Civil society statement on the EU's intellectual property incentives review

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Property Rights Alliance

Civil society statement on the EU's intellectual property incentives review

Summary

- The soon-to-be-released European Commission review of pharmaceutical innovation incentives is likely to recommend weakening key intellectual property (IP) rights to cut spending on medicines and boost generic drug manufacturing.

- Europe is suffering from a number of demographic and economic pressures which mean the EU should proceed with caution.

- Innovation is of paramount importance to Europe's future economic growth. Yet EU member states underspend on Research and Development (R&D) and are outperformed by peer nations, with various emerging markets catching up fast.

- European societies are ageing and there is an urgent need for new technological solutions to mitigate the economic and fiscal effects. More new medicines are needed against diseases that are prevalent among older people, such as neurological conditions and cancer.

- Strong protection for intellectual property rights can help. Europe's current high standards here have contributed to the EU life sciences sector's relatively strong performance.

- Nevertheless, as part of its incentives review the EC may propose weakening Supplementary Protection Certificates, a key intellectual property right.

- Weaker SPCs would undermine research into the diseases of ageing, already difficult due to a combination of fixed-patent terms and growing timelines for mandatory clinical tests.

- Several studies conclude the EU's life sciences sector would be harmed too. Europe's innovation performance and international competitiveness would suffer at a time when competitors elsewhere are upgrading and reforming their IP systems.

- The EC's review, aimed partly at limiting medicines spending, may inadvertently undermine innovation. This would exacerbate predicted spending increases for long-term and out-patient care.

- To promote innovation in the EU and to encourage R&D into diseases associated with ageing, we recommend the EC should maintain its internationally competitive standards of IPR protection.

Introduction

Following growing concern about the sustainability of healthcare systems, in the summer of 2016 EU Health Ministers invited the European Commission (EC) to undertake a review of the Intellectual Property (IP) incentives that underpin biomedical innovation. The ambition is that reform in this area will increase the fiscal sustainability of healthcare systems by reducing medicine prices.

As the EC prepares to publish its review, this document highlights the important considerations that, in our belief, should steer its future policy direction.

First, innovation is of paramount importance to Europe's future economic growth, and by extension, living standards. Yet EU member states underspend on Research and Development (R&D) and are outperformed on a host of innovation measures by peer nations such as the United States, Japan, South Korea and Australia, according to the 2017 European Innovation Scorecard. The incentives review must therefore focus on boosting EU innovation.

Second, European societies are ageing and there is an urgent need for new technological solutions to mitigate the economic and fiscal effects. In particular, there is a growing need for new medicines against diseases that are prevalent among older people, such as neurological conditions and cancer. European companies are making some progress, but research into these diseases is complex, financially risky and extremely slow moving. The EC's review must therefore preserve the delicate innovation ecosystem that underpins continued private sector investment into these diseases.

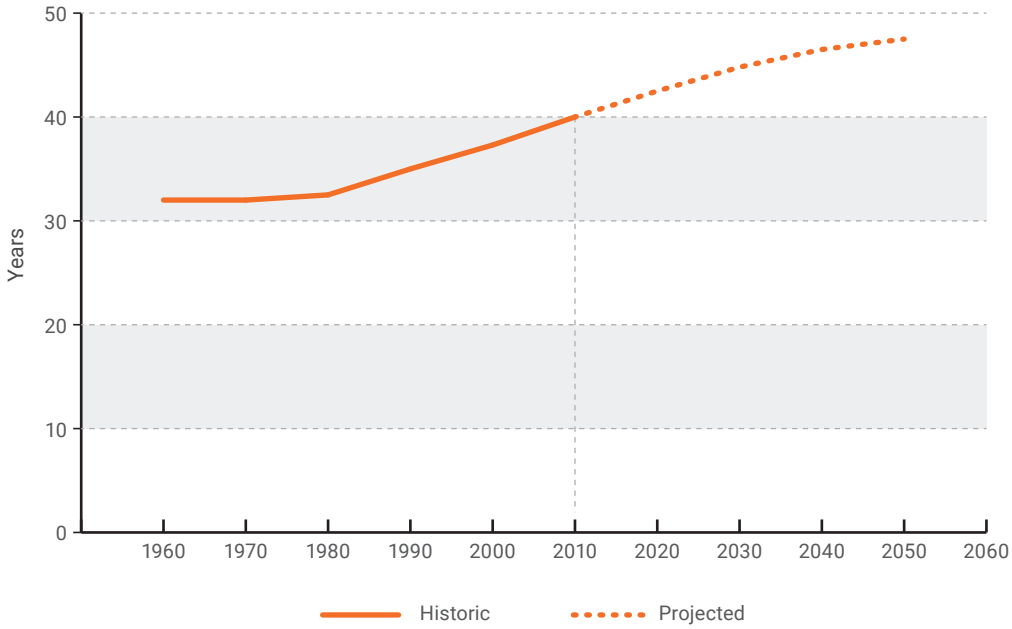
This document is a joint statement on the above by a coalition of like-minded coalition of think tanks, civil society groups and academics who believe that Europe's future prosperity is best secured through open markets and strong respect for property rights (including intellectual property rights), underpinned by the rule of law.

