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Public R&D and Innovation Prizes *Realistic Alternatives to the Current IP System?*[1]

Introduction and Key Points

The value of the current patent-based intellectual property (IP) system in the EU pharmaceutical sector is well established in economic literature, and generally recognised by EU institutions as supporting the development of innovative medicinal products and maintaining the attractiveness of the EU as a region in which to invest.

This literature review finds that there is no sufficiently robust basis in the academic literature or in observed outcomes in pharmaceutical R&D to support replacing the current IP-driven biopharmaceutical innovation model with innovation prizes or public R&D infrastructure.

From a high-level perspective, the literature generally distinguishes between three broad types of systems for pharmaceutical innovation: (i) exclusivity-based systems (patent-based IP systems), in which firms are rewarded through patent-protected market sales; (ii) public funding or public provision models, in which the state finances and may directly organise R&D; and (iii) reward-based or prize systems, in which innovation is incentivised through publicly funded payments or prizes that are delinked, fully or partially, from market sales. Many real-world proposals and reforms combine elements of these approaches.

Notwithstanding its recognised strengths, the current IP system has been subject to increasing criticism in recent years. There have been suggestions of market failure in the pharmaceutical sector, and allegations that industry investments are not fully aligned with the needs of society. For example, it is frequently noted that a large number of rare diseases still lack authorised treatments. Recent contributions in the literature have developed these critiques further. In particular, a growing body of work (e.g. Feldman; I-MAK; Tu) has focused on alleged practices referred to in the literature as secondary patenting, "evergreening," and patent thickets, arguing that these may, in certain cases, extend effective market exclusivity and contribute to sustained high prices.[2] At the same time, a separate strand of scholarship (e.g.

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[2] *See*, e.g., Robin Feldman, *Drugs, Money, and Secret Handshakes* (2019); Initiative for Medicines, Access & Knowledge (I-MAK), *Overpatented, Overpriced: How Excessive Pharmaceutical Patenting Is Extending Monopolies and Driving Up Drug Prices* (2022); Michael A. Carrier, *Pharmaceutical Patent Law* (2nd ed., 2021); and Scott Hemphill and Bhaven Sampat, "Evergreening, Patent Challenges, and Effective Market Life in Pharmaceuticals," *Journal of Health Economics* (2012). This strand of the literature generally argues that practices such as secondary patenting and patent thickets may extend

Kremer; Stiglitz) questions the reliance on exclusivity-based incentives more fundamentally and proposes alternative models, including prize-based mechanisms and publicly funded R&D systems that seek to delink innovation incentives from market prices.[3]

Against this background, some stakeholders argue that alternative product development models could generate better results than the current IP system and that such alternative models should be made part of EU law.

Critiques of the current IP system have proposed a range of reforms, some suggesting changes within the existing patent-based framework, while others advocate more radical changes that would partially or fully replace exclusivity-based incentives.

Based on a comprehensive review of the economic literature, this report concludes that generalised criticisms of the IP system are not well-founded, although certain targeted concerns may warrant further study. A large body of empirical work finds that intellectual property protection is associated with increased innovation activity, higher R&D investment, and improved access to financing in the pharmaceutical sector.[4]

Among the more structural proposals, this report focuses on two alternative models. First, an EU-funded public R&D infrastructure has been suggested as a policy or legislative tool to achieve new products accessible to patients. However, this proposal raises multiple legal and economic questions. While criticisms of the current system often focus on alleged market failures, the economic literature has long emphasised the risks of "government failure," including information constraints, weaker incentive structures, and inefficiencies in resource allocation.[5] The U.S. example (the National Institutes of Health, which largely carries out basic research) is not the precedent that some EU stakeholders claim it to be. Key questions remain unanswered, including basic questions on what research could be pursued with the proposed budget, how R&D would be conducted, and how far along the value chain the public infrastructure would operate, including clinical trials or even manufacturing? There are no serious comparative analyses demonstrating that public R&D could outperform market-based systems, and no impact assessments have been conducted. Even as a complementary solution, current proposals for an EU public R&D infrastructure remain abstract and not sufficiently mature to include in legislation at this stage.

Second, innovation prizes have been suggested as a policy tool to develop new products accessible to patients. However, this is an abstract proposition. Such prizes are generally awarded for ideas or prototypes, and there is no precedent of any new medicinal product brought to market in response to a prize. There is no obvious area where structural use of EU-funded innovation prizes might compare favourably to

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effective market exclusivity and sustain higher prices, and proposes reforms within the existing system, including stricter patentability standards and limits on follow-on patents.

