FROM PATENT TO PATIENT

HEALTHCARE BIOTECHNOLOGY AT THE HEART OF EUROPEAN INNOVATION

THE IMPORTANCE OF IP REWARDS AND INCENTIVES

The findings of a EuropaBio survey

EuropaBio®
The European Association for Bioindustries

CONTENTS

BUILDING ON EUROPE'S SUCCESS

HEALTHCARE BIOTECHNOLOGY IS AT THE FOREFRONT OF MEDICAL INNOVATION

Healthcare biotechnology is at the forefront of medical innovation and the development of medicines that have made life-threatening diseases manageable and cured many of those once thought to be untreatable.

In recent decades we have witnessed many therapeutic breakthroughs as a result of developments in the field of healthcare biologics. Healthcare biotechnology products account for more than half of all medicines in the market and currently in the pipeline. More than 350 million patients worldwide are benefitting from advanced medicines and therapies that have been created by the healthcare biotech industry[1].

New biotechnology-based therapies have helped prevent epidemics and eradicate diseases such as smallpox, measles and polio. They enable patients to manage chronic diseases and have benefitted more than 30 million patients in Europe with rare conditions.

THE OXYGEN THAT ALLOWS THE SYSTEM TO LIVE

At the heart of the European healthcare biotechnology industry success has been Europe's Intellectual Property (IP) rewards and incentives framework that attracts funding and encourages high-risk, complex and long-term research projects.

IP rewards and incentives are often described as the oxygen that allows the fragile ecosystem of healthcare biotechnology development in Europe to live. They fuel innovation and provide the stimulus to drive research and development.

To better understand the importance of IP rewards and incentives, EuropaBio conducted a survey among a cross section of key stakeholders, such as small and medium sized enterprises (SMEs) and venture capitalists involved in the healthcare biotechnology community. The main outcomes of this survey have confirmed:

1. IP rewards and incentives are crucial to healthcare biotechnology innovation in Europe;

2. Many of the innovative medicines benefitting patients today would never have been developed without the IP rewards and incentives framework; and

3. As stated in the European Commission's Renewed Industrial Policy Strategy for Europe[2], the EU needs an IP system that really promotes innovation and creativity.

This report summarises the findings of the EuropaBio survey and provides supplementary information on the value of IP rewards and incentives and for the healthcare biotechnology industry.

1 - 'Valuing Healthcare Biotech in Europe', Charles River Associates, February 2014
2 - A Renewed Industrial Policy Strategy for Europe: http://ec.europa.eu/docsroom/documents/25384 published by the European Commission on September 18, 2017

EUROPEAN IP REWARDS AND INCENTIVES

Developing healthcare biotechnology medicines is a complex and capital intensive task. It typically takes between 10 and 15 years to create and test a new medicine and only around 6% ever make it through to market authorisation[3]. The average cost to produce a new therapy until it is ready for market entry is now estimated to be more than €2.5 billion[4].

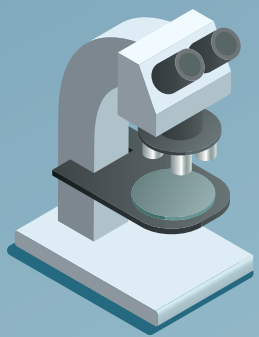
The system of IP rewards and incentives exists and works together to allow adequate time for the companies and investors to recoup their years of investment and fully realise clinical value before their inventions become part of the public domain and can be used by others.

Supplementary Protection Certificates (SPCs) aim to partially compensate for the loss of effective patent protection for pharmaceutical products caused by the lengthy testing and clinical trials required prior to obtaining regulatory marketing approval.

An SPC can extend a patent right associated with a particular product for a maximum of five years. A six-month additional extension is available in accordance with Regulation (EC) No 1901/2006 if the SPC relates to a medicinal product for which data relating to the use in children has been submitted according to a **Paediatric Investigation Plan (PIP)**. This extended SPC protection compensates for the additional clinical trials and testing that PIPs require.

Orphan Medicinal Product Designation is designed to encourage the development of medicines specifically to treat rare diseases and can be awarded to medicines if they can be used to diagnose, prevent, or treat a life-threatening or extremely serious condition which affects no more than 5 in 10,000 people in the European Union.

