
# REVISION OF THE IP FRAMEWORK FOR PHARMACEUTICALS IN EUROPE: IS IT REALLY NECESSARY?

# The pharmaceutical sector and IP rights (1/3)

- The **pharmaceutical sector** is highly **regulated** and **R&D driven;**

- Pharmaceuticals are usually subject to patent protection, which:

  - provides a **compensation** for the often **very high costs** spent on **innovation** and,

  - makes **information** on inventions **public**;

# The pharmaceutical sector and IP rights (2/3)

- Manufacturers of **generic pharmaceutical products** can enter the market with medicines that are "equivalent" to the original ones, after the data protection and exclusivity market period expire

- Their **prices** are **lower** than those of the originator products.

- On one hand, this helps **containing public health budgets** and ultimately **benefits consumers;**

- On the other hand, it is important to guarantee the **right balance** of rewards in R&D projects, quality for customers, and freedom for prescriber

# The pharmaceutical sector and IP rights (3/3)

- **The PHARMACEUTICAL SECTOR is one of the main users of the patent system.**

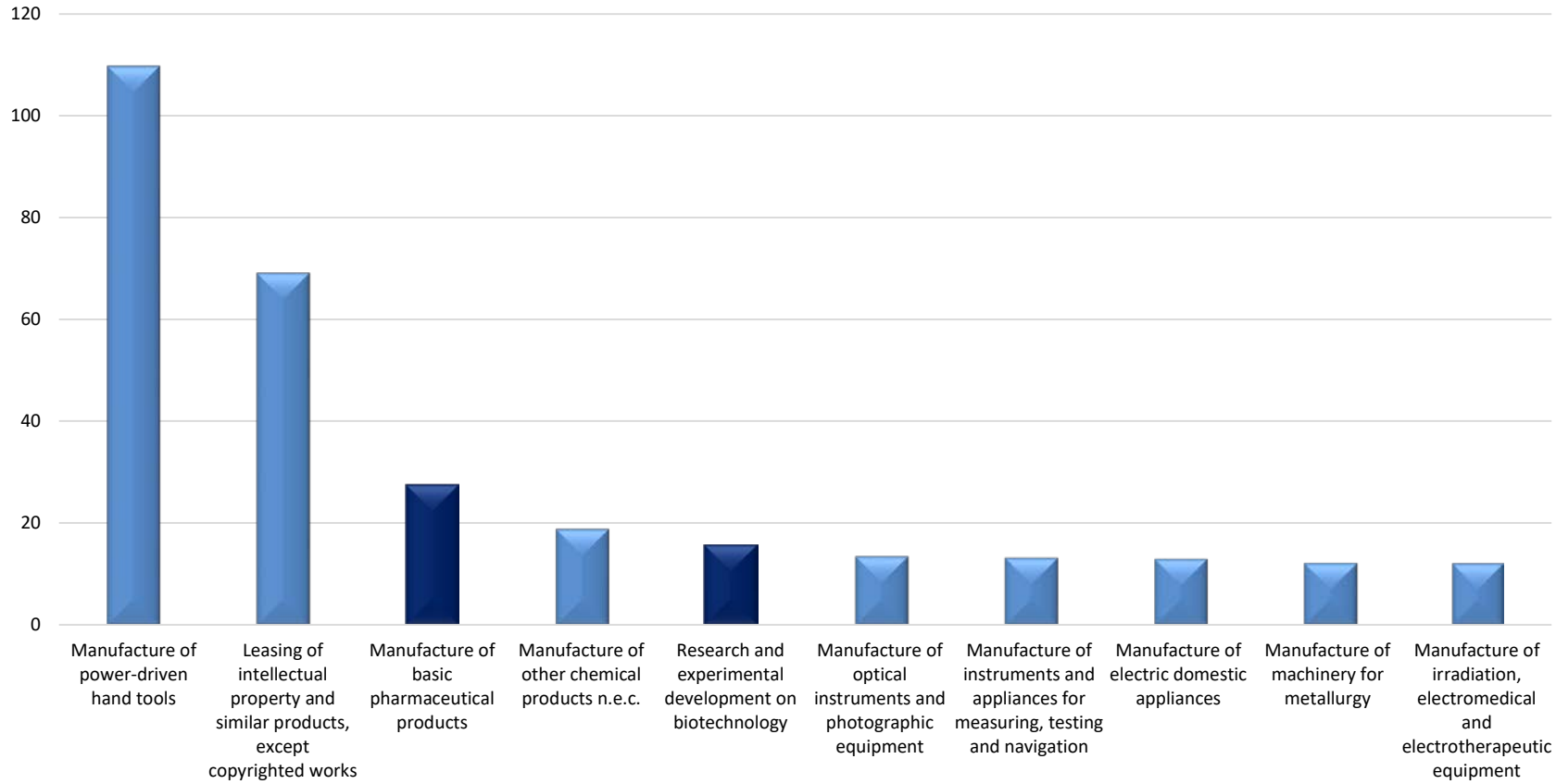
- Pharmaceuticals can be easily replicated by competitors with a pretty low capital investment:

