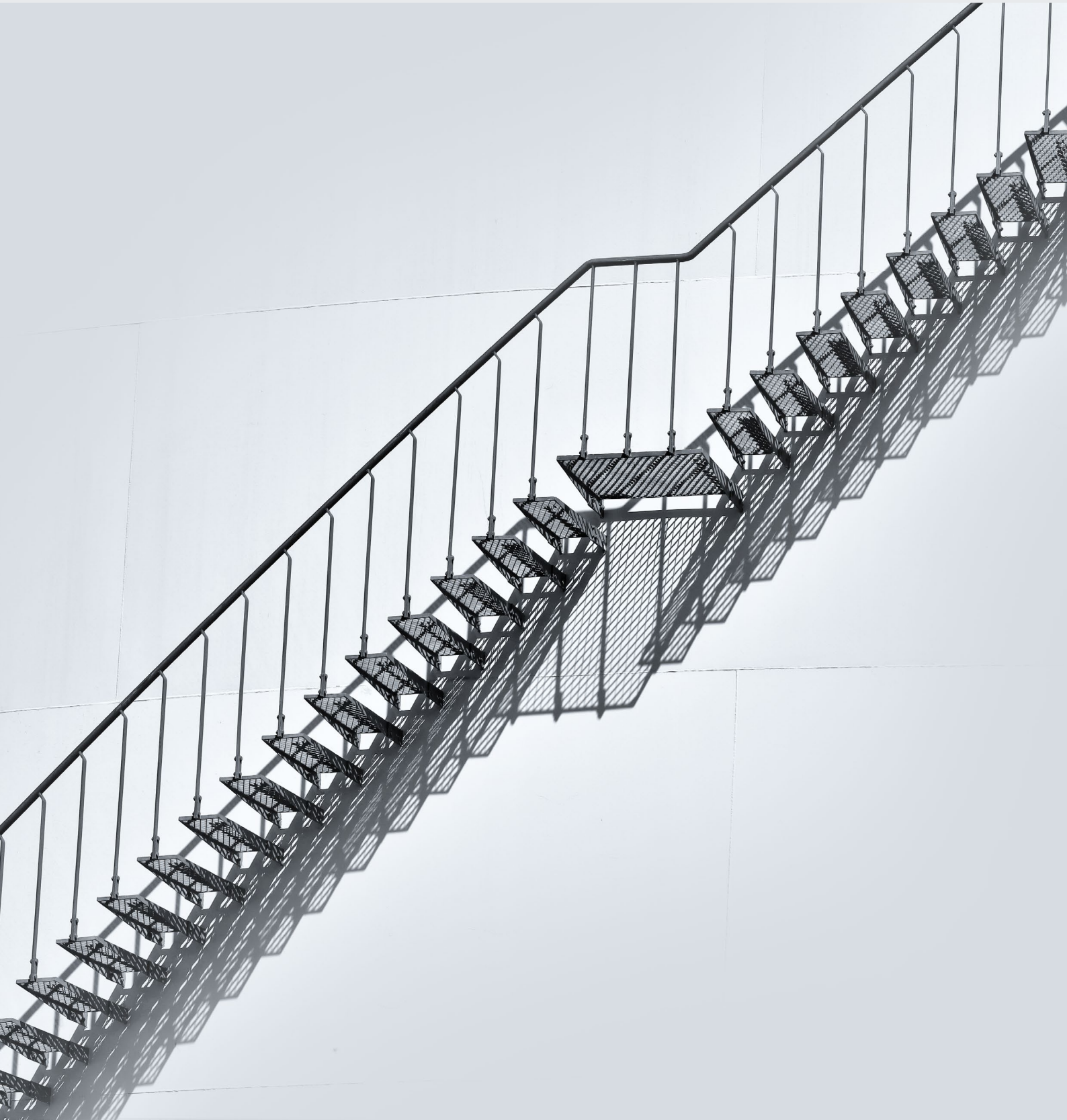
iGEM leiden 2020

PATENTING GUIDE

A quick guide to patenting your project



index

1. Goal of document

The goal of this document is to help your iGEM team understand what a patenting process is like, and what the important aspects of this process are. If you think it may be beneficial to patent your iGEM invention, you must understand the requirements for patenting from the beginning. This can save you time and money, and prevent mistakes that could make your patent application invalid. Therefore, the Leiden iGEM team has made a patenting guide for future iGEM teams.

