

# Upholding Strong Intellectual Property (IP) Protection



## The importance of IP protection in the pharmaceutical sector

Intellectual property protection is the lifeblood of innovation. Patents, trademarks, trade secrets, copyright, and other incentives such as regulatory data protection (RDP) enable the development of new technologies and support a robust, knowledge-based European economy. IP protection provides the incentives and rewards that allow people and companies to make the investments needed to drive innovation forward.

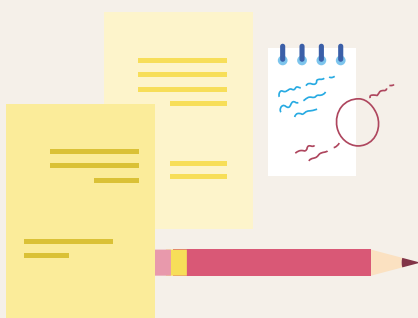
Pharmaceutical incentives and rewards, particularly patents and RDP, provide companies with the certainty that if a medicine makes it to market, it will enjoy a limited period of market exclusivity enabling manufacturers to sustain the long, complex, uncertain and costly R&D investments required to develop new medicines for patients.



These incentives and rewards also support the European knowledge-based economy, contributing to the creation of wealth and jobs, and help strengthen Europe's competitiveness in global trade. We believe that maintaining strong IP protection plays a critical role in driving innovation to tackle unmet medical needs while stimulating economic growth across Europe. The "IP Principles for Advancing Cures and Therapies" (IP PACT) reflect the long-standing commitment of many innovative biopharmaceutical companies, including Pfizer, to keeping patient and societal benefit as a guiding principle in our IP practice.<sup>1</sup>

## The impact of IP in pharmaceutical innovation

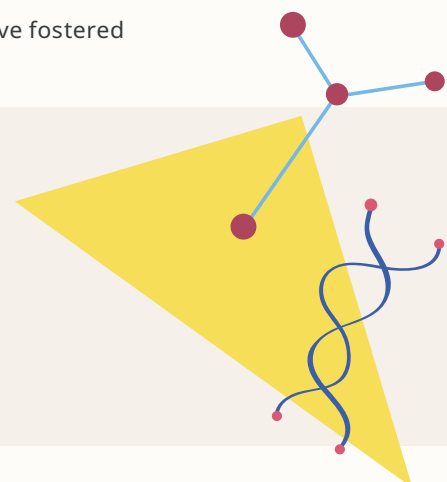
European citizens are living longer, healthier, and more productive lives. A key role in this positive trend is played by innovative medicines developed with support from the system of EU pharmaceutical incentives and rewards.



- 1 Since the 1990s over 1,100 new medicines have been developed for patients in Europe.<sup>2</sup>
- 2 Medicines have increased life expectancy of Europeans, accounting for 73% of gains made between 2000 and 2009.<sup>3</sup>
- 3 There are over 7,000 medicines currently in development by the biopharmaceutical industry with the potential to continue to change the lives of European patients.<sup>4</sup>

Incentives for rare disease (orphan) medicines as well as paediatric rewards have fostered innovation in areas where limited or no treatments were previously available.

- 1 There are now 149 medicines approved for rare diseases in Europe, whereas only 8 were approved prior to the introduction of Orphan Medicinal Products (OMP) Regulation in 1999.<sup>5</sup>
- 2 A 2020 study published by Dolon found that over half (74) of the 142 OMPs developed between 2000–2017 would not have been economically viable in the absence of the EU's OMP Regulation.<sup>6</sup>



IP protection contributes to strengthening Europe's knowledge-based economy by fostering innovative industries and positively impacting jobs and wage growth.

