Stanford – Vienna
Transatlantic Technology Law Forum

A joint initiative of
Stanford Law School and the University of Vienna School of Law

TTLF Working Papers

No. 123

The Role of Tax Incentives for Innovation in Pharma, Biotech, and MedTech: A Comparative Study Between the EU and the US Regulatory Approaches

Amedeo Rizzo

2024

TTLF Working Papers

Editors: Siegfried Fina, Mark Lemley, and Roland Vogl

About the TTLF Working Papers

TTLF's Working Paper Series presents original research on technology, and business-related law and policy issues of the European Union and the US. The objective of TTLF's Working Paper Series is to share "work in progress". The authors of the papers are solely responsible for the content of their contributions and may use the citation standards of their home country. The TTLF Working Papers can be found at http://ttlf.stanford.edu. Please also visit this website to learn more about TTLF's mission and activities.

If you should have any questions regarding the TTLF's Working Paper Series, please contact Vienna Law Professor Siegfried Fina, Stanford Law Professor Mark Lemley or Stanford LST Executive Director Roland Vogl at the

Stanford-Vienna Transatlantic Technology Law Forum
http://ttlf.stanford.edu

Stanford Law School
Crown Quadrangle
559 Nathan Abbott Way
Stanford, CA 94305-8610

University of Vienna School of Law
Department of Business Law
Schottenbastei 10-16
1010 Vienna, Austria

About the Author

Amedeo Rizzo is a Doctor of Philosophy (DPhil) in Law at the University of Oxford, Exeter College, and Academic Tutor at St Catherine's College (Oxford) in the UK. He works as an Academic Fellow at Bocconi University and SDA Bocconi School of Management (Italy), where he coordinates the Master of Corporate Tax Law and several research centers, including the Accounting & Tax Policy Observatory (OFC) and the Transfer Pricing Forum, and the Tax Strategies Project. He is a Visiting Scholar of law and technology at the Singapore Management University, Yong Pung How School of Law.
Professionally, he is the Chairman of Lyra Analytics, a data analytics company, the Executive Director of the Innovation Policy Network, and one of the founding partners of the Italian audit company, Imperium Audit. Previously, he worked for the Directorate-General for Economic and Financial Affairs (DG ECFIN) of the European Commission, for the International Tax and Transfer Pricing Team of PricewaterhouseCoopers in Milan, Italy, and the Centre for Budget and Governance Accountability in India.
Prior to his D.Phil. in Law at the University of Oxford, Amedeo obtained an M.Sc. in Taxation from the University of Oxford (distinction), an M.Sc. in Business Administration and Law (summa cum laude) and a B.Sc. in Business Administration, both from Bocconi University.

General Note about the Content

Suggested Citation

This TTLF Working Paper should be cited as:
Amedeo Rizzo, The Role of Tax Incentives for Innovation in Pharma, Biotech, and MedTech: A Comparative Study Between the EU and US Regulatory Approaches, Stanford-Vienna TTLF Working Paper No. 123, http://ttlf.stanford.edu.

Copyright

Abstract

In this paper, I conduct a comparative study of the tax policies implemented by the European Union and the United States to enhance innovation in the pharmaceutical, biotechnology, and medical technology industries.
These industries are quite peculiar, because of the high social impact of the projects and the specific market dynamics, like, for instance, in orphan drugs and vaccines. The flow of knowledge is a fundamental engine for innovation in these sectors, and the role of intellectual property rights seems uncertain, according to contrasting results in empirical research.
Therefore, the use of the tax system to incentivize investments and R&D activities in these sectors can take on a prominent role. However, tax incentives need to be carefully designed, and their adoption might need some industry-specific considerations. The first part of this work will focus on these considerations of tax policy design, differentiating between human capital- and capital expenditures-oriented tax incentives and identifying the main instruments adopted by the EU Member States and the US. In this context, I analyze different types of tax incentives, both sector-specific and general, like cashable or non-cashable R&D tax credits, Intellectual Property Boxes, personal income tax reductions for highly skilled individuals, and capital gains taxes.
In the second part of the paper, I conduct a comparative analysis of the regulatory frameworks of the European Union and the United States. In comparing the two different ways of achieving similar objectives, I formulate specific considerations on the different designs of the tax policies, underlining potential causes and consequences of different choices. In understanding the effects of the converging and diverging policy choices, which are often rooted in the regulatory structures of the two Transatlantic blocs, I take into account macroeconomic trends and firms' investment data. Consequently, I draw final considerations according to the findings of the analysis, including hints for further research.

Keywords

Intellectual property, Healthcare, Tax incentives, Innovation, Pharmaceutical

Table of contents

1. Introduction

Innovation is a crucial driver of economic growth, especially in high-impact industries such as pharmaceuticals, biotechnology, and medical technology.1 These sectors are characterized by their significant social impact, as they develop vital medical innovation and therapeutic interventions, including drugs and vaccines, and their unique market dynamics. The success of these industries relies heavily on continuous research and development (R&D) activities, which in turn depend on robust knowledge flow and well-structured incentive mechanisms. However, the role of intellectual property rights (IPR) in fostering valuable innovative projects within these sectors is still widely debated, with empirical research producing mixed results.[2]

Among all technological fields, the drug and pharmaceutical sectors clearly exemplify the concept of globalization and the necessity for a robust intellectual property

[1] Gavin F Cameron, *Innovation and Economic Growth* (1996); Basil Achilladelis and Nicholas Antonakis, 'The Dynamics of Technological Innovation: The Case of the Pharmaceutical Industry' (2001) 30 Research Policy 535; Kevin M Murphy and Robert H Topel (eds), *Measuring the Gains from Medical Research: An Economic Approach* (Univ of Chicago Press 2003); Philip Cooke, 'New Economy Innovation Systems: Biotechnology in Europe and the USA' (2001) 8 Industry and Innovation 267; Michael Kuhn and others, 'Medical Innovation, Life Expectancy, and Economic Growth' [2023] SSRN Electronic Journal <https://www.ssrn.com/abstract=4491818>.

[2] Margaret K Kyle, 'Incentives for Pharmaceutical Innovation: What's Working, What's Lacking' (2022) 84 International Journal of Industrial Organization 102850, 3; Giovanni Dosi and others, 'Do Patents Really Foster Innovation in the Pharmaceutical Sector? Results from an Evolutionary, Agent-Based Model' (2023) 212 Journal of Economic Behavior & Organization 564; Giovanni Dosi and others, 'Big Pharma and Monopoly Capitalism: A Long-Term View' (2023) 65 Structural Change and Economic Dynamics 15. See also Paul W Rhode, 'Biological Innovation without Intellectual Property Rights: Cottonseed Markets in the Antebellum American South' (2021) 81 The Journal of Economic History 198; M Kremer, 'Patent Buyouts: A Mechanism for Encouraging Innovation' (1998) 113 The Quarterly Journal of Economics 1137; Michael A Heller and Rebecca S Eisenberg, 'Can Patents Deter Innovation? The Anticommons in Biomedical Research' (1998) 280 Science 698; Lori B Andrews, 'Genes and Patent Policy: Rethinking Intellectual Property Rights' (2002) 3 Nature Reviews Genetics 803; Kenneth G Huang and Fiona E Murray, 'Does Patent Strategy Shape the Long-Run Supply of Public Knowledge? Evidence from Human Genetics' (2009) 52 Academy of Management Journal 1193; Fiona Murray and Scott Stern, 'Do Formal Intellectual Property Rights Hinder the Free Flow of Scientific Knowledge? An Empirical Test of the Anti-Commons Hypothesis' (2007) 63 Journal of Economic Behaviour & Organization 648; John P Walsh, Wesley M Cohen and Charlene Cho, 'Where Excludability Matters: Material versus Intellectual Property in Academic Biomedical Research' (2007) 36 Research Policy 1184; Michele Boldrin and David K Levine, *Against Intellectual Monopoly* (Cambridge University Press 2008).

system.[3] Given that introducing a new drug to the market can have an average cost for a company that goes from $300 million to $1.8 billion, coupled with the significant risks involved during the development stage, companies would be disincentivized in investing in intellectual property without ensuring adequate financial returns, knowing it would become a public good.[4] Competition in the global pharmaceutical industry is primarily driven by scientific expertise rather than manufacturing capabilities. A company's success is often determined by its R&D efforts, leading to a significant portion of total sales being invested in research and development within the drug industry.[5]

The pharmaceutical industry faces increasing challenges due to the extensive documentation required for regulatory approval and the longer approval times, which can negatively affect the effective length of patent protection. As governments may impose stricter price controls to meet public health goals, pharmaceutical companies are pressured to lower development and marketing costs and accept reduced profit margins over extended periods. The industry has a tendency to prioritize the development of drugs targeting lucrative diseases, skewing research priorities, often at

[3] ChandraNath Saha and Sanjib Bhattacharya, 'Intellectual Property Rights: An Overview and Implications in Pharmaceutical Industry' (2011) 2 Journal of Advanced Pharmaceutical Technology & Research 88, 91. On the importance of IP protection in particular in the pharmaceutical sector, see Richard C Levin and others, 'Appropriating the Returns from Industrial Research and Development' (1987) 1987 Brookings Papers on Economic Activity 783.

[4] Saha and Bhattacharya (n 3) 91. See also Sandeep Sinha and Divya Vohora, 'Drug Discovery and Development', *Pharmaceutical Medicine and Translational Clinical Research* (Elsevier 2018); Nancy L Rose, *Economic Regulation and Its Reform: What Have We Learned?* (University of Chicago Press 2014) 408; Joseph A DiMasi and Henry G Grabowski, 'The Cost of Biopharmaceutical R&D: Is Biotech Different?' (2007) 28 Managerial and Decision Economics 469; Joseph A DiMasi, Ronald W Hansen and Henry G Grabowski, 'The Price of Innovation: New Estimates of Drug Development Costs' (2003) 22 Journal of Health Economics 151; Richard G Frank, 'New Estimates of Drug Development Costs' (2003) 22 Journal of Health Economics 325; Joseph A DiMasi, Henry G Grabowski and Ronald W Hansen, 'Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs' (2016) 47 Journal of Health Economics 20; Joseph A DiMasi and Henry G Grabowski, 'Economics of New Oncology Drug Development' (2007) 25 Journal of Clinical Oncology 209; 'Costing Drug Development' (2003) 2 Nature Reviews Drug Discovery 247.

[5] Saha and Bhattacharya (n 3) 91; Sinha and Vohora (n 4) 19.

the expense of more pressing global health concerns.[6] Companies are incentivized to develop treatments for conditions that offer high financial returns, sometimes even non-critical health issues while neglecting diseases that affect poorer populations. Additionally, the current pharmaceutical patent system intensifies the problem by limiting affordable access to essential medicines, further entrenching inequality in global healthcare access.[7] This combination of profit-driven R&D and restricted access highlights significant challenges within the pharmaceutical industry, requiring urgent reform to better align innovation with public health needs.

In this context, tax policies can constitute an important tool that governments can use to stimulate innovation.[8] By providing targeted incentives, tax systems can encourage investments in R&D, helping to overcome the high costs and risks associated with developing new medical technologies. Yet, designing effective tax incentives is a complex task that requires careful consideration of the specific needs and dynamics of these industries.

