

Unintended and Unattended Consequences:

The Opportunity Costs of an SPC Manufacturing Export Waiver

ECIPE Seminar

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1. Why are we here?

2. ECIPE study on IP incentives and the SPC waiver

Why are we here?

- Yet again a debate in Europe about the protection of **intellectual property (IP) in the pharmaceutical sector**
- EU Commission proposal for introducing a so-called “export manufacturing waiver” to Supplementary Protection Certificates. (SPCs)
- A legislative initiative driven by:
 - Healthcare campaigners
 - Some EU governments
 - The EU’s generics industry

Why are we here?

On 28 May 2018, the EU Commission argued that

“[A] targeted adjustment to intellectual property rules [would] help Europe's pharmaceutical companies tap into fast-growing global markets and foster jobs, growth and investments in the EU.”

“The waiver will support Europe's pioneering role in pharmaceutical research and development.”

Why are we here?

Elżbieta Bieńkowska, Commissioner for Internal Market, Industry, Entrepreneurship and SMEs, said

“It could generate €1 billion net additional sales per year and up to 25 000 new [high-skilled] jobs over 10 years. It will particularly benefit the many small and medium-sized enterprises in the field. In the medium term, more competition will improve patients' access to a wider choice of medicines and alleviate public budgets.”

Why are we here?

– **But** all existing “supportive” studies

1. suffer from a profound lack of appropriate industry data regarding market sizes, market shares, prices and market characteristics
2. disregard EU Member States’ opportunity costs of an SPC export waiver

1. Why are we here?

2. ECIPE study on IP incentives and the SPC waiver

Existing economic “impact” analyses

- Conclude that economic activity in the EU’s pharmaceutical sector would **only be marginally affected by an export waiver**
- Nevertheless: **“big numbers”** have been conveyed to the public
- **Do not address dynamic implications** of an SPC export waiver, particularly wrt **future investment** in the EU and **future drug prices** in the EU

Focus of ECIPE study: opportunity costs



You study late night
for a final



The next day you
are very sleepy



Your opportunity cost
is a good night's sleep.

Focus of ECIPE study: opportunity costs

“That which is seen,

and that which is usually not seen” ...

What is currently “seen” ...

- Vicente and Simões (2014): 8,890 new direct jobs and 35,560 new indirect jobs
- Charles River Associates (2016):
 - Increased net sales for the EU-based pharmaceutical (generics) industry by 7.3 to 9.5 billion EUR
 - Additional 20,000 to 25,000 additional manufacturing jobs in Europe by 2025 (study commissioned by the EU Commission already in 2015/16; released in October 2017)

What is currently “less seen” ...

- Sussell et al. (2017): potential job growth **much smaller** if uncertainty is taken into consideration
- Pugatch et al. (2017): 4,500-7,700 **direct job losses** (with an additional 19,000-32,000 **indirect job losses**) and a decrease of between 215 million to 364 million EUR in **R&D investment**

And what is “not seen” ... and has not been taken into consideration by the European Commission

–We look at the **dynamic impact** of an SPC reform taking into consideration **EU governments’ opportunity costs** on the basis of key market fundamentals of the pharmaceutical industry:

1. Trends in drug development costs
2. Price-setting behaviour & Trends in national reimbursement policies

Key message of ECIPE study

- An SPC export waiver would most likely cause the EU's innovative manufacturers to **reconsider** their **global R&D** and manufacturing activities as well as their global and, primarily, **product placement and pricing strategies** to compensate for (the risk of) lower revenues in non-EU countries
- SPC export waiver may cause **disinvestment in Western Europe** and **higher drug prices for Western European patients/governments**

Higher prices and less pharmaceutical investment in Western Europe...

How do we come to these conclusions?