This document consists of two parts. First, we present several important aspects that need to be considered when applying for a patent. Second, we describe the formal process of a patent application.

2. Important considerations

2.1. Requirements for a patent

For an invention to be patentable, it must meet three criteria.[1] Firstly, it must be novel. Novelty means that your invention is a new idea that is not publicly disclosed by anyone, including yourself. Whether or not your invention is novel, therefore depends on all "prior art" (information in the public domain) at the moment of filing the patent application.

Secondly, your invention must contain an inventive step. This means that the idea is not obvious to an expert in your field of technology. For example, imagine that you would be patenting a new type of umbrella. Simply changing the material from which the umbrella is made could be considered obvious. However, if the material would improve the qualities of the umbrella in an unexpected way, then your new umbrella could be considered novel. This requirement is relatively subjective, and in case of doubt, it is up to the examiner to judge whether your application is inventive.

Finally, your invention must have industrial applicability. This means that it is actually useful. For most iGEM teams this is not a problem, since you are using synbio to solve a real-world problem.

2.2. Do a novelty search

You must know for sure whether you are actually working on something new. This is important for most iGEM teams, but especially for those that are considering patenting. It would be quite disappointing to keep your project secret, work on it for many months, and pay a patent attorney, only to find out that your invention has been published in a scientific journal one year prior. This happens more often than you think!

Therefore, we suggest that before you select which topic you will be working on, you perform a novelty search. During this process, a small group of team members looks for articles and patents that might already contain your invention. Here are some tips for the process:

- Make a small group of team members responsible for the novelty search.
- Have them search for your invention online.
- Write down the details of the search.
    - On which platforms did they search (e.g. Google Scholar, Google Patents, ESPACENET, etc.)?
    - What exact search terms did they use?
- Have them list the 10 articles or patents that are 'closest' to your invention.
- Have 1 or 2 people review their search terms and platforms, and give feedback on what terms (or combinations of terms) still need to be looked up.
- Evaluate if these 10 articles or patents threaten the novelty of the invention. Do any of these sources already describe your invention?

Of course, this is a tedious step, and you might want to avoid it at the start of your project as you are very excited about the topic. However, it can save a lot of work and disappointment in the long run, so please don't skip it! If you fail, try to fail as soon as possible!

2.3. Non-disclosure

The novelty requirement means that it is very important not to disclose your idea before filing the patent application. So what counts as public disclosure? Generally speaking, it is telling or showing your idea to anyone, without agreeing beforehand that they will not share it with anyone else. Some examples of public disclosure are:

- Presenting your idea at a conference;
- Writing about your idea on a public forum, or in an email;
- Talking about the idea to someone outside your team, unless they have agreed not to disclose it by signing an NDA (see below);
- Presenting the novelty during an iGEM presentation, on a poster, or on wiki pages.

As an iGEM team, you will be doing human practices. During conversations with experts, you might be tempted to discuss the details of your project in order to improve it. How should you approach this? We suggest two solutions.

1. Talk about your project in general, without sharing confidential information. Often, you can ask experts for advice without telling them exactly how your invention works. For example, our team was working on a new test for detecting pathogens. We could gather a lot of information about which diseases would be valuable to test, which people need testing the most, and how testing currently works in different countries without sharing the details on which chemicals were used in our test.

2. Sign a confidentiality agreement, also called a non-disclosure agreement (NDA). This is a document in which two parties agree not to share confidential information. Keep in mind that most people you will talk to might not be open to signing a confidentiality agreement, as you are placing an extra responsibility onto them. When approaching someone about signing an NDA, it is therefore important to be cautious. During our first meeting with an expert, we only discussed general information. If they were interested in any confidential parts of our project, we would tell them:
"I'm sorry, but we are considering patenting our invention, and so we cannot disclose this information right now. If you are interested in talking about this, maybe we could send you an NDA, and then we can into further detail during our next meeting?"
This gives the person you are talking to the freedom to accept your offer, without making them feel pressured.