Europe's demographic challenge: ageing populations

Member countries of the European Union are undergoing a demographic transition in which increasing life expectancies are coupled with lower fertility rates. A quarter of the EU population is set to be over 60 years of age by 2020, according to the European Commission, rising to a third by 2080.[1]

Figure 1: Median Age in Europe (1960-2050)

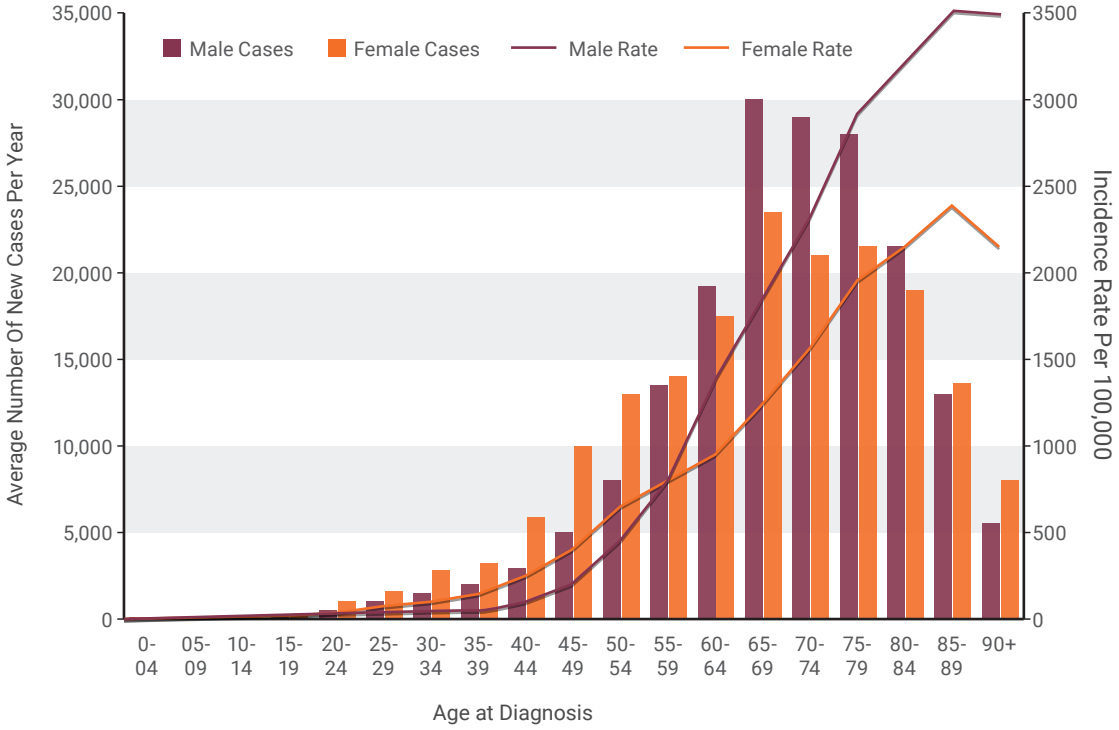
Source: Eurostat



The fact that Europeans on the whole are living longer, healthier lives than ever before is the dividend of decades of income growth is a cause for celebration, and is due to many decades of market-based economic growth, improvements in public health infrastructure and the adoption of innovative health technologies. The flipside of this progress, however, is fiscal pressure. Aside from a greater need for pension and welfare spending, a larger proportion of older people presents a number of challenges to healthcare systems. According to World Health Organization, there is a disproportionately greater prevalence in the elderly of chronic, complex diseases that are debilitating and difficult to treat: cancer and heart diseases appear more frequently in 70-75-year olds than other age groups; 80% of circulatory diseases appear in the over 65s; and the risk of developing dementia rises steeply after the age of 60, with prevalence in men being greater due to increased longevity.[2]

Across the developed world, 90% of all deaths are associated with age-related causes.[3] And an increasing proportion of old age is spent with some kind of illness or disability; European men, for instance, can only expect 61.2 healthy years of life, even though average life expectancy is 77.5 years.[4]

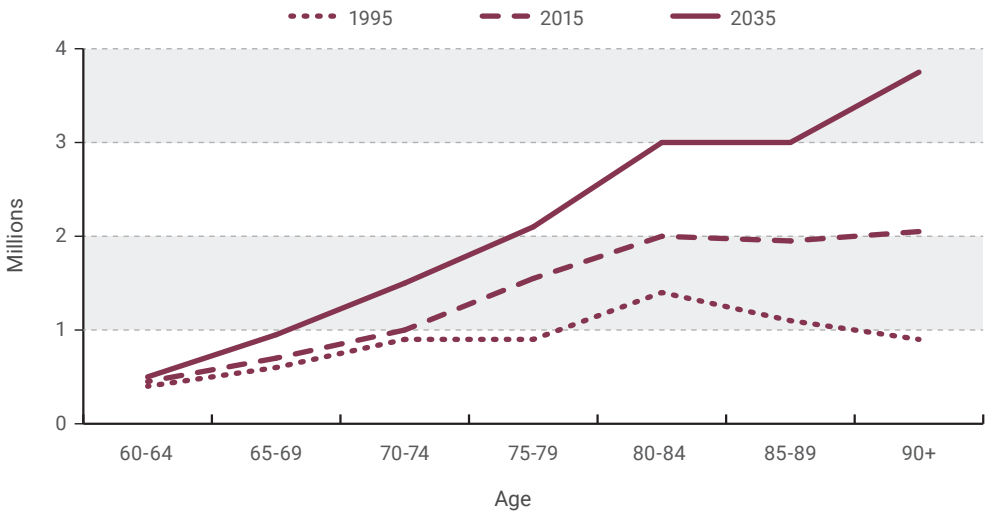
Figure 2: Age incidence of all cancers 2013-2015, United Kingdom



