WHEN AND WHY

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patentree

intellectual property











# DO YOU DEAL WITH TECHNICAL PROBLEMS DURING PHARMACEUTICAL MANUFACTURING?



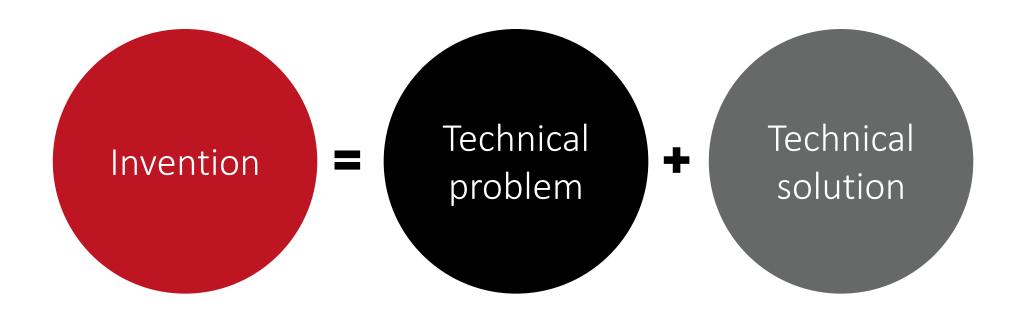


# DO YOU FIND SOLUTIONS?





# What is a patent?







# **Patentability requirements**

**NOVELTY** 

**INVENTIVE STEP** 

INDUSTRIAL APPLICABILITY





# **Patentability requirements**

Unexpected or surprising result?

**INVENTIVE STEP** 

- Not obvious to try?
- Using non-routine techniques?
- Overcoming a technical prejudice?





# Why it is important to protect

- Ensure competitive edge in the market
- Legal right to prevent others from using the patented process or from placing on the market the product obtained directly by that process
- Economic and technological advantage





#### **EXAMPLE - EP3456324B1**

**Background**: Acetaminophen tablets cannot be manufactured through direct compression (flowability issues). Only works through dry granulation – time consuming/ more expensive

**Technical problem**: How to **improve electrostatic charging properties and flowability** of acetaminophen to allow manufacturing tablets through direct compression





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**Background**: Acetaminophen tablets cannot be manufactured through direct compression (flowability issues). Only works through dry granulation – time consuming/ more expensive

**Technical problem**: How to **improve electrostatic charging properties and flowability** of acetaminophen to allow manufacturing tablets through direct compression



**Technical solution**: **Specific particle size distribution** of acetaminophen used as a starting material **allow to apply direct compression** 

Overcoming a technical prejudice



#### **EXAMPLE - EP2377516B1**

**Background**: Manufacturing of liquid injectable composition: requires heating to solubilize acetaminophen -> API degradation

**Technical problem**: How to avoid degradation of acetaminophen during manufacturing?





#### **EXAMPLE - EP2377516B1**

**Background**: Manufacturing of liquid injectable composition: requires heating to solubilize acetaminophen -> API degradation

**Technical problem**: How to avoid degradation of acetaminophen during manufacturing?

**Technical solution**: Liquid injectable composition comprising

- acetaminophen;
- hydroxyethyl starch;
- at least on osmolality agent



It was has surprisingly found that hydroxyethylstarch significantly increases the rate of dissolution of acetaminophen. (lower temperature needed during manufacturing)

Unexpected / surprising result



# PATENT VS TRADE SECRET

- Use of the manufacturing process not traceable in the product?
- Impossible to perform reverse engineering?
- Consider TRADE SECRET!

Internal protocols and NDA agreements should be implemented





# Innovation is your commitment, protecting it is ours.



European Patent Attorneys





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