An orphan medicinal product benefits from ten years market exclusivity with regard to the specific indication for which the orphan designation is granted[5]. If the orphan medicine has a Paediatric Investigation Plan (PIP), the period can be extended for a further two years. SMEs can also obtain administrative and procedural assistance from the European Medicines Agency (EMA) and may benefit from a variety of fee reductions.



3 - http://phrma-docs.phrma.org/sites/default/files/pdf/biopharmaceutical-industry-profile.pdf
4 - http://csdd.tufts.edu/news/complete_story/tufts_csdd_rd_cost_study_now_published
5 – Each incentive was carefully crafted to ensure that they did not stifle healthy competition; for example, while market exclusivity protects against similar medicines with no added value, it allows entry of improved or alternative treatments.

THE EUROPABIO SURVEY

The EuropaBio survey was conducted between July and September 2017 among a cross section of 25 key stakeholders involved in the healthcare biotechnology community.

It included in-depth interviews with venture capitalists, small and medium sized enterprises (SMEs), regional biotechnology clusters and key opinion leaders from academia and the life-sciences community. All interviews were conducted independently by Cambre Associates for EuropaBio and on the agreement of anonymity.

The interviewees were asked questions on the importance of IP rewards and incentives for their respective activities, their perceptions of the EU as a world class performer in healthcare biotechnology compared to other countries and regions, and about the European Commission's evaluation of the IP rewards and incentives framework.

INVESTING IN HEALTHCARE BIOTECHNOLOGY IS LONG-TERM, EXPENSIVE AND RISKY

It was repeatedly highlighted during the survey that healthcare biotechnology is an extremely challenging business that carries a very high risk. Respondents said there are numerous factors which impact on investment and success.

The cost of therapy development can vary greatly depending on its complexity and the trials that have to be conducted. Biotechnology-based medicines can be particularly intricate and require highly skilled research professionals to develop and test them over long periods of time.

There is also no guarantee of success and many new molecules investigated fail in the final stages of development.

THE AVERAGE COST TO PRODUCE A NEW THERAPY UNTIL IT IS READY FOR MARKET ENTRY IS NOW MORE THAN **€2.5 BILLION**[6]

They indicated that to develop a new therapy from early discovery to phase III clinical trials will typically cost €500 to €800 million. However, a 10-year research programme has only around a 6% chance of success, so the true cost per approved therapy is much more. The total investment for getting a new drug ready for market entry is currently estimated to be more than €2.5 billion[7].

Calculating the development cost for a successful drug is of only limited relevance to investment needs.

99.7% OF ALZHEIMER'S RESEARCH PROGRAMMES HAVE FAILED IN LATE-STAGE CLINICAL TRIALS[8]

"These low success rates mean that investors take a huge gamble when they fund the development of a potential therapy or new technology. They are only interested if they know that once the therapy is marketed there will be a period of time during which they can recover the costs and make a return on their capital," explained a venture capitalist.

"This is why IP rewards and incentives, which extend the period of time during which a manufacturer can exclusively market their product, are so crucial for the industry. Development and trials take so long that the period of a standard patent alone would not give enough time for this to happen."

Many of the companies interviewed stated that healthcare biotechnology research would be out of their reach if it weren't for the system of IP rewards and incentives.

6 - http://csdd.tufts.edu/news/complete_story/tufts_csdd_rd_cost_study_now_published
7 - http://csdd.tufts.edu/news/complete_story/tufts_csdd_rd_cost_study_now_published
8 - Survey respondent

THE ENABLERS OF SUSTAINED INVESTMENT AND INNOVATION

According to venture capitalists interviewed for the survey, Europe's IP rewards and incentives are not just 'desired', they are 'essential'. "They attract the necessary funding for biotech SMEs to conduct their research & development (R&D) efforts; for companies to recoup their investment; and to enable funding of the next generation of discoveries," said one.

"Intellectual property protection is the foundation of the industry. Without it, there is no industry," said another.

They rely heavily on IP rewards and incentives to attract investors who fund their work over many years before they begin to see any return on the substantial costs involved.

SMEs need IP protection to ensure they have a strong value to build on for partnership with other companies.

"If we don't have strong IP we simply won't enter into innovative programmes," said one. "Without strong IP we would never be able to attract the funding to exist," echoed the owner of a French SME.

