Potter Clarkson

IP Primer for Scientist Founders

Why do founders need to think about IP?

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Confession time!

When I first started this job, I had very little knowledge about intellectual property (IP) and patents.

Despite spending 15 years of my life in academia, pursuing degrees, a PhD, and postdoctoral research in the field of 'proper' science, IP was never on my radar. Commercialisation was never a topic of discussion. Shockingly, IP was never given any significance.

It was only after leaving academia that I discovered another world, one where research holds value beyond publishing papers.

This new reality focused on translating research into real-world products with tangible benefits and, more crucially, commercial value. In this world, neglecting to protect your IP when sharing your work can have disastrous consequences not least undermining the potential for any practical outcomes.

I understand that scientist-founders often find themselves in a similar position. They know very little about something they need to become very well-versed in. Some of the founders I work with possess limited knowledge, while others have misunderstood key aspects. Both scenarios are incredibly risky.

This why I want to create this IP primer for scientist-founders. I wanted to share the essential information about IP that every scientist-founder should know, and that I wish I'd known 10+ years ago.

As a scientist-founder, you will be required to make a raft of commercially focused decisions. These aren't all about IP but having a solid grasp of IP and patents' fundamentals will enable you to make much more informed choices across the board.

You need to understand what it takes to obtain a patent, its purpose, how the patent system operates, and where critical decision points lie.

As it is highly likely you will be handling much of the research and development yourself, it's absolutely crucial you understand what data you need to secure valuable IP.

My primary goal is to share what I have learned by working with a growing number of scientist-founders. I trust my experience will equip you with enough knowledge to get into good IP habits early and avoid early mistakes that could be challenging or even impossible to rectify further down the line.

Dr Sara Holland

Why should I care about IP?

With so much else to worry about, it is perfectly natural for scientist-founders (and those aspiring to become one) to ask why they should find time to care about IP.

Time and money may be short, but you absolutely should care.

Understanding the concept of IP and the importance of protecting your ideas can be challenging, especially if you come from an academic background where the emphasis has always been on sharing data and making it accessible to everyone.

This difficulty likely stems from a lack of understanding about how and why products, such as therapeutics, make their way to the market. I must admit, I was once guilty of believing in a mythical "commercialisation fairy"! I thought someone would read my research paper and transform my fundamental research into a life-saving drug. All I had to do was publish it, right? No!

In the real world, you, as the founder, are the one responsible for commercialising your research but how do you turn this published work into something tangible? You won't be working for free, and you'll likely be seeking free laboratory space and equipment wherever you can find it.

You will need funding, likely a combination of bootstrapping and investments from individuals or organizations, potentially including non-dilutive government funding. Investors won't provide you with the necessary funds unless they are confident that, after the long and expensive research and development (R&D) journey, you will be able to sell your product, recover costs, and generate profits.

Building this confidence requires demonstrating to funders that you can prevent others from copying your product. In other words, you must have enforceable IP. IP is what will stop your competitors from swooping in at the end of your R&D process and stealing your market share.

The solution lies in having (or planning to obtain) enforceable IP. In the fields of synthetic biology and biotechnology, this often means pursuing patents to protect the innovative aspects of your work.

Investors want to see that you have a strong IP position. Even if you are self-funding and not seeking external investors, you should still prioritize this aspect for your own benefit. After all, you deserve to see a return on your hard work and investment.

The key takeaway is that simply publishing your research won't automatically lead to its widespread impact and it making the difference you want it to.

Being a successful entrepreneur and bringing your product or service successfully to market, you must change your mindset! This applies even if you are still in academia and holding onto the notion of the 'commercialization fairy'. Roll up your sleeves and protect your ideas and innovations!

Furthermore, publishing your research or data before taking steps to secure a patent can make it exceedingly challenging, if not impossible, to obtain a valuable patent.

Before we move on from the reasons why you must care about your IP, there are a few more points I'd like to address. Protecting your IP not only facilitates commercialization and product development but can also be highly lucrative.

Consider your situation as a founder at the very beginning. Typically, you won't own expensive premises; instead, you may be renting lab space. Unless you're exceptionally fortunate, cash will be scarce, and you'll find yourself begging and borrowing lab equipment.

This may not sound promising, but here's what you do have:

- Yourself
- Your ideas
- Some supporting data (hopefully)
- The vision and passion to transform your ideas into reality

This means you have IP even if you haven't realised it yet. But it's there. And it's waiting to be protected. This IP (which might include patents or any of the other forms of IP) may become your most valuable asset over the next few years.

Even if you hire numerous staff members and produce and sell your product on a large scale, the ability to prevent others from copying your invention remains the most significant advantage you hold.

To put things into perspective, consider the recent acquisition of a clinical-stage antibody company for $1.45 billion, a substantial portion of which was attributed to the patent rights for their leading drug candidate. Another company received $6 million as a milestone payment for licensing its patent rights to a third party.

These examples perfectly illustrate the potential value of properly treated IP.

> **A recent study conducted by the European Patent Office revealed some compelling statistics about the economic benefits of owning IP rights, particularly for small businesses.**

The study controlled for various variables and found that companies with a patent, trade mark, and design right had 98% higher revenue per employee compared to those without any IP rights. Even having just one of these rights correlated with a 68% higher revenue per employee. Despite these findings, the report shockingly discovered that 91% of SMEs don't own any IP rights.

Lack of education was cited as a potential reason, emphasizing the importance of becoming IP-savvy to enhance your revenue.

Editor's note
While I wish I could predict the future like a tarot reader or a fortune teller, I must clarify that I can't guarantee the same outcomes for everyone.)

What types of IP should I be thinking about?

When it comes to IP, the start point for most scientist-founders is patents. Patents primarily protect the technical aspects or clever features of an invention.

They grant you the right to prevent others from taking certain actions. However, it's crucial to understand that having a patent does not automatically give you the right to use the invention yourself. This is because there may be overlapping patents owned by others, which is why it's essential to assess your 'freedom to operate' (FTO).

