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THE WORLD-WIDE RETREAT ON PATENT PROTECTION OF BAYH-DOLE MARCH-IN RIGHTS AND EU TAKEOVERS OF LICENSING BY GOVERNMENT DECREE

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ABSTRACT

For many years, patent law as it developed in the United States, Great Britain and Europe started from the central proposition that the party who held the exclusive right to an patented technology need only obey the standard rules that govern all other forms of property, namely that it could set unilaterally the price and other terms of sale or license as it pleased, where the effective limitations on its behavior came from the presence or prospect of other distinct products in the same class to keep that price down. But in recent years, disturbing developments in all these jurisdictions have threatened this model by insisting that some supposed forms of market imperfections justify the intervention of state actors to set prices in order to stop these deviations. Within the American system, the late Biden administration put forward the strong claim that government actors had strong rights to "march in" to counter soaring rates in certain designated products. In Europe, the Commissioner for the Internal Market likewise called for a total revision of the European Union's basic rules of engagement over both Standard Essential Patents ("SEPs") and the Compulsory Licensing, even though its expertise lies with trademarks.

Neither scheme will withstand scrutiny. Rate regulation is difficult enough to execute in monopoly markets, but it is utterly counterproductive and confiscatory in competitive ones. The inability of government agents to decide which products should be regulated and why suffers from two fatal vices. No board has the knowledge to set the right prices. And every such scheme imposes whose high costs and delay with new products, raise administrative costs, and lead to institutional favoritism and political intrigue. The case for overturning well-established principles of patent ownership and licensing has not been made, so that these twin initiatives should be roundly rejected to

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avoid having needless stagnation and corruption take over the market for patented products.

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I. PATENT UNEASE

Today there is much public anxiety about the scope of legal protection for patents, out of the fear that such rights create improvident legal monopolies that will necessarily distort the market for goods and services. That power, the argument goes, should be allowed only on a showing of some strong public justification. The Federal Trade Commission ("FTC") has embarked on a near-sacred mission to counter what it regards as soaring prices for the United States relative to those in other countries — without first asking whether these U.S. prices are too high or whether prices elsewhere, including the EU, are too low.[1]

In the former Biden administration, the FTC's aggressive mood in the patent space tracks similar attitudes of both the Department of Justice ("DOJ") and the FTC on mergers, which they fear are devices to extract higher prices from lower outputs.[2] Similarly, in the

1. For the latest entry FTC Comments on march-in rights, see FTC, COMMENT ON DRAFT INTERAGENCY GUIDANCE FRAMEWORK FOR CONSIDERING THE EXERCISE OF MARCH-IN RIGHTS, NAT'L INST. STANDARDS & TECH. (Feb. 6, 2024), https://www.ftc.gov/system/files/ftc_gov/pdf/2024.02.06March-InRightsComment.pdf [https://perma.cc/7V2K-C2VQ] [hereinafter FTC Comment]. For the case against price controls outside the United States, see Trelysa Long, *The Hidden Toll of Drug Price Controls: Fewer New Treatments and Higher Medical Costs for the World*, INFO. TECH. & INNOVATION FOUND. (July 2023), https://www2.itif.org/2023-drug-free-riders.pdf [https://perma.cc/U72K-UYNC] ("When nations implement pharmaceutical price controls, they reduce pharmaceutical revenues, which then reduces investments in further R&D, limiting future generations' access to new novel treatments needed to fight diseases such as cancer, Alzheimer's, heart disease, and diabetes.").

2. *See* ANTITRUST DIV., U.S. DEP'T OF JUST. & FED. TRADE COMM'N, 2023 DRAFT MERGER GUIDELINES (Dec. 18, 2023),

intellectual property ("IP") space, the parallel concern with monopoly excesses stems in part from a confusion between monopoly power on the one side, and the exclusive right to develop a patented product that is in direct competition with other patents that occupy the same general space on the other side.[3] On this assumption, the modern case law has tended to weaken property rights. Some notable entries in the field include *eBay Inc. v. MercExchange, L.L.C.*,[4] which constrains the availability of injunctive relief; *KSR International Co. v. Teleflex Inc.*,[5] which loosens the standard for obviousness by rejecting the "teaching-suggestion-motivation" test; *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*,[6] which narrows patent protection for medical tests; and *Alice Corp. v. CLS Bank International*,[7] which limits the scope of business method patents.

