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Whitepaper:

Digital lab notebook and intellectual property protection

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Introduction

Securing intellectual property is crucial to any innovative organization that seeks commercialization of their inventions and derived products.

Laboratory notebooks have played a central role in securing intellectual property, as, given they keep to laboratory standards and regulations, they provide proof of invention according to the First to Invent patenting rule. This rule states that the person or organization who conceived an idea is also the party that can make privileged intellectual property claims.

However, in the past few years, there has been a shift in paradigms when it comes to the governing principle of granting intellectual property claims. The First to Invent system is changing to First to File. In the US, under the Leahy–Smith America Invents Act (AIA), from the 16th March of 2013, patenting laws in the US work on the First Inventor to File principle. Within Europe, although Germany and England formerly worked on a First to Invent system, the European Patent Office, which grants patents to many European countries, implements the First to File system. Digital laboratory notebooks continue to play a key role in securing data, defining invention ownership and aid in publishing documents that can be used later to defend an invention.

Although both Europe and the US both use the First to File system, the requirements differ. This whitepaper describes:

- The legal system of European Patent Office.
- The legal system of the United States Patent and Trademark Office.
- The benefits digital laboratory notebooks provide in regard to patenting.

The legal system of the European Patent Office (EPO)

Although patenting systems exist per country in Europe, the patent granted is only valid in that particular country. It is advisable to only apply to individual countries for a patent if you only want protection in a select number of countries. However, filing a patent with the European Patent Office means that the patent is valid across a much greater range of countries within Europe.

The full list of European countries currently participating in this system can be found here.

With this system, an invention is considered new and patentable if it does not form part of the state of the art. The EPO defines state of the art as "everything made available to the public anywhere in the world by means of a written or oral description, by use, or in any other way, before the date of filing or priority."

Therefore, the European Patent Office works on a First to File system. If you are the first to file for a particular patent, one will be granted, as long as no state of the art exists.

An existing patent or patent application can only be challenged if it is opposed up to nine months after the patent is published on the EPO's publication server. A patent or patent application can is opposable if, either;

- a) the patent does not **disclose the invention clearly and completely** enough for it to be carried out by a person skilled in the art,
- b) or, state of the art exists.

Thus, it is possible to claim ownership of an invention by producing state of the art, as well as applying for a patent.

The requirements of state of the art, according to the European Patent Office, are:

- It must have been published **before the filing date**. However, a disclosure of the invention is not taken into consideration if it occurred six months or less before the filing of the European patent application. This denotes that if an inventor discloses prior art, they have up to six month to file for a patent application, and must evidence, within the application, that the state of the art was disclosed within the time limit.
- It must have been made **available to the public**. This means it cannot be confidential and there must be no access restrictions.
- There must be some **written** proof. Although the EPO system does permit an "oral description", there must be a document that reproduces the description or gives an account of prior use (e.g. a display at a public exhibition). However, this document can be published at a later date. The date the state of the art was "made available to the public" is the date when it was orally disseminated.

This means that if a paper is published, disclosing an invention fully, the author can legally oppose a patent, describing the same invention, within Europe. However, the author can only claim ownership of the invention if they file for a patent application within six months after the publication.

The legal system of the United States Patent and Trademark Office (USPTO)

In the US, generally speaking, the inventor is who was the first to register the patent claims ownership of it. However, of course, the law is never that simple and there are many possibilities and variations that can complicate this system.

The First Inventor to File system can be challenged if prior art exists. This is evidence proving that the invention was already known.

The official definition of prior art is: 'A reference is proven to be a "printed publication" "upon a satisfactory showing that such document has been disseminated or otherwise made available to the extent that persons interested and ordinarily skilled in the subject matter or art, exercising reasonable diligence, can locate it."", according to the United States Patent and Trademark Office

This means the owner of an invention can challenge an existing patent if they have published prior art. Put simply, the requirements for prior art are:

- 1) It has to be written and accessible.
- 2) The content has to depict the **fully-completed** invention **in depth**.
- 3) It has to fulfill the requirements above at least a year before the patent application is made.

Below, the details and specifics of these requirements are discussed:

1) a) It has to be written

A "printed publication" does not imply all it suggests. It can also be an electronic written document.

b) It has to be accessible

US patenting law states that those "exercising reasonable diligence" should be able to locate it. These means that it can be proved the document was made available to people interested in the topic and people "ordinarily skilled in the art".

This denotes that abandoned patent applications, which are automatically published 18 months after the application is received, can be used as prior art. Oral presentations can only be held accountable if there is an unrestricted amount of printed copies of it at the time. Documents in libraries with restricted access may also be valid if citations are publicly available. Additionally, publicly displayed documents can constitute a "printed publication", even if the duration of the display is only short term. However, internal documents, intended to remain confidential, do not warrant the term accessible.

A patent can also not be issued if it can be proved the invention was already commercialized.

2) a) The content has to depict the fully-completed invention

For the document to be valid prior art, it has to describe the invention once it has been finished, and therefore not in the development stages.

b) The content has to depict the invention in depth

The content depends greatly on the invention, however there are some guidelines:

- i) The way the article/invention was produced does not have to be mentioned, if there is a reference to each claimed element of the article.
- ii) The mere naming of the article is not enough.
- iii) A picture or a drawing may count if it illustrates all the components and the way they were assembled, and if it is either to scale or shows the dimensions.

3) It has to fulfill the requirements above at least a year before the patent application is made

The date of disclosure is measured by the day it was made available to the public. If this date is irretrievable, it cannot be relied upon as evidence. However, the date itself does not need to be specified, only the fact that it was published at least one year before the application was submitted needs to be verified.

This also signifies that if the inventor chooses, or gives permission to another person, to disclose prior art, they have up to a year to patent their idea. After this twelve-month period, their publication can count against them if these decide to file for a patent.

Digital lab notebooks and intellectual property protection

Comparing the US system to the European system, the main difference is the date the publication is disclosed. With the EPO, the patent can be challenged if state of the art was published at least six months before the application is filed, whereas in the US the time period is twelve months long.

In order to effectively secure your intellectual property in Europe and the US, we recommend the following measures:

- 1) If you want to patent your work, store all your notes in a restricted-access area like in Labfolder's digital lab notebook. Group projects stay confidential within the group and project owners are clearly defined. This ensures the information remains private until publication or patent application.
- 2) Once your invention is fully developed, **file for a patent as soon as possible.** Filing for a patent legally guarantees ownership of an invention. Although state of the art and prior art are useful in opposing an existing patent or patent application, a granted patent provides legal evidence of ownership and lasts for 20 years in the US and Europe.
- 3) If it is worth it, file several provisional patent applications while the invention is still in the process of development. These applications will count as evidence if a patent for the same invention is filed.
- 4) **Publish your work and findings.** By posting your data on publicly available pre-publication servers, you can prevent the patenting of parts of your invention at an early stage. This is especially relevant to Europe, but is also extremely worthwhile in the US. As **figshare is integrated within Labfolder**, it is easy to publicize your research. Through publishing, discoveries are less likely to be copied later on. The author of a publication can still claim ownership of an invention, if someone else files for a patent in Europe within six months after the disclosure, or in the US within a year of the publication date.

If you have any further questions regarding European and US patenting laws or Labfolder please do not hesitate to contact us anytime at feedback@labfolder.com.