- It can take between **10 and 15 years to develop a new medicine**

- It can cost as much as **$2.56 billion** (Tufts Centre for the Study of Drug Development): **$1.39 billion = out-of-pocket costs** and **$1.16 billion = expected returns that investors forego while a drug is in development.**

# Patent intensive industries in the EU

## The 10 most patent intensive industries in the EU
### (patent / 1000 employees)

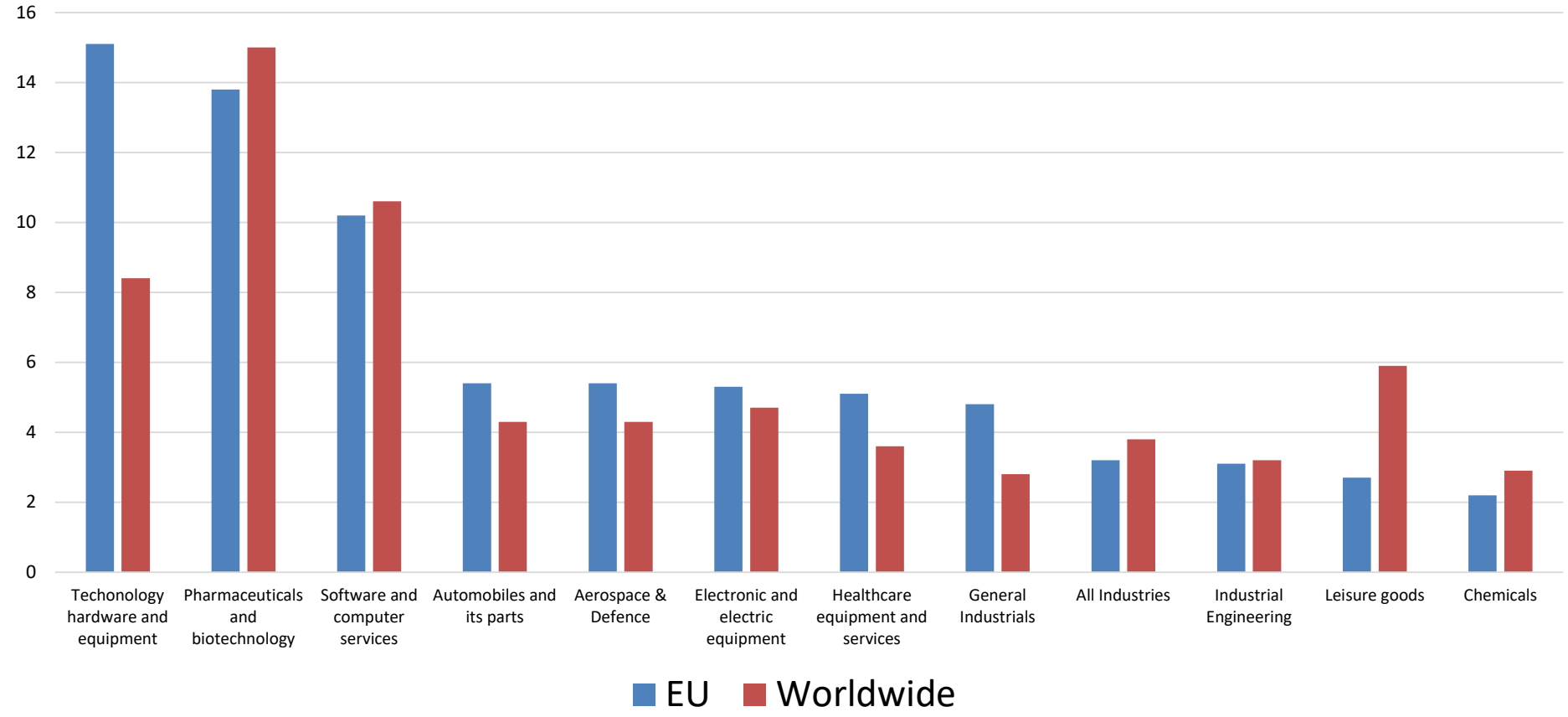





Source: EUIPO, 2016

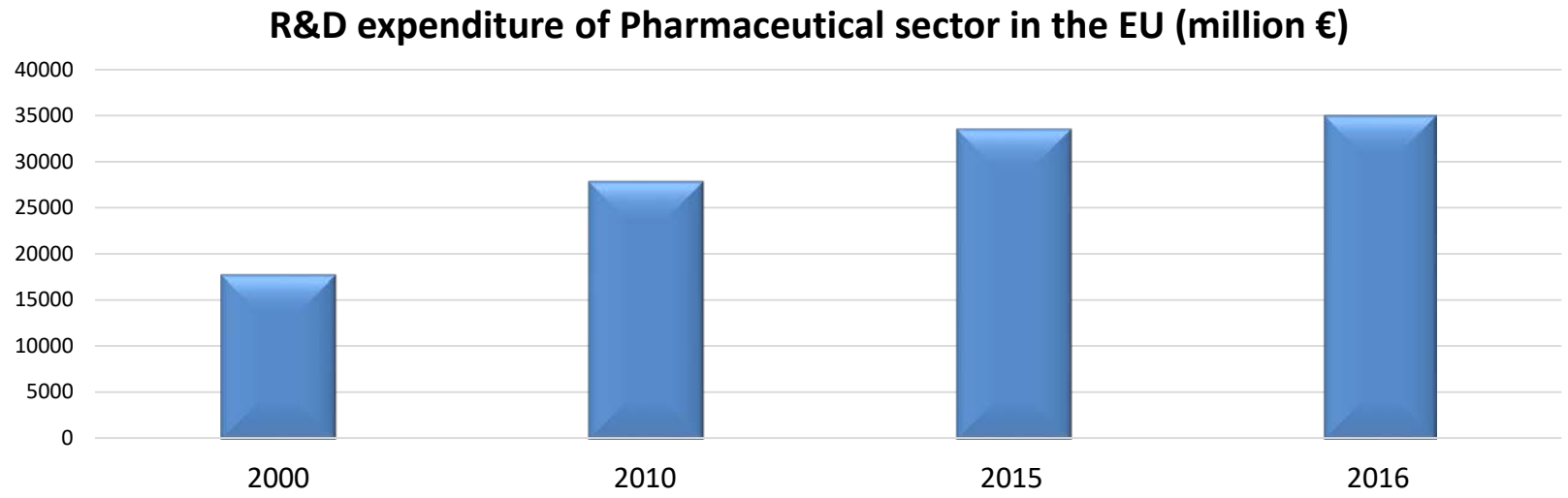
# R&D in the EU Pharma sector (1/2)