This paper explores the tax policies implemented by the European Union and the United States to boost innovation in the pharmaceutical, biotechnology, and medical technology sectors. It offers a policy analysis of the structures of these incentives, focusing on the distinctions between those aimed at human capital and those targeting

---

[6] Valbona Muzaka, 'The Pharmaceutical Patent System and Access to Medicines' in Joan Costa-Font, Alberto Batinti and Gilberto Turati (eds), *Handbook on the Political Economy of Health Systems* (Edward Elgar Publishing 2023).

[7] ibid.

[8] Bronwyn Hall, 'Tax Policy for Innovation' (National Bureau of Economic Research 2019) w25773 <http://www.nber.org/papers/w25773.pdf> accessed 5 April 2023; Ufuk Akcigit and others, 'Taxation and Innovation in the Twentieth Century' (2021) 137 The Quarterly Journal of Economics 329; Andreas Haufler, Pehr-Johan Norbäck and Lars Persson, 'Entrepreneurial Innovations and Taxation' (2014) 113 Journal of Public Economics 13; Pourya Darnihamedani and others, 'Taxes, Start-up Costs, and Innovative Entrepreneurship' (2018) 51 Small Business Economics 355; Catherine Fazio, Jorge Guzman and Scott Stern, 'The Impact of State-Level R&D Tax Credits on the Quantity and Quality of Entrepreneurship' (National Bureau of Economic Research 2019) w26099 <http://www.nber.org/papers/w26099.pdf> accessed 15 February 2023. See also Charles Delmotte, 'The Case Against Tax Subsidies in Innovation Policy' [2020] SSRN Electronic Journal <https://www.ssrn.com/abstract=3564793> accessed 12 November 2022.

capital expenditures. Additionally, the paper examines a variety of tax instruments, including R&D tax credits, Intellectual Property Boxes (IP Boxes), and tax reductions for highly skilled individuals and capital gains taxes, highlighting their application across the EU and the US.

The second part of the paper analyzes the regulatory frameworks that shape these tax policies in both regions. By comparing the approaches of the European Union and the United States, the paper aims to provide a better understanding of the reasons behind different policy designs and their possible implications for the innovation process. The analysis concludes with reflections on the findings and suggestions for future research, contributing to the ongoing discourse on improving the design of tax policy to support innovation.

2. Tax Incentives for Pharma, Biotech, and MedTech Innovation

The intellectual property system is a foundation of innovation policy, designed to stimulate creativity by granting temporary exclusive rights to inventors and authors over their creations.[9] Despite its intent to boost innovation, the system has been a source of ongoing debate.[10] While IP rights are meant to incentivize innovation by allowing creators to profit from their inventions, they also introduce economic inefficiencies by enabling the charging of monopoly prices, which can limit access and

[9] Lionel Bently and others, *Intellectual Property Law* (Sixth edition, Oxford University Press 2022).

[10] Benjamin N Roin, 'Intellectual Property versus Prizes: Reframing the Debate' (2014) 81 University of Chicago Law Review 999; Saha and Bhattacharya (n 3); Kremer (n 2). For specific considerations on IP rights in developing countries, see also C Ford Runge and Edi Defrancesco, 'Exclusion, Inclusion, and Enclosure: Historical Commons and Modern Intellectual Property' (2006) 34 World Development 1713; Peter Evans, 'The New Commons vs. The Second Enclosure Movement: Comments on an Emerging Agenda for Development Research' (2005) 40 Studies in Comparative International Development 85; Clemente Forero-Pineda, 'The Impact of Stronger Intellectual Property Rights on Science and Technology in Developing Countries' (2006) 35 Research Policy 808.

create a deadweight loss. Additionally, the prospect of monopoly profits does not always align perfectly with societal needs, often leading to insufficient incentives for highly valuable innovations while disproportionately rewarding less beneficial, and sometimes even wasteful, inventions.[11]

R&D in these industries carries a significant risk of costly failures, as potential medicines that fail to meet stringent safety standards may be discontinued, often after many years and substantial financial investment. For medicines that successfully navigate the development process, it typically takes about 8-12 years from the initial synthesis of the compound to reach the market.[12] With product patents becoming the primary means of intellectual property protection, companies need to shift their R&D focus from refining processes for existing drugs to developing entirely new drug molecules and new chemical entities (NCEs).[13]

It is recognized that the submission process for regulatory approval involves a substantial amount of documentation. Moreover, regulatory authorities are now taking longer to approve new drugs,[14] which effectively shortens the period during which patent protection is in effect. This creates additional pressure on pharmaceutical companies to maximize profits within a reduced timeframe. The challenge is even greater for drugs developed through biotechnology, particularly those involving genetic research.[15] As a result, industrialized nations tend to advocate for extended patent protection for these drugs, while increasingly implementing price controls to

[11] Saha and Bhattacharya (n 3); Rose (n 4) 410.
[12] Saha and Bhattacharya (n 3) 91; Sinha and Vohora (n 4) 19.
[13] Saha and Bhattacharya (n 3) 91.
[14] N Side's website: https://lifesciences.n-side.com/blog/why-clinical-trial-timelines-are-getting-longer-and-how-to-fix-it (last access, 30 August 2024). See also Jörg J Möhrle, 'How Long Does It Take to Develop a New Drug?' (2024) 43 The Lancet Regional Health - Europe 100998; Nigel SB Rawson, 'Canadian, European and United States New Drug Approval Times Now Relatively Similar' (2018) 96 Regulatory Toxicology and Pharmacology 121.
[15] Saha and Bhattacharya (n 3) 91.

achieve public health objectives. This dual dynamic pushes companies to reduce costs associated with drug development, production, and marketing, while also necessitating a strategy for accepting lower profit margins over a longer period to recoup investments. Consequently, the pharmaceutical industry must navigate a complex landscape of competing demands. Over the past decade, various strategies have been adopted to manage costs and maintain competitive advantages, including outsourcing R&D activities, forming research partnerships, and establishing strategic alliances.[16]

The current state of these industries suggests that IPRs might be misused, undermining competition and consumer welfare. Some examples include the granting of patents for minor modifications of existing drugs, reformulations to secure new patents, and strategies like advertising and brand development that create barriers for generic competitors.[17] The industry can be heavily affected by a lack of genuine risk-taking and innovation, leading to significant inequities that might only be fully addressed through a patchwork of legislative reforms. To improve the firms' risk management strategy towards innovation, there is room for reform in public policy, and some proposed solutions include alternatives to IPRs, such as prizes,[18] advance market commitments (AMCs),[19] governmental participation in the risks and rewards of innovation,[20] but also antitrust law.[21] Indeed, antitrust law can play an important role in

[16] Saha and Bhattacharya (n 3). Mrudula BS, Durgadevi NK, Madhavi BR, Tejeswi B, Durga PV. Intellectual property rights pinpoint at IPR spotlights coveted R and D. Drug Inv Today 2009;2:197-201.
[17] ibid 92.
[18] Roin (n 10); Kyle (n 2) 6.
[19] Kyle (n 2) 6; Michael Kremer and Rachel Glennerster, *Strong Medicine: Creating Incentives for Pharmaceutical Research on Neglected Diseases* (Princeton University Press 2016).
[20] See Mariana Mazzucato, *The Entrepreneurial State* (Demos 2011).
[21] Saha and Bhattacharya (n 3) 92–93. For a thorough analysis, see Giovanni Pitruzzella and Gabriella Muscolo, *Competition and Patent Law in the Pharmaceutical Sector: An International Perspective* (WoltersKluwer 2016).

helping restore the balance between incentivizing innovation and maintaining healthy competition in the industry.[22]

In light of the underlined difficulties faced by the use of IPRs in the pharmaceutical sector, medical technologies, and biotechnologies, well-designed tax policies can also have an important role in the improvement of innovation processes in these industries. Given the high costs, extended development timelines, and significant risks associated with bringing new products to market, targeted tax policies can be designed to encourage investment in R&D, support patent creation, and attract highly skilled scientists.

These types of incentives affect the risk dimension of the innovation process.[23] Pharmaceutical development, as well as biotech and medtech, have high failure rates.[24] It is, therefore, relevant to understand who bears the risk of failure, between shareholders, government, and other actors. The uptake of part of the risk from the government tends to incentivize the conduction of R&D activities, by addressing the typical market failure that characterizes the innovation process. Yet, in order for the government to be incentivized to act in this process, there needs to be a return on the risk. This does not necessarily mean that the government should become a shareholder

[22] Saha and Bhattacharya (n 3) 92. Antitrust regulations can intervene in specific business practices, such as mergers, acquisitions, and non-compete agreements. See Kyle (n 2) 3. The author highlights how innovation is increasingly considered by competition authorities when evaluating mergers and acquisitions. Additionally, empirical evidence suggests that large firms may have a comparative advantage in drug development due to economies of scale and better internal capital allocation. See in this regard Iain M Cockburn and Rebecca M Henderson, 'Scale and Scope in Drug Development: Unpacking the Advantages of Size in Pharmaceutical Research' (2001) 20 Journal of Health Economics 1033; Ilan Guedj and David Scharfstein, 'Organizational Scope and Investment: Evidence from the Drug Development Strategies and Performance of Biopharmaceutical Firms' (National Bureau of Economic Research 2004) w10933 <http://www.nber.org/papers/w10933.pdf> accessed 3 September 2024. However, recent concerns have been raised about the potential for reduced innovation following "killer acquisitions," where larger companies acquire smaller, innovative firms primarily to eliminate future competition, thereby stifling innovation in the industry. See Colleen Cunningham, Florian Ederer and Song Ma, 'Killer Acquisitions' (2021) 129 Journal of Political Economy 649.

[23] Kyle (n 2) 2.

[24] Duxin Sun and others, 'Why 90% of Clinical Drug Development Fails and How to Improve It?' (2022) 12 Acta Pharmaceutica Sinica B 3049.

of the project, or receive part of the economic rewards. As long as the government is capable of finding a way to retain the economic or social benefits of the invention, for instance, by taxing new hires, taxing the revenue or the capital gains deriving from it, or having its economy or society positively affected by it. Measuring these positive effects can often be very difficult for governments.

This section provides an overview of the various tax incentives employed in the European Union and the United States to foster innovation in these critical sectors, providing an overview of different policy designs.

2.1. Policy design of tax incentives

The use of taxation as a tool to incentivize innovation has been discussed in legal scholarship, although not always within the framework of intellectual property law.[25] Tax incentives can be seen as an alternative or a complementary tool to the existing innovation-inducing mechanisms, mainly intellectual property rights and cash-based transfers. The view taken in this paper is that tax incentives cannot substitute IP rights, but ought to be considered a different tool that can help enhance other parts of the innovation process.[26]

Tax incentives for innovation provide tax relief for taxpayers that are engaged in targeted innovation-related activities. They can be described as special provisions allowing for the exclusion, credit, refund, deferral, or any general time-related arbitrage, or rate-reduction of tax liability.