Trends in drug development costs

- Vast empirical evidence that the cost and time of drug development increased **tremendously** since the 1960s
- **Compulsory market approval times** for innovative (incl. orphan) products increased substantially over time
- R&D productivity has **halved about every 9 years since the 1950s** corresponding to an 80-fold productivity drop after adjustment for inflation
- Implication: **extremely complex procedures eat time for the effective “commercial utilisation of the underlying patent”**

Trends in drug development costs

Study	Cost estimates
Morgan et al. (2011)	<ul style="list-style-type: none"> – Estimates of the cost of drug development ranged more than 9-fold, from 92 million USD cash (161 million USD capitalized) to 883.6 million USD cash (1.8 billion USD capitalized) – Authors argue that lack of transparency limits many studies
Mestre-Ferrandiz et al. (2012)	<ul style="list-style-type: none"> – Authors identified 11 studies published since 1979 that estimate mean R&D costs of a successful new drug – The most recent estimate is 1.9 billion USD – Authors report a tenfold increase from the 1979 estimate of 199 million USD (expressed in 2011 prices). – Authors own estimate: R&D cost per new drug of 1.5bn USD (expressed in 2011 prices); out-of-pocket cost ex capital cost: 1.01 billion USD
Herper, M. (2013)	<ul style="list-style-type: none"> – For companies that have launched more than three drugs, the median cost per new drug is 4.2 billion USD – For companies that have launched more than four drugs, the median cost per new drug 5.3 billion USD
DiMasi et al. (2016)	<ul style="list-style-type: none"> – Pre-tax out-of-pocket per approval is 1.4 billion USD (2013 dollars) – Pre-tax capitalized per approval is 2.6 billion USD (2013 dollars) – Total capitalized costs were found to have increased at a real annual rate of 8.5 per cent – With post-approval R&D costs the estimate increases to 2.9 billion (2013 dollars)

Trends in drug development costs

- **Importantly:** safety and pharmacovigilance requirements increased over time and the regulatory requirements are unlikely to be relaxed in the future
- As outlined by the European Medicines Agency and national regulatory experts, “[r]egulators should not, for the sake of affordability, yield to pressure to lower standards.” (Eichler et al. 2016, p. 1808)

Price-setting behaviour and trends in national reimbursement policies

- Global pharmaceutical industry is highly regulated by governments focusing on both **safety and costs**
- EU governments have become **less willing to reimburse** the full market costs of a new drug – cost containment policies
- Governments are increasingly **pushing for value-based payment** and reimbursement systems
- **Cost containment policies**: introduction of **reference pricing**, fee-based systems, centralised bidding-systems and quotas for the use of generics

Price-setting behaviour and trends in national reimbursement policies

- In the EU, the 28 EU member states still have **national** decision-making power over drug prices paid and HTAs
- No two countries regulate their pharmaceutical markets in the same way, resulting in varying reimbursement recommendations
- Manufacturers tend to negotiate over prices and launch new products in high-price countries first – **France, Germany, UK, Denmark, The Netherlands, Italy...**

Innovative manufacturers' strategic response

Innovative manufacturers' strategic response to an erosion of exclusivity rights by a manufacturing export waiver:

1. **Cost containment** to compensate for lower export revenues from exports to non-EU countries
2. **Increase prices** as the producers of branded drugs with SPC exclusivity would have to recoup their investments and generate revenues and profits in **over a shorter period of time**

Cost containment

- Large and mid-size life sciences companies are currently heavily invested in high-income, high-cost Western European countries
- **Divest-EU:** EU pharmaceutical manufacturers scale down their overall R&D activities in high-cost EU countries to the benefit of low-cost countries inside the EU
- **Divest-non-EU:** EU pharmaceutical manufacturers outsource both R&D as well as manufacturing capacities to low-cost countries outside the EU

Increase prices in high-income countries in which protection is still valid

- Revenue stabilisation strategy: EU pharmaceutical manufacturers increase the prices in those markets in which their products still enjoy market exclusivity rights
- Note: in the case of forgone sales of certain products due to an EU SPC export waiver, this is the overall EU market, but **primarily high-income EU Member States** (Germany, the UK, France, the Nordics, and the Benelux)

Final conclusions

- **Little of value** can be said about the **aggregate effects on European exports** and the **alleged value-added** from an SPC waiver
- What we do know though:
 - Several factors already contributed to a **significant erosion** of the market effective exclusivity period of patented drugs
 - SPCs were **intended to compensate** for longer market-approval processes, whose length increased significantly in the past
 - Companies are likely **adopt new product placement and pricing strategies**
- The EU's innovative pharmaceutical manufacturers are likely to **raise prices** in countries which still enjoy protection and/or **divest in high-income countries** (i.e. mainly Western European countries)