It's important to note that the question of whether something is patentable (i.e., new and inventive enough to be granted a patent) is completely separate from whether you have the freedom to operate. You may be able to obtain a patent but still require a license from someone else to utilize your own technology.

Design rights, on the other hand, protect the shape and appearance of a product. Design rights can be highly valuable, particularly for businesses that establish recognition for a specific design. Design rights allow you to prevent others from copying your unique design.

Trade marks play a vital role in distinguishing your goods and services from those of others. They hold significant power, especially for business-to-consumer (B2C) companies, particularly when you aim to capture a significant market share early on. Trade marks safeguard your branding elements such as logos, words, sounds, and colour combinations associated with your com pany. They grant you the right to prevent others from branding their products in a similar way to yours and trying to leverage your market and your reputation.

Branding holds immense importance in various sectors, from luxury goods to tomato ketchup but we can already see its impact in the alternative protein market, with early players like Impossible Foods and Beyond Meat establishing powerful brands.

Know-how and trade secrets are examples of confidential information. Trade secret protection in Europe is robust, but specific criteria must be met for confidential information to be considered a trade secret. Merely stating something is a trade secret is insufficient; you must actively take steps to protect the information.

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Patents and trade secrets form a complementary set of IP rights. We will delve into trade secrets in more detail later on. If you haven't filed a patent application yet, it is always good practice to make sure your ideas and data (hopefully!) remain confidential, and trade secrets could be the most effective option. If you'd like to explore trade secret protection, our unique trade secrets audit, SafeGuard, will help set you on the right path.

Now, let's not overlook another crucial aspect of IP: data.

You might be collecting various data for one purpose without realizing its potential value to others. For instance, remote monitoring of seaweed may generate a wealth of data on optimal growing conditions, which others may find highly valuable for different reasons. It's essential to capture the value of such data in your business plan.

IP ownership: inventor vs author

Before we get right into patents, we need to talk about something else. Who actually owns the IP you create?

In my interactions with aspiring scientist founders, especially during the early stages of their journey while they are still university employees or students, I have often had to deliver a reality check. Many of them are unaware that they do not (or may not) have the freedom to do as they please with their research because the intellectual property associated with that work typically does not belong solely to them, or even to them at all.

The landscape of IP ownership in a university or other collaborative setting is a complex beast, presenting a challenging puzzle to unravel. At the basic level, under Danish law (note that this does change from territory to territory) the first owner of an invention is the inventor. Makes sense. But – if that inventor is employed, and the invention was made in the "normal course of their duties", the employer will automatically own that invention.

For instance, the IP generated by university employees, such as professors and postdoctoral researchers, belongs to the university.
Students often own the IP they generate, since in a lot of cases they are not considered to be "employees".

However, on top of this basic automatic situation written into Danish law, there can be layers and layers of other contractual obligations. For example, there might be grant funding obligations involved, or the work may have been conducted in collaboration with another institution, resulting in joint ownership.

Students may sign up to agreements when they start that says that they do own their own IP, except when they have received input from their supervisors or utilized university resources (literally all cases?).

In most cases of university originating IP, the university will either own all of it, or become a co-owner with you (mostly only if you are a student – if you are a professor or postdoc it is normally quite clear cut that you will not own your IP), necessitating collaboration with the Technology Transfer Office (TTO) to utilize or commercialize the research.

Even if an academic founder intends to spin off a company, they cannot assume that the university will automatically grant them a license. Sometimes, there can be internal wranglings as to which entity the university is going to licence the rights to.

Since IP ownership all starts with the inventor – what is an inventor? And how is that different to an author of a journal publication?

Authorship vs Inventorship

It's crucial to understand that being listed as an author on an academic paper does not determine who the inventors are for a potential patent application based on that paper. Incorrectly naming inventors on a patent application can have far more severe consequences than mistakenly listing authors on a manuscript – the entire patent can be found to be invalid – i.e. gone.

Let's imagine a scenario where a Nature paper has multiple authors, some of whom have been forward-thinking enough to file a patent application based on the research. A test for you – who of the following should definitely be named/not named as an inventor on the patent application?

- The last author on the paper.
- The first author on the paper.
- Someone who is not an author on the paper but provided key insights and direction that contributed to the development of the technology.
- Someone who is listed as an author because their lab provided a plasmid.
- Someone who was added as an author by a friend just to get them on a paper.

To qualify as an "inventor" in the legal sense, there must be some contribution to the inventive concept of the technology, a spark of cleverness, rather than simply following instructions or carrying out assigned tasks.

Being an inventor doesn't require direct involvement in laboratory work; the inventive act often occurs in the mind. Even if someone else performs the hands-on tasks under your direction, you can still be considered an inventor. And if you are merely the hands-on-tasks performer, you might not be an inventor.

Considering the scenarios mentioned above:

Last author: Being the principal investigator (PI) or lab head does not automatically make you an inventor. The key question is who conceived the actual invention, who did the thinking, and whether you had intellectual input into the project, even if you oversee the lab. It can be difficult to challenge a PI as there can be an automatic assumption that as lab head, they are an inventor. But this is not always the case. Make sure you know the facts re inventorship and ownership because getting it wrong can mean that you lose ownership of your own invention and don't have the ability to commercialise it as you would like.

First author: Although you may have collected all the data for the paper, being an inventor depends on whether you contributed to the ideas and thinking behind the research. Did you have moments of creative insight and generate novel concepts, or did you solely execute instructions? If the latter, you are not an inventor.

Not an author: Whether or not you are listed on an academic paper is irrelevant. If you made a contribution to the actual invention through devising novel concepts, congratulations, you are an inventor!

Providing a plasmid: Unless the plasmid is an integral part of the inventive concept, simply supplying it does not qualify you as an inventor.

Added by a friend for no real reason: Absolutely not! Do not include your friend as an inventor just to assist them. Being named as an inventor on a patent application has legal consequences. Getting it wrong could lead to the revocation of any granted patent, resulting in the permanent loss of valuable intellectual property. It can also mean additional parties end up co-owning the IP, which is often not the best of situations. Imagine losing your million-dollar IP because you wanted to be helpful to a friend.