[25] Amedeo Rizzo, 'Intellectual Property and Tax Incentives: A Comparative Analysis of the EU and the US Legal Frameworks' (2023) 43 Virginia Tax Review 291; See also: Jacob Nussim and Anat Sorek, 'Theorizing Tax Incentives for Innovation' (2017) 36 Virginia Tax Review 25; Bronwyn Hall, 'Tax Policy for Innovation' (National Bureau of Economic Research 2019) w25773 <http://www.nber.org/papers/w25773.pdf> accessed 5 April 2023.

[26] The same view is taken in Rizzo (n 25).

Therefore, they can take many forms, according to the way they allow the reduction of tax liability and the triggering factor. However, in this paper, only some of the main forms of tax incentives used by the US and the EU for incentivizing innovation will be analyzed, in particular R&D incentives, IP Boxes, and personal income tax and capital gain tax reductions.[27]

2.1.1. R&D Tax Credits, Exemptions, and Deductions

R&D tax incentives can be provided in different forms, which mainly include allowances, exemptions, deductions, or credits.[28] Tax allowances, exemptions, and deductions subtract from the tax base before the tax liability is computed, reducing the taxable amount of the entity that incurs these expenses before assessing the tax. Relief in the form of a tax credit subtracts directly from the tax due after the gross tax liability has been computed. These can be cashable, meaning that it will be possible for the entity to obtain cash back from the government in case no tax is liable to compensate the credit against, or non-cashable, in which case it will either be possible to set off the credit against other forms of tax liabilities (e.g., VAT) or, if not, only against future tax liability. In the case of accelerated depreciation provisions for R&D capital, R&D capital expenditures can be written off or depreciated at an accelerated/enhanced rate, providing an allowance (reduction in taxable income) to the taxpayer in the first year(s) of investment, i.e. a relief in the form of a delay in paying tax.

[27] For a thorough analysis of other forms of incentives, see Eric M Zolt, 'Tax Incentives and Tax Base Protection Issues' [2014] United Nations; United Nations, *Design and Assessment of Tax Incentives in Developing Countries: Selected Issues and a Country Experience* (United Nations 2018); Sebastian James, 'Tax and Non-Tax Incentives and Investments: Evidence and Policy Implications' [2014] World Bank.

[28] OECD INNOTAX https://stip.oecd.org/innotax/.

The rationale for R&D tax credits, exemptions, and deductions is to reduce the burden of R&D costs, by granting a reduction of the overall tax due. This can be particularly beneficial for companies in biotech and medtech, as they may have long development cycles before generating income.[29] However, a problematic dimension of this type of incentive is that unless it grants a cashable tax credit, it is of marginally little use for loss-making companies, which is often the case for firms in their start-up stage.[30] This can have a strong impact on the effectiveness of the R&D tax incentives.[31]

Overall, R&D tax incentives are quite effective tools, as they tend to be well-targeted and easy to use. Empirical evidence shows there is often a positive effect of R&D tax credits on private R&D activities.[32] In fact, many EU countries offer R&D tax credits, deductions, and super-deductions, or allow for accelerated depreciation to incentivize companies to invest in innovative activities (see Figure 1).

Figure 1. Heatmap of R&D credits, deferrals, and deductions in the EU in 2022 (Source: OECD Innotax)[33]

	R&D Tax incentive		
	Accelerated depreciation	**Tax allowance**	**Tax credit**
Austria	No	No	Yes
Belgium	Yes	Yes	Yes
Croatia	No	Yes	No
Cyprus	No	Yes	No
Czechia	No	Yes	No
Denmark	Yes	Yes	Yes
Finland	No	Yes	No
France	Yes	No	Yes
Germany	No	No	Yes
Greece	No	Yes	No

[29] Scott E Harrington, 'Cost of Capital for Pharmaceutical, Biotechnology, and Medical Device Firms' in Patricia M Danzon and Sean Nicholson (eds), *The Oxford Handbook of the Economics of the Biopharmaceutical Industry* (1st edn, Oxford University Press 2012) 75–76.

[30] See, for instance, Paul D Reynolds, 'Start-up Actions and Outcomes: What Entrepreneurs Do to Reach Profitability' (2016) 12 Foundations and Trends in Entrepreneurship 443, 3.

[31] Irem Guceri and Li Liu, 'Effectiveness of Fiscal Incentives for R&D: Quasi-Experimental Evidence' (2019) 11 American Economic Journal: Economic Policy 266.

[32] ibid; Nick Bloom, Rachel Griffith and John Van Reenen, 'Do R&D Tax Credits Work? Evidence from a Panel of Countries 1979–1997' (2002) 85 Journal of Public Economics 1.

[33] The data used for this chart is taken from OECD INNOTAX https://stip.oecd.org/innotax/. Additionally, in 2022 Sweden, France, Belgium, Hungary, Spain and the Netherlands had also tax incentives related to payroll or social security contributions.

Hungary	No	Yes	Yes
Ireland	Yes	No	Yes
Italy	No	Yes	Yes
Lithuania	Yes	Yes	No
Poland	No	Yes	No
Portugal	No	No	Yes
Romania	No	Yes	No
Slovak Republic	No	Yes	No
Slovenia	No	Yes	No
Spain	Yes	No	Yes

The US offers a federal R&D tax credit that allows companies that incur qualified research expenditures (QREs) to develop new or improved products, manufacturing processes, or software in the United States to claim a credit based on their R&D expenditures. Although there are several methods to calculate the amount of the credit, it is typically around 20% of QREs.[34] The credit can be used also to offset payroll taxes. The Inflation Reduction Act of 2022 (P.L. 117-169) doubled the limit of the payroll tax offset for certain start-ups from USD 250,000 to USD 500,000 for taxable years beginning after December 31, 2022.[35] In order to qualify, the activities conducted must meet the criteria of the IRS's four-part test. The Section 174 Test requires that all expenditures be directly related to the business and classified as R&D costs "in the experimental or laboratory sense." These expenditures must be associated with activities aimed at eliminating uncertainty related to product development or improvement. The Discovering Technological Information Test stipulates that qualified research must be technological in nature.[36] The Business Component Test requires that any newly discovered information be used to improve or develop a new business component. Business components include inventions, formulas, products, and

[34] Internal Revenue Code § 45C - Credit for increasing research activities.
[35] See OECD INNOTAX https://stip.oecd.org/innotax/.
[36] This means the research must rely on the principles of physical or biological sciences, engineering, or computer science. Many countries in the OECD (including EU countries) have a similar stand on the qualified R&D activities. See ibid.

software. The Process of Experimentation Test mandates that during the process of experimentation, the business must identify the uncertainty that is being targeted, explore alternatives to eliminate that uncertainty, and then implement a process for evaluating the different alternatives.[37]

In addition to R&D tax credits, biotech companies that are developing drugs for the treatment of rare diseases (also known as orphan drugs) are also eligible for the orphan drug tax credit.[38] A disease is classified as rare when it affects no more than 200,000 individuals in the United States, or when developing a treatment for it is unlikely to be profitable. To encourage the development of treatments for such conditions, a tax credit is available that covers up to 25% of the expenses incurred during qualified clinical trials. This credit is specifically designed to incentivize biotech companies to invest in developing treatments that address the needs of a small segment of the population, where financial returns may otherwise be insufficient to justify the investment.

Outside of the federal tax credit, some States offer state-level or local-level tax credits, some of them within the framework of the Opportunity Zones, which are tax incentives for investments in economically distressed areas, introduced by the Tax Cuts and Jobs Act of 2017.

Notable examples of state tax credits are the State of California Research and Development Tax Credit, the Biotechnology Investment Incentive Tax Credit (BIITC),

[37] Specifically, in the biotech and life sciences industries, examples of activities that may qualify under these criteria include working on new drugs, medical devices, and drug delivery methods; researching new or improving existing gene therapy treatments; studying interactions between different drugs; conducting clinical trials to compare the efficacy of various drugs; and identifying new indications for existing drugs.

[38] Internal Revenue Code § 45C - Clinical testing expenses for certain drugs for rare diseases or conditions.

offered by the State of Maryland, and the NYC Biotechnology Tax Credit, for businesses in the biotechnology field within New York City.

The State of California Research and Development Tax Credit[39] allows companies to receive a 15% tax credit for qualified in-house research expenses made in California. To qualify for the incentive, a taxpayer's research activities must be conducted within the state and involve basic or applied scientific research. This includes original investigations aimed at advancing scientific or engineering knowledge or enhancing the function of a business component. The focus is on research that seeks to explore new scientific frontiers or improve the functionality and performance of existing technologies or processes within a business. Additionally, the California Manufacturing Exemption[40] allows certain manufacturing and biotech companies to exempt manufacturing and R&D equipment purchases from sales and use tax. To qualify, equipment or machinery purchased must be used for manufacturing at least 50% of the time. Additionally, equipment and machinery acquired for research and development purposes are also eligible. However, the total value of purchases in a calendar year cannot exceed $200 million; any amount beyond this threshold will not be eligible for the exemption. The sales tax exemption applies only to a portion of the state tax, specifically amounting to 3.9375% of the purchase price of the qualifying property.

The Maryland BIITC[41] offers an income tax credit of 33% on an eligible investment in a Qualified Maryland Biotechnology Company (QMBC), up to a maximum of

[39] State of California, Franchise Tax Board website: https://www.ftb.ca.gov/file/business/credits/california-research.html (last access, 30 August 2024).
[40] California Department of Tax and Fee Administration website: https://www.cdtfa.ca.gov/industry/manufacturing-and-research-and-development-equipment-exemption/ (last access, 30 August 2024).
[41] Maryland Department of Commerce website: https://commerce.maryland.gov/fund/programs-for-businesses/bio-tax-credit (last access, 30 August 2024).

$250,000 in tax credits. However, if the QMBC is located in Allegany, Dorchester, Garrett, or Somerset County, the credit increases to 50% of the eligible investment, with a cap of $500,000 in tax credits. To qualify as a QMBC, a biotechnology company must meet several criteria: it must have its headquarters and main operations in Maryland, employ fewer than 50 full-time employees, have been in active business for no more than 12 years, be certified as a QMBC by the Department of Commerce, and its qualified investors must not have received more than $7 million in biotechnology investment incentive tax credits.

The NYC Biotechnology Tax Credit[42] offers various benefits for companies involved in biotechnology within New York City. The credit includes 18% of costs associated with research and development property and other expenses in emerging technology activities, 9% of qualified research expenses, and 100% of high-technology training expenses, up to $4,000 per employee per year. Eligible entities can receive a credit of up to $250,000 for new or expanding firms. If the credit amount exceeds the current year's tax liability, the excess can be refunded or carried forward to the next year. For companies filing as a combined group, the credit is calculated individually and applied against the combined tax liability. To qualify, a company must be engaged in biotechnology, which involves manipulating living organisms to develop products that improve life and health, including related scientific research and services. The company must also meet one of the following conditions: maintain a research and development to net sales ratio that is equal to or greater than the average of all companies surveyed by the National Science Foundation, or have primary products or services classified as emerging technologies. Additionally, the company must employ

[42] NYC Department of Finance website: https://www.nyc.gov/site/finance/business/business-biotechnology-credit.page (last access, 30 August 2024).

no more than 100 full-time employees, with at least 75% based in New York City, and meet other financial criteria such as having a research and development to net sales ratio of at least 6%, annual product sales of no more than $10 million, and gross revenues (including affiliates and related members) of no more than $20 million in the previous year.