> *"The SPC is important because it offers a little bit of extra protection for a product to make up for the time it takes to develop a product from this technology."*
> *(Venture Capitalist)*

There was overall agreement that IP rewards and incentives have proved crucial to biomedical innovation.

For SMEs in particular, IP rewards and incentives are essential to attract the investors on whom they rely.

AROUND 50%
OF ALL MEDICINES IN THE PIPELINE ARE HEALTHCARE BIOTECH PRODUCTS[9]

The majority of the 3,000 companies in the healthcare biotech sector in the EU are SMEs. They are the backbone of the industry, conducting initial research before their innovations are further developed in cooperation with larger companies. They often work in collaboration with Europe's academic institutions.

An IP lawyer from one of the SMEs interviewed said that IP rewards and incentives had been critical to the company's development strategy which focuses on R&D around an emerging new class of therapies with unique potential in treating a wide range of diseases.

Regulatory data protection, orphan medicinal product designation and paediatric extensions have helped the company to raise around €320 million in equity investment and have enabled partnerships with major global biopharmaceutical companies.

A view shared by several venture capitalists and based on the experience of SMEs, is that companies with good IP protection typically grow faster, hire more people and are more successful.

9 - 'Valuing Healthcare Biotech in Europe', Charles River Associates, February 2014

A venture capitalist singled out the importance of SPCs as part of the company's decision as to whether to invest in a healthcare biotechnology company. "An SPC can really make a difference between deciding that there's still a reasonable return and between deciding that there's not."

Several SMEs also stressed the importance of orphan medicinal product designation. "Without such incentives, no company would approach rare disease areas," explained a director of an SME. "The incentives for researching orphan drugs allow us to produce much needed medicines for patients for whom otherwise there would be no treatment."

> *"Without any incentives no company would approach these (rare disease) areas" (SME)*

IP REWARDS AND INCENTIVES ENABLE THE INNOVATION WHICH DRIVES PRICES DOWN THROUGH COMPETITION

Some critics have speculated that IP rewards and incentives are helping to drive up medicine prices. However, this was not an opinion shared by survey respondents who explained that the price of innovative therapies is determined by their value compared to existing treatments.

"It is concerning that a discussion about IP is taking place within a highly politicised and almost feverish debate about pricing," said one of the participants. "There is an important distinction to be made between patents and price. People constantly believe that a patent is a guarantee of a high price, which is absolutely not the case."

"The price of medicines is something negotiated with governments using cost-effectiveness assessments which are based on the value the therapy delivers to patients. Patent protection stimulates competition and so it actually helps to keep prices down," he said.

> *"If the incentives and rewards are reduced, this would be a catastrophe for the biotech industry." (biotech cluster)*

IP IS NO BARRIER TO THE AVAILABILITY OF ESSENTIAL MEDICINES

Healthcare biotechnology specialists are also quick to point out that IP is not preventing or hampering the availability of therapies, especially in developing countries. To illustrate this, 95% of the products on the WHO List of Essential Medicines[10] are out of patent[11].

For all patented products, the World Trade Organisation has made provisions that Intellectual Property Rights for pharmaceuticals do not apply to the 48 Least Developed Countries until 2033, with the possibility to extend the period after that[12].

Furthermore, quite a number of large biopharmaceutical companies have waived their patent rights in developing countries, and have set up voluntary licensing programmes to facilitate generic manufacturers to sell and distribute these patented products. More than 20 such licensing agreements were set up in the last few years, coordinated by the United Nations backed NGO - Medicines Patent Pool[13].

"Eventually medicines will become generic and we all hope that after a certain period of time there will be cheaper access to those medicines" said one of the venture capitalists. "But before this happens and to enable medicines to become generic, they have to make it to market and be profitable in the first place."

10 - 'Patents and the WHO Model List of Essential Medicines (18th Edition): Clarifying the Debate on IP and Access', REED F BEALL, Faculties of Medicine and of Law, University of Ottawa, Canada (2016) http://www.wipo.int/edocs/mdocs/mdocs/en/wipo_gc_ip_ge_16/wipo_gc_ip_ge_16_brief.pdf
11 - IP Watchdog, September 2016 http://www.ipwatchdog.com/2016/09/12/essential-medicines-off-patent/id=72542/
12 - WTO, November 2015: https://www.wto.org/english/news_e/news15_e/trip_06nov15_e.htm
13 - Medicines Patent Pool: https://medicinespatentpool.org/what-we-do/global-licence-overview/update-on-progress-of-mpp-sublicensees/

THE HIGH RISK OF HEALTHCARE BIOTECHNOLOGY DEVELOPMENT

The development of biotechnology-based medicines is a capital-intensive and risky business. Even in the late stages of trials, expensive research programmes often fail which has recently been the case of several medicines developed in the fight against Alzheimer's disease.

