complex system or for features that are short-lived and will quickly become obsolete.

Company stage and patent strategy

In the above sections, I have discussed the various considerations in deciding whether to patent a single invention. The reality is that it is typically only very early stage startups that are considering patenting only a single invention at one time. Innovative companies quickly reach a point where they are developing multiple inventions per year, and it is important to consider patent strategy from a company-wide perspective rather than from the perspective of a single invention.

Multiple patents that are in a single technology area can be grouped together into what is called a patent portfolio. A patent portfolio is usually much more valuable than a single patent, and the value of a patent portfolio tends to increase more than linearly with the number of patents. In other words, five patents in a single portfolio covering a technology space are typically more valuable than five single patents in different areas. This is because a single patent can only cover so much of a technology space. Your competitors may be able to design their products to avoid a single patent, which is known as a *design around*. However, with many patents you can develop multiple areas of coverage in a single space, which you can think of as analogous to a minefield. With enough patents, it can become very difficult for your competitors to avoid all your areas of coverage.

In the early stages of a company, when resources are limited, it is common for life sciences startups to try to focus their patent portfolio around their core technology. This allows them to protect themselves in their area of core value.

As your company grows, your considerations will likely shift from completing the R&D to ensure that your product is effective and safe, to ensuring that you have a defensible position in the market so that you can collect on the value your product has created rather than being undercut by competitors. It's often a good idea to increase your patent coverage on your core technology, for example by patenting the same technology in different ways with patents on the compound, pharmaceutical formulation, diagnostic method, and method of treatment, so that you have a strong and defensible position.

Moreover, it is common that your company will learn more through R&D about how the product works and develop a better understanding about what aspects are more important than others, as well as develop new ideas for additional research and development. As you do so, this would be a good opportunity expand your patent portfolio to cover related or supplemental treatments and related technology areas.

For medical device companies, it is also helpful to develop a large patent portfolio to deter lawsuits against you from other companies. As your company grows to become a mid-size or large entity, it becomes more of a target for patent lawsuits. First, incumbents start to recognize you as more of a threat. Second, the growth of your company means higher revenue and potentially higher monetary recoveries for companies that assert patents against you. Third, as your company expands its product offerings into new areas, there are more potential patents owned by others that might cover your products.

One of the best ways to deter other companies from suing your company for patent infringement is to develop a strong patent portfolio that would allow you to counter sue. This can give you strong deterrence capability because other companies know that if they sue you for patent infringement, then you will sue them back for infringement of your patents by their products.

When two companies with strong patent portfolios sue each other for infringement, the result is often a deadlock where neither company can obtain an advantage because both companies infringe each other's patents. The result is often a cross-license, where each company licenses its patent portfolio to the other. Therefore, if you have a strong patent portfolio that covers another company's product line, it becomes less likely for that company to sue you for patent infringement. They would know that the likely result will be a cross-license with no net gain for them.

In sum, patent strategy should be considered from a company-wide perspective and not just the perspective of a single invention. As your company grows, the strategic considerations are likely to change from wanting to cover a single invention to ensuring a defensible position by developing a portfolio on your core technology and related technology areas.

Chapter Two: How do I obtain a patent?

After you have determined that you can and should obtain a patent on your invention, the next thing to discuss is the process for obtaining a patent.

Patents are granted by the governments of each country and only have effect within the geographic borders of that country. Most of my startup clients are in the United States or are targeting the U.S. market. For these startups, it makes sense to think about obtaining a U.S. patent, which has force within the United States. It will let you prevent others from using your invention, or allow you to collect a royalty from them, within the U.S. If someone decides to use your invention in a country where you do not have a patent, then you would not have a way to stop them. However, importation into the U.S. is covered by U.S. patents.

The way to obtain a patent is by filing a patent application with the patent office of the relevant country. For a U.S. patent, you would file a patent application with the U.S. Patent & Trademark Office. Most often this is filed online, but applications are also accepted by mail and fax. The U.S. Patent & Trademark Office has a significant backlog of patent applications to examine so it can take a long time for it to evaluate your application and grant a patent. At press time, the average time for the patent office to do its first substantive analysis of your patent application and send you an initial response is 16.3 months.¹⁶ Several more rounds of correspondence between your patent lawyer and the patent office would follow over the course of months or years. Currently, the average time from the filing of a patent application to the grant of the patent is 32.5 months.¹⁷

If you want to obtain your patent faster, there is a way to speed things up by paying the patent office additional money to put your patent application on what is known as Track One. Track One status gives your patent application priority in the examination process without any additional substantive requirements needed from you. In this program, your patent application will typically be reviewed within a few months, and the patent office aims to complete its decision process on whether to grant your patent within one year (it usually meets this deadline). The patent office charges \$4,000 for Track One. In some situations, usually involving very early startups that are pre-funding, it may be possible to receive a 50% or 75% discount on this fee. The patent application process with Track One is essentially the same as the regular patent application process and is just faster.

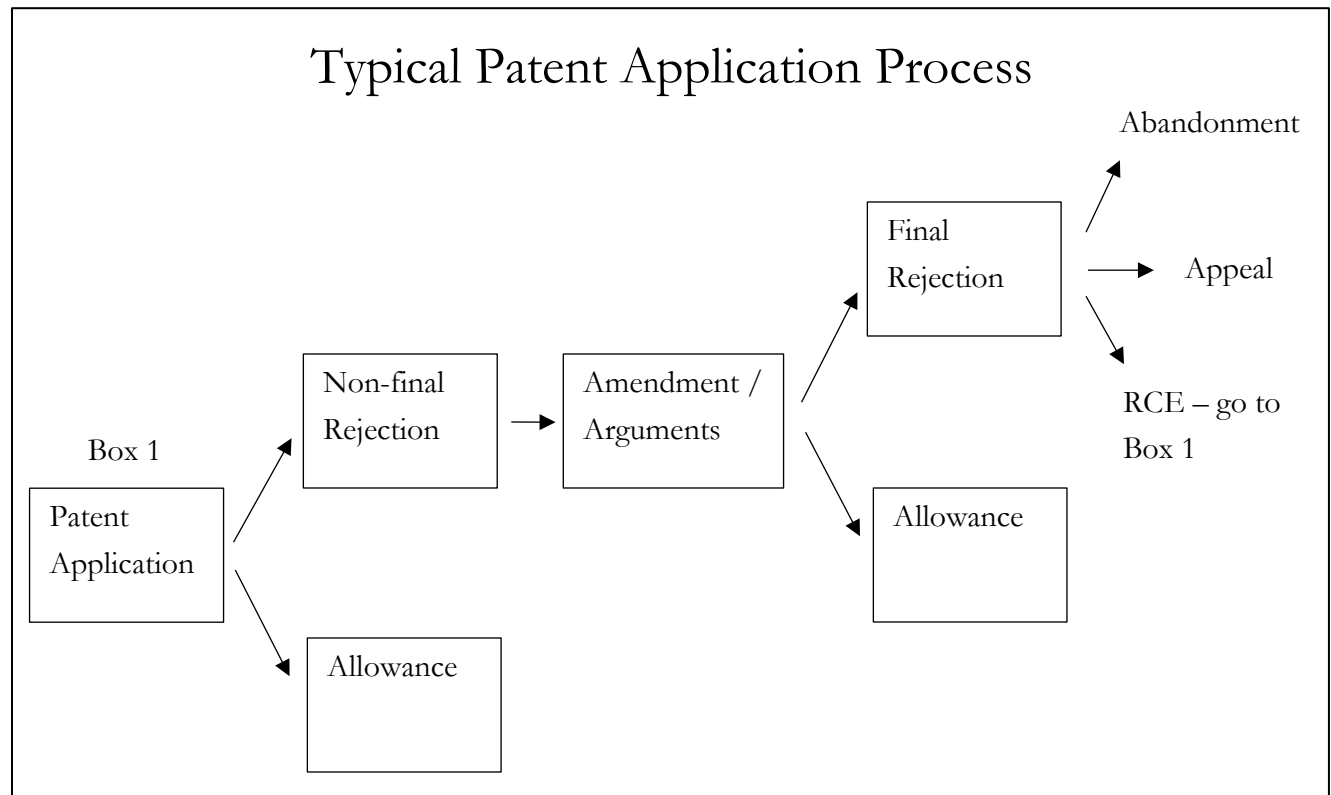
Overview of the patent application process

Filing a patent application with the U.S. Patent & Trademark Office is the first step in obtaining a patent, but the reality is this is just the beginning of the process. As I mentioned above,

¹⁶ U.S. Patent & Trademark Office, Patents Dashboard (<https://www.uspto.gov/dashboards/patents/main.dashxml>).