Other states, such as Arizona[43] and Texas[44], also offer R&D Tax Credits. Arizona incentivizes R&D activities conducted in the state, including research conducted at a state university and funded by the company, whereas Texas does it in the form of sales tax exemption or franchise tax credit for qualified businesses.

2.1.2. Intellectual Property Boxes

IP Boxes are designed as a tax reduction on the revenues obtained by the exploitation of intellectual property. Depending on the country of adoption, IP Boxes can target various kinds of IP assets, normally patents, designs and models, secret formulas and processes, know-how, software copyrights, and, in some cases, trademarks.[45] By 2014, 12 EU Member States had introduced an IP Box in their jurisdiction.[46] When introduced, they had some similarities in the way they worked, but also many divergences in their scopes and tax rates. After the publication of the OECD Action 5, which suggested some restrictions in the qualifying assets that IP Boxes had to allow, the EU witnessed some sort of harmonization, at least in the scope of its IP Boxes. For

[43] Arizona Commerce Authority website: https://www.azcommerce.com/incentives/research-development/ (last access, 30 August 2024). See also Arizona Department of Revenue website: https://azdor.gov/tax-credits/university-research-development-tax-credit (last access, 30 August 2024).
[44] Texas Comptroller of Public Accounts website: https://comptroller.texas.gov/taxes/qualified-research/ (last access, 30 August 2024).
[45] For an extensive analysis of the main IP Box regimes, see Lisa Evers, Helen Miller and Christoph Spengel, 'Intellectual Property Box Regimes: Effective Tax Rates and Tax Policy Considerations' (2015) 22 International Tax and Public Finance 502.
[46] ibid 502.

instance, the possibility of applying the tax reduction on trademarks was removed by all Member States.[47]

In its document on the modified nexus, the OECD proposed some conditions for IP Box regimes to make their use more substance-oriented and avoid harmful tax practices related to their usage.[48] Besides reducing the set of assets, Action 5 affected the way of calculating such reductions, introducing a "tracking and tracing of expenditure" obligation. The set of assets has been narrowed down to (i) patents, broadly defined; (ii) copyrighted software; (iii) in certain circumstances, and only for small and medium enterprises, other IP assets that are non-obvious, useful, and novel.[49]

Table 2 contains a list of the current IP Box regimes that are currently adopted by the Member States of the EU.

Table 2. IP Box regimes in the EU in 2024[50]

	Qualifying IP Assets			Tax Rate under Patent Box Regime	Statutory Corporate Income Tax Rate
	Patents	Software	Other		
Belgium	✓	✓		3.75%	25%
Cyprus	✓	✓	✓	2.50%	12.50%
France	✓	✓		10%	25.83%
Hungary	✓	✓		4.50%	9%
Ireland	✓	✓	✓	6.25%	12.50%
Lithuania	✓	✓		5%	15%
Luxembourg	✓	✓		4.99%	24.94%
Malta	✓	✓		1.75%	35%
Netherlands	✓	✓	✓	9%	25.80%
Poland	✓	✓		5%	19%
Portugal	✓			3.15%	21%
Slovakia	✓	✓		10.50%	21%

[47] OECD, *Action 5: Agreement on Modified Nexus Approach for IP Regimes* (OECD 2015).
[48] ibid., OECD, *Countering Harmful Tax Practices More Effectively, Taking into Account Transparency and Substance* (OECD 2014).
[49] OECD, *Action 5: Agreement on Modified Nexus Approach for IP Regimes* (n 47).
[50] See Tax Foundation's website, "Patent Box Regimes in Europe, 2024", available at https://taxfoundation.org/data/all/eu/patent-box-regimes-europe-2024/ (last access, 30 August 2024). See also the OECD website, "Harmful tax practices", available at: https://www.oecd.org/en/topics/sub-issues/harmful-tax-practices.html (last access, 30 August 2024).

Spain	✓	✓		10%	25%

Italy also had an IP Box until 2021, when it changed its regime to the so-called "New Patent Box", introduced the following year, which substantially consists of an enhanced deduction (110%) of the costs incurred in relation to the eligible intangible assets, mostly software protected by copyright, patents, legally protected models and designs, biotechnological inventions included.[51] Nonetheless, in line with some of the EU IP Boxes that have complied with the nexus, the regime limits the number of years in which R&D expenses need to be conducted before the registration of the patent or copyright, in order to be subject to tax benefit.[52] In the pharmaceutical sector, though the average time for the development of new products is 12 years.[53] This seems to limit the effectiveness of these types of measures for the industry, as relevant expenditures might be left out of the tax benefit.

According to the empirical literature that has been conducted on IP Boxes, these regimes do not seem to necessarily relate to an increase in R&D activities. [54] The idea behind the IP Boxes is that they act at the end of the innovation spectrum, when the invention has already been patented, to provide an additional benefit to the patent monopoly. Receiving a tax benefit on the patent-related revenue should, theoretically, incentivize the activities to get the patent, including R&D. This effect, as previously expressed,[55] might not necessarily appeal more than the rights deriving from the patent

[51] See Fisco Oggi, the Italian Tax Administration's journal, "Italy's new "patent box" regime: how to benefit of the super deduction", available at: https://www.fiscooggi.it/tax-pills/articolo/italys-new-patent-box-regime-how-to-benefit-of-the-super-deduction (last access, 30 August 2024).
[52] In the case of Italy's New Patent Box, the limitation is the previous 8 years. See ibid.
[53] Sinha and Vohora (n 4) 19.
[54] Annette Alstadsæter and others, 'Patent Boxes Design, Patents Location, and Local R&D' (2018) 33 Economic Policy 131; Shannon Chen and others, 'The Effect of Innovation Box Regimes on Income Shifting and Real Activity' [2019] SSRN Electronic Journal <https://www.ssrn.com/abstract=3486428> accessed 5 April 2023.
[55] Rizzo (n 25) 114.

itself, as it basically overlaps with the purpose of the patenting system. It would be interesting, nonetheless, to investigate more within the realm of pharmaceutical, medtech, and biotech companies, in light of the abovementioned issues in the patenting system in these industries.[56] In fact, the reduction of corporate income taxes specifically for socially impactful patents on some types of drugs, which generally require price limitations, might have a positive compensatory effect on the activities in these industries.

The US, on the other hand, does not have a traditional IP Box regime. However, in the Tax Cuts and Jobs Act of 2017, the US adopted several policies also to make itself a more attractive location for intellectual property. First, in line with the global trend, the US reduced its corporation tax to 21%, to be more competitive with other countries' tax rates. Additionally, it introduced a new tax on foreign income, the Global Intangible Low-Tax Income (GILTI), ensuring that companies pay a 10.5 to 13.125% rate on income from overseas. This was adopted to ensure a minimum level of taxation on IP moved outside of the US in an attempt of searching for better tax treatments. As a counterbalance to GILTI, the reform reduced the tax rate on Foreign Derived Intangible Income (FDII) to 13.125%.

GITLI and FDII are quite similar measures. GILTI uses a formulary approach to tax non-US earnings above a 10% return on assets, even when those earnings are not derived from intangibles. The assumption is that the "supernormal" returns are associated with IP or other intangibles. FDII provides a tax reduction on the income produced outside of the US, deriving from the use of US-based intangibles. It provides a special lower tax rate of 13.125%.

[56] Alstadsæter and others (n 54). The Authors conduct an empirical analysis that uses data also from the pharmaceutical sector but, despite finding an effect on the number of patents, they do not seem to find any relevant change in the levels of R&D activities.

2.1.3. Personal Income Tax Reductions for Highly Skilled Individuals

Personal income tax reductions for highly skilled individuals are tax policies aimed at attracting and retaining top talent by offering favorable tax treatment.[57] These reductions are particularly used in regions experiencing a "brain drain" or in sectors requiring advanced expertise. Such tax incentives are designed to enhance the attractiveness of working in a specific location or industry by lowering the personal income tax burden on specific profiles, usually people with advanced degrees or technical profiles, thereby making the region more competitive in the global market for talent and innovation.

Several EU countries offer personal income tax reductions or special tax regimes for highly skilled workers, which can be particularly interesting for R&D-intensive sectors. Some of these incentives are broadly targeted, applying to any foreign individual who moves to the country or repatriates, whereas others tend to be more specific in their requirements. The main ones are the regimes adopted by Italy, Portugal, Spain, The Netherlands, Austria, Sweden, Denmark, and Belgium. Some examples are analyzed *infra*.

Italy offers a significant income tax reduction for highly skilled individuals, providing a 50% reduction in taxable income, capped at € 600,000, under specific conditions. Eligible workers must not have been Italian tax residents in the three years preceding their relocation to Italy and must commit to residing in Italy for at least five years. The employment must be tied to a new job within Italy, with a different employer from the previous foreign one, and must be performed predominantly within Italy. Additionally,

[57] OECD, *Fundamental Reform of Personal Income Tax* (OECD 2006).

the workers must possess high qualifications or specializations as defined by Italian legislative decrees. For researchers and academics, the reduction is increased to 90%.

Portugal has had interesting tax regimes for individuals moving to the country. The current one, which has just been reintroduced, is meant for individuals who become tax residents after not having been residents in the country for the previous five years. The regime applies a favorable 20% tax rate on income from employment and business activities linked to higher education, scientific research, and roles within recognized technology and innovation centers, among other highly qualified professions. Additionally, it includes an exemption on foreign-sourced income, and it is applicable for ten consecutive years. However, it does not apply to those covered by the previous regimes (the so-called "non-habitual" and the "former residents" regimes).[58]

Individuals who relocate to Spain and become tax residents can choose to be taxed under the Non-Resident Income Tax (NRIT) rules rather than the standard Spanish Personal Income Tax rules. Under this regime, they are taxed at a flat rate of 24% on Spanish-source employment income up to € 600,000. To qualify, they must not have been Spanish residents during the five years prior to their move. The regime applies if the move is due to an employment contract, acquiring a position as an administrator of an entity, starting an entrepreneurial activity, or working as a highly qualified professional, especially in emerging companies or in roles involving training, research, or innovation.[59]

---

[58] See PwC Portugal's website on Personal Income Tax: https://www.pwc.pt/en/pwcinforfisco/statebudget/pit-and-social-security.html#:~:text=The%20relief%20is%20capped%20at,residents%20after%2031%20December%202023 (last access, 30 Auguts 2024).

[59] See the Spanish Tax Agency's website: https://sede.agenciatributaria.gob.es/Sede/en_gb/ayuda/manuales-videos-folletos/manuales-practicos/manual-tributacion-no-residentes/regimenes-opcionales/regimen-especial-impatriados.html (last access, 30 August 2024).

