



# The patent cliff

Patents in the pharmaceutical industry

30 April 2024

Dr. Daum

# What is a patent?



mantinov - Fotolia

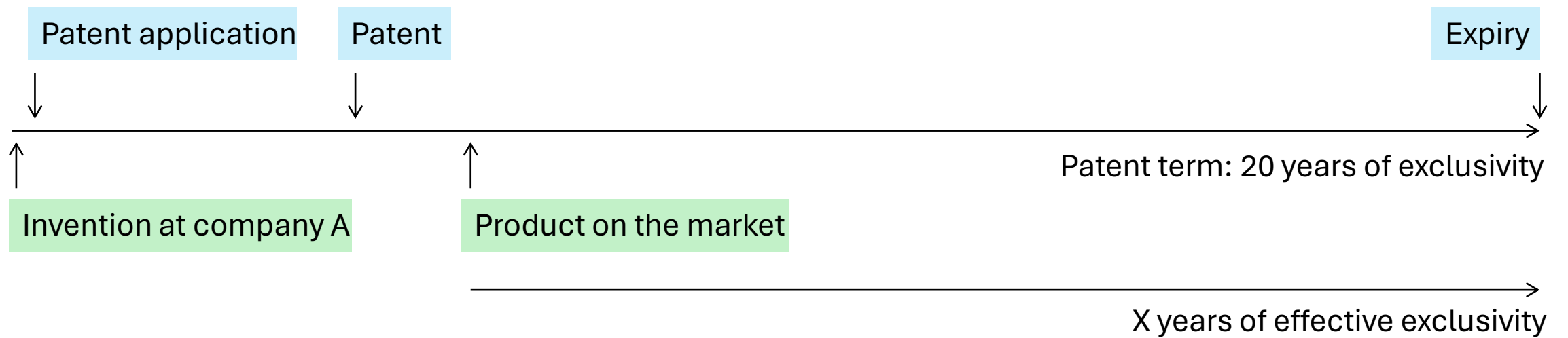
# What is a patent?

F. Effects of  
the patent  
I. Right of  
exclusivity

## **Art. 8** Swiss Federal Act on Patents for Inventions

<sup>1</sup> The patent confers on its proprietor the right to prohibit others from commercially using the invention.

<sup>2</sup> Use includes, in particular, manufacturing, storage, offering, placing on the market, importing, exporting and carrying in transit, as well as possession for any of these purposes.



# Patent departments in the pharmaceutical industry

Monitor patent rights of others: to be **free to act** on the market

**Create** patent rights

**Enforce & defend** patent rights

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# Patent law in different areas of technology

It's pretty much the same!

## Classification schemes

Patent offices worldwide use the International Patent Classification (IPC). There are approximately 70 000 different IPC codes for different technical areas.

**A**

**HUMAN NECESSITIES**

**AGRICULTURE**

**A01**

**AGRICULTURE; FORESTRY; ANIMAL HUSBANDRY; HUNTING; TRAPPING; FISHING**

**A01B**

**SOIL WORKING IN AGRICULTURE OR FORESTRY; PARTS, DETAILS, OR ACCESSORIES**

holes for sowing, planting or manuring [A01C 5/00](#); machines for harvesting root crops [A01D](#); mowers  
working implements [A01D 43/12](#); soil working for engineering purposes [E01](#), [E02](#), [E21](#))

**A01B 1/00**

**Hand tools** (edge trimmers for lawns [A01G 3/06](#)) [\[2006.01\]](#)

**G**

**PHYSICS**

**G10**

**MUSICAL INSTRUMENTS; ACOUSTICS**

**G10C**

**PIANOS, HARPSICHORDS, SPINETTS OR SIMILAR STRINGED MUSICAL**

Note(s) [\[2019.01\]](#)

In this subclass, the specific types of musical instruments are covered by group  
[G10C 9/00](#).