¹⁷ U.S. Patent & Trademark Office, Patents Dashboard (<https://www.uspto.gov/corda/dashboards/patents/main.dashxml?CTNAVID=1004>).

once you file your patent application the process of applying for a patent is not done because you still must go through a series of correspondence with the U.S. Patent & Trademark Office to obtain a patent. The typical process looks like this:



As shown in the chart, the process starts with filing the patent application. This initial step is labeled *Box 1*. You then wait for a response from the U.S. Patent & Trademark Office, which will typically be either a non-final rejection or an allowance. A non-final rejection means that the patent office has determined that it will not grant your patent application as submitted and that it wants you to make changes. If you receive a non-final rejection do not worry. Rejections are the most typical first response from the patent office and experienced patent applicants know to expect them. Studies show that 86.4% of patent applications are initially rejected.¹⁸ Only 11.4% of patent applications receive an allowance on their first try.¹⁹

The reason that the U.S. Patent & Trademark Office rejects so many applications is not to prevent you from getting a patent. Patent Examiners typically issue patent rejections as a way of telling you to narrow down the coverage of your patent. Patent Examiners do not want to grant a

¹⁸ Michael Carley, Deepak Hegde, and Alan Marc, “What is the Probability of Receiving a U.S. Patent?” 17 Yale J.L. & Tech. 203, 208 (2015).

¹⁹ *Id.*

patent that is too broad—in other words, that covers too much stuff—because this could give one company a monopoly on a large field of technology. They would rather give you a patent that is a tighter fit around what they think it is that you invented. The patent office calls this “right sizing” patents, granting patents that are a good fit around what was invented and are not too broad.

An analogy you can use is to think of it as a negotiation process where you are the seller and the patent office is the buyer. Your patent application is your initial high bid, and the patent office’s rejection is the lower bid they are giving you in response. The rejection does not mean that a deal will not be made. It just means that the patent office wants you to bring your bid down to something it considers more reasonable.

Much of the current focus on “right sizing” patents comes from the patent office’s experience in the late 1990s and 2000s when some broad patents were issued that became the basis of many lawsuits. Some patent owners had patents that were so broad that they sought to collect royalties from hundreds or even thousands of companies. The U.S. Patent & Trademark Office seems to view these past patents as a mistake or even an embarrassment. Since then it has enforced new initiatives to train Patent Examiners to issue narrower patents.

The ultimate takeaway is that you should fully expect your patent application to be rejected the first time around. The chances that you will ultimately obtain a patent, after an initial rejection, are still very good.

There are a small number of cases where a patent application may be allowed by the Patent Examiner without a rejection. An allowance means that the Patent Examiner will allow your patent application to issue as a patent. Once you receive an allowance, your patent lawyer must still file an additional “issue fee” for you to receive the patent along with a simple form to indicate that the patent should issue. Make sure you do not stop responding to the patent office after you have received your allowance. The allowance alone is not a patent. The patent is issued a few weeks or months after the patent office has received your “issue fee” payment and associated paperwork. After you receive your patent, you are done, though you must pay fees every few years to maintain your patent.

If your patent application was not allowed right away, then it is your turn to respond with amendments and arguments. This is your opportunity to change your application to make it suitable for issuance as a patent. These changes are called *amendments*, and, along with amendments, you would also typically make written arguments about why your patent application should be allowed.

Your lawyer will typically make amendments by looking at why the Patent Examiner rejected your application. Patent Examiners must provide detailed reasoning of why the rejection was made. Based on this reasoning, your lawyer will typically narrow the scope of your patent (with your input) to something that the Patent Examiner might be willing to allow.

Amendments are voluntary and, if you think your patent application is fine the way you submitted it, then you can instead make arguments about why it should issue as a patent without any

amendments. Making arguments might be appropriate if the Patent Examiner made a mistake or completely misunderstood your invention. However, arguments alone are much less likely to persuade the Patent Examiner to allow your application than making amendments along with the arguments.

You typically have 2–3 months from the time of receiving the non-final rejection to respond with your amendments and arguments. The time limit is stated in the rejection. The time can be extended up to a point, but extensions require an additional fee.

After you file your amendments and arguments, the patent office will review your application again considering the amendments and arguments. It can either give you a final rejection or allow your patent. This stage is very similar to the prior one where the patent office either provided you with a non-final rejection or an allowance.

If you receive a final rejection, you can respond with an amendment and arguments, and this is the route that most clients opt to take. However, this time you would have to pay a fee along with a form called a Request for Continued Examination (RCE). This is because the initial fee you paid the patent office only entitles you to have your application to be evaluated twice—once for the non-final rejection and once for the final rejection. You must file the RCE and RCE fee to have the patent office to give your application further consideration.

If you file the RCE and the associated fee, then the process essentially goes back to Box 1. The patent office would consider your amendments and arguments and give you a non-final rejection or an allowance. If rejected, you have the opportunity to make amendments and arguments so that the patent office can give you either a final rejection or allowance. In other words, the RCE gives you another two opportunities for the patent office to consider your patent application.

There is no limit to the number of RCEs that you file. If your application keeps getting rejected, you can keep filing RCEs to have the patent office evaluate it again. The patent process could go on for many years because of RCEs, and some companies do have patent applications that have been on file for 5–10 years or more. For this reason, the term “final rejection” is a bit of a misnomer because it tends to lead clients to believe that the process is over when it is not. The rejection is only “final” in the sense that if you do not want to pay an RCE fee or other fees then your application will be abandoned.

That take us to the next point. If you choose not to file an RCE, the other two major options are appeal or abandonment. Abandonment means that you are giving up on the patent application. Your patent will not issue, and you do not receive any refund of fees you have paid to the patent office.

On the other hand, an appeal is used to essentially go over the Patent Examiner’s head and have your patent application reviewed by the next highest body, which is the U.S. Patent & Trademark Office’s internal court known as the Patent Trial and Appeal Board (PTAB). This can

be an effective path if you are dealing with an Patent Examiner who has made a clear mistake or for some reason will not grant a patent application that should clearly be allowed. However, it is a longer and more complex process than filing amendments and arguments. Also, the typical time from filing your appeal to receiving a decision is 2–3 years.²⁰ For these reasons, working with the Patent Examiner using amendments and arguments is the most typical path. Appeals are usually saved for instances where there is an impasse in the negotiation between the startup client and Patent Examiner. The Patent Examiner wants the patent coverage to be narrower, but the startup refuses to amend the patent application to be narrower.