In Austria, foreign scientists and researchers relocating from abroad may qualify for significant tax benefits under the Tax Benefits for Incoming Scientists and Researchers ("Zuzugsbegünstigung") if their move serves Austria's public interest in advancing science and research. Eligibility requires the relocation to support scientific endeavors that wouldn't occur without the applicant's involvement, and the applicant must have high academic qualifications. Additionally, the applicant's primary residence must shift to Austria, and if they previously lived in Austria, a gap of 5-10 years between their departure and return is necessary.[60]

In the Netherlands, employers who hire highly skilled workers from abroad can offer them the 30% ruling, a tax benefit designed to offset the additional costs of relocating to the Netherlands. This ruling allows these employees to receive 30% of their gross salary tax-free, providing a significant financial advantage as they transition to living and working in the Netherlands.[61] A highly skilled migrant is defined as a highly trained professional who comes to work and live in the Netherlands, referring, for example, to managers or specialists, scientific researchers, physicians, and lecturers.[62] Germany's Minister of Economics, Robert Habeck, has also recently announced that the German government is considering adopting a very similar 30% tax break on foreign skilled workers moving to the Country.[63]

While the US does not have specific personal income tax reductions for R&D workers, it provides other incentives such as the H-1B visa program, which allows companies to

[60] Innsbruck University's website : https://www.uibk.ac.at/personalabteilung/wissenschaftliches_personal/zuzugsbeguenstigung.html.en (last access, 30 August 2024).

[61] See the Dutch Government's website for Entrepreneurs, https://business.gov.nl/running-your-business/staff/terms-of-employment/the-30-ruling-for-your-foreign-employees-in-the-netherlands/ (last access, 30 August 2024).

[62] See the Dutch Government's website for Entrepreneurs, https://business.gov.nl/regulation/employing-highly-skilled-migrants/ (last access, 30 August 2024).

[63] Tamsin Paternoster, Germany's proposed tax rebate for skilled foreign workers 'socially explosive', *Europe News* July 2024, available at https://www.euronews.com/my-europe/2024/07/09/germanys-proposed-tax-rebate-for-skilled-foreign-workers-socially-explosive (last access, 30 August 2024).

hire highly skilled foreign workers in specialized fields, including those related to R&D.

However, States do have some state-level regimes to attract employees. For example, California has the so-called California New Employment Credit, a 35% credit available to qualified taxpayers that can generate up to 56,000 $ over a five-year period for hiring qualified employees. To qualify, a business must be located in a Designated Geographic Area, operate in specific industries like manufacturing or technology, and show a net increase in jobs over a base year.

2.1.4. Capital Gains Tax Incentives

Another dimension of taxation that can be reduced through incentives is capital gains. A capital gains tax reduction can benefit innovative sectors, including pharmaceutical, biotech, and medtech, by encouraging investment in startups and high-risk ventures within the industry. Investors might be more likely to provide funding when they know they can retain a larger portion of their profits from successful exits, such as through stock sales or acquisitions.[64] This influx of capital can accelerate the development of new drugs and technologies, foster innovation, and enhance competitiveness.

The majority of EU countries offers favorable capital gains tax rates on the sale of shares for long-term investments. However, conditions for obtaining the so-called "participation exemption" and capital gains tax rates differ throughout EU Member States, both for individuals and corporations.[65] On the other hand, EU countries have implemented exit taxes on unrealized gains in a harmonized way, as part of the

[64] Lora Dimitrova and Sapnoti K Eswar, 'Capital Gains Tax, Venture Capital, and Innovation in Start-Ups' (2023) 27 Review of Finance 1471, 1.
[65] For a general overview, see the Tax Foundation's website, "Testimony: Capital Gains Taxation in the EU": https://taxfoundation.org/testimony/capital-gains-taxation-eu/ (last access, 30 August 2024).

transposition of the Anti-Tax Avoidance Directive (ATAD).[66] Some Member States also allow for other specific exemptions dedicated to venture capital and angel investors investing in start-up companies, sometimes affecting capital gains, but not necessarily.[67]

The US, in a similar way, provides a reduced capital gains tax rate for long-term investments, which can benefit investors in innovative companies, specifically when they make investments that are meant to pay off after some time. Furthermore, the US has a so-called Qualified Small Business Stock (QSBS) exclusion, a tax benefit under Section 1202 of the Internal Revenue Code, designed to encourage investment in startups by reducing the capital gains tax burden on eligible shareholders. When an investor sells or exchanges their qualified stock in a Qualified Small Business, they may be eligible for up to 100% exclusion of the tax on capital gains. This tax relief can mitigate the risks associated with founding, investing in, and working for startups, making it more attractive for individuals to engage in these high-risk ventures.

In the US, VC firms are generally structured as "pass-through entities," meaning the firms themselves do not pay taxes. Instead, profits are distributed to the partners, who then report these earnings on their individual tax returns. When partners sell capital assets for a profit, they typically pay federal and state taxes on the gains. These pass-through distributions represent about 50% of the total realized capital gains in the US.[68] Therefore, capital gains tax policy might be particularly significant for VC firms.

[66] Council Directive (EU) 2016/1164 of 12 July 2016 laying down rules against tax avoidance practices that directly affect the functioning of the internal market. See also Giulia Letizia, 'The Recent Restrictive ECJ Approach to Exit Tax and the ATAD Implementation' (2020) 29 EC Tax Review 33.

[67] For example, Italy offers a personal income tax reduction for investments in "innovative" start-ups and companies, which is a specific category of enterprises operating with highly skilled individuals and in innovative sectors, including healthcare.

[68] Dimitrova and Eswar (n 64) 2.

2.2. Human capital- vs capital expenditures- based incentives

In the context of encouraging innovation in industries such as pharmaceuticals, biotechnology, and medical technology, tax incentives can be split into those that focus on human capital and those that target capital expenditures. Each type of incentive plays a distinct role in encouraging different aspects of the innovation process.

It is important to make this distinction, as a balanced combination of human capital and capital expenditures is crucial for driving innovation in these industries.[69] Human capital, which includes skilled researchers, scientists, and technicians, is essential for generating new ideas, conducting research, and developing novel products. However, this expertise must be supported by substantial capital investments, particularly in R&D infrastructure, technology, and equipment.

Scholarship in the field of innovation indicates that while large firms often benefit from economies of scale and can allocate capital more efficiently across projects, the availability of highly skilled personnel is equally critical to turning these investments into successful innovations.[70] For instance, the pharmaceutical industry has seen increased R&D spending alongside growing employment in R&D roles, which are necessary to keep up with global demand and leverage new scientific discoveries into marketable products.[71] However, the success of these efforts depends not only on financial resources but also on the effective utilization of human capital to overcome the challenges associated with drug development, such as long development cycles and regulatory hurdles.

---

[69] Ute Laermann-Nguyen and Martin Backfisch, 'Innovation Crisis in the Pharmaceutical Industry? A Survey' (2021) 1 SN Business & Economics 164; Harrington (n 29); Jiayan Huang and others, 'Human Capital Mismatch and Innovation Performance in High-Technology Enterprises: An Analysis Based on the Micro-Level Perspective' (2023) 8 Journal of Innovation & Knowledge 100452.

[70] Laermann-Nguyen and Backfisch (n 68).

[71] ibid.

Therefore, boosting innovation seems to require both substantial financial investment in cutting-edge technologies and facilities, as well as the cultivation of a highly qualified workforce capable of driving scientific and technological advancements. Well-designed tax incentives, as analyzed *infra*, might constitute a useful policy tool to affect both these dimensions.

2.2.1. Human Capital-Based Incentives

Human capital-based tax incentives are designed to attract, retain, and enhance the skills of the workforce involved in R&D. These incentives recognize that the expertise, creativity, and knowledge of skilled individuals are critical drivers of innovation, particularly in high-tech and knowledge-intensive industries like pharma, biotech, and medtech. The policy objectives of adopting such incentives range from attracting and retaining highly skilled individuals, including "star scientists," to creating an environment that enhances the quality and productivity of innovative projects, knowledge spillovers, and the exchange of ideas and expertise.

An extremely important type of human capital-based tax incentive is the R&D tax credit or allowance, as in most jurisdictions it includes salaries for R&D scientists. The incentive can have a strong impact on the firm's ability to offer competitive salaries to their scientists by providing tax relief that lowers overall operational costs. This financial relief enables companies to allocate more resources toward attracting and retaining top talent.

R&D tax credits can also have an effect on attracting star scientists from outside. Indeed, by making the hiring of the highly skilled individuals less expensive through the tax credit or deduction, the salaries can accordingly be more generous and have a positive impact on the attractiveness of the company (and the country) in the global

competitive scenario. However, countries lack highly skilled individuals, an alternative policy that is adopted at times is the reduction of personal income taxation for individuals that move to the country. Highly skilled individuals and superstar scientists often embrace international mobility and seem to be quite elastic to tax rates, especially when working for multinationals.[72] As per the policy design of the reduction, the two main factors to consider are the final effective tax rate that the individuals will be subject to and the conditions to qualify for the incentive. The success of the policy, nonetheless, is also related to non-tax factors (including the stability of the country – and of these incentives –, the overall economic and social conditions) but well-designed policies might still have a positive impact on the so-called "brain gain".

Both the US and most EU countries adopt R&D tax credits, deductions, and exemptions, which include salaries of researchers and R&D scientists. As seen *supra*, personal income tax reductions are quite a popular tool in the European Union but less so in the US. Indeed, state-level policies in the US tend to incentivize employment in different ways, such as the California New Employment Credit. The empirical literature suggests that US state measures can be effective, particularly in producing cross-state migration.[73]

2.2.2. Capital Expenditures-Based Incentives

Capital expenditures-based incentives focus on the physical and financial investments required to carry out R&D activities. These incentives target the tangible and intangible assets that companies need to develop new products, processes, or

[72] Ufuk Akcigit, Salomé Baslandze and Stefanie Stantcheva, 'Taxation and the International Mobility of Inventors' (2016) 106 American Economic Review 2930, 2978.
[73] Enrico Moretti and Daniel J Wilson, 'State Incentives for Innovation, Star Scientists and Jobs: Evidence from Biotech' (2014) 79 Journal of Urban Economics 20, 26.

technologies. In industries with high upfront costs, these incentives can reduce the financial barriers to innovation. By doing so, these incentives can also have the effect of improving the accessibility to curring-edge technology, such as IT equipment, when included in the base of the incentives, and encourage long-term investments by reducing the overall cost of capital.

The most relevant capital expenditures-based incentives, especially for physical investments, are R&D tax credits, allowances, and deductions, together with accelerated depreciation. By reducing the corporate tax liability based on qualifying R&D expenses, including capital expenditures on equipment, facilities, and technology, these incentives make it more convenient for companies to purchase the necessary equipment for R&D. A similar phenomenon happens with accelerated depreciation of capital assets used in R&D, which allows companies can deduct the cost of these assets more quickly, reducing taxable income in the early years of investment and potentially improving cash flow.

As mentioned, both the US and EU countries tend to adopt these kinds of incentives. What differs in every jurisdiction is exactly what type of expenses the incentives apply to. The definition of qualified expenses tends to differ in the way it is formulated, including or excluding different types of assets, depending on their nature (for example, whether software used in the process is eligible) or use (is the asset used for the purpose of R&D or while conducting the R&D process). Some incentives overlap in their scope, such as the US Investment Tax Credit (ITC)[74] for renewable and clean energy projects, which allows a credit for some type of energy-efficient investments, which can be applied to similar capital expenditures in the biotech and medtech sectors.