It is also a good idea to sign a confidentiality agreement within your iGEM team. Employees of your university may already have confidentiality requirements stated in their contracts, but your student team members probably will not. If your team wants to keep your invention undisclosed before filing a patent, it can be valuable to put this in writing.

2.4. The university's claim on intellectual property

If you are considering patenting your invention, you will need to know whether the university has a claim on the resulting intellectual property (IP). Some university policies state that IP generated by students can be partially or entirely claimed by the university, and this is important to know before deciding whether to patent your idea. Their involvement is not necessarily disadvantageous. It may give you access to their expertise, facilities, or business development services. Furthermore, having your company supported by the university may increase its credibility.

Whether or not the university claims IP that students generate differs between universities. To find out your university's policy, we advise you to talk to the technology transfer office (TTO), sometimes referred to as the technology licensing office. If possible, try to get their policy in writing, e.g. an e-mail or a link to official university documents. Besides, discuss how the involvement of your supervisors in the creative process will influence the ownership of the IP. It is likely that your supervisor is an employee of the university, and that IP generated by your supervisor is treated differently than the IP generated by students. Always keep a good relationship with your TTO - they may be able to help you with finding a patenting attorney, funding, and advice in the future.

2.5. Financing your patent

Patents cost money. Before you set your hopes on filing for one, you should also think about where the money will come from, at least for the initial stages of the process. Here are some examples of financing sources for a patent:

- You and your team members. This is a logical source of money, but not everyone may be on the same page about committing hundreds of dollars per person for a patent. Patenting is always a risk, and you cannot know for sure if the money will ever be earned back.

- Sponsorships. Often, companies will be open to sponsoring your iGEM team. If your team's sponsorship money gets collected into your university's bank account, it is best to discuss with your supervisors before obtaining the sponsorship whether you could use it for your patent application. Furthermore, it's important that the companies agree that their sponsorship will be used to obtain a patent.
Sponsorships from law firms deserve a separate mention. Patent attorneys are specialized in the area in which they operate, and may even have a PhD. If you can convince them about your invention's novelty and importance, they may be willing to sponsor you by writing the provisional patent application for free. Another option is to agree that they write the provisional application "for free" now. If you would choose to continue to the next steps of the patent application, you can pay for it retrospectively. Patent attorneys who work together with your university's TTO are probably the best candidates for this kind of set-up.
- Money allocated to your iGEM team by your university. Keep in mind to discuss this with your university in advance, including the terms upon which the funds are used and whether any of the generated IP will be claimed by the university.
- Investments/licensing fees from companies. In later stages of the patenting process (PCT and beyond), it may be wise only to continue if you find a company that is willing to commit to the patent. This could be your start-up or an external investor. If it is the latter, they may be willing to pay the costs for the patenting application. However, this is probably not yet relevant for the first (provisional) step of the application process.

3. The patenting process and costs

The patenting process consists of several steps. These steps have multiple names, and the sequence is often very hard to figure out. Therefore, this paragraph presents a short overview of the various stages of a patenting application. Keep in mind that the costs can differ per project and per country.

3.1. National (or provisional) application

Sometimes referred to as priority application, first filing, local or regional application.

The national application (or provisional application, in the US) is not an obligatory step but can be very valuable. During this step, you file the first 'version' of the patent. This means that your invention is recorded, together with the date on which you filed the national application (the so-called "priority date"). This is important for iGEM teams since you would want to disclose your invention before the Wiki Freeze. It also gives you 12 months to perform additional experiments, which provide you with evidence that your invention actually works.

Even though you are allowed to file a patent application yourself, it is highly advisable to hire an attorney to draft your application. This will prevent you from making mistakes that could make your patent unenforceable in the future. A national application could cost you approximately 3,000 to 6,000 USD, depending on the time your attorney spends drafting your claims. After this filing, you need to file the next application (the PCT application) within 12 months. The main benefit of a national application is that your PCT application may include claims described in the national application. Therefore, in the national application, you write down your claims as broadly as possible. After that, you will be able to remove the claims that are not valid from your application.

Let's give an example: you are developing a new polymerase, and you want to specify at which pH it will work in the patent application. However, you have not conducted any experiments on the pH yet.