In an appeal, your lawyer will file an initial brief, which is a formal document that fully sets out your arguments. The Patent Examiner will respond with a brief explaining why he or she thinks the patent application should be rejected. Your attorney then writes another brief in response to the Patent Examiner. Finally, there is an option to have an oral hearing before the board of three judges that will be deciding your case. The oral hearing will be handled by your attorney. It revolves purely around legal argument so there is typically not an opportunity for a startup client to make any statement.

The judges will then make a decision based on the written briefs and oral argument and will explain the reasons for their decision in a written opinion. If the decision is in your favor, then the patent application goes back to the Patent Examiner, where the Patent Examiner must follow the decision of the judges. Most of the time, this means that the Patent Examiner will allow your application to become a patent. However, in a few cases, it is possible for the Patent Examiner to reject your application on other grounds—so long as it does not conflict with the judges’ decision. This would be uncommon and usually only occurs if the patent office feels your patent application is way too broad and would be a serious problem to issue.

If the decision goes against you, then the Patent Examiner’s rejection stands. The most typical route in this case is to go back into the patent application process by filing an RCE with amendment and arguments, which takes you back to Box 1. The alternative would be to abandon the application or appeal to the next high court, which would be a federal court. You would have the choice of appealing to the U.S. Court of Appeals for the Federal Circuit or the U.S. District Court for the Eastern District of Virginia. This leads to another appeal process with more briefing and another decision that could change the result in your favor.

The above section has explained how the typical patent application process plays out in a nutshell. There are many other events that can happen in the patent application process, which I have not described for purposes of simplicity. I would not suggest that you try to file your own patent application just based on reading this section because there are a lot of nuances that I cannot

²⁰ U.S. Patent & Trademark Office, “Appeal and Interference Statistics” (September 30, 2016) (<https://www.uspto.gov/sites/default/files/documents/Appeal%20and%20Interference%20Statistics%20September%202016.pdf>).

cover in this short space. You can probably see just from the simplified description above that this is a complex process, and you will want an experienced lawyer to help you.

Speaking with the examiner

At this point, I would like to share one big tip for obtaining a patent from the U.S. Patent & Trademark Office: have your attorney speak with the Patent Examiner. In the patent process, there are opportunities to speak with the Patent Examiner, either in person, by video conference, or by phone. This is done by filing a request for an interview with the Patent Examiner. Though they are called “interviews,” they are not interviews in the sense of “job interviews.” Instead, it is just an opportunity for your patent attorney to speak with the Patent Examiner to reach an agreement about how to amend the patent application so that it issues as a patent. For most applications, I highly recommend having an interview with the Patent Examiner because it is generally faster and easier to figure out what the real stumbling block is in having the patent granted when talking to the Patent Examiner than by sending written documents back and forth. If you filed the patent application yourself (which I do not recommend), then you can have an interview with the Patent Examiner just as you would if you were represented by an attorney.

You must submit a request for an interview before being able to schedule your interview with the Patent Examiner, but Patent Examiners will usually grant reasonable requests. A typical stage at which to schedule an interview is after receiving a non-final rejection. At this point, the Patent Examiner has had a chance to review your application and identify the problems that he or she wants resolved before granting it. It often makes sense to request an interview to discuss potential ways you can amend the application, to make arguments, or to clarify certain issues. Interviews are requested by filing a form with the patent office or by using the online Automated Interview Request (AIR) form.²¹ Interviews typically last 30 minutes or less, though they can go longer if there are more complex issues involved.

The best option is usually to have your lawyer meet the Patent Examiner in person at the patent office. It is advantageous to let your lawyer sit down with the Patent Examiner so that there is a face behind the application, and you are not just a name on a piece of paper. Also, an in-person meeting provides an opportunity for your lawyer to demo your product or prototype, if you have one. However, meeting in person is not always possible, especially because the U.S. Patent & Trademark Office now allows many Patent Examiners to work from home. The next best option is a telephone call or video conference. I try to be sensitive to the Patent Examiner’s situation, since this person is making the decision on the patent application after all. If the Patent Examiner seems to be more comfortable with a telephone call than an in-person meeting or video conference, then that is often the best bet.

²¹ U.S. Patent & Trademark Office, Automated Interview Request (AIR) Form (<https://www.uspto.gov/patent/uspto-automated-interview-request-air-form>).

One last tip I would like to share on this point is the First Action Interview Program (FAIP).²² The FAIP is a relatively new program that I think is underused by many patent lawyers, even though it makes sense for many patent applications. Enrolling your application in the program does not cost any additional fees to the patent office and only requires filling out a simple form.

By enrolling in the FAIP, the patent application process changes slightly so that you receive additional contact from the Patent Examiner. After you file your patent application, if the application is not immediately allowable, the Patent Examiner will send you a FAIP Pre-interview Communication before sending you a non-final rejection. This FAIP Pre-interview Communication is basically a mini-version of the non-final rejection. The Patent Examiner will evaluate your application and send you a brief explanation of any issues he or she sees with granting the patent. Your patent lawyer will then schedule an interview with the Patent Examiner to discuss amendments or arguments to try to obtain allowance of the patent.

The first advantage of this program is that, for no additional patent office fee, you receive three evaluations from the patent office (FAIP Pre-interview Communication, Non-final Rejection, Final Rejection) instead of just two. Plus, you receive two chances to respond (the interview after the FAIP Pre-Interview Communication and the amendments and arguments after the Non-final Rejection) instead of just one.

The second advantage is that your patent lawyer can speak with the Patent Examiner to explain the invention before the Patent Examiner goes through the process of writing out the full Non-final Rejection. This gives your lawyer the chance to explain why the invention is new and patentable before the Patent Examiner gets into a mindset of rejecting the application.

Studies conducted on FAIP applications show that they are granted by the patent office at a slightly higher rate than applications not in the FAIP, and they are, on average, allowed by the patent office 5 months sooner than other applications and with less correspondence required.²³

For these reasons, it is worth considering the use of the FAIP for your patent application. It is not always the best choice for every application, and in some types of applications it cannot be used. Ask your lawyer whether it would make sense to use for your application.

Provisional patent applications

Another useful tool for startups is the provisional patent application. A provisional patent application differs from a regular patent application, which is called a *non-provisional patent application*, in that it gives you a filing date at the patent office but is not examined and never becomes a patent. The way you use a provisional patent application is to hold your place in line, so that no one else files a patent application on your invention first. You would then file a regular, non-provisional

²² U.S. Patent & Trademark Office, First Action Interview Pilot Program (<https://www.uspto.gov/patents-application-process/applying-online/full-first-action-interview-pilot-program>).

²³ *Id.*

patent application later based on the provisional patent application. Your non-provisional patent application can claim priority to the provisional patent application so it would be as if it had been filed on the date that you filed the provisional patent application.

The provisional patent application is good for one year. After one year, it automatically becomes abandoned. To use it, you must file a non-provisional patent application that claims priority to it within the one-year time limit.

A provisional patent application is simpler and easier to fill out than a non-provisional application. It takes less attorney time to prepare, and the fees charged by the patent office are lower. It can therefore be a more affordable option for startups that do not have the resources for a complete non-provisional application. This gives them the opportunity to try their invention in the marketplace for one year to see if it is worth pursuing the patent. If a startup launched its product without a provisional patent application in place, it faces the risk that someone else will file a patent application on the same thing or that someone else will release the same or a similar product in the market, which would cause their patent application to no longer meet the novelty and non-obviousness requirements to become a patent.

