

Differences between US and EU Patent Laws that Could Cost You and Your Startup

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Quiz Questions

- 1) A priority claim made in an EP patent by a University is invalid if the inventors haven't assigned the priority application to the University. **True or False?**
- 2) A claim granted by an EPO examiner is valid and cannot be revoked even if it lacks explicit written description support in the specification. **True or False?**
- 3) You can get a patent on the same inventions in Europe as you can in the US. **True or False?**

EPC versus Title 35

Absolute Novelty
Inventive Step
Clarity
Support – **Strict Basis**
Sufficiency of disclosure

Novelty
Nonobviousness
Clear and Definite
Written Description
Enablement
Best Mode
Duty of Disclosure

US Novelty in a Nutshell

Prior art 35 USC 102(a)	Exception 35 USC 102(b)	Declaration in Support of Exception
102(a)(1): Disclosure anywhere of patent/ application, publication, public use, on sale, or otherwise available to the public before the effective filing date of claimed invention	102(b)(1)(A) Grace period for inventor originated disclosure	37 CFR 1.130(a) Declaration of attribution
	102(b)(1)(B) Grace period intervening disclosure by third party	37 CFR 1.130(b) Declaration of prior public disclosure
102(a)(2): U.S. Patent, U.S. Patent Application, or PCT Application effectively filed before effective filing date of claimed invention	102(b)(2)(A) Inventor originated disclosure	37 CFR 1.130(a) Declaration of attribution
	102(b)(2)(B) Intervening disclosure by third party	37 CFR 1.130(b) Declaration of prior public disclosure
	102(b)(2)(C) or 102(c) Commonly owned disclosure Joint research agreement	37 CFR 1.104(c)(4)(ii) Declaration of co-ownership

European Approach - Absolute Novelty

- The invention is new if it is not part of the state of the art, which comprises all matters made available to the public, without any limitation regarding time, space and form
- 6 month grace period for direct filings in some European countries

Novelty - Availability of Reference

The piece of prior art is available to the public if:

- at least one person,
- not bound to secret either expressly or implicitly,
- could, at least theoretically, have access to the piece of prior art,
- and if it revealed the claimed means sufficiently clearly so that the skilled person could reproduce them

Inventive Step

- Overcoming inventive step rejections by the EPO relatively easier than overcoming obviousness rejections in the US
 - EPO's problem-solution approach is formulaic and does not allow much room for interpretation
 - Unlike the US, a large number of references used to make the asserted combination can weaken an inventive step rejection

A Word of Caution

- There is a fine line between the EPO type of problem-solution approach and taking the Examiner's hand and walking down the path of obviousness in the US

Priority

Often priority claims to a prior application are made to preserve novelty and nonobviousness and delay having to file in other countries

Priority for European Applications

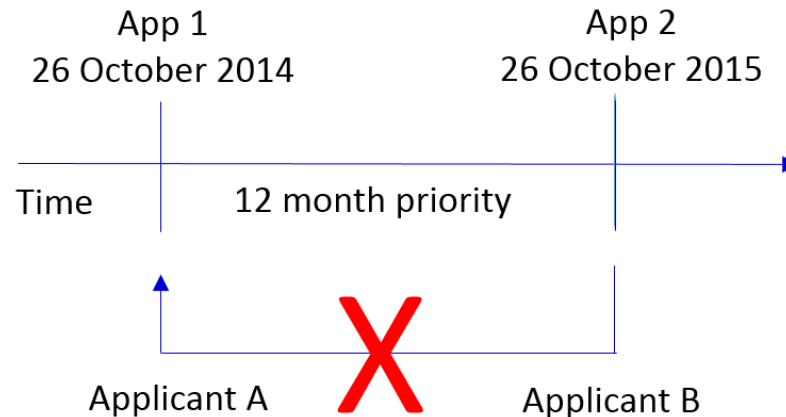
European Patent Convention states:

A. 87 EPC

- (1) Any person who has duly filed, in or for
- Any State party to the Paris Convention...
- Any member of WTO
- An application for a patent, a utility model or a utility certificate, or his successor in title, shall enjoy, for the purpose of filing a European patent application in respect of the same invention, a right of priority during a period of twelve months from the date of filing of the first application.