[74] Internal Revenue Code § 46.

2.3. Industry-specific and general tax incentives

Tax incentives can also broadly be categorized into industry-specific incentives, tailored to particular sectors like pharmaceuticals, biotechnology, and medical technology, and general incentives, which apply across various industries. Understanding the distinction between these types of incentives can be relevant for tax policy, in particular, to identify the different potential and effectiveness of both categories and, therefore, to figure out what mix to adopt in a specific country.

Some scholars state that in order to function properly, tax incentives need to be well-targeted.[75] Targeting, however, is not easy, as tax measures can cause unexpected and sometimes undesirable distortions in the system, which are often difficult to identify.[76] Indeed, targeting does not necessarily refer to a specific sector but rather to a specific dimension that the tax system is trying to incentivize.

In a situation where the policy objective is defined but there are different ways to achieve it, governments should generally opt for the most efficient option, meaning the one that maximizes the targeted dimension, while trying to minimize the costs and the deadweight losses (inefficiencies) caused by the option.[77] For example, when the government needs to incentivize R&D, tax incentives for innovation are not the only way to achieve the objective. Before choosing to adopt tax incentives, the government should consider whether the same objective of economic growth could be reached through other kinds of non-tax or tax measures.[78] In a similar way, and as per the

[75] United Nations (n 27).
[76] *Id.* at 18–20.
[77] In the analysis of the costs of the tax incentives, this phenomenon is sometimes referred to as "resource allocation cost", meaning that the tax incentive provides an exaggerated state investment in a specific business sector. See United Nations (n 27) 15.
[78] *See* Louis Kaplow, *How Tax Complexity and Enforcement Affect the Equity and Efficiency of the Income Tax*, *in* TAX POLICY IN THE REAL WORLD 381–93 (Joel Slemrod ed., 1999), https://www.cambridge.org/core/product/identifier/9780511625909/type/book (last visited Apr. 5, 2023).

analysis conducted in this section, when the objective is to address a specific issue in a particular industry, countries can opt for extremely targeted measures, including industry-specific incentives, whereas when the objective has a broader scope, generic incentives might be a better choice, when they target the right dimension.

2.3.1. General Tax Incentives

General tax incentives are available to companies across a wide range of industries, not just those in a specific sector. They include all those incentives that target some specific stages of the innovation process in any industry. These incentives can have different impacts on various industries, as the innovation process in specific industries might be more elastic to specific incentives.[79]

Generic tax incentives are designed to meet multiple needs by offering a broad and flexible approach to economic stimulation. They might positively affect the dimension that they aim to incentivize in a wide range of industries, therefore positively contributing to the overall innovation process.[80]

In fact, general incentives for innovation tend to incentivize one specific dimension of the innovation process. For example, R&D tax credits, while not industry-specific, can have a positive impact on companies in the pharmaceutical, biotech, and medtech industries, due to their significant R&D needs. A similar logic applies to accelerated depreciation and other R&D allowances that are adopted both in the US and in EU countries. Other types of general incentives include IP Boxes, which are generally aimed at incentivizing the registration of patents from any industry, personal income tax reductions, which within the EU are designed to attract highly skilled individuals in any field, and capital gains tax reductions.

[79] See, for instance, the example of IP Boxes in Alstadsæter and others (n 54).
[80] Guceri and Liu (n 31).

2.3.2. Industry-Specific Tax Incentives

Industry-specific tax incentives are those incentives that are designed to be specifically aimed at addressing a specific need of a particular industry, in this case medical technology, biotechnology or the pharmaceutical industries. From a policy perspective, it is interesting to consider industry-specific tax incentives as an opportunity for the government to be more specific in the targeting abilities of the incentive and consequently improve its efficiency and effectiveness. In the innovation process, there are some features and needs that are common to most industries, and these are normally addressed with general tax incentives. Industry-specific tax incentives can align companies' R&D and innovation efforts with broader public health objectives, such as advancing medical technologies or developing treatments for rare diseases.

Indeed, orphan drug tax credits constitute an emblematic type of industry-specific incentive in the pharmaceutical sector. As seen *supra*, the US Orphan Drug Tax Credit provides a significant incentive for the development of treatments for rare diseases, known as orphan drugs. Companies can claim a tax credit of 25% of qualified clinical testing expenses for drugs that have been designated as orphan products by the FDA. The incentive is designed to offset the high costs associated with developing treatments for small patient populations. In the EU, Italy has a tax allowance for orphan drugs equal to 65% of expenses incurred, up to an annual maximum of 200,000 € per beneficiary, with an overall annual expenditure limit of 10 million €. Italian Law 175/2021 establishes this tax incentive for public or private entities that (i) engage in the development of therapeutic protocols for rare diseases or the production of orphan drugs, and (ii) fund research projects on rare diseases or orphan drugs carried out by

public or private research institutions. Other EU countries tend to have non-tax policies for orphan drugs.[81]

Additionally, within the framework of Opportunity Zones in the US, some states have adopted state-level and local incentives specifically addressing biotechnology companies. As mentioned *supra*, Maryland has a specific income tax credit of 33% on an eligible investment in Qualified Maryland Biotechnology Companies, which is increased in specific counties. New York City also offers various benefits within the framework of the NYC Biotechnology Tax Credit. These benefits are meant to and are generally offered together with non-tax benefits, including grants, loans, loan guarantees, technology transfers, training, and other services and venture capital opportunities, which are meant to develop the area, making it well suited for becoming a business hub in the specific field.

3. Comparing the EU and the US Regulatory Approaches

The regulatory environments of the European Union and the United States share the common goal of fostering innovation and protecting public health and seem to show several similarities. However, in some cases they seem to differ in terms of structure, philosophy, and implementation, probably reflecting broader economic, legal, and cultural contexts that influence how policies are designed.

In the EU, the regulatory framework is characterized by a diverse, though often coordinated, approach across Member States, with central institutions like the European Medicines Agency (EMA) playing a central role in coordinating and

[81] See EMA website: https://www.ema.europa.eu/en/human-regulatory-overview/orphan-designation-overview (last access, 30 August 2024).

implementing regulations.[82] This system aims to balance the diverse interests of 27 Member States while ensuring a high level of safety, efficacy, and accessibility for new products. The EU's regulatory approach often emphasizes precaution, consumer protection, and the promotion of a competitive single market.

In contrast, the US regulatory system is more centralized, with federal agencies such as the Food and Drug Administration (FDA) exerting significant authority over the approval and oversight of pharmaceuticals, medical devices, and biotechnologies.[83] The US approach is often seen as more streamlined and flexible, focused on encouraging rapid innovation and bringing new products to market. This regulatory environment is designed to balance the need for innovation with the protection of public health, often placing a higher emphasis on market-driven solutions.

However, on key issues, such as orphan drugs, the EU and the US have established a collaboration between the EMA and the FDA, providing parallel scientific advice (PSA).[84] The PSA program is designed to facilitate concurrent exchanges between EMA assessors and FDA reviewers and sponsors on scientific issues during the development of new medicinal products, including new human drugs and biologics. The program aims to enhance communication between the two regulatory agencies and sponsors early in the product's lifecycle, leading to a better understanding of

[82] EMA website: https://www.ema.europa.eu/en/homepage (last access, 30 August 2024).
[83] FDA website: https://www.fda.gov/ (last access, 30 August 2024).
[84] See on both EMA and FDA websites: "General Principles EMA-FDA Parallel Scientific Advice (Human Medicinal Products)" https://www.ema.europa.eu/system/files/documents/other/psa_general_principles_document-en.pdf or https://www.fda.gov/drugs/news-events-human-drugs/fda-ema-parallel-scientific-advice-psa-program-03162022 (last access, 30 August 2024). See also Shannon Thor and others, 'EMA-FDA Parallel Scientific Advice: Optimizing Development of Medicines in the Global Age' (2023) 57 Therapeutic Innovation & Regulatory Science 656.

regulatory decisions, streamlining product development, and reducing unnecessary testing or the use of divergent testing methodologies.[85]

This section compares the regulatory frameworks of both blocs, with a focus on tax incentives for innovation. By exploring the similarities and differences in regulatory philosophy, process, and outcomes, it is possible to gain a deeper understanding of how these two global leaders in innovation navigate the challenges and opportunities presented by rapidly evolving industries.

3.1. Macroeconomic trends

The pharmaceutical, biotechnology, and medical technology industries in the United States and the European Union have been significantly influenced by various macroeconomic trends in recent years.

In the United States, the pharmaceutical sector continues to lead globally, fueled by substantial investments in R&D and a strong pipeline of new drug approvals. The industry remains focused on innovation, particularly in personalized medicine and biotechnology. However, it faces challenges such as pricing pressures, regulatory scrutiny, and ongoing debates over drug pricing reforms.[86] The European pharmaceutical market, while being the second-largest globally, is characterized by a more fragmented regulatory environment, which can at times affect the approval process for new drugs. The EU market is increasingly oriented towards sustainability and green pharmaceuticals, driven by regulatory initiatives that encourage environmentally friendly practices.[87]

---

[85] ibid.

[86] Cristian Lieneck and others, 'Stakeholder Perspectives of the Inflation Reduction Act's (2022) Impact on Prescription Drugs: A Narrative Review' (2023) 11 Pharmacy 187.

[87] See, for instance, the Medical Device Regulation: Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC,

Despite a challenging macroeconomic environment, marked by rising interest rates and inflation, the biotechnology sector continues to innovate in areas like CRISPR gene editing, mRNA technology, cell therapies, and machine learning-enabled drug discovery.[88]

The medical technology sector has been undergoing a period of adjustment following the COVID-19 pandemic. After experiencing explosive growth in 2021, the sector saw stabilization in 2022 and 2023, with growth rates returning to pre-pandemic levels.[89] The industry faces challenges such as increasing complexity, local competition, and volume-based procurement.[90] Nevertheless, the ongoing digitalization of healthcare, including wearable technologies and the integration of generative artificial intelligence (gen-AI), mostly focused on device enablement, functionality, and R&D, with untapped opportunities in commercial, supply chain, and other business functions. presents new growth opportunities.

3.2. Evidence from pharma, biotech, and medtech firms

In recent years, both the United States and the European Union have seen significant activity in patenting and R&D investments across the pharmaceutical, biotechnology, and medical technology sectors. In 2023, more than 15,900 patent applications were filed with the European Patent Office (EPO) in the field of medical technology, representing a 1.3% growth in patent applications compared to the previous year.[91] The

---

Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

[88] McKinsey's website: "What early-stage investing reveals about biotech innovation" https://www.mckinsey.com/industries/life-sciences/our-insights/what-early-stage-investing-reveals-about-biotech-innovation (last access, 30 August 2024)

[89] McKinsey's website: "What to expect from medtech in 2024" https://www.mckinsey.com/industries/life-sciences/our-insights/what-to-expect-from-medtech-in-2024 (last access, 30 August 2024)

[90] ibid.