[3] *See*, e.g., Joseph E. Stiglitz, "Economic Foundations of Intellectual Property Rights," *Duke Law Journal* (2008); Michael Kremer, "Patent Buyouts: A Mechanism for Encouraging Innovation," *Quarterly Journal of Economics* (1998); Initiative for Medicines, Access & Knowledge (I-MAK), Overpatented, Overpriced (2022); and S. Sean Tu, "Drug Reformulation and Evergreening," *Houston Law Review* (2014). This strand of the literature argues that the current patent-based system may be structurally misaligned with public health objectives and supports more fundamental reforms, including limiting exclusivity (e.g. proposals such as one patent per drug) or replacing price-based incentives with publicly funded reward mechanisms. At the same time, recent analyses question the empirical basis of some of these claims, emphasising that patents have fixed terms, that later-filed patents do not extend earlier ones, and that generic entry has remained broadly stable.

[4] *See*, e.g. Arora et al., 2008; Qian, 2007; Kyle & McGahan, 2012.

[5] *See*, e.g. Shleifer & Vishny, 1994; Vining & Boardman, 1992; World Bank, 1995.

the current system. A limited number of one-off innovation prizes funded by EU Member States could be pursued separately to generate early-stage ideas, such as proof of concept, or medical plausibility of efficacy of a new active substance. The economic literature on innovation prizes highlights both their potential and their limitations, particularly in complex, high-risk innovation settings.[6] In this context, virtually all instances of biopharmaceutical innovation fall within this category. However, the impact assessments that would be required to include innovation prizes in EU legislation have not yet been made.

We conclude that there is no serious basis to consider innovation prizes as an EU policy tool to replace or complement the IP system. An EU-funded public R&D structure could, in theory, contribute to useful basic research for a small number of products. However, the costs and risks of pursuing EU-funded applied research – meaning actual product development – should not be pursued unless and until the requirements and consequences have been properly assessed.

The present report aims to provide a basis for discussion and summarises the main economic literature.

A Law and Economics Perspective on the Current Patent-Based System

There is broad consensus in the economic literature that developing new medicinal products is risky, lengthy and costly. In particular, the overall probability of success from early-stage discovery to market approval is very low, typically around 1-2% or lower.[7] The average time for a new drug to reach the market has been estimated at least ten years.[8] The capitalised costs for a single approved medicinal product have been estimated at approximately EUR 2.4-3.0 billion.[9] This is reflected in the pharmaceutical industry's R&D spending as a share of revenue with many companies allocating around 15-20% of their revenue to R&D. The top-22 pharmaceutical companies spent on average 19.6% of their revenue on R&D in 2021.[10]

Based on economic principles, no rational actor would undertake investments of this magnitude without protection against free-riding in the form of patent protection and other IP rights. Even with such protection, each product development decision depends on several key questions, including:

- What is the cost of investment in R&D?
- What is the expected level of revenues in case of success, and for how long can revenues be generated?
- What are the probabilities of success / risks of failure?

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[6] *See*, e.g. Murray et al., 2012; Kay, 2012; Roin, 2014.

[7] *See*, e.g., DiMasi et al. (2016); Hay et al. (2014); IQVIA Institute (2025); see also Sun et al. (2022). IQVIA reports clinical success rates (i.e. from Phase I to marketing approval) typically in the range of approximately 5–12%. These figures do not capture attrition at earlier stages of development. Taking into account additional evidence on substantial preclinical attrition, the overall probability of success from early-stage discovery to approval is generally understood to be significantly lower, typically on the order of 1–2% or lower.

[8] *See* DiMasi et al. (2016), DiMasi & Wilkinson (2020) and

[9] Kalindjian et al. (2022), p. 22. Available here.

[10] *See* https://www.drugdiscoverytrends.com/top-pharma-rd-spenders-2022.

- How long does it take for a new drug to reach the commercialization stage?

The most commonly used quantitative method to answer these questions, and estimate the economic viability of an investment over time, is the risk-adjusted net present value (rNPV) approach, which estimates the value of all future cashflows while considering the risk of failure specifically with regard to the individual product.