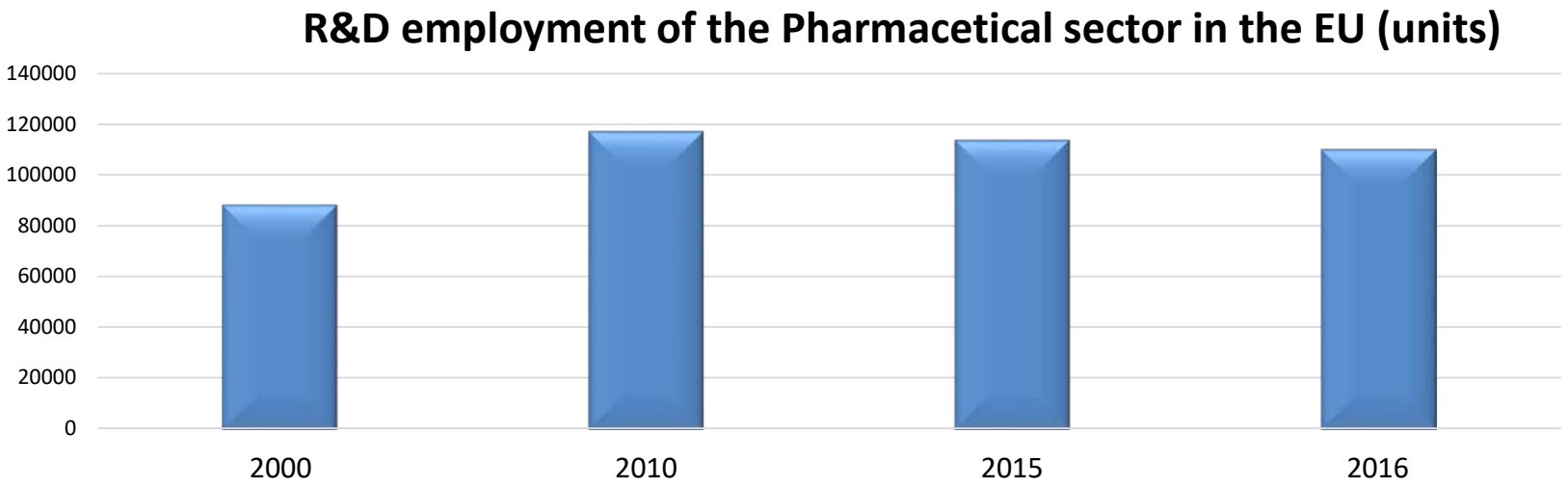
## Comparison of R&D intensity across sectors (2016, %)




Source: European Commission, R&D investment scoreboard 2017

# R&D in the EU Pharma sector (2/2)






Source: European Commission, R&D investment scoreboard 2017

# Levels of patent legislation governance

- Patent legislation is currently governed at **3 levels**:

1. The **National patent acts** of the Member States for **national patents**;

2. The **European Patent Convention** for the granting of **European patents**;

3. The **Unified Patent package** which will introduce, during the **course of 2018**, the **Unitary Patent (UP)** and the **Unified Patent Court (UPC)** in order to supplement and strengthen the existing centralised European patent granting system.

**UP**

Unitary Patents will make it possible to get PATENT PROTECTION in up to 26 EU Member States by submitting a SINGLE REQUEST to the EPO, making the procedure SIMPLER and more COST EFFECTIVE for applicants .

**UPC**

The Unified Patent Court (UPC) is an international court set up by participating EU Member States to deal with the INFRINGMENT and validity of both Unitary Patents and European patents, putting an END to COSTLY PARALLEL LITIGATION and enhancing LEGAL CERTAINTY.

# EU IP incentive framework (1/2)

At present the European incentives framework for the **biopharmaceutical sector** comprises several components with **different degree of protection**:

- **Patents** reward the inventors by providing a timeframe **(20 years)** during which it is possible to avoid others to reproduce their inventions and put it on the market. They are particularly relevant to medicines, as medicines take a lot of time and effort to develop but require relatively little effort to replicate;

- **Supplementary Protection Certificate (SPC)** have been created to compensate for the loss of effective patent protection due to the length of the development and regulatory approval processes.
- SPCs provides a **supplementary protection** period **(up to 5 years)** to the term of a patent right **(20 years).**
- In this framework, the **Bolar patent exemption** aim at speeding up the entry of generic medicines into the market by allowing early preparatory development on generics to obtain pre – market regulatory approval even when the SPC of the reference medicine is still in force. The latter case is regulated only for the pharmaceutical industry.

# EU IP incentive framework (2/2)

- **Regulatory data protection** aims at protecting company data on quality, safety and efficacy from unfair commercial use. The EU regulatory framework provides a **8 years period of RDP**, starting on the day of marketing authorisation, **followed by 2 years of market exclusivity**. During the first period generic / biosimilar companies cannot rely on pre-clinical and clinical data produced by the innovator company to apply for a generic marketing authorisation. During the following two years generic / biosimilar companies can rely on the data package for registration but cannot market the product;

- **Paediatric rewards and Orphan Medicinal Products**
- **1)** Paediatric rewards was created to encourage investments in paediatric research and development. It provides either an **extension of 6 month to the SPC** of a drug under patent protection **or** a **2 year extension of orphan exclusivity** if the manufacturer effectively complies with the requirements to conduct a Paediatric Investigation Plan (PIP).
- **2) Market exclusivity for Orphan Medicinal Products (OMPs**) provides a **10 years period** during which no copy or similar products can receive market authorisation in the same indication: the aim is to generate a return for companies that invest in a rare disease indication, correcting the kind of market failure that exists in therapeutic areas affecting a small population, which would usually disincentive investments if only due to commercial interest.