Basically, the provisional patent application requires only a detailed description of your invention and a cover sheet. However, be careful of providers out there who claim to file a provisional patent application for you for very low prices. You can find many providers like this on the Internet. What these providers typically do is copy the description you give them, put a cover sheet on it, and file it with the U.S. Patent & Trademark Office. This is very risky because your provisional patent application can only give you protection if your description fully describes all the aspects of your invention that you want to protect. That is why it is worthwhile to have an experienced patent lawyer review your description and edit it—edits are almost always needed in my experience—before filing it with the patent office.

Related patents and patent families

As discussed above, patent applications do not always have to stand alone. Sometimes they can be related back to other patent applications by making a claim for priority. A claim for priority is basically a claim that your patent application should be treated as if it had the filing date of an earlier patent application that you filed because the content of the two applications is the same. In this case, the later application is said to *claim priority* to the earlier application. The patent applications, and the resulting patents, are then said to be *related* and to be in the same *patent family*.

The advantage of making a claim for priority is that the earlier filing date allows you to avoid references that might make your invention not novel or obvious by using a filing date that pre-dates them. You may wonder why you would want to file another application that has the same contents as an application you already filed. The typical reason for this is to obtain more patent coverage of your invention. Once an original patent application is allowed to become a patent, it is common for

clients to identify other features in the application that they would like to obtain coverage over but that were not covered by legal scope of the original patent application. In this case, filing a new patent application that claims priority to the original patent application would be a typical solution.

There are several different ways of claiming priority to prior applications. One is the use of provisional patent applications, as described above. Another is the use of continuation patent applications, also called “continuations,” which are new patent applications that have identical content to a prior application to which they claim priority. The continuation is treated as if it was filed on the same day as the earlier application. Finally, there is the continuation-in-part (CIP) patent application, which contains some of the same content as a prior application but also adds new material. The content that is identical to that of the prior application receives priority to the filing date of the prior application, but the new content that was added does not receive any additional priority. There are a few other types of priority claims as well.

Priority claims can also be chained, such as a continuation claiming priority to a continuation claiming priority to an original application claiming priority to a provisional application. If all the links in the chain are good, then the latest filed application can claim priority all the way back to the earliest application.

Using “Patent Pending” in marketing

Let’s now assume that your patent application is filed with the U.S. Patent & Trademark Office. As soon as the patent application is filed, you are entitled to refer to your invention and product as “Patent Pending.” This includes both provisional and non-provisional patent applications. Even if you filed a provisional patent application, which by itself will never be examined by the patent office or issue as a patent, you are still entitled to use the term “Patent Pending.”

You can use the term “Patent Pending” alone or include your application serial number if you wish, for example “Patent Pending App. No. 09/485,218.” If you do not mind pointing people to your application, there can be a small benefit to including your application serial number. Patent applications are generally published 18 months after filing (although there are ways to keep them private if you wish). If someone else reads your patent application and creates a product or service that uses the invention covered by the patent application *and* the coverage of your patent application does not substantially change between the time it was published and when it issues as a patent, then you might be able to receive royalties from them for the time even before the patent issues.²⁴ It’s not that common for that situation to happen, so it’s not something I would spend a lot of resources worrying about.

In terms of where to put “Patent Pending,” you can include this in your marketing, advertisements, emails to clients, or essentially any place you want. Some clients like to put it on

²⁴ 35 U.S.C. § 154(d). Keep in mind, however, this does not apply if the patent never issues.

their product to warn competitors that a patent has been applied for. For a physical object, companies can print “Patent Pending” on the object itself such as with an engraving.

After I file a patent application, can I stop competitors from using my invention?

One question that startups sometimes ask me is whether they can stop competitors from using their invention after they have applied for a patent. The answer to this question is no. A patent application does not give you legal rights until the patent itself is granted. Once you obtain a patent, then you can start the process of identifying companies that are using your invention and either stopping them or charging a royalty. However, before the patent is granted, you do not have exclusive rights to the invention.

Can I sell my patent application?

Startups also sometimes ask me if they can sell their patent application to other companies. Usually they are asking about selling a patent application that they have filed on a cool idea to a larger company in their space. However, the answer to this question is “probably not.” Legally, you can sell a patent application. In practice, companies are unlikely to buy a patent application because they know that there is a significant risk that the patent application will not be granted or that the coverage of the patent application will end up being reduced through the amendment process. Companies will usually only buy a patent that has been granted.

Can I add something to my patent application after I filed it?

It is also quite common for my clients to ask me if they can add something to a patent application after we have filed it. Innovative companies are often coming up with new ideas and changing the way they do things, so it’s understandable that, after filing the patent application, the inventors may come up with new techniques or variations that they want to add. This is especially true given that the process of obtaining a patent takes on average over three years, due to the patent office’s backlog.

The answer to this question is basically no, you cannot add anything to a patent application after you have filed it. You would not be able to add new techniques or information about your invention to the application. The reason for this is that the patent office gives priority according to the date that you filed your patent application. This is known as “first to file” and means that the first inventor to file a patent application on an invention is the one entitled to the patent. If the patent office allowed you to add things to a patent application, then you could file a patent application very early to obtain a good priority date and then add more information later to cover more inventions. This would be a problem because you would be getting an early priority date for inventions that you did not necessarily have at that time. As a result, the basic rule is that your patent application is frozen in time from the moment that you file it. Nothing new can be added.

However, you are allowed to change your application without adding information. The primary way this occurs is by changing the scope of coverage that you are seeking to obtain with

your patent. This happens through the amendment process that I explained above. In the amendment process you are never adding new information to the application. Instead, you are simply changing the parameters of what you are trying to obtain a legal monopoly on, and these parameters always stay within the bounds of what was in your initial patent application.

If you need to add new information to your patent application, then the way to do this is to file a new patent application. You can either file a new patent application unrelated to your prior application, or you can file a continuation-in-part (CIP) application, which was discussed above. A CIP tells the patent office that your new patent application is related to your old one and any inventions in the CIP that were already previously described in your old application are given priority back to the date of the old application. In other words, it's as if you filed your CIP on the date of your original application, at least for inventions that you already disclosed at that time. For any new information that you add, you have priority only from the date that the CIP was filed.

Chapter Three: The parts of a patent application

Now that we have discussed whether you should file a patent application and the process for doing so, let's discuss the parts of a patent application in more detail.

The content of your patent application comes down to your (1) claims, (2) specification, (3) drawings, and (4) abstract. These parts of your patent application ultimately become the parts of your patent. The claims are the absolute most important part of the patent application and, as you go through the patent process, are the part that you will hear about over and over again from your patent lawyer and from the patent office. In the prior section, we talked a lot about the “coverage” of your patent application and how the patent office likes to make sure it does not grant patents that cover too much. The claims are the part of your patent application that determine how much the patent will cover. When we talk about narrowing the patent application to cover less or broadening it to cover more, all of this is happening in the claims.

The specification and drawings, on the other hand, are also important because they are needed to support the claims. This is due to the fact that patent claims can only cover what is described in the specification and drawings. The abstract is technically part of the specification but is on a separate sheet and is intended to be a short description that helps with indexing.

Claims

The claims of your patent application, and which will ultimately be in your patent if it is issued, determine the scope of your patent coverage. A patent application typically has multiple claims and each claim is a single sentence that describes one thing. To make this concrete, let's consider the following real claim from a patent owned by AstraZeneca:²⁵

1. An enteric coated oral pharmaceutical formulation comprising:
 - (a) a core material which comprises an active ingredient selected from the group consisting of omeprazole, an alkaline salt of omeprazole, one of the single enantiomers of omeprazole and an alkaline salt of one of the single enantiomers of omeprazole;
 - (b) a separating layer; and
 - (c) an enteric coating layer,

wherein the separating layer comprises a hydroxypropyl cellulose (HPC) with a cloud point of at least 38° C., and

wherein the light transmission at cloud point of a system comprising the HPC dissolved in a concentration of 1.0% (w/w) in a mixed solution of disodium hydrogen phosphate buffer 0.086 M and hydrochloric acid 0.1 M in the proportions 7:3 at a pH of 6.75-6.85 is 96%.