"In the case of Alzheimer's, 99.7% of research programmes have failed in late-stage clinical trials," commented a venture capitalist. "Very few companies would be comfortable without a very strong ecosystem that has IP incentives at the heart."

Alzheimer's is considered one of the areas of great need, but as one of the survey respondents pointed out, finding the appropriate patients to determine effectiveness before significant onset of the disease is difficult. The trials need to be conducted over many years. Only four medicines have been approved for Alzheimer's patients by the US Food and Drug Administration (FDA) and the last time a new therapy was given the green light was in 2003[14].

It is why the IP rewards and incentives framework is so crucial to biomedical research say respondents.

Fortunately, there are medicines for many illnesses that have been successfully developed and despite the setbacks, the fight against Alzheimer's[15] continues thanks to Europe's IP rewards and incentives regime.

In recent decades, the use of biotechnology in medicine has led to significant and important breakthroughs, particularly in areas such as cancer, cardiovascular disease, diabetes and chronic respiratory diseases.

It provides further evidence that a well-designed IP rewards and incentives framework helps to stimulate research and sends a strong signal to innovative companies to direct their R&D efforts towards unmet medical needs.

14 - Financial Times, Axovant's Azheimer drug fails late-stage trial, 26 September 2017.
15 - https://www.lifesciencesipreview.com/article/the-innovation-paradox-why-complex-drug-research-is-not-being-rewarded

THE GLOBAL COMPETITIVENESS OF EUROPEAN HEALTHCARE BIOTECHNOLOGY AND INNOVATION

The EU was recognised by respondents as a world-class performer in healthcare biotechnology, but overall it was ranked a distant second to the United States of America (USA).

Asked to score the perceived competitiveness of various countries and regions in terms of healthcare innovation, most gave the US a score of 8 or 9 on a scale of 10, compared to scores ranging from 5 to 7 for Europe.

Asian countries mostly scored between 4 and 6, with China and Korea both mentioned several times as up-and-coming geographies to be watched.

In terms of pure innovation in healthcare biotechnology, Europe is not regarded as lagging behind the US, but it is weaker in terms of its drive to attract private investment.

"We have world-class research facilities so the whole ecosystem is very strong in Europe compared to other regions," commented a government official.

The main issue in Europe regarding competitiveness of the sector is the scarcity of funding and investment relative to other global regions such as the US. This issue was one that was repeatedly mentioned by respondents. One of the European biotech clusters explained the lack of funding being due to the much greater aversity to risk in Europe compared to the US. Others suggested it had more to do with the overall availability of funds.

"From our point of view, the big difference in the US is simply the scale of capital that is available," said a venture capitalist. "There are a lot more funds available in the US and they have a lot more capital so they can of course be much more ambitious."

He pointed out that in the US a great deal of the investment in the healthcare biotechnology sector comes from private investors.

"The European Commission should initiate the creation of a single capital market for biotech companies and should introduce tax incentives for investment," suggested one venture capitalist.

> *"An SPC can really make the difference between deciding that there's still a reasonable return there and between deciding that there's not."*
> *(Venture Capitalist)*

An academic suggested that more emphasis should be placed on promoting biotech clusters. Several exist around Europe but they are considered much smaller than Boston or San Francisco. "If there was a conscious decision at EU level to promote let's say a cluster per country, it would help concentrate the effort and by concentrating the effort you can compensate for other weaknesses," added a venture capitalist.

However, research produced by The Boston Consulting Group (BCG) and published in The Journal of the American Medical Association (JAMA)[16] at the beginning of 2015 showed that the US's global leadership role for spending on biomedical research and health service innovation is eroding. Other global players such as China are increasing their funding abilities and reinforcing their intellectual property framework[17].