[91] MedTech Europe, Facts & Figures 2024, available at: https://www.medtecheurope.org/wp-content/uploads/2024/07/medtech-europe--facts-figures-2024.pdf (last access, 30 August 2024);

medical technology field accounts for 8% of the total number of applications, the second highest among all industrial sectors in Europe, after the Digital communication sector. A consistent 40% of these patent applications were filed from EPO countries (including the EU, UK, Norway, and Switzerland), 38% from the US and the remaining 22% originated from other countries.[92] The European medical technology industry employs directly more than 880,000 people.[93] Germany had the highest absolute number of people employed in the medical technology sector, with 257,000 employees, followed by Italy with 117,607 employees.[94] The number of medtech employees per capita is highest in Ireland and Switzerland. In comparison, the European pharmaceutical industry employs around 900,000 people.[95]

The level of R&D expenditure in the pharmaceutical sector has grown significantly over the last two decades.[96] The USA has consistently maintained the highest pharmaceutical R&D spending. By 2022, US expenditure reached €71.45 billion, a dramatic increase from €7.76 billion in 1990. Europe's pharmaceutical R&D spending has also seen considerable growth, rising from €6.46 billion in 1990 to €47.01 billion in 2022.[97] However, its growth rate lags behind the US, particularly over the last two decades.

Overall, while both the US and the EU are leaders in patenting and R&D investments in these sectors, the US typically shows higher levels of activity, supported by a more centralized regulatory system and greater financial resources. The EU, while highly

---

European Patent Office (EPO) "Patent Index 2023" available at: https://www.epo.org/en/about-us/statistics/patent-index-2023 (last access, 30 August 2024).

[92] ibid.

[93] ibid.

[94] ibid.

[95] ibid.

[96] European Federation of Pharmaceutical Industries and Associations – EFPIA's website: https://efpia.eu/ (last access, 30 August 2024).

[97] ibid.

innovative, must navigate a more complex regulatory and market environment, which can sometimes slow down the pace of patenting and R&D efforts.

3.3. Comparative analysis of the tax incentives

As seen throughout the analysis, the EU and the US seem to have quite similar regulatory approaches to innovation-oriented tax incentives for pharma, biotech, and medtech, though with some fundamental differences. They both adopt several types of incentives, which incentivize several stages of the innovation process, and both are oriented toward human capital and capital expenditures.

Nonetheless, the philosophy behind the adoption of the tax incentives seems to be different. The US, with its Opportunity Zones, seems to be willing to encourage the formation of innovation hubs within the country. It has become increasingly uncommon for a large production or research facility to be established in the US without some form of subsidy from the local government.[98] A growing trend in place-based policy involves states providing subsidies specifically for high-tech and life sciences firms to encourage the development of innovation-based clusters. Urban economists have long believed that industries like high-tech and life sciences benefit from significant localized agglomeration economies.[99] For instance, the biotechnology industry is highly concentrated in specific regions, with a significant portion of industry employment found in areas such as Boston/Cambridge, the San Francisco Bay area, San Diego, New Jersey, Raleigh-Durham, and the Washington, D.C. area. This geographic clustering supports the idea that strong localized agglomeration externalities are at play. Additionally, local governments are increasingly focusing on

[98] Moretti and Wilson (n 72) 21.
[99] ibid; Genevieve Giuliano, Sanggyun Kang and Quan Yuan, 'Agglomeration Economies and Evolving Urban Form' (2019) 63 The Annals of Regional Science 377.

developing self-sustaining life science research hubs. To achieve this, many have introduced targeted incentives for the biotech industry.

The EU has a different approach, shaped by the unique nature of its institutional and political structure. Member States tend to be free in the adoption of tax incentives in their direct taxes (corporate income taxes, personal income taxes, and capital gains taxes, where different from the other two), under the principle of subsidiarity contained in Article 5(3) of the Treaty of the European Union (TEU). However, Member States need to act within several limitations, which include State aid regulation (Articles 107-109 of the Treaty of Functioning of the European Union – TFEU) and peer pressure among Member States, exercised in various ways, like for instance the Code of Conduct Group on Business Taxation. Even though State aid regulation will now also apply to non-EU countries, to some extent, due to the EU Foreign Subsidies Regulation,[100] what seems to differ from the US is the philosophy behind the adoption of tax incentives for the creation of innovation hubs. While this is encouraged in the US, similar measures should be adequately justified if adopted by an EU member state and would be subject to deep scrutiny by the European Commission. Also, the EU as an institution, would probably prefer a steady improvement of all Member States, rather than encouraging the creation of specific innovation hubs. Additionally, the EU internal market is characterized by the fundamental freedoms, which prohibit discrimination between economic actors. Therefore, when a Member State adopts a tax incentive, it needs to make sure not to discriminate against other Member States' companies.

3.3.1. Main findings

[100] Amedeo Rizzo, 'The EU Foreign Subsidies Regulation: A Structural Change to the Internal Market' [2023] Transatlantic Antitrust and IPR Developments <https://www.ssrn.com/abstract=4609016>.

When it comes to tax incentives for innovation in pharma, medtech, and biotech, the US tends to incentivize innovation more at a local/state level, though incentives are provided also a the federal level.[101] By doing so, the US seems to encourage the creation of hubs, making the distribution of such industries heavily clustered.[102] In contrast, the European Union's approach to tax incentives is more varied, reflecting the diverse economic structures and policy priorities across its member states. While some EU countries offer generous R&D tax credits and deductions similar to those in the US, the overall framework is less uniform. EU countries also tend to compete with each other, creating situations where EU institutions need to intervene by limiting some actions, like what happened with IP Boxes,[103] or by removing restrictions, to allow the functioning of the internal market.

Because of its unique structure, the EU has a more complex structure and patchwork of economic and political interests. Therefore, it is hard to find a coordinated tax policy that can work in the interests of all Member States, at the same time. The economic interest of adopting an incentive is mostly in the hands of the single Member State that adopts them, which tends to retain the benefits of innovation happening in its own territory. Nevertheless, incentives need to be adopted within the framework of EU regulation, not to violate State aid legislation, fundamental freedoms, and other forms

[101] Some estimates from the Government Accountability Office in 2012 reported that in the US, state and local governments used to spend $80 billion per year on these policies while the federal government used to spend $15 billion. See Moretti and Wilson (n 72) 2.

[102] ibid 2.

[103] For an analysis of this, see Rizzo (n 25); Chu Shi, 'IP Boxes in Light of the BEPS Project and EU Law – Part II' 56 European Taxation 371; Lilian V Faulhaber, 'The Luxembourg Effect: Patent Boxes and the Limits of International Cooperation' [2017] Minnesota Law Review; Joris Luts, 'Compatibility of IP Box Regimes with EU State Aid Rules and Code of Conduct' (2014) 23 EC Tax Review 258; Ivan Zammit, 'Centralized Intellectual Property Business Model – Tax Implications of EU Patent Box Regimes' [2015] Bulletin for International Taxation 540. After the publication of the OECD nexus approach, which was proposed as a compromise between Germany and the United Kingdom, the EU witnessed some sort of harmonization, at least in the scope of its IP Boxes.

of restrictions on competition. Therefore, when it comes to incentivize a specific industry, the EU does not seem to act as a compact bloc.

Another peculiarity concerns tax policies for highly skilled individuals. In the US local incentives help attract "star scientists" from all over the world, but also from other states within the US. Indeed, some findings in the empirical literature seem to suggest that when the measures are effective enough to create some sort of displacement, it is likely to be national in scope.[104] This is also because it is easier for people to move within the US. In the EU it is fairly more difficult, probably for language-related reasons, and other socio-cultural reasons, making employees virtually less elastic to tax incentives.

Despite these differences, both regions face common challenges, such as balancing the need to incentivize innovation with concerns over public expenditure and ensuring that the benefits of these incentives are equitably distributed, especially in the healthcare sector. The US tends to be more aggressive in leveraging tax policy to drive private sector innovation, whereas the EU seems to be more cautious, balancing incentives with an overall policy equilibrium to preserve the internal market and the interests of different member states. This divergence highlights the complex interplay between tax policy, innovation, and economic strategy in global competition.

4. Conclusion

The comparative analysis of tax incentives for innovation in the pharmaceutical, biotechnology, and medical technology sectors between the EU and the US reveals some insights into the role of fiscal policy in driving R&D in these industries. The

[104] Moretti and Wilson (n 72) 26.

study discusses how well-designed tax incentives can help address the inherent challenges faced by these sectors, particularly in light of the limitations of IP rights. The high-risk, capital-intensive nature of R&D in these industries, coupled with long development timelines and stringent regulatory requirements, calls for some complementary measures that can improve the innovation process beyond traditional IP protections. In particular, R&D tax allowances, which are widely adopted both in the US and the EU, can reduce the cost of both human capital and capital expenditures associated with the innovation process. At the same time, industry-specific incentives, like orphan drug tax credits, can be effective tools for helping address issues that are typical of these industries. Additionally, tools like IP Boxes, which have been criticized for their inability to incentivize R&D, could potentially play a complementary role in specific situations, in particular when price fixing is necessary for societal reasons.

The contrasting approaches adopted by the US and the EU offer valuable lessons for policymakers. The US model, characterized by a mix of federal R&D tax credits and state-level targeted incentives, has shown significant success in promoting innovation clusters, patenting activities, and rapid growth of emerging companies. In contrast, the EU's peculiar structure does not allow for a similar approach but requires instead a two-fold strategy. On the one hand, trying to harmonize the approaches of Member States, by formulating some specific legislation and mutual objectives, though bearing in mind the different economic interests of EU countries. On the other hand, limiting competitive strategies, in order to avoid aggressive policies that could harm the internal market. While this balanced approach promotes economic stability and cohesion across Member States, it might be inadvertently limiting potential growth, especially when compared to the rapid expansion seen in certain US biotech hubs.

In the context of innovation hubs, enhancing coordination between tax incentives and other innovation policies, including grants, public-private partnerships, and regulatory fast-tracks, can also be relevant. Developing more nuanced incentives that account for the different objectives of the innovation process, from basic research to clinical trials, commercialization, and patenting, could potentially optimize the impact of these policies, though further research on this would be needed.

In conclusion, by addressing the unique challenges of the pharmaceutical, biotech, and medtech sectors, tax incentives can play an important role in complementing IP rights, acting in the various stages of the innovation process, from the mitigation of market failures to the incentivization of the obtainment of patents. Ultimately, while both the US and EU approaches have their strengths, the philosophy behind the creation of industry-specific innovation hubs, accompanying tax incentives with non-tax incentives, seems to be rather attractive.