- 1 IP-intensive industries generated 45% of economic activity in the EU in 2016.<sup>7</sup>
- 2 IP-intensive industries accounted for one third of all jobs in Europe in 2016<sup>8</sup> (63 million direct jobs) and support an additional 21 million jobs in their supply chains.<sup>9</sup>
- 3 IP-intensive industries accounted for 82% of EU goods exports (contributing to €182 billion trade surplus).<sup>10</sup>
- 4 As one of the most IP-intensive industries in the European economy, the biopharmaceutical industry accounts for over 20% of total cross-industry R&D spending<sup>11</sup>, employing 830,000 people across Europe, including 115,000 in R&D related jobs, and positively contributing €122 billion to the EU's balance of trade.<sup>12, 13</sup>

## The importance of IP in the development and production of COVID-19 vaccines

The incentives provided by the IP system have enabled innovative biopharmaceutical companies to build an infrastructure that allowed them to quickly mobilize and devote the resources, technical knowledge and know-how that is required to combat the COVID-19 pandemic, and facilitate the advancement of cutting edge technologies, such as mRNA vaccines.

When Pfizer and BioNTech developed the Comirnaty vaccine, there was no manufacturing production of any mRNA vaccine or medicine anywhere in the world. Nonetheless, Pfizer deployed 2 billion USD at risk, its manufacturing infrastructure, and its highly-skilled scientists, engineers and manufacturing workers to develop and manufacture our COVID-19 vaccine in record time. The IP system has also facilitated the advancement of an unprecedented number of collaborations between biopharmaceutical innovators and governments, universities and other research partners that are essential to finding solutions — one of those collaborations being Pfizer's successful partnership

with BioNTech. Currently, there are over 300 manufacturing and production deals underway for COVID-19 vaccines.<sup>14</sup>

As it currently stands, intellectual property is not a bottleneck to manufacture faster, scarcity of highly specialized raw materials is. This is why the proposed IP waiver for the COVID-19 vaccine would threaten to disrupt the flow of raw materials necessary for vaccine production, thus unleashing a scramble for critical inputs required to make a safe and effective vaccine. Furthermore, waiving patent protection will disincentivise future biopharmaceutical entities from taking the risks Pfizer took in its effort of developing lifesaving medicines.

A reliable and effective intellectual property framework is foundational for the continued research and development of safe and effective treatments and vaccines to address a disease that is rapidly changing and affecting the most vulnerable populations.

## Policy recommendations

- 1 Maintain the EU's pharmaceutical incentives and rewards framework, supporting the innovation process that patients, healthcare systems and society relies on.
- 2 Strengthen IP rights and enforcement in free trade agreements (FTAs) with third countries negotiated by the EU.
- 3 Strengthen the IP incentives ecosystem to address areas of unmet medical need. This will enable Europe to remain a globally competitive epicentre for pharmaceutical R&D.



1 [INTERPAT website, IP Principles for Advancing Cures and Therapies](#); see also <https://www.pfizer.com/purpose/health-policy/ip-pact>

2 [Evaluate Pharma Database](#)

3 [Lichtenberg, Pharmaceutical innovation and longevity growth in 30 developing OECD and high-income countries, 2000 - 2009 \(2012\)](#)

4 [Health Advances Analysis: Adis R&D Insight Database](#)

5 [EMA, Orphan Medicines Figures 2000 - 2020](#)

6 [Dolon, Estimated impact of EU Orphan Regulation on incentives for innovation \(2020\)](#)

7 [European Patent Office and the European Union Intellectual Property Office, Intellectual Property Rights and Firm Performance in the EU \(2021\)](#)

8 [European Patent Office and the European Union Intellectual Property Office, Intellectual Property Rights and Firm Performance in the EU \(2021\)](#)

9 [EU Industrial R&D scoreboard \(2020\)](#)

10 [European Commission Staff working document: Report on the protection and enforcement of intellectual property rights in third countries \(2021\)](#)

11 [EU Industrial R&D scoreboard \(2020\)](#)

12 [EFPIA The Pharmaceutical Industry in Figures \(2021\)](#)

13 [International trade in medicinal and pharmaceutical products - Statistics Explained \(europa.eu\)](#)

14 [IFPMA COVID-19 Hub - IFPMA](#)