Priority Pitfall 1 – Change of Applicant

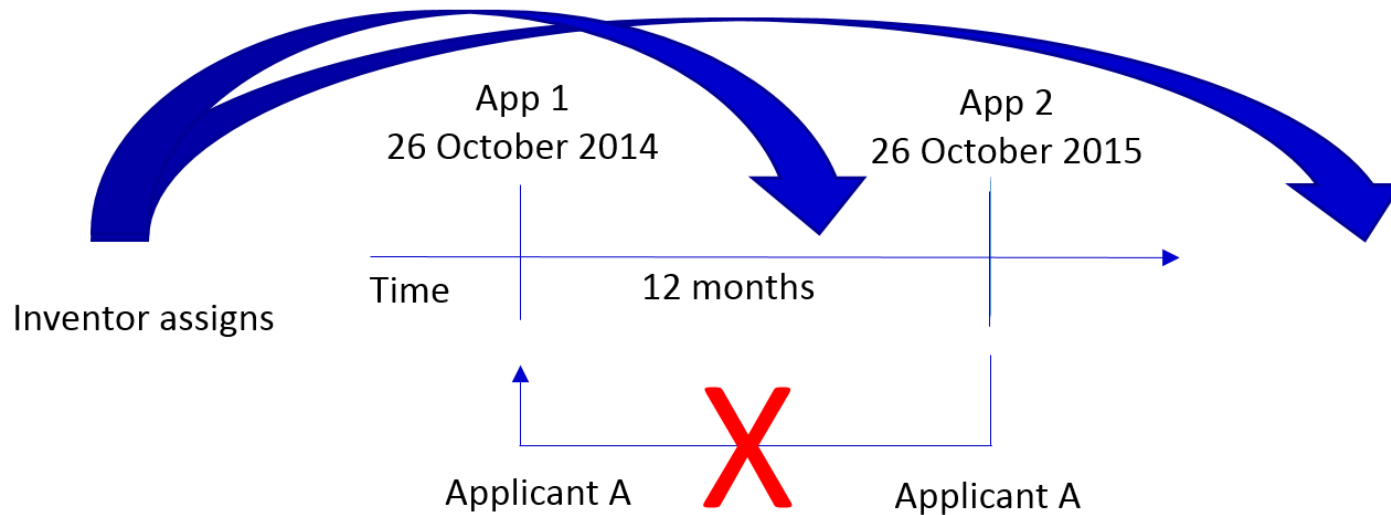
- Any person... or his successor in title...
- EPO applies strict interpretation: eg. daughter company and parent company – no valid priority claim



- Assign right to priority from A to B before claiming priority

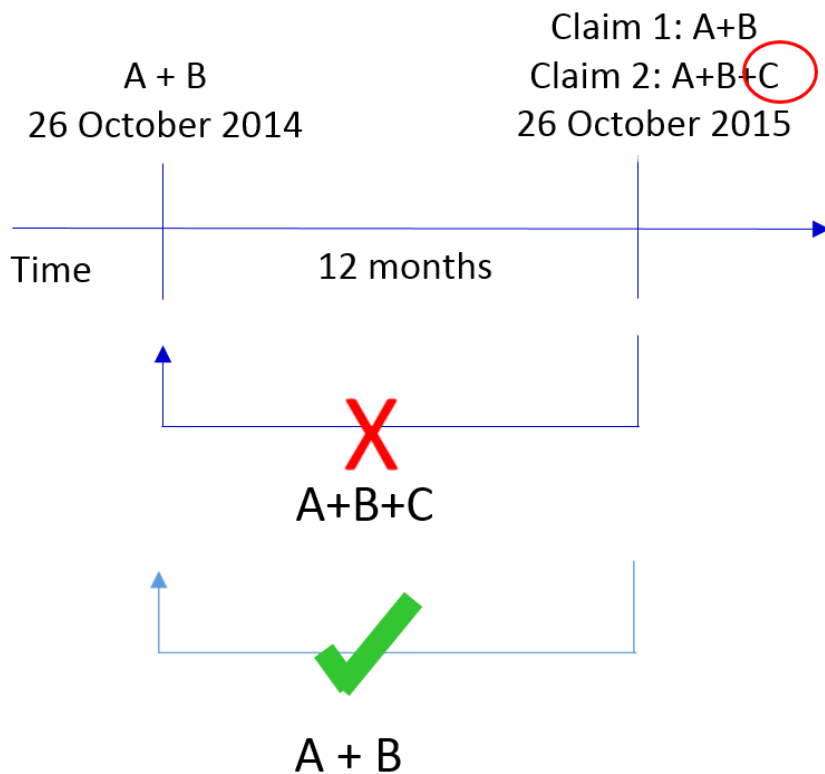
Priority Pitfall 2 – Date of Assignment

- Any person... or his successor in title...
- Assignments signed after filing date may invalidate a priority claim



- Assignments must be signed before filing applications

Priority Pitfall 3 – Same Invention



- Priority recognized for the same invention – “if the skilled person can derive the subject-matter of the claim directly and unambiguously, using common general knowledge, from the previous application as a whole”
- Make sure your priority is preserved if changes are required when filing a later application (e.g. PCT)
 - e.g., Keep identical wording of claims from the priority application in an annex