As you can see, the claim relates to a pharmaceutical formulation for omeprazole with a separating layer with a hydroxypropyl cellulose (HPC) with certain properties and an enteric coating layer.

²⁵ U.S. Patent No. 6,428,810

The first clause of this claim, the part where it states that it covers an “enteric coated oral pharmaceutical formulation,” is called the “preamble” and serves as a sort of introduction to what the claim is going to cover. The preamble is considered introductory and usually does not substantively affect your patent coverage, though it occasionally does in the right circumstances.

The clauses following the preamble are the meat of the claim and define the scope of what the claim covers. Each of these clauses is called an *element* or *limitation* of the patent claim because they limit the scope of the patent. The above claim has five limitations, and the first limitation is “a core material which comprises an active ingredient selected from the group consisting of omeprazole, an alkaline salt of omeprazole, one of the single enantiomers of omeprazole and an alkaline salt of one of the single enantiomers of omeprazole.” To determine if a company is using, or *infringing*, your patent, you must determine if the company making something that meets all the limitations of the patent claim.

The above type of claim is what is known as an “apparatus” claim because it covers a physical product. Apparatus claims are used to cover compounds, pharmaceutical formulations, and medical devices. The other main kind of claim is a method claim, which is described by a series of steps. Method claims are often used in the life sciences to cover diagnostic methods and methods of treatment. The following is a real example of a method claim in a patent owned by AstraZeneca:²⁶

1. A method of treating Helicobacter infections comprising the administration of an effective amount of the magnesium salt of S-omeprazole trihydrate and an antibacterial compound to a patient in need thereof.

Method claims are very similar to apparatus claims with the difference that the limitations are not different parts of a physical product but are steps to be performed.

In both apparatus and method claims, infringement only occurs if someone performs makes a product or performs a service that meets every requirement of every limitation. If any limitation is not met, then there is no infringement. There is one small exception to this called the Doctrine of Equivalents, where sometimes a limitation that is not met can be met by an equivalent, but this exception is narrow.

Writing a good set of claims for your patent application is probably the single most important job for your patent attorney and is where most of his or her skill and experience comes into play. You usually want broad claims, which have fewer limitations and therefore cover a broader range of products and activities. However, if you write a claim that is too broad, then you risk your patent being rejected or invalidated for being not novel, obvious, or too abstract.

Broader claims are more likely to have a novelty problem because novelty is a mirror image to infringement. That is, if a product, patent, or reference that existed before your patent would infringe your patent claim, then your claim is invalid as not novel. You would be trying to obtain

²⁶ U.S. Patent No. 8,466,175

patent coverage on something that is not new. The same reasoning applies to obviousness. The broader your claim is, the easier it is for the Patent Examiner to find pre-existing references that meet each limitation and therefore show that your invention is obvious. Broader claims also face more abstractness concerns because they cover more activity and might be considered by the Patent Examiner to cover a general concept.

These potential issues with broad claims still exist even after the patent office issues your patent. Patents that are issued by the patent office can still be invalidated by courts if they fail the novelty, obviousness, or abstractness criteria. Courts are an independent arbiter of these criteria and can disagree with the patent office on whether those requirements are met. So even if the patent office is willing to grant a broad claim, another consideration is whether the claim will hold up in court.

Narrower claims are less likely to be rejected or invalidated but are also less valuable because they cover a smaller range of activity. If you make your claims extremely narrow, then you maximize your chances of obtaining a patent, but your patent may have very little economic value. Determining how broadly or narrowly to draft patent claims is a balancing act and is where your attorney's skill and experience comes into play.

Specification

A specification must also be submitted with your patent application and ultimately becomes part of the patent. The purpose of the specification is essentially to describe your invention. As we saw in the previous section, the claims are short and simple descriptions of the invention that define your patent's coverage. The specification is needed to provide a much more extensive description of the invention. Including detail in the specification does not limit your patent's coverage the way that it would if it were included in the claims. Generally, it is a good idea to include a lot of detail in the specification.

The specification plays two important roles. First, the specification must provide enough description of the invention to meet the two legal requirements of *enablement* and *written description* or your patent application will be rejected. Second, the specification provides the definitions for the terms used in the claims, either explicitly or implicitly. This latter aspect means that the specification indirectly affects the scope of your patent coverage.

Enablement requirement

Let's consider the first legal requirement of enablement. The enablement requirement is that the specification must include enough detail so that a person having ordinary skill in the field of the invention could make and use the invention that you described in your claims. This requirement is evaluated on a per claim basis. Any claim that is insufficiently described by the specification so that someone having ordinary skill in the field would not be able to make and use it is invalid and cannot be issued in a patent.

The point of the enablement requirement is to only allow inventors to obtain patent coverage of inventions that they have actually invented and described to the public. One of the bases of patent law is the value that inventors provide by describing new inventions. The government is effectively granting you a patent in exchange for, in part, your disclosure to the public of how to make and use your invention. If you do not hold up your end of the bargain by describing your invention so that others can make and use it, then your claims are no good.

Now, the enablement requirement does not require you to go through and describe every aspect of your invention in micro-detail. Most of the time it is sufficient to focus on providing more detail on the new aspects of your invention and discuss any older building block technologies that you are using at a higher level. This is because the enablement requirement is evaluated from the perspective of a person having ordinary skill in the field of the invention. For most inventions, a person having ordinary skill in the field is going to be an engineer or scientist, and most likely would be assumed to have a few years of experience.

Also, although the enablement test is framed in terms of a person of ordinary skill in the field, you can assume that this person has infinite time and resources. It's okay if the invention that you are describing would, in reality, require more than one person to build. The focus of the test is on the level of skill of this hypothetical person, not how much a single engineer or scientist could realistically build.

In sum, the enablement requirement requires that you provide enough detail in your specification to allow a person of ordinary skill in the field to make and use the invention, but you can typically assume that this person knows about existing technologies and can use that as a base.

Written description requirement

The written description requirement is similar to the enablement requirement and requires that the invention be described in enough detail to show that you had possession of the claimed invention. The difference between this requirement and the enablement requirement is subtle.

One way to think of the written description requirement is that it disallows filing a patent on an invention when the applicant has merely provided a research plan for finding the invention, rather than describing the invention itself.²⁷ For example, a large pharmaceutical company sought to patent the use of certain molecules for reducing NF-kB activity in human beings to reduce the symptoms of certain diseases.²⁸ While the patent's inventors discovered the importance of NF-kB and hypothesized three classes of molecules that could reduce NF-kB, they did not describe the structure of any molecule that actually did so in the patent.²⁹ In this case, it was found that the written description requirement was not met.

²⁷ *Ariad Pharm. V. Eli Lilly and Co.*, 598 F.3d 1336, 1354 (Fed. Cir. 2010).

²⁸ *Id.* at 1340.

²⁹ *Id.* at 1354.

In sum, the written description requirement is meant to ensure that you in fact invented and possessed the invention that you are attempting to patent.

Defining claim terms

The other important role of the specification is to provide definitions for terms used in the claims. The specification can define claim terms explicitly or implicitly. The claims determine the scope of your patent, but the specification plays a key role in determining the meaning of the claims.

In your specification, you are allowed to explicitly define terms if you wish, and these definitions will be used as the meaning of those terms when they appear in the claims. You are not required to define your claim terms. However, if you provide an explicit definition for a term then this is generally considered to take precedence over any other meanings, even if the term typically has a different meaning.