Against this backdrop, the Biden administration has sought to require the pharmaceutical companies to share their patented technologies for various vaccines with underserved foreign nations,[8] without authorizing compensation to the patent holders. More recently, the Biden administration has pointed to the dangers of monopoly power to expand the number of occasions on which the federal government can exercise "march-in" rights under the 1980 Bayh-Dole Act,[9] which has never been done even once in the last forty-four years.[10] At this point, it is unclear about the extent that the incoming Trump administration will take on this issues, an important problem that will have to await further developments.

The Biden administration's move toward greater government control of private sector innovation has its European parallel, which is unchanged by what is happening in the United States. The European Union now expresses its view about the monopoly risk by seeking to

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https://www.ftc.gov/system/files/ftc_gov/pdf/2023_merger_guidelines_final_12.18.2023.pdf [https://perma.cc/W7B8-6C8L]. I raised initial concerns about this general position in Richard A. Epstein, *Comments on the FTC and DOJ Request for Information with Proposals to Strengthen Enforcement Against Illegal Mergers* (Apr. 21, 2022), https://www.regulations.gov/comment/FTC-2022-0003-0828 [https://perma.cc/UJ8X-UFJ9]. I then updated these concerns in Richard A. Epstein, *The DOJ and FTC's Misguided Attack on Mergers*, 49 J. CORP. L. 275 (2024).

3. For my discussion, see Richard A. Epstein, *Patent Originalism*, 71 CASE W. RES. L. REV. 699, 705–07 (2020).

4. 547 U.S. 388 (2006).

5. 550 U.S. 398 (2007).

6. 566 U.S. 66 (2012).

7. 573 U.S. 208 (2014).

8. *See* Andrea Shalal, Jeff Mason & Davis Lawder, *U.S. Reverses Stance, Backs Giving Poorer Countries Access to COVID Vaccine Patents*, REUTERS (May 5, 2021, 3:10 PM EDT), https://www.reuters.com/business/healthcare-pharmaceuticals/biden-says-plans-back-wto-waiver-vaccines-2021-05-05/ [https://perma.cc/5TT6-YTP7].

9. Bayh-Dole Act, 35 U.S.C. §§ 200–12 (1980).

10. EMILY G. BLEVINS, MARCH-IN RIGHTS UNDER THE BAYH-DOLE ACT: DRAFT GUIDANCE (2024), https://crsreports.congress.gov/product/pdf/IF/IF12582 [https://perma.cc/3LCL-76X4].

impose what amounts to a general system of price controls, also to counteract the perceived dangers of monopoly power. But in both markets, the proposed remedies are destructive, counterproductive, and disproportionate responses to minor risks of these long settled administrative practices.

This Article will discuss in sequence these two assaults on IP rights in two different jurisdictions, in the hope that both of these regulatory initiatives can be stopped before any real harm is caused.

II. MARCH-IN RIGHTS UNDER BAYH-DOLE

A. Background and Origins

The enforcement of patent protection in the U.S. has alternated between periods of strong and weak protection. Thus, the 1940s were a period in which the United States Supreme Court, under the leadership of Justice William O. Douglas, favored weak patent rights.[11] In response, patent protections were strengthened by the Patent Act of 1952,[12] after which a group of Supreme Court decisions in the 1960s and 1970s once again weakened protection.[13] But 1980 marked a sharp reversal of fortune, first with the notable decision in *Diamond v. Chakrabarty*,[14] which held that "Congress intended statutory subject matter to 'include anything under the sun that is made by man.'"[15] In the same year, Congress passed Bayh-Dole, whose primary purpose was moving patented technologies more rapidly from the laboratory bench to commercial markets.[16] This bipartisan patent law was widely recognized as one of the great legislative achievements of the half-century.[17] Bayh-Dole has given a massive boost to innovation and

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11. *See Cuno Eng'g Corp. v. Automatic Devices Corp*., 314 U.S. 84, 91 (1941) (requiring a "flash of creative genius" for patent protections); *see also* Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127 (1948) (rejecting biotechnology company's patent claim of bacteria strain for lack of invention). For the decisive counterattack, see Giles S. Rich, *The Relation Between Patent Practices and the Anti-Monopoly Laws*, 24 J. PAT. OFF. SOC'Y 85 (1942). Part II of Rich's series of articles begins *id.* at 159; Part III, *id.* at 241; Part IV, *id.* at 328; and Part V, *id.* at 422.

