

# PHARMACEUTICAL PATENTS ON MANUFACTURING METHODS

WHEN AND WHY

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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

INVENTIVE STEP

- Unexpected or **surprising result**?
- 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?

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**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 one osmolality agent

*It was 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.*



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