In your provisional application, your attorney writes that your polymerase works at pH 0, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, and 14. After filing the provisional application, you have 12 months to conduct experiments and find out which pH values are suitable. You conduct the experiments and find out that values 7, 8, and 9 work, and the rest do not. Because you had these values specifically included in the

national application, you can include them in the PCT application (while removing the other ones).

Some extra information about the differences between the European national application and the US provisional application can be found here.[2]

After your national application, you work on your invention for another year. If you still believe that a patent for your invention is valuable, you can choose to go for the next step: the PCT application.

3.2 PCT route: international phase

Sometimes referred to as an international application.

The PCT (Patent Cooperation Treaty) is an agreement between more than 150 countries, in order to make patenting easier. The benefit of following the PCT route is that you can make one PCT filing and then turn your patent into a national patent in all the participating countries. This can save a lot of money, especially on search fees.

The PCT route consists of two phases: the international phase (discussed in this section) and the national phase (discussed in section 3.3). The international phase begins with a PCT application. This application will be handled through your attorney, and its costs will be between 5,000 and 10,000 USD (the costs can differ per case). However, the costs of the patenting process will strongly increase from this point onwards, so it is likely only useful to file this application if you have found someone to exploit the patent, e.g. your start-up or another company.

4 months after filing the PCT (16 months after your first filing), one of the International Search Authorities (ISAs) will present a search report about your application. In the search report, they document inventions that are similar to yours (so-called "prior art"). They will also present a written opinion, in which they describe whether your invention is novel and inventive. You can use these findings to slightly amend your patent application, to make sure it fits these criteria.

6 months after filing the PCT (18 months after your provisional application), your invention is disclosed to the world in the International Publication. If you change your mind about patenting and do not want to disclose your application to the world, you need to withdraw it before this date.

10 months after filing the PCT (22 months after the provisional application), you may request an international preliminary examination. You receive the international preliminary examination report (IPRP) 6 months later. In this step, an examiner from one of the ISAs determines the patentability of your application. The advice given by the examiner will be used by national authorities in future steps to decide whether your patent will be granted. This step is very valuable since it allows you to respond to the examiner's remarks and influence his or her recommendations.

After receiving the IPRP, you can enter the national phase. This must be done within 30 months of the initial filing date.

Most information presented here about the PCT step was obtained from the WIPO, and additional details can be found here.[3]

3.3 PCT route: national phase and further

The national phase is the part of the process, in which you actually obtain a patent. In this phase, the international application is turned into a patent in each country or region in which you apply.

Because the exact process of the national phase differs per country, we will not go into detail in this document. By the time you have reached this phase, you will have developed a close relationship with your patenting attorney, and he will be able to give you more advice about it. However, it is important to keep in mind that this is the most expensive phase since costs are made in each country where you apply. Furthermore, after your patent is granted, you will have to pay maintenance fees for your patent. The total costs of a

worldwide patent application including maintenance fees can reach over 100,000 USD.[4]

4. Final notes

As this document shows, the patenting process is quite long, tedious, and expensive. Because it takes multiple years, you want to ensure that someone in your team would like to commit themselves to the process. Furthermore, because the costs are high, it is important to understand beforehand whether a patent is truly valuable. Are the benefits of your solution significant enough that you will be able to attract investors?

Often, people who want to start the patenting process are excited by the idea of 'having' a patent. They imagine themselves being named an inventor. However, it is likely that you will abandon the patent before it is ever published. Consider to what extent your desire to patent is driven by vanity instead of practical interests. If this is the case, publishing your work in an academic journey may help you reach your goals in a faster, less expensive way.

Finally, make sure to maintain a good relationship with your university, its TTO, and your patenting attorney. These are the most important stakeholders during the patenting process, and their support can determine whether you will ultimately succeed or fail. Approach them well in advance and do not be afraid to ask them questions: they have gone through this process before and can give you valuable advice.

Notice: This document was put together by an iGEM team. We are biologists, not lawyers. All information presented in this document is solely based on our understanding and has not been reviewed by a patent attorney. If you need legal advice, we suggest you contact a patenting attorney or your local patenting office.

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