12. Patent Act of 1952, 35 U.S.C. §§ 1–371.

13. *See, e.g.*, Parker v. Flook, 437 U.S. 584 (1978).

14. 447 U.S. 303 (1980).

15. *Id.* at 309.

16. For my favorable account, see RICHARD A. EPSTEIN, OVERDOSE: HOW EXCESSIVE GOVERNMENT REGULATION STIFLES PHARMACEUTICAL INNOVATION, ch. 5 (2006).

17. *Innovation's Golden Goose*, THE ECONOMIST (Dec. 14, 2002), https://www.economist.com/technology-quarterly/2002/12/14/innovations-golden-goose [https://perma.cc/78PZ-R8FH]. For an exhaustive account of the successes of Bayh-Dole in improving the international competitiveness of American innovation, see Gabrielle A. Athanasia, *The Legacy of Bayh-Dole's Success on U.S. Global Competitiveness Today*, CTR. FOR STRATEGIC & INT'L STUD. (Jan. 12, 2022), https://www.csis.org/blogs/perspectives-innovation/legacy-

economic growth by incentivizing professors, researchers, and universities to commercialize their new inventions. It does so, paradoxically, by removing their commercialization from public control by the federal government. It funds basic research, but not the elaborate processes needed to turn these basic ideas into patentable products, all of which rest heavily on private investment.[18]

In the face of these conspicuous successes, the Biden administration has recently announced novel plans (already backed by the FTC) to use this venerable law to impose a general system of government price controls over any inventions funded, in whole or in part, by federal research grants.[19] The path for this control comes not from new legislation but from extensive new regulations that originated in the executive branch.[20] This announcement was accompanied by stern warnings from the President himself, who touted the program as a way to control "Big Pharma price gouging,"[21] while his White House National Economic Advisor, Lael Brainard, stated, "We'll make it clear that when drug companies won't sell taxpayer funded drugs at reasonable prices, we will be prepared to allow other companies to provide those drugs for less."[22]

Brainard's program is tantamount to using Bayh-Dole to convert the pharmaceutical industry into a regulated public utility, even in the absence of any demonstrated monopoly power. That new program is backed by the threat to confiscate a drug patent if the firm does not comply with the government dictate. But why now? The government acknowledges, "To date, no agency has exercised its right to march-in,"

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bayh-doles-success-us-global-competitiveness-today [https://perma.cc/8LDB-JGC4]. *See also* Arvin Patel, *Both Sides Agree: Undermining Bayh-Dole Will Have Tragic Consequences for Innovation*, IP WATCHDOG (May 7, 2024, 7:15 AM), https://ipwatchdog.com/2024/05/07/sides-agree-undermining-bayh-dole-will-tragic-consequences-innovation/id=176207/ [https://perma.cc/SN39-8URG].

18. *See Who Develops Medicines? An Analysis of NIH Grants*, VITALTRANSFORMATION, https://vitaltransformation.com/2021/05/who-develops-medicines-an-analysis-of-nih-grants/ [https://perma.cc/FX4U-AGWL] (noting that, for 18 approved medicines, the private sector contributed $44.2 billion in total investment, relative to $670 million from NIH funding).

19. Jamie Bennet, *NIST Opens Public Comment for Draft Guidance on March-in Rights to Federally Funded R&D; Gina Raimondo Quoted*, EXECUTIVEGOV (Dec. 8, 2023), https://executivegov.com/2023/12/nist-seeks-comment-on-draft-guidance-on-march-in-rights-to-federally-funded-randd/ [https://perma.cc/EUC6-AY53]. NIST stands for National Institute of Standards and Technology.

20. Request for Information Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights, 88 Fed. Reg. 85593 (Dec. 8, 2023), [hereinafter NIST Proposed Regulation on March-In Rights].

21. David Dayen, *On Drug Prices, Biden Opts for Talk Over Action*, THE AMERICAN PROSPECT (Dec. 8, 2023), https://prospect.org/health/2023-12-08-biden-drug-prices-march-in-rights/ [https://perma.cc/6P8T-HQ6D].