16 - Moses H, Matheson DHM, Cairns-Smith S, George BP, Palisch C, Dorsey ER. The Anatomy of Medical Research US and International Comparisons. JAMA. 2015;313(2):174–189. doi:10.1001/jama.2014.15939
17 - Statement of the China Food and Drug Administration (CFDA), http://www.cfda.gov.cn/WS01/CL1746/178364.html

BIOTECH INNOVATION – FUNDAMENTAL TO EUROPE'S ECONOMIC GROWTH

Among IP intensive industries, the healthcare biotechnology sector is one of the top contributors of growth and economic sustainability in Europe. More than 170,000 people are directly employed in the industry – many of them in highly skilled jobs – and a further 700,000 benefit indirectly through the industry's activities[18].

"Importantly there is also €30 billion a year that is spent on medicine research (in Europe)," pointed out a key opinion leader. "It is thanks, in very large part, to the IP rewards and incentives that are driving it."

Most traditional pharmaceutical companies now have biologic medicines in their pipeline[19] and there are more than 7,000 innovative medicines under development.

According to the EU R&D scoreboard for 2016[20], the top 50 large companies listed by R&D intensity (R&D to sales ratio) are dominated by the high tech sectors of pharma and biotech, software and technology hardware.

The pharma and biotech sector keeps its first position in the R&D ranking, increasing its share of the total R&D investment to 19.1%, ahead of Automobile & Parts (15.6%) and Technology Hardware & Equipment (14.4%).

European Patent Office (EPO) data shows that the biotech sector - both innovator and generic - is still filing more European patents than many other sectors[21].

Many survey participants pointed out that a strong, stable and predictable IP framework is needed to enable financial and scientific investments in innovation across the region, strengthening the EU's industrial base, attracting world class talent, and boosting Europe's competitiveness.

Numerous studies have also shown the positive link between IP, R&D, investment and growth. One such study, by Stanford academic Stephen Haber found that countries that protect patents enjoy stronger economic growth and that there is a causal relationship between strong patents and innovation[22].

Another paper, from the National Bureau of Economic Research in the US, found that holding a patent – and being able to defend it – increases the probability of securing venture capital funding by 53 per cent, start-up job growth by 36 per cent and start-up sales by 51 per cent. "Proposals for patent reform should consider these benefits of patents alongside their potential costs," say the authors[23].

IP contributes to sustainable R&D that supports the knowledge-based economy. Furthermore, it boosts competitiveness. But with a weaker IP and incentives framework, technology transfer is less likely to take place.

18 - 'Valuing Healthcare Biotech in Europe', Charles River Associates, February 2014
19 - http://phrma-docs.phrma.org/sites/default/files/pdf/biopharmaceutical-industry-profile.pdf (p.63 and p2 –key facts)
20 - http://iri.jrc.ec.europa.eu/scoreboard16.html
21 - https://www.epo.org/news-issues/issues/biotechnology-patents.html
22 - Haber, Stephen, Patents and the Wealth of Nations (May 6, 2016). George Mason Law Review, Vol. 23, No. 4, 2016. Available at SSRN: https://ssrn.com/abstract=2776773
23 - Joan Farre-Mensa, Deepak Hegde, Alexander Ljungqvist, the Bright Side of Patents, NBER Working Paper No. 21959, February 2016. Available at http://www.nber.org/papers/w21959

IP REWARDS AND INCENTIVES IN THE EU CONTEXT

The European Commission evaluation of IP rewards and incentives under EU pharmaceutical law followed the Employment, Social Policy, Health and Consumer Affairs Council (EPSCO)[24] Council conclusions under the Dutch Presidency in 2016 on the one hand, and ordinary reviews required in certain regulations on the other.

Among the changes to the European IP system understood to be under consideration by the European Commission is a manufacturing and export exemption to the Supplementary Protection Certificates (SPCs), which would allow generic manufacturers to manufacture medicines in the EU whilst the original product is still under the protection of SPCs, though they could only be sold to countries outside the region.

> *"A reduction of exclusivity would be dangerous for innovation in Europe and could be difficult to manage." (SME)*

Generic medicine manufacturers argue that such a waiver would create jobs in Europe allowing the EU to better compete with India and China.

However, survey respondents indicated significant disagreement with this assumption. Most healthcare biotechnology developers and manufacturers said they believed it would lead to job losses in the sector and a rapid erosion of innovation investment.