The economic costs of ageing for Europe are significant. Aside from greater liabilities for pensions, increasingly elderly populations will continue to put significant upwards pressure on healthcare systems. As a result of ageing, the EC predicts that average EU-27 healthcare spending will have risen from 7% of GDP in 2010 to 12.6% of GDP by 2050.[5] Public spending on long term care as a proportion of GDP is expected to rise from 1.8% in 2010 to 3.6% by 2060.[6]

Figure 3: Estimated Number Of People With Dementia In Eu Countries, By Age, 1995, 2015, 2035

Source: OECD analysis of data from Prince et al (2013) and the United Nations



Innovation's contribution to the European economy

European economies recovering from long recessions are also looking for sustainable sources of economic growth, particularly given the fiscal pressures that are building from ageing populations. Growing global competition and technological change mean that many of Europe's historic central industries such as manufacturing and agriculture will no longer provide meaningful amounts of jobs and growth. New sources of sustainable economic growth are therefore needed.

Given that other parts of the world are now able to manufacture more competitively than most EU states, future growth is more likely to come from sectors were the EU has a comparative advantage: in particular, high technology and knowledge intensive sectors such as biopharmaceuticals, information technology, environmental technology automation, advanced robotics and artificial intelligence.

Europe's knowledge-based sectors hold significant potential. According to the European Patent Office and European Union Intellectual Property Office, knowledge-intensive industries[7] were responsible for 42% of EU GDP between 2011-2013. It is a large job creating sector, with IP-intensive industries generating 27.8% of all jobs in the EU during the period 2011-2013, rising to 38% if indirect jobs are included.[8] Jobs in knowledge-intensive sectors also come with an average wage premium of 46% over other sectors. Knowledge-intensive sectors account for the bulk of EU exports (93%) which constitute a trade surplus of €96bn with the rest world.

The European biopharmaceutical sector is a particularly important contributor to this trade surplus. In 2014, just seven biopharmaceutical companies contributed a total of €77.9bn to Europe's Gross Domestic Product (GDP) in 2014, with €34.6bn generated in direct gross value added effects and a further €43.3bn in indirect and induced effects.[9] The sector is a significant contributor to EU innovation, with these companies have an R&D intensity (% of total revenues reinvested in R&D) of 17.4%.

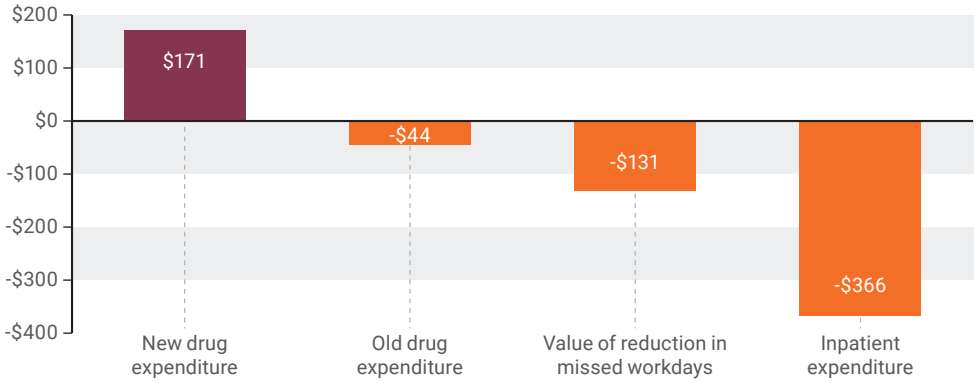
The health benefits of innovation

Given the above, European Union public policy should be focused on encouraging innovation, both to ensure the development of innovative medicines and technologies that will help mitigate some of the problems associated with ageing societies, and to ensure Europe is able to sustain economic growth and higher living standards into the future.

In particular, innovation in the medicines sector can deliver enormous fiscal benefits by increasing individual productivity and reducing in-patient care costs. In the context of the demographic pressures facing Europe, innovative medicines that can keep the elderly at home in their communities and out of expensive hospitals will have significant benefits for national health systems already struggling with cost pressures (Figure 4). Care systems and hospitals are particularly pressurised by providing long-term care for older people suffering from conditions for which there is no satisfactory biopharmaceutical treatment, including neurological conditions such as Parkinson's disease, many forms of osteoporosis and rheumatoid arthritis, cancers, and various rare and more common cancers. Given that long-

term care costs represent a significant and growing liability for many countries, encouraging biopharmaceutical innovation in such disease areas should therefore be a priority for public policy.

Figure 4: Impact of pharmaceutical innovation on per capita drug expenditure, work-loss days, and inpatient expenditure, USA, 2010



Source: Frank Lichtenburg, Pharmaceutical Innovation and Longevity Growth in 30 Developing and High-income Countries, 2000-2009 Health Policy andTechnology 3(1): 36-58, March 2014

Innovation, health and economic growth

Innovation is also recognised by economists as an important driver of economic growth. In simple terms, innovation is the application of ideas and technology to improve goods or services, or to make their production more efficient. Innovation in the ICT sector, for instance, has enabled all kinds of businesses to work more efficiently, while opening up new markets and business models, improving productivity and contributing to economic growth.