**G10C 1/00**

**General design of pianos, harpsichords, spinets or similar stringed musical i**

**G10C 1/02**

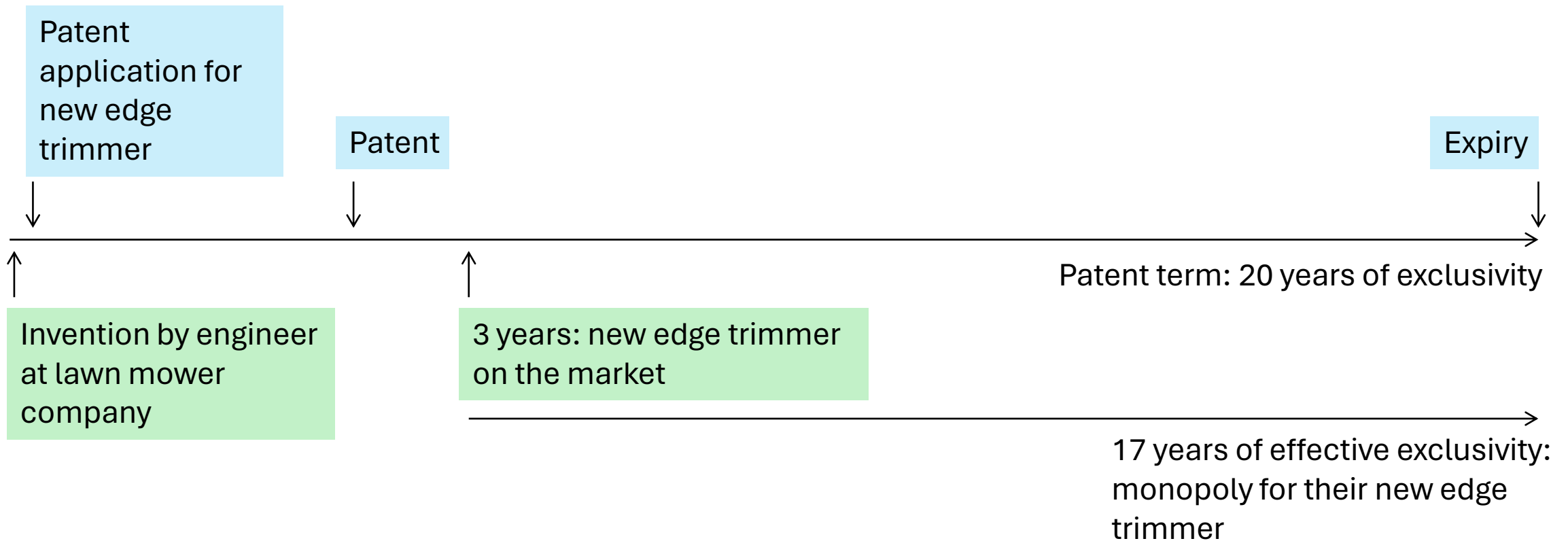
• of upright pianos [\[2006.01\]](#)