22. Sydney Lupkin, *White House Proposes to 'March In' on Patents for Costly Drugs*, NPR (Dec. 7, 2023, 1:54 PM ET), https://www.npr.org/sections/health-shots/2023/12/07/1217882958/white-house-proposes-to-march-in-on-patents-for-costly-drugs [https://perma.cc/ZA5U-R4AM].

which allows the government to take control of patents, and grant, where necessary, compulsory licenses to third parties.[23] It should, therefore be incumbent on both the White House and the FTC to explain what pressing change in the business or legal environment requires the complete reversal of a stable patent policy since 1980. Are there any real or threatened breakdowns in the patent licensing system that require prompt attention? I know of no official response.

But there are negative consequences. If successful, the proposal will kill this golden goose of innovation. Before 1980, innumerable inventions developed with upstream federal research funding were owned by the government, which had no tools for development. Too often these technologies sat on the shelf unused because federal policy allowed the government to issue only *nonexclusive* licenses to all comers.[24] The inability of any inventor to claim exclusive control over development rights chilled innovation because no firm knew how many of its direct competitors were actively developing the exact same technology.[25] In the absence of that information, no firm could make any reliable estimates of its anticipated revenue stream. The removal of this uncertainty made the financial projections more manageable, spurring research efforts. Of course, some residual risk necessarily remains, given that other inventions sold in the same space could still be produced — thereby creating a wide array of new drugs with partially overlapping uses. That is why there exists a suite of statins on the market used to control the bad side effects of cholesterol: Lipitor, Lesco XL, Altoprev, Crestor, and Zocor, each of which has, or will have generic competitors.[26]

Yet this phenomenon is the sign of a vigorous competitive market that Bayh-Dole helped create, which is desirable in every product area with or without federal funding. Firms must, and can, deal with that risk when calibrating the direction and focus of their investments.

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23. NIST Proposed Regulation on March-In Rights, *supra* note 20, at 85596. Note the relative ratio of public ($670 *million*) to private investment ($442 *billion*). *Who Develops Medicines? An Analysis of NIH Grants*, *supra* note 18. Public contributions account for about 1.5 percent of investments.

24. Senator Bob Dole put it as follows:

> A wealth of scientific talent at American colleges and universities — talent responsible for the development of numerous innovative scientific breakthroughs each year — is going to waste as a result of bureaucratic red tape and illogical government regulations. The problem, very simply, is the present policy followed by most government agencies of retaining patent rights to inventions.

Athanasia, *supra* note 17.

25. EPSTEIN, *supra* note 16, at 42.

26. For a measure of the full range of options, see Carmen Pope, *Medications for High Cholesterol*, DRUGS.COM (Feb. 19, 2024), https://www.drugs.com/condition/hyperlipidemia.html [https://perma.cc/KHC7-M7JT]. Sites like this allow for easier price comparisons.

Arming licensees with the ability to purchase exclusive intellectual property rights drives venture capital investments in startups. These new inventions could then be shared through a set of licenses linked to global supply chains driven by entrepreneurial activities. These downstream licenses may be on exclusive or nonexclusive terms, which may themselves give rise to substantive disputes in other agreements. But in general, it appears that firms are adept at avoiding impasses that leave everyone worse off.[27] These industry agreements may impose reciprocal obligations on the licensor and licensee that could include various cooperative activities to improve the performance of the licensed patented technology for the benefit of both parties, including data sharing agreements that allow better understanding of mishaps in drug application.[28] Similar arrangements cannot be negotiated by government bureaucrats who will never have the localized knowledge held by commercially active parties, and who may not be able to keep this information confidential, so that it would be unwise to create any system in which any set of government officials takes over the task of commercialization, a specialized skill not available in government laboratories which are devoted to basic research.[29]

The hard question is what the government can do to launch and sustain this virtuous cycle of innovation. The system used by Bayh-Dole recognized that no inventor or university was duty-bound to exploit any given invention. It is commonplace that many patentable inventions are not commercially viable, so Bayh-Dole would fail if some required duty toward commercialization were mandated by government decree.[30] No government examiner could determine the optimal level of investment at the outset, who should run the show, or why and when the project should be shut down going forward. To make these fundamental business decisions, Bayh-Dole developed the alternative approach that gives *options* first to the sponsoring university, which could then decide whether it would commercialize the invention through its own "tech transfer" office, or pass on rights to the invention to individual firms in which they held either an equity

27. Richard A. Epstein, F. Scott Kieff & Daniel Spulber, *The FTC, IP and SSOS: Government Hold-Up Replacement Private Coordination*, 8 J. COMPETITION L. & ECON. 1 (2012).