As the European Central Bank puts it, "innovation can lead to higher productivity, meaning that the same input generates a greater output. As productivity rises, more goods and services are produced – in other words, the economy grows."[10] Innovation now is a major contributor to economic growth, responsible for up to 50% of annual GDP growth in the United States, for example.[11] Innovation in healthcare can also contribute to economic growth through increased productivity and longer working lives. Innovative drugs are instrumental to driving these health improvements with those introduced between 1970-80 and 1980-91 responsible for increased average incomes of between 0.74% to 1% per year.[12]

Innovation

New ideas and technologies are developed and applied, generating greater output with the same input

Productivity

Growth

More goods and services are produced, stimulating wages and business profitability

Europe is becoming an innovation laggard

The European Commission has long recognised the importance of innovation to achieving important economic and social objectives. Accordingly, boosting European innovation has long been a preoccupation of the Commission. First, the 2002 Lisbon Strategy aimed to make the EU the most competitive knowledge-based economy in the world, with a target of raising overall investment into R&D to 3% by 2010. More recently, the Innovation Union initiative has attempted to raise R&D spending levels to the highest in the world.

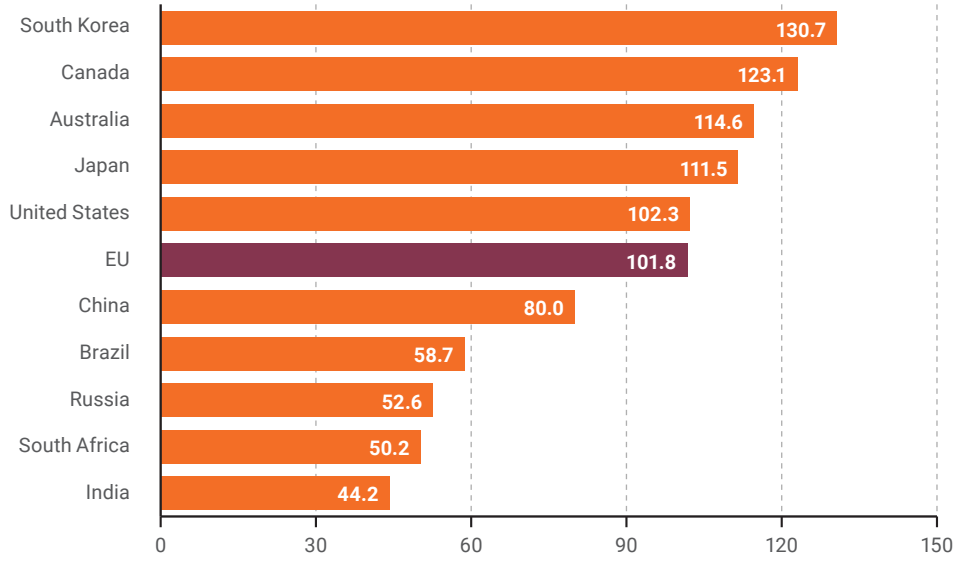
While Europe is the home to many innovative companies and individuals, it is falling behind other parts of the world. Only three Eurozone countries feature in the World Economic Foundation's 2017 Global Competitiveness Index, for instance. EU member states continue to underspend on R&D relative to competitors. The Lisbon Strategy target of spending 3% of GDP on R&D by 2010 was completely missed; in 2017 R&D spending stood at 2%, while the United States, Japan and South Korea invest 2.8%, 3.3% and 4.2% respectively. China, at 2.1%, has also recently overtaken the EU.[13]

According to the EU Innovation Scoreboard the EU is outperformed on innovation by Australia, Canada, Japan, South Korea, and the United States, with Japan and Korea pulling away from Europe particularly swiftly. The EU maintains a performance lead over China, but this lead is decreasing rapidly with China having improved more than seven times faster than the EU.[14] (Figure 5)

Europe fares particularly poorly at diffusing innovation within its borders, with European Central Bank studies show major differences in productivity between firms, suggesting that many companies do not benefit much from innovation. Unlike in the United States, EU start-ups rarely grow to scale, and there are significant gaps in innovation between EU member states.

Figure 5: Global Performance

Source: European Innovation Scoreboard, 2017



Bars show countries' performance in 2016 relative to that of the EU in 2010

Turning to the pharmaceuticals sector, investment in R&D by European pharmaceutical companies remains a bright spot in the overall picture, with EU companies outperforming or equal in R&D intensity (R&D as a % of sales) compared to similar companies elsewhere, and contributing significantly to Europe's overall R&D expenditure.[15] However, the sector faces competitive challenges from other parts of the world. The 2016 Biopharmaceuticals Competitive and Investment Survey, a global executive opinion survey and index of countries' biomedical investment attractiveness, shows that emerging innovation locations such as Singapore, Israel and China are in the process of upgrading and reforming their policy environments to encourage local investment in biomedical R&D. Established European players such as Germany, the United Kingdom, Ireland and especially Italy, on the other hand, are beginning to lose out on R&D investment due to medicine cost containment measures and discrimination against Intellectual Property (IP) owners.[16]