Their views are supported by the findings of a recent study commissioned by among others, the US Chamber of Commerce[25]. The study suggests that a manufacturing and export exemption is likely to have a detrimental effect on the European research-based biopharmaceutical industry and is unlikely to provide a significant and sustained positive economic impact on the European generics industry.

The study finds that implementation of an EU wide SPC manufacturing and export exemption would potentially result in annual losses ranging between EUR 2.30 billion and up to EUR 4.61 billion to the global innovative biopharmaceutical industry, with approximately EUR 1.15 billion to EUR 1.96 billion of these attributed to the European innovative biopharmaceutical industry.

Translating these losses to current levels of biopharmaceutical sector employment and R&D investment the effect of the introduction of an EU wide SPC manufacturing and export exemption could be between 4,500-7,700 direct job losses (with an additional 19,000-32,000 indirect job losses) and a decrease of between EUR 215 million to EUR 364 million in R&D investment.

On the other hand, there was support from stakeholders for the idea of introducing unitary SPCs, in line with the unitary patent scheme, especially if it involved the establishment of a virtual body composed of SPC experts from national patent offices, as an authority to grant them.

Similar to a unitary patent, a single SPC application that is valid in all member states would simplify the complex terrain of intellectual property across Europe and would reduce internal time and resources.

The overwhelming majority response from the EuropaBio survey was that the current IP system should be preserved as it provides a balanced framework enabling medical innovation. "The industry is operating within a very fragile ecosystem," said a survey respondent. "It is important the Commission at least maintains the status quo."

24 - The EPSCO Council works to increase employment levels and improve living and working conditions, ensuring a high level of human health and consumer protection in the EU.
25 - Unintended consequences, Pugatch Consilium, October 2017. http://www.pugatch-consilium.com/?m=20171012

THE CONSEQUENCES OF CHANGE

Many of the stakeholders interviewed for the survey warned that if changes are made to the current EU framework of IP rewards and incentives it could be very damaging to patients, the industry, and to Europe's ambitions to become a leading centre of innovation.

"Any reduction of exclusivity would be dangerous for innovation in Europe and could be difficult to manage," explained the managing director of an SME that relies entirely on IP rewards and incentives to attract long-term funding.

Another SME spokesman from France said that for biotechnology-based medicines, SPCs are something that you cannot do without given that much of the 20 years patent lifetime are used for clinical development. "It takes so long to go through all the phase 1, 2 and 3 studies. By the time you are in a phase 2 study the patent will run out in five or six years and then we still have to make sure that we can still sell it to whoever wants to bring it to the market."

A leading healthcare biotechnology business leader told us that if the current framework of SPCs and other incentives is diluted it would significantly weaken the EU's intellectual property system for medicines. "We would risk losing much of the €30 billion invested annually (in Europe) to countries and regions that put a higher value on their knowledge-based economy. I would prefer to see Europe take the opportunity to increase its share of the global biopharmaceutical investment in research (expected to reach close to €140 billion in 2017), than to lose it," he said.

A spokesperson from a biotech cluster went further and stated "If the rewards and incentives are reduced, this would be a catastrophe for the biotech industry."

CAN WE REGAIN EUROPE'S COMPETITIVE EDGE?

The European Parliament has highlighted that Europe spends 0.8% of GDP less than the US and 1.5% less than Japan every year on research and development (R&D). In addition, some brain drain effect occurs as our best researchers and innovators move to countries where conditions are more favourable. "Although the EU market is the largest in the world, it remains fragmented and is not sufficiently innovation-friendly," says a European Parliament factsheet[26].

It is with a view to reversing these trends, that the EU has developed the concept of an 'Innovation Union', which aims to make Europe a world-class science performer; remove obstacles to innovation and to revolutionise the way the public and private sectors work together, notably through the implementation of Innovation Partnerships between the European institutions, national and regional authorities and business.

"The Innovation Union is a crucial investment in our future," says the factsheet. "For example, achieving our target of investing 3% of EU GDP in R&D by 2020 could create 3.7 million jobs and increase annual GDP by EUR 795 billion by 2025,"

In our 2014-19 manifesto Time to reap the benefits in Europe, EuropaBio emphasised to policymakers that in order for the region to remain competitive for biotech companies, it would be necessary to address Europe's growing loss of attractiveness compared to other geographic areas.