The specification also provides implicit definitions of claim terms. This is when the specification defines a claim term by how it is used rather than defining it explicitly. Implicit definition of claim terms occurs even when you are not intending to define terms. Everything you write in the specification can implicitly affect the interpretation of the claims.

The interpretation of claim terms is surprisingly important in patent cases. It turns out that in many cases the meaning of claim terms is critical to determining if a patent is infringed. In other words, the patent is infringed if the claim is interpreted one way but is not infringed if the claim is interpreted slightly differently. For example, the term “approximately” appears in some life sciences patents and typically needs to be interpreted by a Court. Depending on the patent, “approximately” could be interpreted to mean a specific range, a percentage variation, or a general degree of closeness.

The specification, since it describes the invention in detail, is the most important source of information for the court in determining the meaning of a claim—after the claim itself of course. Courts consider the specification to be even more important than dictionaries and how the term is used in the field. This is because different dictionaries can often conflict, and, likewise, people often have conflicting understandings of a term. The specification is considered to be the best source for determining the meaning of terms because it is the inventor’s own description of the invention. Most of the time patent owners do not explicitly define all claim terms, so courts spend a lot of time interpreting terms based on their implicit meaning in the specification.

Writing the specification

You should have a patent lawyer write your specification, but it is very helpful to the lawyer if you can provide a detailed written document that describes your invention. This is what lawyers refer to as an *invention disclosure*. A good invention disclosure document ensures that your lawyer has a comprehensive understanding of your invention, and the attorney can sometimes use parts of this document in the specification.

The following is a typical methodology that a patent lawyer might use to write the specification:

1. Describe the invention in general terms. This may include copying the claims into the specification and re-writing them in plain English. Doing so helps ensure that all the elements of the claims are in the specification and have enough support to meet the enablement and written description requirements.
2. Describe one or more specific examples of the invention. Part or all of the inventor's invention disclosure document might be included here. This helps add more detail and ensures that the specification includes everything that the inventor wants to cover.
3. Describe any additional important details.
4. Describe any variants of the invention.

Writing a specification is a task that requires expertise, so even though this section describes a rough guideline on one way to do it, I do not recommend trying to write the specification yourself.

Specification pitfalls

There are many potential pitfalls to specification writing, and someone who is inexperienced in patent law can easily fall into one of these traps. I will cover just two common pitfalls here, though there are many more.

First, you should typically not use the term “invention” in your specification, except in a very narrow range of circumstances. The problem with using the term “invention” is that it has a specific meaning to refer to the legal coverage of your patent. If you use the term invention, courts can interpret this to be a statement about all inventions that are covered by your patent. This risks narrowing your scope of coverage by adding a limitation to your claims.

The correct way to say something like this is to use the term “an embodiment of the invention,” or just “an embodiment,” for short. Embodiment is the legal way of saying that this is an “example.”

Second, the specification is required to include a “Background” section that describes the state of the art that existed before the invention. The general point of this section is to describe how people did things before the invention, so that the Patent Examiner can see the advantages that the invention creates.

The pitfall that I often see in “Background” sections written by inexperienced specification writers is including too much detail on what technology existed in the past. You usually want to make the “Background” section short and to the point. The more statements you make about what technology existed in the past, the more things you are effectively admitting to not be part of what makes your invention novel and non-obvious. The Patent Examiner can use your statements, which

are called “admissions,” as part of his or her reasoning to reject your application.³⁰ If you make an admission that a technology was already known, the Patent Examiner no longer has to find a reference to show that this technology pre-existed your patent application and can instead rely on your own statement.³¹

These are just two common pitfalls to watch out for, and there are many more that I do not have space to cover in this short section. Due to pitfalls like these I recommend that startups and other companies use an experienced patent lawyer to prepare their patent applications. Without legal assistance, there are many seemingly small mistakes that can be made that sometimes turn into huge problems.

Drawings

The drawings of a patent application go hand-in-hand with the specification and help to fully describe and explain the invention. The drawings are considered part of the specification and fulfill the same purposes, namely meeting the enablement and written description requirements and helping to define claim terms.

It is technically not required to have any drawings in your patent application,³² but, in practice, patent applications are rarely submitted without at least one drawing. Drawings are typically very helpful in explaining the invention. They help the Patent Examiner understand the invention, and, if the patent is granted, patent drawings are a great tool for explaining your invention to judges and juries when you use your patent in court.

The U.S. Patent & Trademark Office has specific guidelines on the format the drawings must take.³³ The drawings should be black and white with solid lines. It is usually not allowed to use color drawings or photographs, except in rare circumstances where you can show that they are necessary. Also, reference numbers are usually included in the drawings so that parts of the drawings can be referred to in the written part of the specification.

While this sounds like a lot of requirements, there are professional illustrators who specialize in preparing patent drawings. They know all of the requirements and prepare high quality drawings based on your prototypes, screenshots, or sketches. I like to use professional illustrators for most drawings, unless they are very simple diagrams.

Abstract

The abstract is a simple part of the patent application. It is a brief description of your invention that helps the patent office and the public understand what your invention is about. You will want to keep this brief and high level. The abstract is usually 150 words or less. You do need to be careful with the abstract, though, because it is part of the specification and so what you write in

³⁰ Manual of Patent Examining Procedure § 2129.

³¹ *Id.*

³² Manual of Patent Examining Procedure § 608.02.

³³ *Id.*

the abstract can affect the interpretation of your claim terms—just like other parts of the specification.

The abstract is the last part of the content of your patent application. In the next section, I will discuss other forms that must be submitted with your patent application but which are not part of the content that becomes part of the patent.

Other forms

In addition to the parts above, your patent application will include a number of other forms. These forms do not add content to your patent but are necessary to submit certain information to the patent office. Many of the forms are provided in PDF format by the U.S. Patent & Trademark Office and can be downloaded from its website.³⁴

Inventor's declaration

A declaration is needed from each inventor of the patent application that essentially states that the inventor believes himself or herself to be the original inventor of the invention. The declaration may also include a few other statements. The patent office provides this form, and each inventor needs to sign one.

One question that startups sometimes have is who should be listed as an inventor on the patent application. This is an important point, and you must get this right to avoid problems with your patent. It is not like authoring a scientific paper together where you can generally list whoever you want as an author.

On a patent, every person who contributed to the conception of the invention should generally be identified as an inventor. “Conception” basically means coming up with the idea. Any person who contributed to coming up with any feature that appears in the claims of your patent application should generally be listed as an inventor, and people who do not fit this description should generally not be listed as inventors. People who were told the idea after it had already been conceived of and simply worked to build the product or prototype are generally not considered to be inventors.

Application data sheet

The application data sheet (ADS) is a form provided by the patent office that allows you to provide bibliographic information for the patent application. This includes things like the names and addresses of all the inventors, the title of the invention, the address to use for correspondence, and so on.

One of the important pieces of information that you input in this form is the identification of any prior applications to which you are claiming priority. We discussed earlier that you can sometimes gain the benefit of an earlier filing date, such as with a provisional patent application,

³⁴ U.S. Patent & Trademark Office, Patent Forms (<https://www.uspto.gov/patent/patents-forms>).

continuation application, or continuation-in-part application. There are other ways of claiming earlier priority as well, and you input this information in the ADS.

Information disclosure statement

The Information Disclosure Statement (IDS) is a very important part of the patent application process. Once you submit a patent application, you have what is known as a *duty to disclose* information that you know to be *material* to the patentability of your patent application to the patent office. This duty to disclose means that you have an obligation to submit certain information to the patent office. You must disclose any information that you know to be material, or in other words relevant, to the patent office's decision on whether to grant you a patent. If you fail to abide by this duty, then you may be found to have sought a patent in bad faith and your patent will not be enforceable. It will basically be worthless.