The role of intellectual property rights

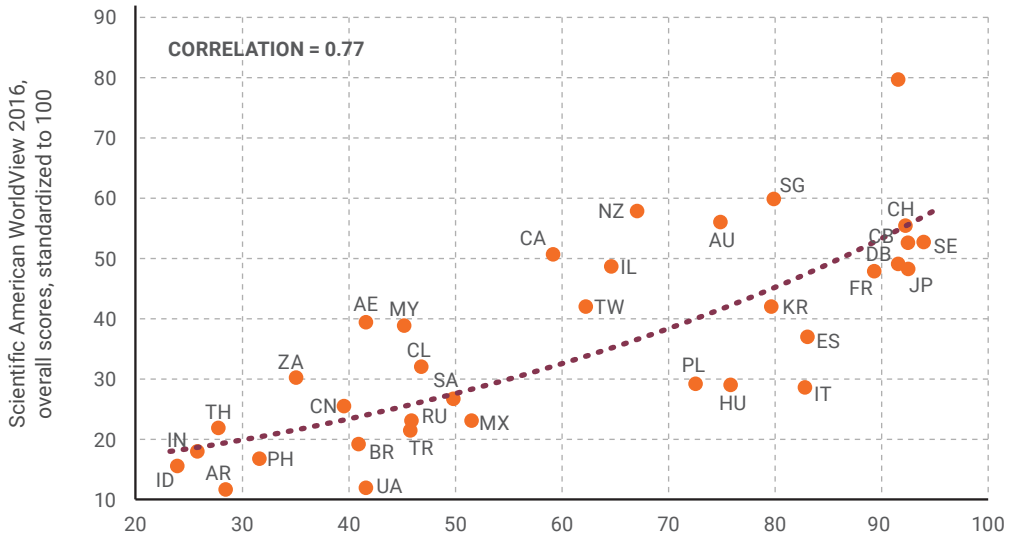
Europe's competitive advantage in pharmaceutical innovation therefore cannot be taken for granted. Policy focus from the Commission should therefore be on creating an environment that sustains innovation and investment.

Alongside taxation and regulatory policy, and support for academic science, strong protection for intellectual property rights (IPRs) is a fundamental component of Europe's innovation ecosystem, with those countries that afford the highest levels of protection of IP performing the best in biopharmaceutical innovation (Figure 6).

Intellectual property rights such as patents grant inventors a time-limited period of market exclusivity before others can copy and sell their inventions. This gives inventors enough time to recoup their initial investment and turn a profit. IPRs are therefore considered very important for sustaining investment in innovation in high-tech sectors such as life sciences. They are particularly important for medicines given the sector's high upfront investment costs (€1.13bn

Figure 6

Source: Global Intellectual Property Center, IP-A Global Navigation Center for the Knowledge Economy



Index 5th edition, life sciences-related indicators scores, standardized to 100

to €2.44bn, according to various studies) and significant risk of research failure. Aside from their role in incentivising investment in R&D, IP rights such as patents fulfil a number of roles in the market-based system of innovation.

- **IP rights allow research collaboration between different organisations.** Today, scientific knowledge, technological know-how and the required R&D capital are dispersed globally. Pharmaceutical companies are moving away from the traditional "vertically-integrated" model in which all medicines are created in-house from start to finish. Today, multinational companies collaborate with small companies, academia and the public sector at all stages of the R&D cycle, often across borders. Robust protection of intellectual property rights allows these different players to collaborate, by giving them legal certainty that they can share valuable proprietary knowledge according to pre-agreed terms and conditions. Without this protection, particularly for patents, modern collaborative pharmaceutical innovation would be extremely difficult.

- **Patents promote competition by sharing the knowledge behind an invention with the world.** Patent applications, which must include detailed information about new products and processes, are freely searchable by the public – even before patents expire. This disclosure accelerates innovation and empowers potential competitors to design around inventions without re-inventing the wheel. They can use information in patent applications to develop different or improved products to compete with the original. In medicine, this has resulted in more drugs in the same therapeutic class which gives more options for patients, as well as acting as a price constraint. Competition between new therapies for cancer, high cholesterol and other conditions is expected to drive prices down in the coming years.[17]

- **Patents help patients access new medicines faster.** Numerous econometric analyses have found that stronger IP protections are associated with speedier in-country launches of new drugs; and conversely, weak IP rights being associated with new drug launch delays of many years.[18, 19, 20, 21]

- **Robust intellectual property protection drives Foreign Direct Investment,** with the OECD finding that a one percent increase in the strength of patent protection equates to a nearly three percent increase in FDI across all countries (OECD, 2008).[22]

What is a patent?

A patent is an exclusive right **granted for an invention**, which is a product or process that provides a new way of doing something or offers a new technical solution to a problem.

In exchange for **disclosing a detailed description of an invention**, a patentee may prevent others from making, using, distributing, selling or importing a protected invention for a limited time.

Patents are temporary. They protect inventions for a limited period of time, typically 20 years from the date a patent application is filed.

Patents are **granted by national or regional patent offices** and applicable only in those jurisdictions. Firms doing business worldwide must secure patents in multiple countries.

Patentees are solely responsible for enforcing their patents when and where necessary, usually through national administrative and judicial systems.

Source: WIPO, USPTO

The EC review of pharmaceutical innovation incentives and its risks

These benefits notwithstanding, certain European governments have suggested that weakening IPRs will help constrain healthcare expenditures. The Dutch government, for instance, has questioned the appropriateness of modern IP standards higher than the basic 20 year patent term,[23] with the implication that weakening such rights will increase access to innovative medicines by reducing prices. Accordingly, the European Council in summer of 2016 agreed to support an investigation into the impact of pharmaceutical innovation incentives on competition, health care budgets and how they incentivise R&D.