Understanding patents

The first rule of patent club ...

Never disclose your invention to anyone before filing a patent application!

Once you've filed a patent application, it will undergo examination by a patent examiner. During this process, the examiner will focus on two key aspects:

1. Novelty (newness)
2. Inventive step

These are the primary hurdles you need to overcome (there are others, such as sufficiency and support, which I'll cover as they relate closely to the data in your patent application). However, both novelty and inventive step are assessed in relation to ANYTHING that has been publicly disclosed before you filed your patent application.

And by anything, I mean **anything.**

This includes:

- Journal articles
- Published poster abstracts
- Advance pre-print articles
- Blog posts
- LinkedIn posts
- YouTube videos
- Conference presentations
- Information on you own home page
- Discreet one-liners tucked away at the end of your journal articles (which often become stumbling blocks for inventive step!)
- Unread theses hidden away on shelves
- Conversations overheard in a pub

Collectively, we refer to this collection of material as "prior art." Prior art can also be identified by using "Wayback machines" thus, deleting already published information e.g. from a company homepage cannot necessarily fix a publication problem.

A patent examiner will examine your patent application and search the available prior art that existed BEFORE you filed your application, looking for anything they consider relevant.

Many academic inventors are surprised to learn that their own publications are part of the prior art. I've encountered several instances where academic inventors failed to inform the technology transfer office about something they had published because they didn't realize its significance.

But it does matter.

For academics, their own publications often represent the closest and most detrimental prior art.

This also includes review papers. You know those papers where you engage in some speculative thinking like, "It might be a good idea if someone explored X and Y." While this may be exciting from the perspective of being the first to propose an idea, it can be problematic for patents. It could potentially jeopardize something you later wish to protect.

One observation I've made is that academics often describe their inventions within the context of their entire body of research.

Me:
Why do you believe your invention is new?

Inventor:
Well, we were the first to demonstrate X.

Me:
Yes, but you published that three years ago.

Inventor:
But we were the first ones to show it.

Unfortunately, it doesn't matter! The patent examiner can use your entire body of research that was published BEFORE you filed your application against you, even if it was just the day before!

One more point to note is that some countries have a 'grace period' for an inventor's own publications. For instance, if you published a paper before filing a patent application (and you should never do this), you might not be able to obtain a patent in Europe. However, in the US, it might still be possible as long as you file the patent application within 12 months of the publication.

But best practice is almost certainly to avoid relying on grace periods.

Now you understand the importance of not disclosing your invention before filing a patent application (or ever, if you decide to keep it as a trade secret), let's address a common dilemma. What if, in one aspect of your life, you still need to publish? Perhaps you're still connected to academia or collaborating with students who will need to publish their work.

The simple answer is that you can both publish and attempt to patent your invention. You can discuss your invention at conferences and then pursue a patent. However, this requires careful consideration and planning.

If necessary, patent attorneys can expedite the patent application process, turning it around in a few days. While not ideal, it is feasible.

So, if you find yourself thinking, "Oh no, my work is publishing next week, and it could have been a ground breaking commercial product," don't worry. It's not too late from the patent attorney's perspective. Just keep in mind that getting things through the tech transfer office may take longer.

When submitting a manuscript for publication, the process usually involves writing, submitting, and reviewing, allowing ample time to consult with a patent attorney.

Once your patent application is filed, you have a filing date (or priority date). This allows you to proceed with publishing your work. You just need to be cautious not to include additional details in the publication that were not considered in the patent filing.

It's worth noting that even if journal publishers claim they won't publish your paper online early, they sometimes do and if they do, you can't undo it. Therefore, once you've submitted to a journal, the timing of when the paper becomes public is largely out of your control.

Regarding oral and poster presentations, it is possible to deliver engaging and informative talks while withholding the crucial aspects that constitute your invention. This happened at a UK synbio conference in Nottingham. A contact of mine was giving a talk and realised a few days before that they should consider protecting their invention. We had a quick discussion, identified the key parts to withhold, and delivered an amazing talk while preserving the opportunity to file a patent later.

Beware of casual disclosures

"I shared my invention with my friends at the pub.

Will that prevent me from obtaining a granted patent?"

Probably not, depending on how trustworthy your friends are and how they handle the information. However, it's important to note that such a casual disclosure could potentially be considered a public disclosure, depending on how it was presented.

As mentioned earlier, once you file a patent application, a patent examiner will search for "prior art". While they'll look online and search the available databases, these sources won't include notes from a chat in the pub. This means the chat alone is unlikely to have a significant impact on whether your patent gets granted or not. However, there are potential consequences associated with such a chat.

Firstly, if your good friend ends up sharing the information with others, especially if there is a public trail like an online blog post saying, "Hey, I just heard about this amazing idea..." Although it may lack details, this kind of public disclosure can be detrimental if it occurs before you file a patent application.

Another concern arises if your good friend turns into a competitor or behaves unfavourably.

While a patent examiner may not have discovered details about your chat during the examination, once your patent gets granted, the entire situation can collapse in post-grant invalidity proceedings.

Invalidity proceedings essentially question whether your patent should have been granted in the first place, i.e., was it truly novel and inventive? These proceedings typically occur when someone actively tries to invalidate your patent to gain freedom to operate, or as a defence because you attempted to sue them for infringement.

Did the examiner take the casual chat you had with your friend (who is now your competitor) into account several years before? No, because the examiner was unaware of it. (which usually take place in national/regional courts), these types of disclosures can become highly relevant.

Lengthy and detailed discussions can arise regarding whether a disclosure occurred before you filed your patent application, potentially rendering your patent partially or wholly invalid. Were there any notes or relevant emails from the meeting? Are there any witnesses? All these factors could come into play during the discovery/ disclosure process in court.

Therefore, although it may seem absurd that a conversation at a coffee shop (or any other venue) could disrupt your business, it is indeed possible. So, please exercise caution and, at the very least, ensure that any discussions about your invention are held under a non-disclosure agreement (NDA).