Now, halfway through the 2014-19 mandate of the European Commission and Parliament, industry observers are concerned that there are more EU barriers to innovation and investment in bioindustries than ever before[27].

> *"Eventually medicines will become generic and we all hope that after a certain period of time there will be cheaper access to those medicines. But before this happens and to enable medicines to become generic, they have to make it to market and be profitable in the first place." (Venture capitalist)*

26 - European Parliament Innovation Policy, available at http://www.europarl.europa.eu/atyourservice/en/displayFtu.html?ftuId=FTU_5.9.7.html
27 - Half a Term Left to Boost Jobs, Growth and Competitiveness Through EU Bioindustries, EuropaBio September 2017. https://www.theparliamentmagazine.eu/system/files/protected/whitepaper/11%20SEP%20Mid-Mandate%20review%20LAYOUT.pdf

THE IMPORTANCE OF THE BIOTECH INDUSTRY

GLOBAL BIOPHARMACEUTICAL INVESTMENT IN RESEARCH IS EXPECTED TO REACH CLOSE TO **€140 BILLION** IN 2017[28]

55% OF ALL PATENTS IN BIOTECHNOLOGY ARE FOR PHARMACEUTICALS[29]

350 MILLION PATIENTS BENEFIT FROM BIOTECHNOLOGY-DERIVED MEDICINES WORLDWIDE[30]

APPROXIMATELY **30 MILLION** PATIENTS IN EUROPE SUFFERING FROM RARE DISEASES BENEFIT FROM BIOTECHNOLOGY DERIVED MEDICINES[31]

AROUND 50% OF ALL MEDICINES IN THE PIPELINE ARE HEALTHCARE BIOTECH PRODUCTS[32]

ACCORDING TO A STUDY CARRIED OUT BY THE EU INTELLECTUAL PROPERTY OFFICE (EUIPO) AND EUROPEAN PATENT OFFICE, **39%** OF TOTAL ECONOMIC ACTIVITY AND **26%** OF ALL EMPLOYMENT IN THE EU IS DIRECTLY GENERATED BY IPR-INTENSIVE INDUSTRIES[33]

THERE ARE MORE THAN **3,000** COMPANIES IN EU (SMES-VERY LARGE) ACCOUNTING FOR **170,000** DIRECT JOBS AND MORE THAN **700,000** INDIRECT JOBS IN THE HEALTHCARE BIOTECH SECTOR[34]

26% OF GLOBAL BIOLOGICAL MANUFACTURING AND **80%** OF GLOBAL VACCINES COME FROM EU[35]

THE HEALTHCARE BIOTECHNOLOGY INDUSTRY HAS INVESTED AN ESTIMATED **€200 BILLION** IN R&D IN EUROPE IN THE PAST SIX YEARS[36]

INVESTING **3%** OF EU GDP IN R&D BY 2020 COULD CREATE **3.7 MILLION** JOBS AND INCREASE ANNUAL GDP BY **EUR 795 BILLION** BY 2025[37]

28 - https://www.ifpma.org/wp-content/uploads/2017/02/IFPMA-Facts-And-Figures-2017.pdf
29 - European Patent Office: https://www.epo.org/news-issues/issues/biotechnology-patents.html
30 - 'Valuing Healthcare Biotech in Europe', Charles River Associates, February 2014
31 - 'Valuing Healthcare Biotech in Europe', Charles River Associates, February 2014
32 - 'Valuing Healthcare Biotech in Europe', Charles River Associates, February 2014
33 - http://ec.europa.eu/internal_market/intellectual-property/docs/joint-report-epo-ohim-final-version_en.pdf
34 - 'Valuing Healthcare Biotech in Europe', Charles River Associates, February 2014
35 - 'Valuing Healthcare Biotech in Europe', Charles River Associates, February 2014
36 - Survey respondent
37 - European Parliament Innovation Policy, available at http://www.europarl.europa.eu/atyourservice/en/displayFtu.html?ftuId=FTU_5.9.7.html

EuropaBio aisbl
Avenue de l'Armée, 6 1040 Brussels, Belgium
T. +32 2 735 03 13 | **F.** +32 2 735 49 60
www.europabio.org

EuropaBio®
The European Association for Bioindustries