The purpose of the rule is to prevent inventors from submitting patent applications on things that they know to not be patentable and hiding prior references from the patent office. Moreover, by requiring inventors to submit information, the patent office can be more certain that the patents that it issues are on inventions that are actually new.

Most of the time, the information that you and your lawyer would submit to the patent office using an IDS is prior references that are similar or related to the patent application and that you know to have existed before the filing of the patent application. Typically, these would be references that you found during your patentability search.

The duty to disclose does not require that you search and find all prior references related to your application. It just requires that you disclose information that you *know of*.

Patent assignment

A patent assignment is not part of the patent application but is typically completed around the same time and filed with the U.S. Patent & Trademark Office through a separate process. The reason you probably need a patent assignment is that inventions are by default owned by the inventors, and, likewise, a patent application is owned by the inventors listed in the patent application. You need a patent assignment to assign the rights in the patent application to your startup. The word “assign” as it is used here just means to give.

Usually, it makes sense to include a provision in your founder agreements and in your employment agreements with employees that all inventions that they come up with while they are employed are automatically assigned to your company. This provision is fairly typical now. In addition to that, it is usually worthwhile to also have them complete another patent assignment for each patent application that they are an inventor on just to confirm that they have assigned the application to your company.

It is not legally required to file your patent assignment with the patent office, but there are significant benefits to doing so. If you do not file your patent assignment, then there are a variety of

situations in which your ownership of the patent may not end up being clear. It would be similar to buying a house and not recording the chain of title. In most cases, it makes sense to file your patent assignment.

Patent assignment is an important part of the patenting process. You do not want to go through all of the hard work of obtaining a patent only to find out that your company does not own it.

Chapter Four: I have a patent, now what?

In this section, I will assume that you have a patent and will discuss how you can go about using it in your business. One of the initial ways to use your patent is in marketing. Once your patent is issued, you are allowed to advertise the fact that your product is patented. It can be a selling point to tell your customers that the special features of your product are patented. The fact that your product is patented indicates to customers that your product is new and that they cannot get the same product somewhere else.

Advertising that your product is patented can also serve another useful purpose: deterring competitors from copying you. If competitors know that you have a patent, then they may be more careful about copying your patented features because this could lead you to sue them. In this way, you may be able to stop copying before it starts.

This leads to another patent concept that you should know about, that is *patent marking*.

Patent marking

Patent marking is the process of marking your product with the patent numbers of the patents that cover the product. You have probably seen products at the store that include a notice such as “Pat. No. 7,087,088.” On a physical product, this is often engraved on the product or sometimes printed on the packaging. From a business perspective, this is a good practice because it can dissuade competitors from copying your product. There are also legal reasons to do this.

If you make a product that uses your patent, you are required to mark the product with a notice of the patent numbers of the patents that cover it, in order to be able to recover the most amount of money in a lawsuit. That is, failing to meet this requirement will not invalidate your patent, but it can significantly reduce the amount of money you can recover. Specifically, if you fail to mark your product, then you can only recover damages starting from the time you file the lawsuit or send your competitor a letter notifying them that they are infringing. By contrast, if you had marked, then you could recover damages for up to 6 years in the past. This can lead to a huge difference in the amount of your recovery.

In addition, if you license your patent to another company to allow that company to make products using your patent, then you need to make sure that this company is marking its products too. Typically, you want a provision in the patent license to require your licensee to mark its products with your patent, and you should periodically review your licensee’s products to ensure that they are complying with the marking requirement. You ideally want all the products that use the patent to be marked. However, if only a small number of products are not marked (despite your efforts), then courts have sometimes found this to be acceptable compliance with the marking requirement. The exact percentage of what is acceptable will depend on the case. One court found

that marking 95% of products was enough to meet the marking requirement.³⁵ However, there is no exact range of percentages that are acceptable because it depends on the specific facts of your case.

There is one exception to the marking requirement, which is if your patent only contains method claims—no system claims or product claims. In that case, you do not have to mark because methods technically cover the act of doing something and not an actual product. This is a tricky exception though because if your patent includes even one system claim or product claim, then you do have to mark.

What do I do if someone is infringing my patent?

Despite your efforts to mark your products and advertise your patent, it may happen that some competitors will still copy your patented product. If it appears that someone is using, or *infringing*, your patent, then you should contact a patent lawyer. Dealing with patent infringers is complex, and there is no effective way to do this without legal guidance.

In fact, if your company wants to file a patent infringement case in a court you will need to hire an attorney because you cannot represent yourself in this situation. The reason is that your company is a separate entity from you and your employees. Individuals can represent themselves, but only lawyers can represent other people and entities. Neither you nor your employees can represent another entity, including your company, unless one of you is a lawyer. While you could represent *yourself* in a court case, you cannot represent your company.

Once you contact a patent lawyer about the infringement, one of the first steps for the lawyer is to legally determine if patent infringement is occurring. This is called an *infringement analysis*. Determining if someone is infringing your patent requires legal skill because patents are legal documents that need specialized expertise to interpret. We discussed the claims section of your patent previously and how the claims determine whether someone is infringing or not. A patent lawyer will need to read the claims of your patent very careful to see if someone else is using every element, or limitation, of at least one claim. If at least one of your claims is infringed, then we would say that your patent is infringed.

The infringement analysis sometimes requires taking apart a competitor's product or doing a chemical analysis. It can be more challenging to determine infringement in this case than if all the elements of the claim can be determined just by looking at a product. However, there are services that specialize in doing the technical analyses and testing needed to prove infringement.

I should also mention that there is a narrow exception to the rule that a product only infringes if it has every element of your claims, and this is called the Doctrine of Equivalents. Under this doctrine, sometimes there can be infringement if not all the claim elements are present in a product, but there are equivalent features. Determining that something is an equivalent requires

³⁵ *Maxwell v. Baker*, 86 F.3d 1098 (Fed. Cir. 1996).

meeting a detailed legal test that can be challenging to satisfy. As a result, use of the Doctrine of Equivalents is fairly uncommon.

In addition to the infringement analysis, your lawyer will typically check on a few other aspects of the patent. Usually, your lawyer will analyze the economic value of your patent to determine how much money you could expect to recover from a competitor. If the value is too low, it may not be worth filing a lawsuit. It is also typical to analyze the validity of the patent. Patents issued by the patent office can still be invalidated by courts based on lack of novelty, non-obviousness, abstractness, or other reasons. Lawyers who are helping you to assert your patent typically want to analyze these factors to ensure your patent will not be invalidated. In addition, the chain of title will be checked to ensure that you own the patent, as well as your history of communications with the patent office during the process of obtaining the patent.

If your patent passes these checks, then you have a couple of options on how to approach your competitors about your patent. First, you could have your lawyer send a letter to your competitor demanding that they stop infringing. This is called a *demand letter*. Second, you could have your lawyer file a patent infringement lawsuit without sending a letter.

Starting with a demand letter has advantages and disadvantages. The purpose of a demand letter is to start negotiations with your competitor for them to either stop using your patented invention or pay you a royalty. If you can negotiate a favorable agreement without filing a lawsuit, that can save both time and money.

However, there are at least two downsides to sending a demand letter. First, some companies will not negotiate with you outside of a lawsuit. From the perspective of a company receiving a demand letter, they do not know how serious you are about enforcing your patent. There are some companies that send out demand letters hoping that recipients will pay up without intending to ever file a lawsuit. So, the recipient of the demand letter may not respond if they think there is a chance you will go away without payment.