'Prior art' and public disclosures

There are a few additional points that merit consideration, particularly early on in your entrepreneurial journey

These are especially important if you have decided to keep your technology a secret and not pursue patent protection, or at least keep it confidential for now.

Depending on your product or service, there may be aspects of your technology that you are required to make public to meet regulatory criteria. These public disclosures then become prior art that can affect any future patent applications you file.

The most evident example is in the therapeutic field, but it can apply equally to areas such as food and construction, or – indeed – any industry with established standards that you must meet to demonstrate effectiveness and safety. In such cases, you will need to disclose certain information about your technology:

- What it is
- How it works
- Its composition

While some of this information can be kept confidential, not all of it can be. Therefore, it's crucial to identify early on what needs to be made public.

Since much of synthetic biology applies engineered organisms in new contexts, a lot of these regulations haven't even been written or decided yet – but it is important you engage with who you think are the relevant regulatory bodies early on so you know what you are facing down the line. If you engage properly, you may even be able to influence these regulations for *your* sector!

The purpose of this is to encourage you to consider the entire pathway your product will take from development to the market. You need to understand these requirements and integrate them into your business plan and intellectual property (IP) strategy.

And your business plan and IP strategy are not mutually exclusive. One should map directly to the other.

If you know that you must publicly disclose the new and inventive ingredient in your diagnostic test to gain market approval, it's advisable to pursue patent protection early on. As I mentioned earlier, for a patent to be granted, the invention must be both new and inventive. It can't be if your secrets are already public.

If you don't have to disclose such details, trade secrets remain a valuable option.

Another potential disclosure point to be aware of is clinical trial protocols. In many countries, these protocols must be made public. If the details become public before you file a patent application, it can pose challenges. Even if you don't disclose all the intricate details or the effectiveness of the therapy, simply stating that you are treating certain patients with a specific combination of drugs X and Y can make it 'obvious to try' rendering your drug combination lacking in inventiveness.

Therefore, when considering your IP and how it can support your business, it's not just past publications that you have to take into account. You also need to anticipate potential publications you might be obliged to make years down the line.

What do you want your patent/s to do?

Before discussing how to obtain a patent, it's essential you understand what a granted patent is and what you want your patent to achieve.

These answers are vital to how you craft your patent claims and will also stop your attorney from suggesting claim amendments that may appear reasonable to us but don't give you what you want and need.

A patent grants you the right to prevent others from performing the actions covered by your patent. This scope is defined by the claims (the numbered portions at the end of a patent document).

If someone performs actions falling within the scope of your claims without your permission, they are infringing your patent. In response, you can take legal action, sue for damages, and request that they cease their infringing activities. Alternatively, a more amicable approach is to negotiate a licensing agreement.

The scope of your patent establishes your 'turf', the exclusive space in which only you can operate. Naturally, you want your turf to be as extensive as possible. This is why we advocate for broad claims rather than capitulating to examiner demands after the initial examination report.

On this point, be wary of marketing tools by some attorney firms, such as grant rate or grant speed – it is very easy to get something granted if you do not put up a fight and just give the examiner what they want – this is not best serving you!

But what does it mean for an activity to fall within the scope of a patent? What constitutes patent infringement? (The interpretation of claim scope is assessed by courts, and we will explore this later.)

There are two main types of claims:

1. Those that cover a product
2. Those that protect a method

Infringement occurs when someone tries to make, use, and/or import a patented product or uses a patented process.

To infringe a product claim, a third party would need to make, use, or import a product that includes all the features specified in the claim. Generally, if their product includes additional features, it will still infringe your patent. The terms 'comprising' or 'consisting' in the claim can affect the interpretation (we will discuss this later).

For example, if your product claim includes features A, B, and C, it would be infringed by a product with features A, B, C, and D. However, a product with only features A and B would not infringe the claim.

To infringe a method claim, a third party would need to perform each step outlined in the claim. If the method claim involves steps A, B, and C, it would be infringed by someone performing steps A, B, C, and D. On the other hand, someone performing only steps A and B would not infringe the method claim.

So, is a claim to a product with features A and B broader or narrower than a claim to a product with features A, B, and C?

From the above discussion, you can see that a claim with fewer features (product features or method steps) is generally broader. This means that if feature C is not necessary, it's advisable to exclude it from the claims and the fewer features you include in a claim, the broader it becomes. This can be a hard concept to appreciate, and I have had clients trying to insist on including all of the specific features of the invention in the main independent claims, when the invention is new and inventive without them!

Understanding novelty in patentable inventions

If scientist-founders could have one superpower it should be the ability to spot inventions.

This goes beyond simply recognizing potential patentability; it involves the skill to identify the true magnitude of an invention, which often surpasses the initial perception of the inventor or founder.

To spot inventions effectively, one must understand what constitutes a patentable invention. The fundamental requirements for an invention are novelty and inventiveness. Simple, right?

Or is it?

What does it really mean for an invention to be new (novel) or inventive?

In the realm of patents, these concepts are defined by the respective legal frameworks of each country. Generally, the thresholds are similar across countries.

One aspect that often surprises inventors, especially those with an academic background, is the absence of a notion of 'partial novelty'. Novelty is not a matter of shades of gray. It is a black and white concept. Something is either new or it isn't.

During my time in the lab, I was guilty of dismissing certain findings or developments, thinking, "Oh, someone has already done it before." Looking back now, I realize that I couldn't determine whether it had been done before because I didn't grasp the concept of novelty.

For your technology to be considered 'new' it must not have been disclosed in the prior art. Remember, prior art encompasses any public disclosure made before the date you filed your patent application. This includes journal articles, oral presentations, showcasing your product at a trade show, and more.

But what does it mean for something to "not have been disclosed in the prior art"?

> *For your technology to be considered 'new' it must not have been disclosed in the prior art.*

Essentially, it means that unless your 'invention' has been fully described in a single document or presentation, it is new. And when I say "fully described," I mean that the prior art disclosure must include all the details of your invention.

Even small differences can render your invention new. For example, if you have a method that differs only in the temperature of cell incubation compared to a method described in a nature publication, or in the duration of a specific step, or in a single amino acid change in a protein used in the method, your invention is still considered new. Remember, there are no degrees of newness!