A major focus of these investigations is the system of "supplementary protection certificates" (SPCs), an important form of intellectual property right which can extend a medicine's patent by up to five years (plus an additional six months, in the case of paediatric drugs). SPCs are designed to compensate for the time taken by the mandatory period of regulatory review, which can consume up to 15 of the 20 years of a patent term.[24] Given that that regulatory requirements and time required to approve a drug have been growing for some time.[25, 26] SPCs are an increasingly important property right to ensure the patent system performs its role of incentivising investment into R&D, and particularly R&D into rare diseases where smaller markets mean lower overall returns. Similar systems exist in Japan, South Korea, the United States (where it is known as Patent Term Restoration) and others.

However, in the context of contemporary debates around drug pricing, SPCs have attracted criticism for being overly generous addition to the IP system that contribute to medicine price inflation (EPHA, 2016).[27] While the Commission has not openly echoed this view, it has proposed various modifications to the system that it suggests will boost jobs and competitiveness in the European generic medicines manufacturing industry. These include most notably the dilution of SPCs to allow generic companies to export copycat versions outside the EU while the SPC is still in force, and new rules that would allow companies to start manufacturing and stockpiling generic drugs prior to the expiration of an SPC. This would allow generic drugs to enter the market at the very moment of SPC expiry.

Given the various economic and demographic challenges faced by Europe, such a policy change is not without risk, particularly given the economic and demographic factors previously outlined in this document.

In particular, the EU incentives review risks further weakening Europe's innovation performance, costing investment and jobs; and undermining Europe's ability to mitigate the challenges posed by ageing populations, specifically by making it more difficult to develop treatments for diseases of ageing with long R&D timelines such as cancer and neurological conditions.

Undermining innovation around the diseases of ageing

For many of the diseases that are becoming increasingly prevalent as populations age, there are too few medicines. This situation is complicated by the fact that research and development for Alzheimer's, immunological conditions and a host of neurological diseases associated with ageing are scientifically challenging and can take many years.

Before any drug can be approved as safe for marketing, it has to undergo an extensive period of pre-clinical and clinical testing in volunteers. This period of regulatory review is essential to ensure that all marketed drugs are both safe and efficacious, with any side-effects well documented. It is a lengthy process, taking up to 15 years.

The interaction of this period of regulatory review with the fixed-term patent system is problematic, however. Typically, an innovator will register a patent at the very beginning of this process, at which point the twenty-year patent term also starts. If a drug takes 15 years to successfully compete clinical trials and achieve marketing approval from the drug regulator, this leaves only five years effective patent life, which may not be enough time to recoup the initial R&D investment and make a return.

Policymakers have responded to this problem by allowing innovators extensions to the 20-year patent term of up to five years in both the United States (under the 1984 Patent Term Restoration Act) and the European Union (1996 EU Regulation 1610/96). This system provides compensation for the increasing time-demands of regulatory review, but it does not take account of the fact that some diseases take longer to research than others. As such, diseases with longer research timelines are systematically under-rewarded by the patent system compared to easier, quicker research areas. This creates the paradox wherein the most challenging yet most needed forms of drug R&D – Alzheimer's and multiple sclerosis, for instance – get the least reward from the IP system.

This "innovation paradox" has been recently quantified in a study by Professor Erika Leitzan. Her examination of a dataset of drugs approved by the FDA between 1984 and 2016 found an average clinical testing period of between five and seven years. This is getting longer with each year, however, and quarter of all drugs now have a clinical testing period of over seven years. Importantly, clinical trials take longer for different therapeutic classes of drug: for instance central nervous system drugs, and anti–Parkinson's agents take significantly longer in clinical testing than antibiotic and antiviral drugs (Figure 7).[28] These are also areas for which there are few effective treatments, and for which there is growing demand as populations age.

If the average 5.61 years taken up by pre-clinical testing are also considered, drugs for certain therapeutic categories might lose most of the 20-year term on their first and most important patent before the drug even enters the market.