There is a substantial body of economic evidence showing that IP rights – which form a crucial component of every single decision to develop a new medicinal product – are generally considered pro-competitive and promote knowledge diffusion.[11] This helps explain why the EU and its Member States have supported the current patent-based IP system, comprising of patents, supplementary protection certificates, regulatory data protection and orphan market exclusivity. Limited exceptions to such rights have been made to facilitate faster generic or biosimilar entry after expiry of the main IP rights.

Numerous high-quality empirical studies find that IP rights stimulate domestic technological effort and spur innovation in the country,[12] increase the propensity to invest in innovation,[13] and increase R&D expenditure in the pharmaceutical sector[14] with India being a prime example. More specifically, when India joined the TRIPS agreement in 1994, IP protection measures increased significantly. Empirical evidence suggests that stronger patent protection pursuant to India's TRIPS commitments resulted in a positive and significant increase in R&D spending in the Indian pharmaceutical industry.[15] Other studies also found that higher IP protection improves access to financing.[16]

General criticisms of the patent system do not acknowledge that patents only confer the right to exclude others from practicing the invention, but that does not mean that the patent holder has market power or even monopoly power: such power depends on the situation on the relevant market.[17] Many firms are not protected against new and superior products and against non-authorised competing products. Furthermore, many national health systems wield significant buyer power even against products perceived as the sole medicinal product in a therapeutic class.

Claims of over-investment in crowded markets appear to be based less on economic reasoning and more on a moral judgment, and we find no evidence of claims that the IP system could be considered "broken" in any way.[18]

Public R&D Structures: Overview of Evidence and Economic Literature

The current status quo of public funding in the pharma sector can be described as one where public R&D contributes to drug development narrowly through *basic* research, while the private sector is dominant in *applied* research. In that sense,

[11] Scotchmer & Green (1990), Borrell (2005), pp. 380-382; Hall & Harhoff (2012), pp. 10-11, 16-21; Lévêque & Ménière (2006), pp. 11, 35-45.

[12] *See* Panda et al. (2020)

[13] *See* Allred & Park (2007).

[14] *See* Arora et al. (2008), Kyle & McGahan (2012), Qian (2007), Cockburn et al. (2016).

[15] *See* Jagadeesh & Sasidharan (2014).

[16] *See* Ang et al. (2012).

[17] Joined cases C-241/91 P and C-242/91 P, *Radio Telefis Eireann (RTE) and Independent Television Publications Ltd (ITP) v Commission of the European Communities* [1995] EU:C:1995:98.

[18] Khan (2020), p. 69, Gould & Gruben (1996), pp. 331-346; *See* also Cockburn et al. (2016).

public and private R&D are highly complementary, as evidenced by several successful public-private collaborations.[19] However, this does not imply that *all* efforts in the context of public pharmaceutical R&D have been resounding successes and certain high-stakes failures have cost taxpayers millions of euros.

Nevertheless, certain stakeholders, including the authors of the STOA Report, have voiced dissatisfaction with the existing status quo of R&D in the European pharmaceutical sector. Their criticisms can be synthesized as (i) "taxpayer pays twice", (ii) "market failure" leading to excessive prices and Unmet Medical Needs (UMN), and (iii) a demand for a more active role for the state that emphasizes a "market-creating", rather than a "market-healing" role for states and government bodies. As a remedy for these perceived flaws of the status quo, stakeholders have proposed the creation of a "mission-oriented public infrastructure" – the "European Medicines Infrastructure" (EMI). The goal of the EMI is to be autonomously engaged in the entire pharmaceutical-product lifecycle – from basic research to manufacturing, marketing, and distributing the approved drugs. This suggests that the newly established EMI would co-exist, and, to an extent, compete, with the private sector.

Even if one were to assume the diagnosis of the status quo is correct and well-substantiated (*quod non*), there would nevertheless be several fundamental problems with arguments to establish an EMI as a "public option" in the EU pharma sector. For example, there are no studies or reports explaining *how* the establishment of EMI would overcome the alleged market failures (and do better), and whether an EMI represents the most efficient (and least intrusive) solution. Furthermore, there are no studies or reports comparing the alleged market failure of the status quo with potential "government failure" – the intended and unintended consequences in connection with market participation of state-run organizations – that may result from public R&D in the pharma sector.[20] In other words, the reports available to date address the alleged disadvantages of the status quo, but none address the very real economic and legal challenges that the EMI may entail.