Determining whether a single document discloses all the features of your invention is not straightforward either. Suppose you have an invention involving steps A, B, and D, and you come across a document that describes two methods: one involving steps A, B, and C, and another involving steps C, D, and E.

In this case, the document may not be considered to disclose your 'invention'. Although the document describes each feature, they are not combined in the way required by your invention (unless the document explicitly allows for combining different elements). Patent examiners are not allowed to combine features from different specific embodiments, or examples, in an earlier publication to say your invention is not new. But they are allowed to do that for inventive step!

Assessing inventiveness for patentability

What makes an invention inventive enough to qualify for a patent?

To obtain patent protection, your technology must not only be new but also inventive or 'non-obvious' considering everything that has been made public before you filed your patent application, as we discussed for the novelty requirement. And here the examiner is allowed to combine prior art documents e.g. document 1 says X, document 2 says Y – it would be obvious to stick them together to get to your invention that is XY.

But what does it truly mean for an invention to be inventive or non-obvious?

Firstly, it's important to note that inventive or non-obvious does not necessarily mean ground breaking or revolutionary. In fact, most patentable inventions often stem from small modifications or improvements to existing things that, while non-obvious, may not elicit a "wow" reaction.

Another aspect to consider is who the invention has to be "obvious" to, to lack inventive step. This role is typically assigned to a fictional character known as the 'skilled person', someone who:

- Lacks imagination
- Can follow established protocols and refer to other documents if a clear indication exists
- Does not combine different teachings to come up with something new unless there is a specific motivation to do so
- Does not have spontaneous breakthroughs or generate new hypotheses

If the assessment of inventive step relied on an imaginative person who can connect unrelated ideas and think outside the box, nothing would be deemed 'inventive' and patents would rarely if ever be granted.

When a patent examiner evaluates your invention and examines the publications, presentations, and posters that were made public before your application, they aim to determine if there is anything in those materials that would lead the skilled person, who thinks within established boundaries, to arrive at your invention.

Are there any documents targeted at solving the same problem your invention addresses? This is often the starting point for examiners at the European Patent Office.

Do those documents suggest any features or characteristics similar to your invention? Do they propose that a higher temperature would yield better results? Or that mutations in a specific region of an enzyme could be beneficial? Or that using a particular strain of yeast for protein expression would be advantageous?

Do the documents recommend consulting other sources on a particular subject?

If these documents fail to provide any indication that would prompt the non-imaginative skilled person to modify existing knowledge and arrive at your invention, then you may indeed have an inventive invention on your hands.

The importance of sound data in patent applications

When it comes to publishing in a scientific journal, you strive for perfect images and flawless curves.

When it comes to publishing in a scientific journal, you strive for perfect images and flawless curves. Publishers prefer clean and polished representations, devoid of any distractions like fingerprints. However, in the realm of patent applications and securing a granted patent, the emphasis shifts from visual aesthetics to the breadth of the data.

When I was transitioning from a postdoc to patents, I was surprised by the acceptable quality standards for data in patent applications. There are two aspects of 'quality' to consider. One is the visual appeal. The other is the reliability and validity of the data.

While your data needs to support the claims you make, it doesn't have to be flawless or visually appealing. Imperfections like irregular gel bands are acceptable and not even commented on.

Moreover, the data doesn't have to be overly comprehensive. It should primarily demonstrate that your invention is mechanistically plausible and supported by evidence. You can rely on previously published information, in addition to your own data, to strengthen your case. However, excessive reliance on already-published information may risk making your invention appear 'obvious'.

Nevertheless, it is crucial for your data to be scientifically sound. During patent examination data is not often scrutinised, but if your patent gets opposed or otherwise challenged post grant, you can bet you will have someone like you spending hours reviewing your experimental protocols, looking at your error bars, and seeing if your conclusions are valid. So, ensure it stands up to this scrutiny – proper controls please!

Even if a certain amount of data supports the viability of your invention, be prepared for potential challenges. In opposition proceedings or infringement/invalidity cases, opposing patent attorneys will scrutinise your data.

Did you conduct replicates in triplicate or more?

Are the error bars representative of the standard error of the mean?

Did you adequately control for variables to ensure the reliability of your conclusions?

While your data doesn't need to be visually appealing, it should possess scientific integrity to ensure the validity of your patent. A patent that may collapse post-grant due to weak data is not desirable.

The importance of breadth of data

Your patent attorney should possess a strong technical background and a thorough understanding of your technology.

This is crucial because we can provide valuable advice on fine-tuning your experimental plan to obtain data that would greatly contribute to achieving a broad scope of claims.

The type of data we find useful may seem mundane or tangential. It may not directly drive your project forward, and you may not initially consider it significant. However, you should consider prioritising the collection of this data.

Having an early understanding of what we require can help you efficiently plan your experimental work. For instance:

- **Testing** one mutation? Why not test multiple mutations simultaneously to assist us?
- **Having** data for only one mutation makes it harder for us to argue that other mutations might also work, and we might end up with claims restricted to that specific mutation.]
- **Investigating** the effects of a drug on a specific cell line? Consider including additional cell lines in your experiments.

Examiner's will often argue that all cancers are different and may behave differently – if you only have data for breast cancer, we might only be able to get claims that cover breast cancer. If you had data for - for example - breast, colon and lung, it makes it easier for us to say that the mechanism by which the drug is acting is more generally useful for all cancers.

For example, let's say you discover that a A100C substitution in S. cerevisiae pyruvate dehydrogenase increases its activity by 50%. While that finding might be sufficient for your immediate needs, it may not lead to a broad granted claim for cerevisiae pyruvate dehydrogenase with the specific mutation. Such a claim would be narrow and easily circumvented.

However, if that's the only data available, it might be what you end up with.

What we truly desire is a claim along the lines of:

> *A pyruvate dehydrogenase enzyme with a substitution at residue 100 relative to S. cerevisiae pyruvate dehydrogenase.*

This claim is not limited to S. cerevisiae or even to yeast (although data from various species demonstrating the same mutation's effect would be necessary).