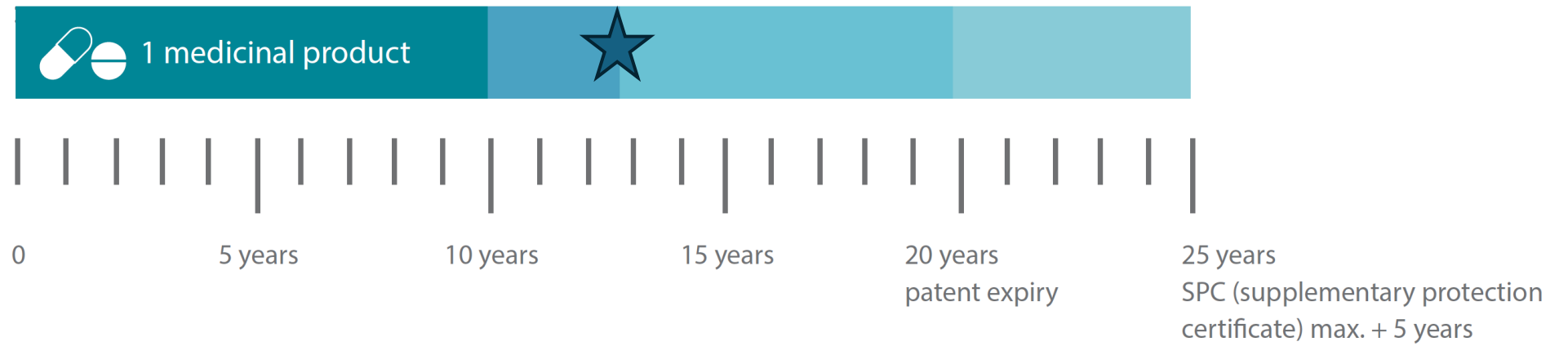
**+ 69'997**



# The pharmaceutical industry

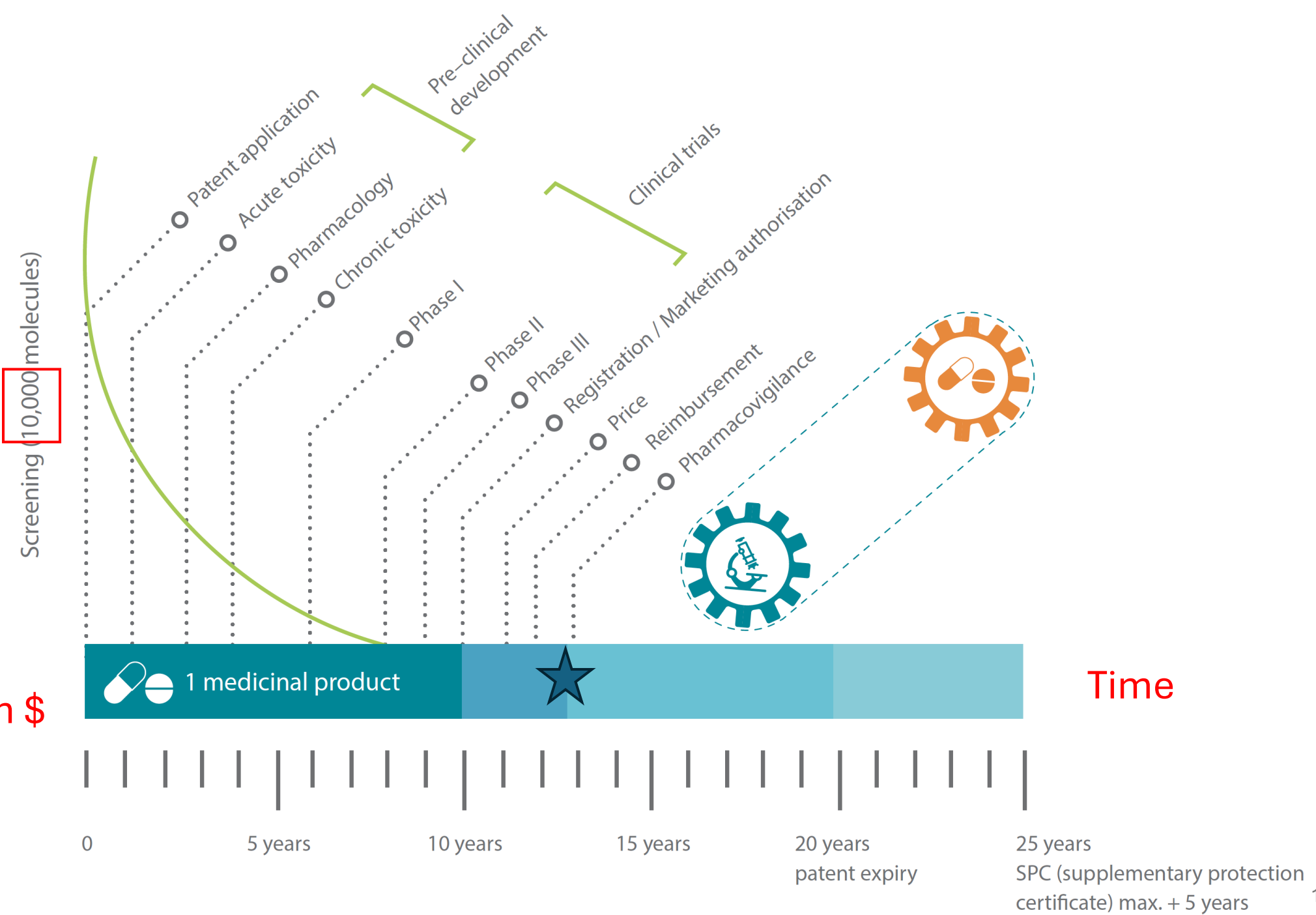
So what's the difference? Time & cost & risk!