Our review of the economic literature on government failure shows that an EMI would face multiple challenges. Starting with the determination of the "right" areas of engagement, it is questionable whether policymakers and public managers are able to agree on, let alone select and prioritize, the drug targets with the greatest need and/or biggest potential and the best therapeutic approach, substance, or agent, which brings with it another set of fraught choices. Next, it is well-documented in the economic literature that, compared to the private sector, government provision of goods and services is associated with higher costs and lower technical efficiency, meaning efficiency at what the organization is designed to do; in the case of EMI successful R&D, development, launch, and distribution of new drug.[21] A study by the Asian Development Bank Institute showed that state-owned enterprises (SOEs) tend to be more dependent on debt for their financial needs, are more labour intensive and have higher labour costs.[22] Turning to profitability, a study by the European Union found that SOEs tend to be less profitable than private companies, and that the gap is

[19] *See*, *e.g.*, Cleary et al. (2018), who note that more than 96% of NIH funding concerns basic research.

[20] *See* World Bank (1995) and Tullock et al. (2002).

[21] For example, public managers in charge of an EMI would effectively be insulated from important managerial disciplinary mechanisms that exist in the private sector, such as strict disclosure requirements, the market for corporate control, or the threat of bankruptcy. Coupled with weak institutional oversight and objectives that are imprecisely formulated, difficult to measure, or even conflicting, this results in reduced managerial incentives to maximize organizational performance (however defined) at the lowest cost.

[22] *See* https://www.adb.org/sites/default/files/publication/503476/adbi-wp950.pdf.

particularly big in the manufacturing sector.[23] An often cited factor contributing to the failure of public enterprises has been political interference in their operations. Governments have often used these enterprises as tools for political patronage, appointing individuals with limited managerial experience or expertise to leadership positions.[24]

The literature further confirms that public infrastructures offer weak incentives for innovation, risk-taking, and entrepreneurship. This is important for the context at issue, because the central task of the envisioned EMI would be to innovate and to constantly launch and market new drugs in a highly dynamic and complex environment. Also, public infrastructure has lower allocative efficiency compared to market solutions, thus resulting in under- or over-provision and/or investment; in the pharma sector allocative inefficiencies evidently can impair human health.[25] Another important aspect of government failure is the crowding out of private investment, leading to a partial or complete exit of private investment in certain drug spaces; lower numbers of innovative medicines may be the inevitable result. Finally, a crucial type of government failure is rent-seeking behaviour by state actors, i.e., attempts by (groups of) individuals to extract private benefits by manipulating or influencing political processes, rather than by adding social value. In the context of the envisioned EMI rent-seeking may become difficult to control: The organisation may face pressures ranging from politically biased guidance by Member States or the Commission to undue preferencing in procurement, outsourcing, pricing, or licensing.[26] This can take the form of lobbying or other activities aimed at influencing government policies or regulations to secure economic rents. This could result in wasted funds and could damage the reputation for the EMI, without achieving the results sought.

A key issue that remains insufficiently addressed by advocates of a publicly funded R&D infrastructure, is the allocation of risk. As discussed earlier, pharmaceutical R&D is characterised by extremely high failure rates, with the vast majority of projects never reaching the market. Under the current system, these risks are borne primarily by pharmaceutical companies. By contrast, a publicly funded R&D infrastructure would shift a significant share of these risks to taxpayers. It is unclear whether such a transfer of risk would be politically or economically sustainable, particularly given the scale of potential losses associated with unsuccessful R&D projects.

From the legal perspective, there has been no attempt to identify or answer the key questions, which include the following:

- How could an effective EMI be set up without falling afoul of the EU law prohibition on granting an overly wide margin of discretion to EU institutions, and the prohibition in the Financial Regulation to delegate budget implementation tasks that "involve a large measure of discretion implying political choices"?
- Where would the funds come from? How would the relevant drug targets be selected?

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[23] *See* https://economy-finance.ec.europa.eu/publications/state-owned-enterprises-eu-lessons-learnt-and-ways-forward-post-crisis-context_en, p. 58.

[24] Haile-Mariam & Mengistu (1988), Ayub (1987).

[25] *See* Vining & Boardman (1992); Goldeng et al. (2008); Barberis et al. (1996); Ehrlich et al. (1994); Vernon & Aharoni (2014).

[26] Shleifer & Vishny (1994), pp. 997.