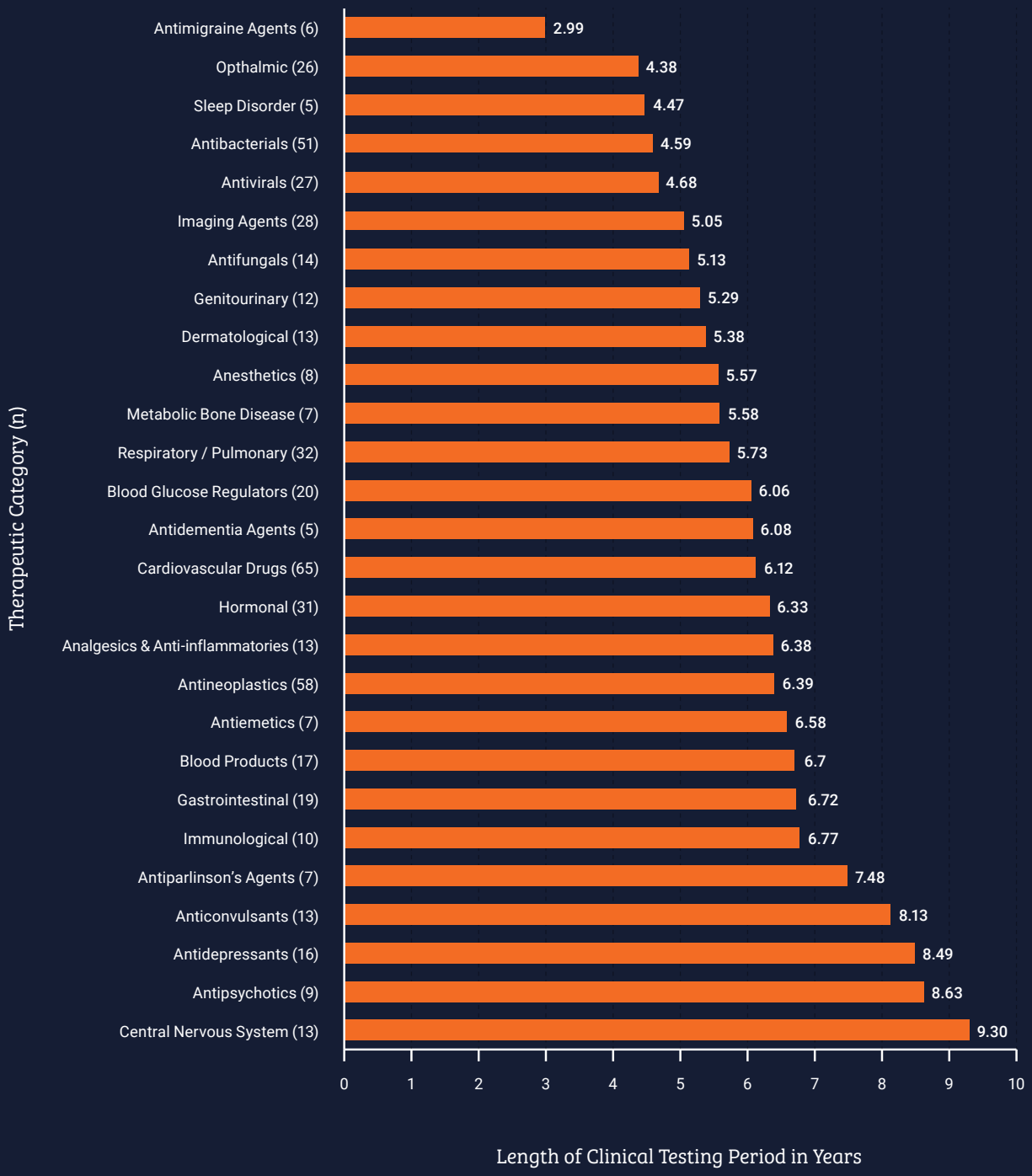
The mismatch between the patent system and the mandatory period of regulatory review might be responsible for decreasing R&D investment into diseases that have particularly lengthy R&D timelines, which also happen to be those most associated with ageing. One recent study found that firms are under-investing in the development of cancer drugs that require long-term trials, for instance.[29] Several research-based pharmaceutical companies also terminated their neuroscience research programs in the late 2000s, citing the higher failure rates and the longer development times than for other medicines.[30]

There is therefore a case for reforming incentives such as SPCs to take account of longer development pathways for certain categories of medicine. Unfortunately, the proposed SPC manufacturing waiver would take reform in the wrong direction, further undermining incentives to invest into drugs for the diseases of ageing that are inherently more difficult to develop. Given the demographic pressures facing Europe, this would be a major mistake.

Figure 7

Average Clinical Testing Period by Therapeutic Category

Source: Leitzan (2017)



Damage to EU innovation

Although much of the political impetus behind the pharmaceutical incentives review is related to drug prices, a supplementary driving factor is the potential of weakening SPCs to create jobs in the generic drug manufacturing sector. A study commissioned by the EC and published 2016 argued to that an SPC export waiver would create several thousand jobs in this sector by making it more globally competitive.[31]

That study has been followed by numerous others commissioned by non-government sources that dispute its findings, arguing it overestimates the benefits to the generic industry and relies too much on incomplete data.[32] Further, the European generics sector faces a number of market headwinds, such as very tight margins, increased competition from non-EU companies that have lower operating costs, and a decreasing rate of patent expiry for blockbuster drugs,[33] that are unlikely to be reversed by a manufacturing export waiver.

The EC commissioned study on the SPC manufacturing export waiver also fails to consider the unintended consequences that would arise as manufacturers of innovative drugs respond and adapt to revenue losses. Chief among these would be a divestment of R&D activities from high-cost EU countries such as Germany, France and the United Kingdom to lower-cost jurisdiction, potentially outside the EU.[34] One analysis has quantified this as up to 7,700 direct and 32,000 indirect job losses within the European Union, and a loss to Europe of $364 million dollars in research and development investment.[35]

Such an outcome would be a major blow for the EU's struggling "Innovation Union" initiative which aims to re-establish Europe as one of the most innovation-friendly regions in the world. This in turn would have as yet uncalculated implications for economic growth.

The risks to EU's international competitiveness

The European Union has long considered high intellectual property standards as a major plank of its trade and investment strategy, and has required negotiating partners in Free Trade Agreements to upgrade domestic IP laws beyond the minimum standards required by the WTO TRIPS Agreement. The requirement to update domestic legislation to include provision for SPCs are included as part of the EU FTAs with Korea, Japan, Vietnam, Colombia and Peru and Mercosur, none of which have a manufacturing waiver. The introduction of a manufacturing waiver by the EU could therefore provoke tensions and potentially trade disputes with these trading partners.