References

Achilladelis B and Antonakis N, ‘The Dynamics of Technological Innovation: The Case of the Pharmaceutical Industry’ (2001) 30 Research Policy 535

Akcigit U and others, ‘Taxation and Innovation in the Twentieth Century’ (2021) 137 The Quarterly Journal of Economics 329

Akcigit U, Baslandze S and Stantcheva S, ‘Taxation and the International Mobility of Inventors’ (2016) 106 American Economic Review 2930

Alstadsæter A and others, ‘Patent Boxes Design, Patents Location, and Local R&D’ (2018) 33 Economic Policy 131

Andrews LB, ‘Genes and Patent Policy: Rethinking Intellectual Property Rights’ (2002) 3 Nature Reviews Genetics 803

Bently L and others, *Intellectual Property Law* (Sixth edition, Oxford University Press 2022)

Bloom N, Griffith R and Van Reenen J, ‘Do R&D Tax Credits Work? Evidence from a Panel of Countries 1979–1997’ (2002) 85 Journal of Public Economics 1

Boldrin M and Levine DK, *Against Intellectual Monopoly* (Cambridge University Press 2008)

Cameron GF, *Innovation and Economic Growth* (1996)

Chen S and others, ‘The Effect of Innovation Box Regimes on Income Shifting and Real Activity’ [2019] SSRN Electronic Journal <https://www.ssrn.com/abstract=3486428> accessed 5 April 2023

Cockburn IM and Henderson RM, ‘Scale and Scope in Drug Development: Unpacking the Advantages of Size in Pharmaceutical Research’ (2001) 20 Journal of Health Economics 1033

Cooke P, ‘New Economy Innovation Systems: Biotechnology in Europe and the USA’ (2001) 8 Industry and Innovation 267

‘Costing Drug Development’ (2003) 2 Nature Reviews Drug Discovery 247

Cunningham C, Ederer F and Ma S, ‘Killer Acquisitions’ (2021) 129 Journal of Political Economy 649

Darnihamedani P and others, ‘Taxes, Start-up Costs, and Innovative Entrepreneurship’ (2018) 51 Small Business Economics 355

Delmotte C, ‘The Case Against Tax Subsidies in Innovation Policy’ [2020] SSRN Electronic Journal <https://www.ssrn.com/abstract=3564793> accessed 12 November 2022

DiMasi JA and Grabowski HG, ‘Economics of New Oncology Drug Development’ (2007) 25 Journal of Clinical Oncology 209

DiMasi JA and Grabowski HG, ‘The Cost of Biopharmaceutical R&D: Is Biotech Different?’ (2007) 28 Managerial and Decision Economics 469

DiMasi JA, Grabowski HG and Hansen RW, ‘Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs’ (2016) 47 Journal of Health Economics 20

DiMasi JA, Hansen RW and Grabowski HG, ‘The Price of Innovation: New Estimates of Drug Development Costs’ (2003) 22 Journal of Health Economics 151

Dimitrova L and Eswar SK, ‘Capital Gains Tax, Venture Capital, and Innovation in Start-Ups’ (2023) 27 Review of Finance 1471

Dosi G and others, ‘Big Pharma and Monopoly Capitalism: A Long-Term View’ (2023) 65 Structural Change and Economic Dynamics 15

Dosi G and others, ‘Do Patents Really Foster Innovation in the Pharmaceutical Sector? Results from an Evolutionary, Agent-Based Model’ (2023) 212 Journal of Economic Behavior & Organization 564

Evans P, ‘The New Commons vs. The Second Enclosure Movement: Comments on an Emerging Agenda for Development Research’ (2005) 40 Studies in Comparative International Development 85

Evers L, Miller H and Spengel C, ‘Intellectual Property Box Regimes: Effective Tax Rates and Tax Policy Considerations’ (2015) 22 International Tax and Public Finance 502

Faulhaber LV, ‘The Luxembourg Effect: Patent Boxes and the Limits of International Cooperation’ [2017] Minnesota Law Review

Fazio C, Guzman J and Stern S, ‘The Impact of State-Level R&D Tax Credits on the Quantity and Quality of Entrepreneurship’ (National Bureau of Economic Research 2019) w26099 <http://www.nber.org/papers/w26099.pdf> accessed 15 February 2023

Forero-Pineda C, ‘The Impact of Stronger Intellectual Property Rights on Science and Technology in Developing Countries’ (2006) 35 Research Policy 808

Frank RG, ‘New Estimates of Drug Development Costs’ (2003) 22 Journal of Health Economics 325

Giuliano G, Kang S and Yuan Q, ‘Agglomeration Economies and Evolving Urban Form’ (2019) 63 The Annals of Regional Science 377

Guceri I and Liu L, 'Effectiveness of Fiscal Incentives for R&D: Quasi-Experimental Evidence' (2019) 11 American Economic Journal: Economic Policy 266

Guedj I and Scharfstein D, 'Organizational Scope and Investment: Evidence from the Drug Development Strategies and Performance of Biopharmaceutical Firms' (National Bureau of Economic Research 2004) w10933 <http://www.nber.org/papers/w10933.pdf> accessed 3 September 2024

Hall B, 'Tax Policy for Innovation' (National Bureau of Economic Research 2019) w25773 <http://www.nber.org/papers/w25773.pdf> accessed 5 April 2023

Harrington SE, 'Cost of Capital for Pharmaceutical, Biotechnology, and Medical Device Firms' in Patricia M Danzon and Sean Nicholson (eds), *The Oxford Handbook of the Economics of the Biopharmaceutical Industry* (1st edn, Oxford University Press 2012)

Haufler A, Norbäck P-J and Persson L, 'Entrepreneurial Innovations and Taxation' (2014) 113 Journal of Public Economics 13

Heller MA and Eisenberg RS, 'Can Patents Deter Innovation? The Anticommons in Biomedical Research' (1998) 280 Science 698

Huang J and others, 'Human Capital Mismatch and Innovation Performance in High-Technology Enterprises: An Analysis Based on the Micro-Level Perspective' (2023) 8 Journal of Innovation & Knowledge 100452

Huang KG and Murray FE, 'Does Patent Strategy Shape the Long-Run Supply of Public Knowledge? Evidence from Human Genetics' (2009) 52 Academy of Management Journal 1193

James S, 'Tax and Non-Tax Incentives and Investments: Evidence and Policy Implications' [2014] World Bank

Kremer M, 'Patent Buyouts: A Mechanism for Encouraging Innovation' (1998) 113 The Quarterly Journal of Economics 1137

Kremer M and Glennerster R, *Strong Medicine: Creating Incentives for Pharmaceutical Research on Neglected Diseases* (Princeton University Press 2016)

Kuhn M and others, 'Medical Innovation, Life Expectancy, and Economic Growth' [2023] SSRN Electronic Journal <https://www.ssrn.com/abstract=4491818>

Kyle MK, 'Incentives for Pharmaceutical Innovation: What's Working, What's Lacking' (2022) 84 International Journal of Industrial Organization 102850

Laermann-Nguyen U and Backfisch M, 'Innovation Crisis in the Pharmaceutical Industry? A Survey' (2021) 1 SN Business & Economics 164

Letizia G, 'The Recent Restrictive ECJ Approach to Exit Tax and the ATAD Implementation' (2020) 29 EC Tax Review 33

Levin RC and others, ‘Appropriating the Returns from Industrial Research and Development’ (1987) 1987 Brookings Papers on Economic Activity 783

Lieneck C and others, ‘Stakeholder Perspectives of the Inflation Reduction Act’s (2022) Impact on Prescription Drugs: A Narrative Review’ (2023) 11 Pharmacy 187

Luts J, ‘Compatibility of IP Box Regimes with EU State Aid Rules and Code of Conduct’ (2014) 23 EC Tax Review 258

Mazzucato M, *The Entrepreneurial State* (Demos 2011)

Möhrle JJ, ‘How Long Does It Take to Develop a New Drug?’ (2024) 43 The Lancet Regional Health - Europe 100998

Moretti E and Wilson DJ, ‘State Incentives for Innovation, Star Scientists and Jobs: Evidence from Biotech’ (2014) 79 Journal of Urban Economics 20

Murphy KM and Topel RH (eds), *Measuring the Gains from Medical Research: An Economic Approach* (Univ of Chicago Press 2003)

Murray F and Stern S, ‘Do Formal Intellectual Property Rights Hinder the Free Flow of Scientific Knowledge? An Empirical Test of the Anti-Commons Hypothesis’ (2007) 63 Journal of Economic Behaviour & Organization 648

Muzaka V, ‘The Pharmaceutical Patent System and Access to Medicines’ in Joan Costa-Font, Alberto Batinti and Gilberto Turati (eds), *Handbook on the Political Economy of Health Systems* (Edward Elgar Publishing 2023)

Nussim J and Sorek A, ‘Theorizing Tax Incentives for Innovation’ (2017) 36 Virginia Tax Review 25

OECD, *Fundamental Reform of Personal Income Tax* (OECD 2006)

OECD, *Countering Harmful Tax Practices More Effectively, Taking into Account Transparency and Substance* (OECD 2014)

OECD, *Action 5: Agreement on Modified Nexus Approach for IP Regimes* (OECD 2015)

Pitruzzella G and Muscolo G, *Competition and Patent Law in the Pharmaceutical Sector: An International Perspective* (WoltersKluwer 2016)

Rawson NSB, ‘Canadian, European and United States New Drug Approval Times Now Relatively Similar’ (2018) 96 Regulatory Toxicology and Pharmacology 121

Reynolds PD, ‘Start-up Actions and Outcomes: What Entrepreneurs Do to Reach Profitability’ (2016) 12 Foundations and Trends in Entrepreneurship 443

Rhode PW, ‘Biological Innovation without Intellectual Property Rights: Cottonseed Markets in the Antebellum American South’ (2021) 81 The Journal of Economic History 198

Rizzo A, ‘Intellectual Property and Tax Incentives: A Comparative Analysis of the EU and the US Legal Frameworks’ (2023) 43 Virginia Tax Review 291

Rizzo A, ‘The EU Foreign Subsidies Regulation: A Structural Change to the Internal Market’ [2023] Transatlantic Antitrust and IPR Developments <https://www.ssrn.com/abstract=4609016>

Roin BN, ‘Intellectual Property versus Prizes: Reframing the Debate’ (2014) 81 University of Chicago Law Review 999

Rose NL, *Economic Regulation and Its Reform: What Have We Learned?* (University of Chicago Press 2014)

Runge CF and Defrancesco E, ‘Exclusion, Inclusion, and Enclosure: Historical Commons and Modern Intellectual Property’ (2006) 34 World Development 1713

Saha C and Bhattacharya S, ‘Intellectual Property Rights: An Overview and Implications in Pharmaceutical Industry’ (2011) 2 Journal of Advanced Pharmaceutical Technology & Research 88

Shi C, ‘IP Boxes in Light of the BEPS Project and EU Law – Part II’ 56 European Taxation 371

Sinha S and Vohora D, ‘Drug Discovery and Development’, *Pharmaceutical Medicine and Translational Clinical Research* (Elsevier 2018)

Sun D and others, ‘Why 90% of Clinical Drug Development Fails and How to Improve It?’ (2022) 12 Acta Pharmaceutica Sinica B 3049

Thor S and others, ‘EMA-FDA Parallel Scientific Advice: Optimizing Development of Medicines in the Global Age’ (2023) 57 Therapeutic Innovation & Regulatory Science 656

United Nations, *Design and Assessment of Tax Incentives in Developing Countries: Selected Issues and a Country Experience* (United Nations 2018)

Walsh JP, Cohen WM and Cho C, ‘Where Excludability Matters: Material versus Intellectual Property in Academic Biomedical Research’ (2007) 36 Research Policy 1184

Zammit I, ‘Centralized Intellectual Property Business Model – Tax Implications of EU Patent Box Regimes’ [2015] Bulletin for International Taxation 540

Zolt EM, ‘Tax Incentives and Tax Base Protection Issues’ [2014] United Nations