# EC INCEPTION IMPACT ASSESSMENT

**October 2015**, the European Commission announced its plan to "consult, consider and propose further measures to improve the patent system in Europe notably for pharmaceutical and other industries whose products are subject to regulated market authorisations"

**February 15th 2017** the European Commission published an **Inception Impact Assessment** to evaluate options to optimize the legal framework concerning Supplementary Protection Certificates (SPCs) and patent research exemptions for sectors whose products are subject to regulated market authorisations;

**October 12th2017 - January 4th 2018** Public Consultation (closed)

# EC INCEPTION IMPACT ASSESSMENT: Elements for consideration

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## Key elements for consideration:

1. **Loss of export market and lead time to entry into Member State markets for EU based generics and biosimilars** deriving from EU's SPC which prevents EU based generic manufacturers from producing for export during the period of SPC protection of the reference medicine = advantage for non EU based operators;

2. **SPC protection might not be adapted to changing global trade and innovation model;**

3. **Fragmented implementation of the Bolar-like and research patent/SPC exemptions.** Member States do not always exempt the same innovation and testing practices under these patent exemptions;

4. **Fragmentation resulting from the current SPC regime**. Multiple national SPCs result in high costs of registration and maintenance.

# EC INCEPTION IMPACT ASSESSMENT: Objectives

## The Commission's objectives include:

- **Increasing** the **global competitiveness** of EU-based manufacturers;
- **Increasing business predictability** and **legal certainty** and in doing so increase the **attractiveness of Europe** as a hub for innovation and manufacturing;
- **Facilitating research and clinical trials** by **reducing** the **fragmentation** in the internal market **associated with** the **current Bolar system**, and to provide the upcoming Unitary Patent Court with clear best practice in relation to patent exemptions;
- **Increasing the reliability** of the registration and enforcement of SPCs, and maximizing the benefits of the Unitary Patent system to those sectors relying on SPC protection.

## Policy options:

1) **No policy changes**

2) **Non legislative instruments aiming at improving implementation of existing EU legislation related to SPC protection and patent exemptions**

3) **Legislative changes (options):**

1. The introduction of an SPC manufacturing waiver for **export** purposes;
2. The **modernization of the existing SPC** Regulations (eg amendments to SPC-eligibility, scope of protection, registration procedures, etc);
3. The **clarification and recalibration** of the scope of the patent **Bolar** exemption;
4. The creation of **a single European SPC title** (and a "virtual authority" for European SPCs combining expertise currently residing in national patent offices).

# Key Questions

- **Do you agree** with the need to consider a **revision** of the current IPR framework, namely for pharmaceuticals, in Europe? Why?

- Do you believe it is necessary to **coordinate SPC rules** and practices among Member States? Harmonization?
  *If yes, what is the best way to reach this goal (promoting guidelines, voluntary cooperation, creating a European SPC title)?*

- Do you agree with stating a **direct link between IP based incentives and P&R** for pharmaceuticals?

- Do you think that a review of IP based incentives **will help to solve pricing issues** at a national level meanwhile supporting access to treatment?

- Broadly speaking, what should **orphan drugs** and **paediatric medicines** developers expect from a revision of the IP based incentives at European level?

# PROS & CONS

## ✓ Why to review :

i) An increase in investment in manufacturing activities in the EU as a result of the SPC waiver for export purposes with related increase in job's creation;
ii) Timely entry of generic / biosimilars on the market instrumental for the sustainability of public health budgets in a context of ageing population in the EU;
iii) Innovation costs money and patent monopoly enables industry to keep prices as high as the market can bear, engaging in the so called "evergreening" (variation on existing drugs with no added therapeutic benefit);
iv) To avoid lack of protection due to regulatory delays an efficient regulatory system is needed, not an extension of IPRs.

## ❖ Why not to review:

i) Controversial impact on pharmaceutical pipelines and on R&D investments, undermining innovation;
ii) Legal uncertainty for the industry and disinvestments on the EU market;
iii) Unsolved pricing issues at a national level where public budgetary constraints and reduced healthcare expenditure (often) need to be addressed with a global review of the healthcare governance.


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