Risk:  
9'999  
failed

Cost:  
1-2 billion \$



# Time of effective exclusivity

- Blockbuster drugs = annual global revenue greater than \$1 billion
- Recoup investment for the developed drug
- Recoup investment for the 9'999 failed drugs
- Generate return on investment

# And then?



Warner Bros.

# Patent cliff

- Immediate & sharp **decline in revenues** after patent expiry of one or more leading products of a company.
- A patent cliff is when a company's revenues could "fall off a cliff" when one or more established products go off-patent, since these products can be replicated and sold at much cheaper prices by competitors
- If several products at the same time: problem

# The competition

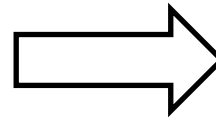
- Original = copy (generic product)
- The law requires:
  - Same active ingredient
  - Same dose
  - Same disease
  - Same manufacturing quality standards
  - Only the inactive ingredients (e.g. starch, gelatine...), appearance and packaging may be different



# Generic company

- No significant research departments
- No clinical trials to conduct
- Lower burden for the approval process
- Little or no marketing needed

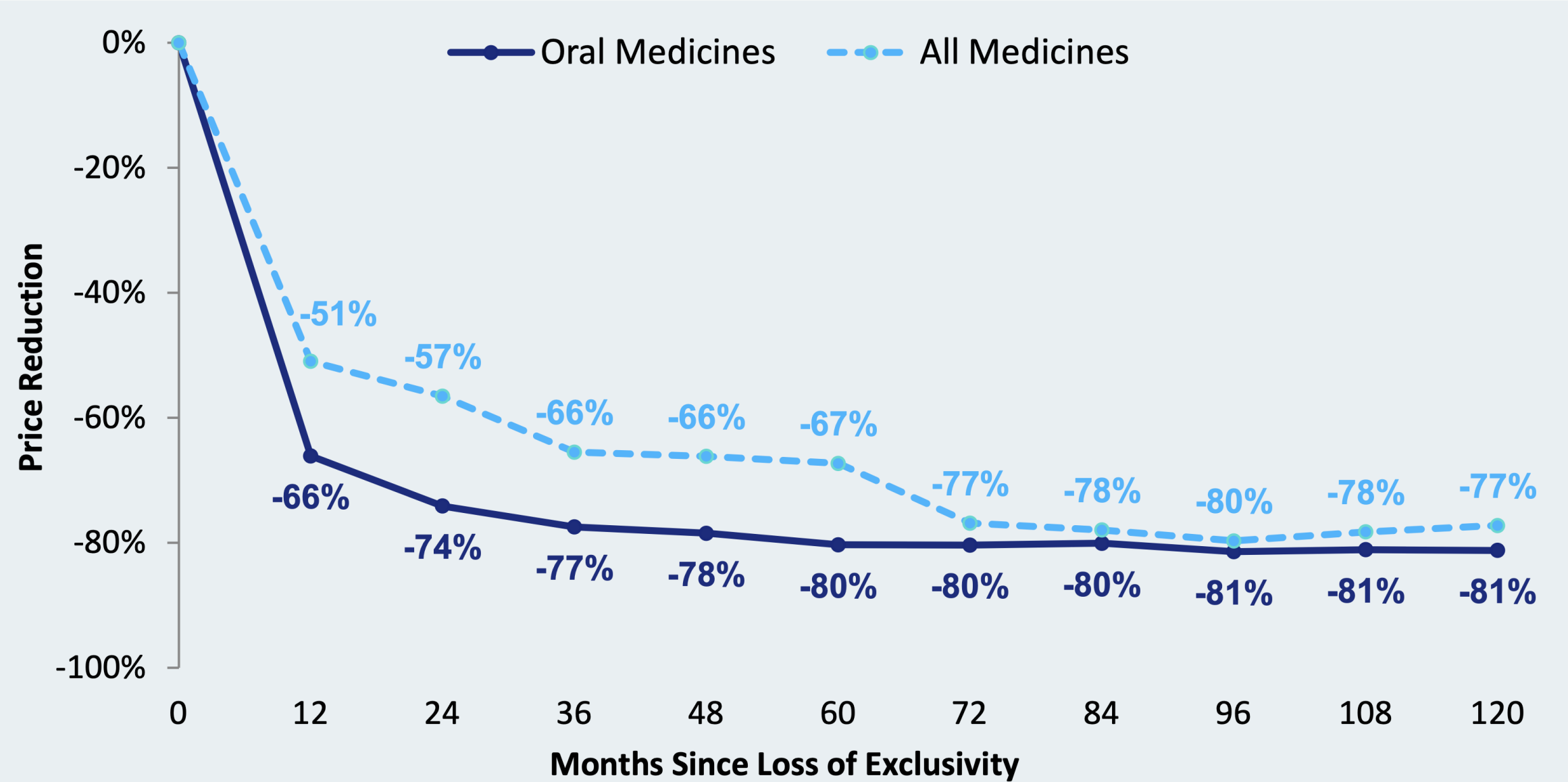
# Healthcare spending



# Important to be READY



# Monthly Price Reductions after Loss of Exclusivity



Source: IMS Health, National Sales Perspectives, March 2015

# Number of patents

- Pharma vs. tech
- Few patents, and those are critical
- iPhone: many, many patents

# Strategy

**Find blockbuster**  
**Cliff dive**  
**Repeat**

# Strategy



# Different formulations



apomediat.de