- How far down the value chain would the EMI go?
- What degree of autonomy would the EMI have? What would be the role of the private sector, if any?
- What types of contracts would the EMI conclude, and by what procurement procedures?
- How would the EU ensure compliance with EU obligations under the WTO agreement on Subsidies and Countervailing Measures (SCM)?

In sum, the proposal of a public R&D infrastructure, at this stage, is no more than an abstract idea. Basic economic, legal and financial questions remain unanswered and challenges have not been discussed. There have been no impact assessments of any kind. The economic literature cautions against public R&D rather than supporting it, and unresolved legal issues abound. In these circumstances, the notion of public R&D infrastructure is not sufficiently mature to contemplate including in EU law.

Innovation Prizes: Overview of Evidence and Economic Literature

The concept of promoting R&D through instituting innovation prizes has been around for centuries. Certainly, there have been examples of successful prizes. Perhaps the best-known example is the Ansari X Prize, which, after 10 years of preparation, attracted a sizable number of participants to launch a reusable crewed spacecraft twice within two weeks.[27] While the literature agrees that innovation prizes can accelerate R&D activities in limited areas, they acknowledge that innovation prizes also come with significant challenges.

While the policy debate on innovation prizes has intensified in recent years, developments in the academic literature have been largely incremental, with much of the recent work building on earlier contributions. The focus has also shifted towards the design of incentive mechanisms and the interaction between prizes and other policy tools, rather than on the application of prizes in specific industries such as pharmaceuticals. Notwithstanding this shift, innovation prizes have remained active in the policy space, where they are typically considered as a complementary instrument within a broader innovation policy toolkit.[28]

Lessons learned from the most recent available literature demonstrate that (i) innovation prizes have been used only in a limited number of industries, such as the aerospace or aviation industries, and have not played an important role in the pharmaceutical industry; (ii) when used, the focus has been to promote R&D in basic research; (iii) prize competitions appear to work particularly well in combination with patents; and (iv) successful prize competitions have been limited in scope and maturity, and most (if not all) of the examples discussed in the literature have been linked to demonstrating a proof of concept, a prototype, or achieving a one-off result – and not products ready for market launch.[29]

The development of a new drug is a lengthy and risky process, comprising of a number of distinct steps ranging from the development of a new molecule to clinical trials, to production, distribution and marketing. Advocates of the introduction of innovation prizes in the EU do not explain how competition prizes could be used to

[27] Kay (2011).

[28] *See*, e.g., OECD (2024)

[29] Hemel & Ouellette (2019), Adler (2011), Ridley et al. (2006).

promote the development of new drugs (beyond, perhaps, proof of concept), and whether prize competition would overcome the alleged shortcomings of the current patent-based IP system.

One example often mentioned is the Longitude Prize 2014 that will award a team of innovators that manages to develop a prototype of a point-of-care diagnostic test that can help conserve antibiotics for future generations. However, this is a prototype of a testing process or medical device, and not a medicinal product. There are no known examples of any innovation prize for a new medicinal product brought to market, and we are not aware of any published examples of such a prize.

There are no known in-depth analyses on innovation prizes demonstrating how they could be used in the pharmaceutical sector. For instance, the literature stresses the complexity of the endeavour and the significant resources that would have to be mobilized to properly organise and execute a successful prize competition. There are no studies discussing the costs of organizing competition prizes in a systematic way and who would be responsible for funding.

Other well-known challenges mentioned in the economic literature have not been addressed by advocates of innovation prizes. Among the most important ones are: (i) prize fatigue, *i.e.*, the widespread use of prizes reduces the incentives to participate in a prize competition; (ii) duplication efforts, *i.e.*, duplication efforts are more likely to occur under prize competition than under a regular system, because several participants seek to gain the prize trying to achieve the same objective; (iii) deadweight losses, *i.e.*, it is a well-known fact that raising taxes leads to inefficiencies in the economy, other inefficiencies arise when the prize fails to reflect the social value of the potential new innovation.[30] Another potential risk of innovation prizes is that R&D undertaken for the purpose of combating a disease A, might only be useful for disease B. However, innovation prizes would not provide an incentive structure for R&D into disease B. To conclude, there is significant risk for prize competitions to fail and to cause more harm than good.[31]

From the legal and financing/budget perspective, there are several questions that remain unaddressed. It is not clear where the funds would come from. For the COVID-19 pandemic, EU institutions and Member States cooperated under high time pressure to secure funding using novel and unorthodox methods. Absent the pressure of a pandemic, it is unclear how the significant sums required to trigger substantial innovation efforts could be made available. No attempt has been made to determine how the prize would be organised; how the drug target would be selected; how access criteria could be made consistent with EU law, WTO law and Free Trade Agreements; whether patent and regulatory protections would be available; which phases of development would have to be completed; or what would happen after the grant of the prize – would the winner be obliged to go through pricing and reimbursement procedures? Last but not least, no attempt was made to discuss the impact of innovation prizes on the standard rNPV model.