Priority Best Practices

- Ensure inventorship and applicant information is correct
- Obtain executed assignments for applications each time new subject matter is disclosed
- Immediately return executed assignments to the patent attorney

Claim Amendments

Often claim amendments are necessary to overcome art and clarity rejections

Admissible Amendments

- Claim amendments that have either explicit or implicit support in the original application as filed are admissible in both the US and Europe
- The principles behind the prohibition against “new matter” are substantially similar in the US and Europe

The Application “As Filed”

- Specification, claims, and drawings
- Refers to the original language text
- If a national or regional phase entry, the PCT application
- In exceptional circumstances, cross-referenced documents mentioned in the specification

The Application “As Filed”

- Specification, claims, and drawings
- Refers to **English language translation**, if filed as part of the original application papers
- If a US national phase entry, the PCT application
- Cross-referenced documents, sequence listings, computer listing, and other items **if properly incorporated by reference** in the specification

Strict Basis

- Amendments can be based on explicit or implicit disclosure
- There is no requirement to use the exact wording from the application as filed.
 - However, it often seems like word for word support is required. This is likely because of the requirement for implicit disclosure.
- Implicit disclosure: The clear and unambiguous consequence of what is explicitly disclosed.

The Inescapable Trap

- If a European patent contains a feature that was not disclosed in the application as filed and if the removal of the feature would extend the scope of protection beyond the scope conferred by the patent as granted, the patent must be revoked
 - It does not matter whether the amendment leading to such a situation was approved during prosecution

An Oral Lesson

Claim 10 of Pfizer's EP 702 555 B1 (Sildenafil):

- The use of a cGMP PDE inhibitor, or a pharmaceutically acceptable salt thereof, or a pharmaceutical composition containing either entity, for the manufacture of a medicament for the curative or prophylactic oral treatment of erectile dysfunction in man.
- The word “oral” was added during prosecution

Support in the Specification

- Two types of teaching in Pfizer's application:
 - Use of compounds of a defined general formula; and
 - Use of compounds defined only by their function of enzyme inhibition without a general formula.
- Unfortunately:
 - The administration of the structurally defined compounds was originally said to be oral,
 - BUT the administration of the functionally defined compounds was not originally disclosed.

Avoiding the Trap

- Set forth all possible combinations when working the draft application
- Don't try to get away with amendments that are acceptable in the US
 - Rely upon the expertise of your patent attorney and the European foreign associate
- Treat strict basis as quite strict

Patent Eligible Subject Matter

Any inventions which are susceptible of industrial application, which are new and which involve an inventive step

Any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof... subject to the conditions and requirements of this title.

Negative Definition of “Invention”

The following in particular shall not be regarded as inventions:

- discoveries, scientific theories and mathematical methods
- aesthetic creations
- schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers
- presentations of information

Ineligibility Uncertainty in the US

Judicial exceptions to patent eligibility

- Abstract Ideas
- Laws of Nature (and Products of Nature)
- Natural Phenomena
- ??? Diagnostic methods and purified natural products ???

However, treatment methods are eligible in the US...

No Treatment Methods

- Art. 52-4 EPC: “Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body shall not be regarded as inventions which are susceptible of industrial application ...”
- “This provision shall not apply to products, in particular substances or compositions, for use in any of these methods.”

However...

- Only methods are not patentable; the substances (i.e. drugs) and medical devices (i.e. prostheses, scales, etc.) are patentable.
- “Swiss-Type” and various “Use” claims are eligible
 - Use of a Product P in the manufacture of a medicament for the treatment of Disease D
 - Compound C for use in the treatment of Disease D
- EPC 2000 claims
 - Product P for use in therapy
 - Product P for use in the treatment of Disease D

Second (or Further) Medical Use

- Use of known pharmaceutical composition for treatment of
 - a new indication
 - a known indication in a new patient group
 - a known indication in a new dosage form
 - a known indication with a new dosage regime
- When inventing, think about different routes of delivery and/or different dosage regimes for different indications

Skinny Labels and Off-Label Prescribing

- Skinny labels carve out the patented second medical use
 - Summary of product characteristics (SmPC)
 - Market Authorization
 - Patient Information Leaflets
- Doctors can prescribe off-label
 - Approximately 83% of prescriptions are written generically
 - Approximately 95% of prescriptions do not state the indication for which the drug has been prescribed

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Suzannah is a US patent attorney registered to practice before the USPTO. Suzannah practices all aspects of intellectual property law including patent preparation, and prosecution, licensing, opinion work, client counseling, and enforcement strategy relating to diverse technologies including biochemistry, molecular biology, pharmaceuticals, industrial chemicals, microfluidics, diagnostics, medical devices, and nanotechnology. Suzannah has a technical degree in biochemistry and molecular biology and was a cytogeneticist on one of the major genome projects.



Thank You!

Questions?

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