This claim is not restricted to a specific substitution at residue 100 (although data indicating the effect of other residues besides C at position 100 or a subset of substitutions would be required).

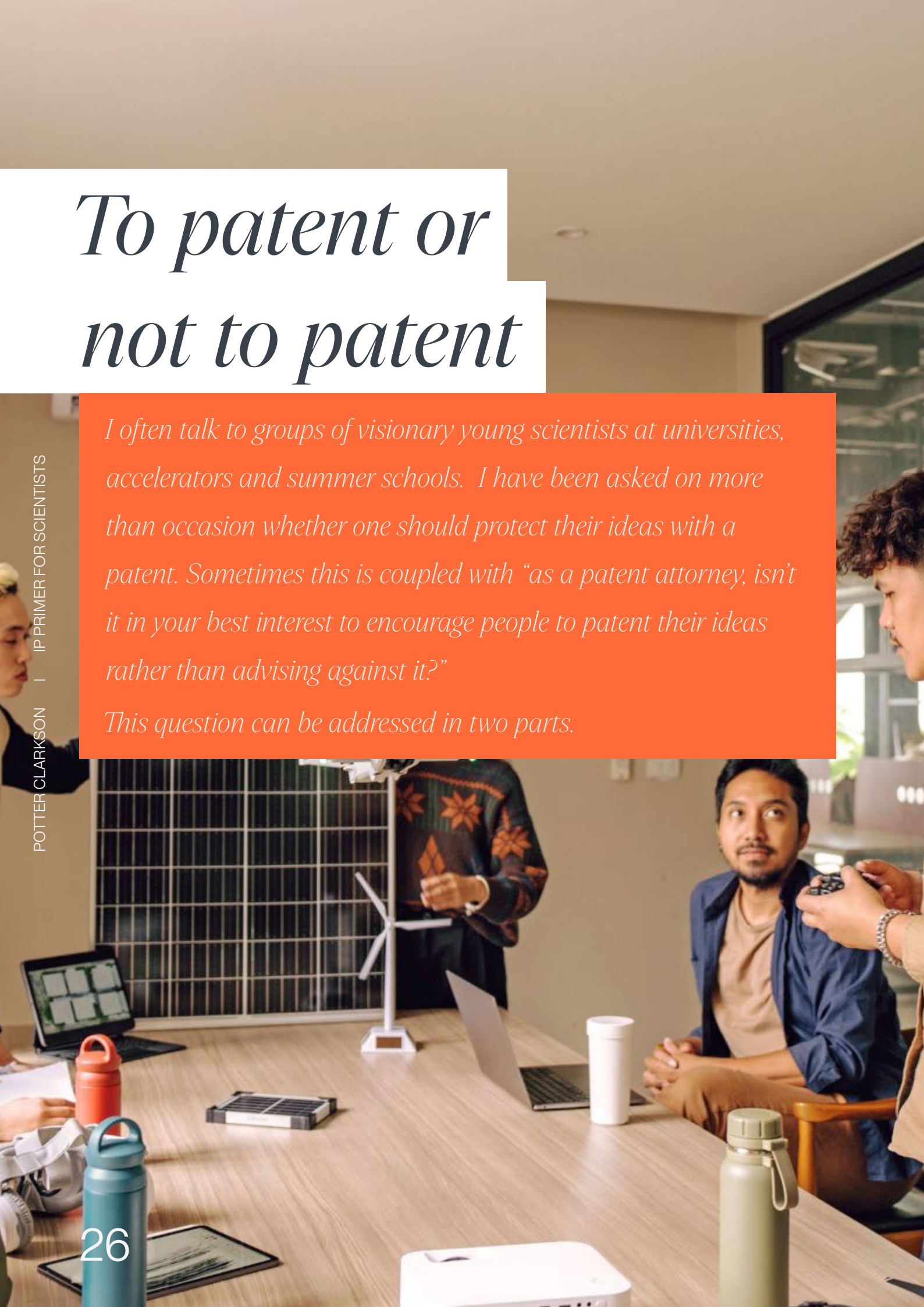
This claim is not confined to a particular sequence, ensuring protection for pyruvate dehydrogenase with other mutations elsewhere in the protein (though a few examples of the mutation at position 100 in combination with other mutations, demonstrating the sustained increased activity, would likely be necessary).

The key point is that understanding what data will facilitate a broader claim scope before conducting laboratory work enables you to work more efficiently.

To patent or not to patent

I often talk to groups of visionary young scientists at universities, accelerators and summer schools. I have been asked on more than occasion whether one should protect their ideas with a patent. Sometimes this is coupled with "as a patent attorney, isn't it in your best interest to encourage people to patent their ideas rather than advising against it?"

This question can be addressed in two parts.



The answer to "should you always protect your idea with a patent" is a resounding no!

But when you ask a patent attorney the same question, their response should never be a straight yes (even though it might be the ultimate answer), they should ask why you want a patent.

Personally and professionally, our main objective is to help our clients turn great ideas into great businesses.

We genuinely care about our clients and their technologies and work closely with them, establishing strong relationships along the way. Many of the projects we engage with focus on products that benefit both society and the planet, motivating us to do our best in supporting their market entry.

While it might seem beneficial to us to advise everyone to file patents for any and every idea to generate quick revenue, that approach is not suitable for every business every time. Filing a patent for something unnecessary consumes financial resources that could be better allocated elsewhere. Similarly, unnecessary patent filings may jeopardize the chances of obtaining a granted patent for something genuinely valuable in the future.

Moreover, filing a patent makes your technology public, whereas it might have been more advantageous to keep it as a trade secret.

Taking a holistic, long-term approach to intellectual property is more likely to lead to overall success for our clients, which benefits everyone involved. This is why the answer to the question "should you always protect your idea with a patent" is a resounding no and when you ask a patent attorney the same question, their response should always be why?

We have already touched on the difference between patents and trade secrets, but this is a crucial element in the question of whether to patent or not to patent.