Moreover, the recipient of the demand letter may not be entirely sure if they are infringing your patent. Patents are complex documents and determining that a patent is infringed and not invalid requires a detailed analysis by a skilled patent lawyer. A company may not want to invest a lot of resources evaluating the strength of your case until after you have filed suit.

The second disadvantage of a demand letter is that it may allow the recipient to preemptively file a lawsuit against you to argue that they do not infringe your patent or that it is invalid. Your demand letter can give them a basis to argue that there is now a dispute between your company and theirs that a court needs to resolve. Moreover, the infringing company can file their lawsuit in a court that is nearer and more convenient to them but far away and inconvenient for you. If you had filed your lawsuit first, you would have more opportunity to choose a court that was local to and convenient for your company.

The other approach you can take is to have your lawyer file a lawsuit without sending a demand letter. Lawyers will typically handle patent lawsuits either on an hourly fee or a contingency fee. A contingency fee arrangement means that your lawyer does not charge you a fee but collects a percentage of the amount that you collect. There can also be mixed arrangements that are part hourly and part contingency. In addition to your lawyer's fee, there are also fees for the costs of the case. This includes things like fees for the court, travel expenses, information technology and support expenses, and payments to consultants.

There are two types of outcomes you can hope to achieve with your lawsuit. First, you can try to obtain a court order to force your competitor to stop using your patented invention. This is called an *injunction*. To obtain an injunction there is a legal test that you must satisfy. The test has multiple parts,³⁶ but one of the key factors is whether you are making a product that uses the patented invention and whether you are a direct competitor with the company that is infringing that patent. If so, then your chances of obtaining an injunction to stop your competitor are higher. Otherwise, if you do not make a product covered by the patent, or do not compete with the copycat company, then your chances are lower.

The second type of outcome you can achieve is receiving monetary compensation for the use of your patented invention. The most typical way that this is calculated is as a royalty. A court would try to determine what a reasonable royalty is in the market and award that amount to you. An alternative way of determining your compensation is lost profits, in which case a court would try to determine how much profit you would have made if not for the other company's infringement of your patent.

To achieve either outcome you would first have to prove that your patent is infringed. Your lawyer will collect the evidence to prove this from your company and the infringing company. Some startups wonder how their lawyer will be able to obtain things like internal product development and research documents from the infringing company that may be needed to prove infringement of the patent. There are legal procedures that allow your lawyer to access some of the internal documents of your competitor for use in the lawsuit. Your lawyer can only use these documents for the purposes of the lawsuit, such as to prove infringement of the patent, and you will not be able to see most of these documents if they contain your competitor's confidential information.

The company that you have accused of infringing your patent will likely try to prove that it does not infringe your patent or that your patent is invalid. It will likely try to come up with arguments that its product does not include every limitation from the claims of your patent and

³⁶ The applicable case is *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391 (2006), which states that a company must show the following to obtain an order to stop a patent infringer: "(1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction."

therefore does not infringe. It will also likely try to find prior products, patents, and other references that do something similar to your invention to argue that your patent is not new or is obvious.

Your case will proceed to a trial, where you will make your arguments through your lawyer and the infringing company will make its arguments through its lawyer. On average, it takes 2.5 years for a patent case to reach a trial.³⁷ It takes this long because parties need time to collect evidence, and there are many other document filings and hearings that can happen along the way. Your patent case may be decided by either a judge or a jury. If you are seeking any monetary recovery in your case, then either you or the infringing company can require that a jury decide the case by making the appropriate request. However, if you are only seeking an injunction, in other words to stop your competitor from infringing your patent, then it is typical for a judge to decide the case.

After the trial, you will receive the decision on whether you have won your case. In a trial by jury, the decision is made very quickly because the jury must provide its verdict before the jurors are dismissed and can go back to their regular lives. A jury will often make a decision within a few hours or perhaps up to a day. However, if your case is being decided by a judge, then the decision can take longer—often months. The judge will typically provide a written opinion that explains his or her reasoning, and this opinion could be lengthy depending on the complexity of the case. Juries do not provide written opinions. You typically just get their decision with no reasoning behind it.

An appeal can be made from a decision that is not in your favor. Appeals in patent cases are decided by a specialized court called the U.S. Court of Appeals for the Federal Circuit (the “Federal Circuit”). An appeal does not require a new trial, which is good because you would not want to go through the time and expense of another trial. Instead, the appeals court just reviews the decision made by the lower court to determine if any errors were made. If errors were made, then the appeals court can correct the errors. This is a simpler affair and an appeal to the Federal Circuit is typically decided in about a year.³⁸

If the decision of the appeals court is not favorable, then you can appeal to the Supreme Court of the United States. However, the Supreme Court hears only a small number of cases and denies the opportunity to review the vast majority of cases that are submitted to it. Out of 7,000 to 8,000 cases submitted to the Supreme Court each year, it usually makes a decision in less than 200.³⁹ In recent years, about three or fewer patent cases have been decided by the Supreme Court annually. The Supreme Court is usually only interested in deciding cases that will have significant legal

³⁷ PwC, “2016 Patent Litigation Study: Are We at an Inflection Point?” at 3 (May 2016) (<https://www.pwc.com/us/en/forensic-services/publications/assets/2016-pwc-patent-litigation-study.pdf>).

³⁸ U.S. Court of Appeals for the Federal Circuit, “Median Time to Disposition in Cases Terminated After Hearing or Submission,” (<http://www.ca9.uscourts.gov/the-court/statistics>).

³⁹ Supreme Court of the United States, “The Justices’ Caseload,” (<https://www.supremecourt.gov/about/justicecaseload.aspx>).

consequences, and the probability that the Supreme Court will hear your case is very low. Therefore, the decision of the Federal Circuit is effectively final most of the time.

This probably sounds like a long process, but the vast majority of cases will not go through all of these stages. Most cases never go to trial. Instead, the companies involved in a patent case will usually reach a settlement. In a settlement, they will sign a contract so that the company that filed the lawsuit will dismiss the case, and the company that was accused of infringing might pay some money or agree to change its product so that it is not infringing.

A recent study found that only around 6% of patent cases make it all the way to a trial.⁴⁰ Another few percent of cases are decided by a court prior to a trial.⁴¹ The majority of patent cases, over 90%, end with a settlement.⁴²

You may wonder what the point of filing a patent lawsuit is if the most likely outcome is settlement. The lawsuit is actually very important. The filing of a lawsuit, and the potential for a trial and a decision in your favor, is what gives you leverage. It helps bring the other company to the settlement table when they might otherwise have ignored your demands.

If you have a good case, then you will typically have much better chances of negotiating an agreement regarding your patent by suing a company than by trying to negotiate without a lawsuit. After the lawsuit is filed, the other company must thoroughly evaluate your patent and your claims of infringement in order to defend itself in court. If they find that they are likely to lose the case, then they might enter into a favorable settlement agreement with you. Moreover, many companies prefer to settle to avoid a trial and avoid the risk of a negative decision. The potential for a trial sets a deadline for your companies to reach an agreement.

In conclusion, the process of dealing with other companies infringing your patent is complex. I have only outlined the process above, and there are many other details that I do not have space in this section to go into. You will want an experienced patent lawyer to help you. Hopefully this book has helped increase your understanding of this process and other aspects of patent law.

⁴⁰ John R. Allison, Mark A. Lemley, and David L. Schwartz, “Understanding the Realities of Modern Patent Litigation,” 92 Texas L. Rev. 1769, 1779 (2014).

⁴¹ *Id.* at 1780.

⁴² *Id.*