Assessed from the perspective of the Commission's Better Regulation agenda, the proposal for innovation prizes, like the proposal for an EMI, would be at the very beginning of the EU policy and law-making cycle, where the appropriate first step would be to issue Calls for Evidence and public consultations before preparing a policy proposal.

[30] Roin (2014a), pp. 1053-1062; Khan (2020), pp. 427-430.

[31] Edler Paul et al. (2013), p. 12; Murray et al. (2012), pp. 1784-1786; Roin (2014), Note 31, p. 1008.

Public R&D and Innovation Prizes Do Not Constitute Serious Alternatives

As mentioned above, developing a new drug is a complex and costly process that is characterized by long development periods and substantial scientific and financial risks. One of the main issues of the proposed public infrastructure EMI is its vanishingly small budget. With a budget of EUR 6.5 billion in its most ambitious form, it would roughly be only 15% of the NIH budget, which is USD 47.7 billion per year.[32] For instance, in 2021 the R&D spending of the top-22 pharmaceutical companies was USD 127.8 billion, which is almost 20 times larger than that of the EMI under its most ambitious form.[33] The EMI could theoretically bring roughly 2.5 products per year to market. This is unlikely to make a significant contribution, given the thousands of research targets envisaged by the EMI in the fields of vaccines, infectious diseases, neurodegenerative disorders, rare diseases, cancer, and genetic disorders.

Another issue ignored by the proponents of public infrastructure is the time it takes for a new drug to reach the commercialisation phase, which is at least 10 years.[34] Hence, the EU could potentially pour up to EUR 6.5 billion annually for over a decade (EUR 65 billion) into the envisaged EMI before even having the prospect of seeing the first return on its investment in the form of even one new drug. Compared to the current patent-based system with 55 newly approved drugs by the FDA in 2023, it might take the EMI more than 25 years to match the number of new drugs that the private sector brings to the market in only one year. [35]

The proposed innovation prize system seems equally unsuited to reach the proposed political objectives. *First*, competition prizes tend to work best when they are limited in time and scope. In contrast, the development of a new drug takes at least a decade and faces multiple challenges and risks along the way.[36] *Second*, the monetary award of an innovation prize directed at developing and bringing a new drug to market would have to be sufficiently high. Under current market conditions, the monetary award for such a prize competition would have to be orders of magnitude higher than the highest known prize – the *Ansari X* Prize, which was USD 10 million.[37]

A final point seems in order here: Any official EU proposals in favour of a policy change, be they in favour of the EMI or innovation prizes, must perform and pass an apples-to-apples comparison to the status quo, in this case against market-based development supported by a patent-protected IP system. In other words, any proposal needs to make transparent the trade-off between the (dis-)advantages of the status quo and those in connection with the proposed policy change; moreover, any option must be benchmarked against the *same* value criteria. The current proposals for the EMI, as well as the increased use of innovation prizes, are biased in that they discuss advantages only, and are vague on fundamental methodological and practical details. The results of the proposed EMI and innovation prizes risk being underwhelming, both in terms of output and delivery timelines. Lest the objective of the two proposed systems is simply gesture politics, the Commission will have to put a lot more thought and argument into EMI and innovation prizes, especially seeing

[32] *See* https://www.nih.gov/about-nih/what-we-do/budget.

[33] *See* https://www.drugdiscoverytrends.com/top-pharma-rd-spenders-2022.

[34] Lyng et al. (2016).

[35] *See* https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/novel-drug-approvals-2023.

[36] DiMasi et al. (2016), p. 21; *See* DiMasi & Wilkinson (2020), pp. 1453, 1458.

[37] Kay (2012).

that it proposes to (partially) compete with the current market-based patent system, which has a proven track record of success. As noted, in terms of the Commission's own Better Regulation Agenda, we would be at the very start of development of a new policy proposal.

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