Your ultimate answer as to which you should use will stem from the key differences between patents and trade secrets (and, therefore, which is most suitable for your idea, your objectives and your business model):

- Patents have a duration of 20 years, while trade secrets can be maintained indefinitely if properly safeguarded.
- Patents cost, whereas trade secrets are free (although you should take legal advice as to how you identify and protect your secrets).
- Patents grant you the right to prevent others from utilizing your claimed invention, regardless of whether they independently developed the same idea or obtained it unlawfully. Trade secrets only safeguard against theft.
- Patents disclose your technology to the public, trade secrets remain confidential.

The factors to contemplate include:

- Is your business model based on selling a product or providing it to third parties, and can it be reverse engineered? If so, a patent may be more appropriate.
- Do you experience a high turnover of staff? This could make your trade secret more vulnerable.
- Do you have the necessary data to file a patent application? If not, ensure that all information remains confidential until you are ready.
- Does your innovative technology pertain to an in-house method or process used exclusively when providing a service to third parties? In such cases, keeping it as a trade secret may be better.
- Are you planning to license your process? If so, pursuing a patent might be more suitable.

Patentability and Freedom-to-Operate (FTO)

As a founder or early-stage start-up, it is crucial to conduct preliminary searches to evaluate the patentability and freedom-to-operate (FTO) of your invention.

These searches will help determine if your invention is definitely novel and inventive, as well as whether you may encounter any obstacles in implementing your invention without infringing existing patents. But whether you have FTO or not is different to whether you have something that you can patent yourself – your invention can be new and inventive, but you might not have FTO.

Firstly, let's clarify the distinction between patentability and FTO.

Patentability refers to determining whether your invention meets the criteria for obtaining a patent. To assess patentability, you need to search for documents that disclose features of your invention and identify any prior art that might render your invention obvious. Remember, prior art can be journal articles, abstracts and patents.

FTO analysis focuses on determining whether your invention could potentially infringe on existing patents or other intellectual property rights. Infringement occurs when your invention utilizes each step or feature of someone else's patented method or product claim. FTO searches only look for patents.

So, when you are looking for prior art documents, the types of searches you will want to do to look at patentability vs FTO are actually pretty different.

As an example, we can pretend your invention is to a new combination of Pichia mutations (A, B, C and D) that when together make the cells gigantic and blue (you never know – it might be a useful feature!)

When conducting a patentability search, you need to explore a wide range of sources, including journal articles, patents, patent applications, posters, abstracts, even social media posts. Look for documents that disclose the specific features of your invention, as well as those that might suggest combining the elements of your invention. For example:

- → Documents disclosing Pichia mutations A, B, C, and D (indicating lack of novelty)
- → Documents describing yeast or microbes with mutations A, B, C, D, and possibly additional mutations (including E, F, G)
- → Documents disclosing yeast/microbes with any combination of mutations A, B, C, D (to assess obviousness)

These patentability searches can be conducted independently.

However, a full FTO search require more comprehensive and careful consideration. To ensure FTO, you should focus on patents and patent applications that disclose the individual features of your intended actions, as well as their combinations. For example:

- Claims related to microbes with only mutation A, mutation B, mutation C, or mutation D (your cells with mutations ABCD would potentially infringe on a claim covering a microbe with just mutation A)
- Similar claims but specifically targeting yeast/Pichia
- Broad claims encompassing microbes/yeast with unspecified mutations resulting in gigantic cells (your gigantic cells may fall under the scope of such broad claims)
- Broad claims covering microbes/yeast with unspecified mutations resulting in blue cells

It's important to note that even if your specific mutation A is clever and potentially patentable, it may still fall within the scope of other claims that, for example, protect a glucanase with increased activity. A thorough FTO analysis requires careful consideration of all aspects of your intended actions to identify potential infringement risks.

To conduct a comprehensive FTO search, we'd always recommend you ask for help from a search specialist. Additionally, it is crucial to have the results evaluated by a patent attorney, as interpreting the claims can be a complex not to mention time-consuming task.

If you come across any potentially concerning findings during your searches, it is advisable to consult with an attorney. They can help determine whether the identified 'patent' was actually granted, maintained or abandoned.

Moreover, an attorney can assess the interpretation of claim wording by a court.

Even the most innocuous issues can become significant problems in a legal context.

Understanding the limitations of the research exemption

The 'research exemption' is a concept that often leads to misunderstandings regarding patent infringement.

The 'research exemption' is a concept that often leads to misunderstandings regarding patent infringement.

Many individuals mistakenly believe that they are exempt from infringing patents if their activities fall under the category of 'research'. However, it is essential to understand that the research exemption has specific limitations and requirements that vary from country to country.

In Denmark and numerous other jurisdictions, the research exemption applies only when the research pertains to the subject matter of the patented technology itself. If you are utilizing patented technology for a purpose other than the specific subject matter of the patent, the research exemption does not apply, and you may be infringing on the patent.

Let's take a made-up example.

Suppose there is a well-known method for accelerating Western blot experiments, which you apply in your academic research on protein expression in Pichia. Although this method does not require a specific kit and can be implemented using general laboratory equipment, it is protected by a patent.

As an academic researcher solely within academia and without commercial expectations, you may be relatively safe from patent infringement claims. However, this does not imply that you do not infringe on the patent because you do – you are using a patented method as a tool in your own research. The protection from being sued here comes from the fact that companies generally hesitate to sue universities due to reputational concerns.

On the other hand, when you spin out or establish a private company and start commercializing your research, the situation changes. As a commercial entity, you become a potential target for patent infringement claims.

Therefore, when you transition from research to commercialisation, it becomes crucial to assess the technology you have used (methods, products, kits), the context in which you utilized them, and the evidence trail you have left. Did you disclose the specific methods you used in your publications?

It is important not to dismiss potential patent infringement during the research phase based on a presumed 'research exemption'. In many cases, you will be using patented technology as a tool, rather than actually researching the subject matter of the patent. In the above example, if your research was into how to further improve the faster method for Western blots, then there may be a case that you fall under the research exemption – simply using the patented method in your research is not.