The potential for trade disputes aside, the pharmaceutical innovation incentives review is sending troubling signals to the wider world. Is Europe a hospitable place for innovation, or is it more concerned with low-value manufacturing? In a world where investment capital is mobile, Europe cannot be complacent. There are new competitors alongside old rival the United States. As already stated, China for instance now has an innovation performance growth rate five times that of the EU and is undergoing serious reforms that improve its standards of intellectual property protection, particularly those that relate to pharmaceuticals.[36] While it still has some way to go before it matches the highest international standards of IPR protection, China correctly senses that future prosperity will come from innovation rather than manufacturing products invented elsewhere. Such developments suggest that Europe has

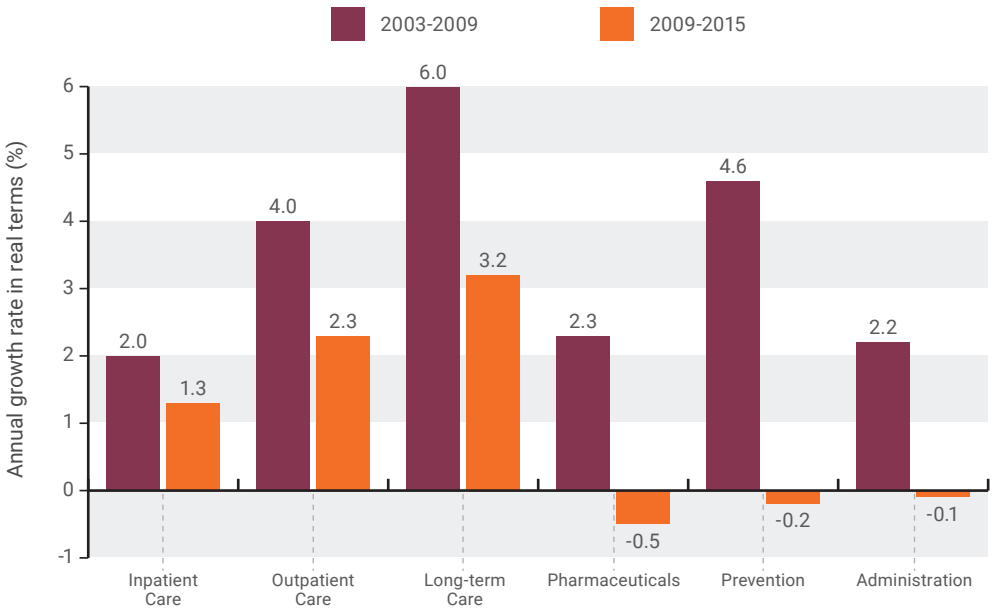
minimal room for complacency if it wishes to remain a competitive investment destination in coming decades, particularly for knowledge-based sectors.

Medicine expenditures are stable

The EC's review of innovation incentives for pharmaceuticals is based in part on the premise that drug expenditures represent a major challenge to the financial sustainability of healthcare systems. In fact, Europe is not spending dramatically more on drugs than the past, and only modest increases are forecast in coming years. According to the OECD, retail expenditures on medicines in the EU-15 decreased steadily as a proportion of total healthcare spending from 2004 to 2014, while per capita expenditures on drugs remained stable. Across the OECD more broadly, pharmaceutical spending actually fell by 0.5% between 2009-15 (Figure 8).[37]

Looking to the future, European drug spending is predicted to grow at a compound annual rate of just one percent to four percent from 2016-2021,[38] roughly in line with the predicted rate of inflation for Europe over the same period.

Figure 8: Growth rates of health expenditure per capita for selected services, OECD average, 2003-2015



Source: OECD Health Statistics 2017

As these numbers indicate, drug costs have not played a significant role in rising overall healthcare expenditures, which grew from an average of 8.8 percent of GDP to 9.9 percent across the EU from 2005-2015. Rather, increasing healthcare costs are largely the result – in Europe as in the rest of the developed world – of growing demand for long-term care (expected to double to 3.6 percent of GDP by 2060)[39] , out-patient care, as well as new technology and stagnant productivity.[40] The demand for long-term care in particular is a major policy challenge for all EU member states, and underscores the need for continuing investment in innovative cures and treatments, as well as market-based reforms of healthcare systems.

Conclusion and policy recommendations

The potential benefits of an SCP export waiver have been poorly defined and are highly uncertain. What can be stated with more certainty is that any move to dilute a key intellectual property right could upset the delicate ecosystem which has enabled Europe to become a world leader in medicines innovation.

Innovation is fundamental to economic growth, yet Europe is becoming something of an innovation backwater, easily outspent on R&D by peer nations such as the United States, Japan, South Korea and Australia. The EU's precautionary, risk-averse attitude to regulation has already chilled investment in innovative sectors such as chemical and agricultural biotechnology, and is currently undermining Europe's role in the Artificial-Intelligence based "Fourth Industrial Revolution". Europe is at risk of confirming its growing reputation as an inhospitable place for innovation, more concerned with protecting the low-value manufacturing industries of yesteryear. This will have an inevitable economic cost and is especially troubling in the context of a pressing need for innovative medicines to mitigate the problems associated with an ageing population.

Given the need to promote innovation in the EU and to encourage R&D into diseases associated with ageing, the following policy principles are recommended to the Commission:

- Recognise the importance of innovation for future economic growth and prosperity.
- Use the pharmaceutical incentives review to ensure the EU's framework for the protection of IPRs retains the highest standards globally.
- Reject proposals that would weaken European IP incentives.
- Consider reforming and strengthening the system of SPCs to promote pharmaceutical innovation for diseases of ageing.
- Recommend to EU members market-based reform of healthcare systems, particularly in the area of long-term care.

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