# How to patent a formulation?

- Novelty and inventive step
- If:
  - Compound X plus other inactive ingredients = new
  - Technical effect, e.g.:
    - Make it soluble in water
    - Fit it all into a smaller pill
    - Better to store
  - Not obvious
- Then: patentable

# How to patent a dose?

- Again, als always: novelty and inventive step
- If:
  - Compound X at once daily dosage = new
  - Technical effect, e.g. more convenient
  - Not obvious
- Then: patentable (as 2<sup>nd</sup> medical use)

# The claim

Claim compound:

“Compound X (+ chemical structure).”

Claim first medical use:

“Compound X for use as a medicine.”

# Examples

Compound claim from 1948

The crystalline d-lysergic acid diethyl amide, which crystallizes from benzene in prisms melting with decomposition at 80–85° C., which is difficultly soluble in water but easily soluble in methanol and in ethanol, which possesses the specific rotation  $[\alpha]_D^{20} = 30^\circ$  ( $c = 0.4$  in pyridine) and which corresponds to the formula  $C_{20}H_{25}ON_3$ .

ARTHUR STOLL.

1-(p-Methoxybenzyl)-2-pyrrolidinone for use as a therapeutically active substance.

First medical use claim

# Examples of 2<sup>nd</sup> medical uses

- New **dose**
- New **disease**
- New **mode of administration**

# The 2<sup>nd</sup> medical use patent

Claim new dose:

“Compound X for use in the treatment of disease A,  
at a **once daily dosage of 0.5 mg.**”

Claim new disease:

“Compound X for use in the treatment of **disease B.**”



Warner Bros.