To navigate these complexities, it is advisable to stay informed about the rights associated with the technologies you use in academia. However, it is understood that awareness in this regard is often lacking, and people tend to not care until they do commercialise something.

As soon as a scientist-founder embarks on commercialisation or establishes a company, you immediately become more susceptible to patent infringement claims. This makes it essential to carefully consider the implications of using patented technology and consult with legal professionals when necessary.

FTO for pre-seed/seed

A full FTO search and analysis can be costly. As scientists we get the concept of not being able to prove a negative, and all the searching and analysis in the world cannot prove that there are no problematic rights out there.

All we can do is balance where you are in the business, budget, and comfort in terms of the risk you are willing to take on.

Budget wise you are probably running almost on empty. But you still need to show investors and grant funders that you've done something, you are taking it seriously, and you have a plan.

Firstly, you definitely need to understand the concept of FTO. It is the one thing that founders generally give bad answers to and these answers show the founder doesn't really get what it is all about.

Secondly, you can do some searches yourself. All patent applications are published 18 months after they are filed (with the exception of some applications relating to national security). There is nothing you can do to find these unpublished applications – but do keep this in mind as doing top up searches every few months or so will let you find these 'new' (18 months ago) applications as they start to be published.

A useful search to do is for patents and applications in the names of known competitors (search the Applicant field). But note that the Applicant may be different to the actual name of the competitor. For example, your competitor Company X may in-licence patents from Company Y. Searching the databases for patents in the name of Company X will not find the relevant patent. But it is a good place to start.

Also, if you know of a journal publication that might be problematic if there is an associated patent application, do a search separately for each of the authors as inventors, and institutes as applicants. As we have already said, not all authors will be inventors.

Finally, when you search the 'title or abstract' field in a patent database, the titles can often be very vague and you will miss things if you only search in the title.

Keyword searches really ought to be broad. If your invention is a method of making a purple dye using E. coli, a third party claim to "A method of making a dye using bacteria" will be problematic for you. Searching using "E. coli" and "purple dye" would likely be too narrow as these aren't features of the claim and this wouldn't come up in your search results. Instead, in order to have the best chance of finding relevant citations, you might have to go broad with your searches expecting to get a lot of non-relevant hits to filter through (this is one reason why it is very hard for us to give an accurate cost for an FTO until we've got the full list of results and sorted through them!).

Thirdly, you will need to do some sort of triage. The list you have will have a lot of pending applications, and some granted patents.

The list will likely include patents and applications from all over the world. It is not unreasonable to focus your analysis on European and US patents and applications, the majority of applicants will file in one of these places. You will miss some that only file in China for example, but you don't have the time and budget to do everything so pull out the European and US applications and patents (the numbers will begin with EP or US).

A patent can only be enforced once it is granted, so these are the highest priority ones. A second level of triage can be to focus on granted patents only and save the pending applications for later.

Pending applications may grant, and may grant soon (so keep redoing your searches and checks), but early on with limited time and resources, focus on granted patents. You can normally tell if a patent is granted as the number will end in a B. For example, in the patent family below from Espacenet there is a granted EP patent and a granted US patent, and some other pending applications in other countries:

Note that for a patent to be enforced against you, it must be granted and in force. This means that the renewal fees must have been paid to maintain the patent. If the fees haven't been paid, it will still show up as granted as above (with a number ending in B) but will not be in force. This is a bit harder to look up, but just ask us if you find anything you are worried about.

Fourthly, you now have a list of granted EP and US patents and you need to sort out which, if any, might be a problem. You will need to analyse the granted claims. This really is where you'll need a patent attorney to help out. The interpretation of claim scope is very much a legal thing, and how a claim is interpreted can vary quite a lot from territory to territory. How a court in the Danish construes term can be very different to the interpretation given by the German court.

But as a starter for you take an initial opinion, for you to infringe a claim your product or method must have every feature or step set out in the claim (see the previous section). Your method or product may have additional steps or features not set out in the claims. This is still an infringement.

So, does it look like what you are wanting to do ticks off each feature of the claim in the patent/application?

If it is very clear that the claim requires something pretty different to what you are doing, then you can put that in the 'not relevant' pile (and maybe make a note as to why you decided it is not relevant).

There will be some patents and applications that are a bit border line. There might be some terms that could mean one thing, or something else. It's better to err on the side of caution here and put them in a 'potentially relevant' list that you can come to later.

Then there will be some (but hopefully not too many) that stand out to you as potential red flags, you share all of the features so are possibly infringing. Put these in a 'high priority' list.

Whilst is possible to carry out a search yourself, it is a complex process and often the time investment needed in order to learn how to search correctly and efficiently is not worth it for a busy founder.

In addition, the process of screening the documents found and of evaluating their relevance requires both a technical and legal understanding of the claim scope. This can be tricky for the untrained reader.

A preferred option is therefore to engage patent attorneys like us, at least for screening the results, if not for carrying out the complete process from searching to providing the final opinion. Working closely with a patent attorney, , will provide you with the best-quality FTO for your budget. It also provides you (or at least your patent attorney) with full overview of the process such that updating the FTO at a later date, for instance shortly before launch of a new technology, is straight-forward and cost-efficient and you may therefore be able to avoid commissioning a full new FTO search.

We have several available tools that allow us to tailor the scope of the FTO search and analysis, including the use of AI. If the purpose of the FTO is, for example, as part of a grant application, the scope might be different than an FTO conducted before a final product is placed on the market. Additionally, we can adjust the scope and budget of the FTO based on the level of risk that needs to be mitigated. This flexibility ensures that you receive a thorough and relevant FTO analysis that aligns with your specific needs and risk tolerance. This will also give you something from a 'proper' law firm that you can refer to credibly in your pitch deck or grant applications.

If this is still beyond you at the moment, you can still present the approach you have taken and your findings in a way that shows investors you know what you are doing, you are taking it seriously, and you have a plan.

Are they highly problematic? Could you seek a licence? Could you design around so you don't infringe? What is your plan going to be?

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