28. *See, e.g.*, LICENSE AGREEMENT BETWEEN CYDEX PHARMACEUTICALS, INC. AND METPHARMA, INC. (2012), https://www.sec.gov/Archives/edgar/data/1262104/000119312512465326/d408096dex101.htm [https://perma.cc/XD4Z-KGGE] (including cl. 6, dealing with developing and commercialization by company, with subclause 6(2)(c) dealing with adverse events).

29. *See Who Develops Medicines? An Analysis of NIH Grants*, *supra* note 18.

30. *See* EPSTEIN, *supra* note 16, at 35–42.

stake, a management position, or both.[31] Private decisions are thus focused on making sure that the most promising inventions no longer languish on the shelf. Thus, after and on account of Bayh-Dole, innovation hubs have sprung up all over the United States, where all the money for these new programs is privately funded,[32] with zero cost to the federal government for the downstream commercialization — which is a gain, not a loss, for the government.

The rest is history, as they say. There's been an explosion in new products and services, from Allegra to the Honeycrisp apples to HD TVs to the Google search algorithm, driven in part by basic work done within the Bayh-Dole framework.[33] Studies show that between 1997 and 2017, university licensing of Bayh-Dole patents has led to more than 13,000 startups, almost one-half million new inventions publicly disclosed through patents, 5.9 million new jobs, and $1.7 trillion added to the GDP.[34] There is no reason to think that this durable industrial structure cannot continue to work well into the indefinite future.

Enter the Biden administration, which twists a minor provision of the Bayh-Dole Act — known as the statutory "march-in" power — to justify its comprehensive price-control plan. What is to be done if a patent owner or a licensed manufacturer is not making and selling the patented invention? Bayh-Dole answered this query textually by authorizing the funding agency to "march-in" in rare cases and issue nonexclusive licenses to other companies to achieve commercialization of the invention in the market. But this has never happened, especially for drugs that are now actively sold. Nonetheless, the Biden administration wants to authorize agencies to issue licenses to rival companies for the sole purpose of selling the patented invention at a lower price, thereby undercutting the patent owner (or its licensed

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31. For an early positive assessment of the effectiveness of these offices, see Donald S. Siegel, David Waldman & Albert Link, *Assessing the Impact of Organizational Practices on the Relative Productivity of University Technology Transfer Offices: An Exploratory Study*, 32 RSCH. POL'Y 27 (2003).

32. *See* Stephen Ezell, *Information Technology & Innovation The Bayh-Dole Act's Vital Importance to the U.S. Life-Sciences Innovation System* INFO. TECH. & INNOVATION FOUND. (Mar. 4, 2019), https://itif.org/publications/2019/03/04/bayh-dole-acts-vital-importance-us-life-sciences-innovation-system/ [https://perma.cc/ERF5-XRRG] ("[E]ffective technology transfer and commercialization policies that enable federally funded basic life-sciences research, often taking place at U.S. universities, to lead to research discoveries and inventions that can be patented and licensed to private-sector entities, which then undertake the risky, complex, and expensive process of bringing innovative new medicines and therapies to market.").

33. John Lovett, *Honeycrisp Apples and Drug Prices: A Background on Changes to the Framework of the Bayh-Dole Act's March-In Provisions*, PINKSTON (May 29, 2024), https://pinkston.co/blog/framework-bayh-dole-acts-march-in-provisions [https://perma.cc/7BA6-GVFQ].

34. *See supra* notes 16–18 and accompanying text; *see also Driving the Innovation Economy: Academic Technology Transfer in Numbers*, ASS'N UNIV. TECH. MANAGERS, https://autm.net/AUTM/media/Surveys-Tools/Documents/AUTM_FY2018_Infographic.pdf [https://perma.cc/4E6M-C2DH].

company) in the marketplace. This proposal contains no provision for compensating the patent owner for any loss of revenue, present or future, from the government's interventions.[35] But even if it did, the practice of selective intervention would still distort product markets. Indeed, the proposal offers no analysis of the impact — with or without compensation — that lowering the cost of one patented invention in any given market niche will have on other firms that now face one (or more) subsidized competitor selling goods at below-market prices.[36]

Given the huge risk of market distortions, it is fair to ask: Is there any evidence that Bayh-Dole patented inventions today are sold at too high prices? The go-to example is prescription drugs. This claim, recently restated by the FTC, runs as follows: "the federal government has never exercised march-in rights — despite the high price of taxpayer-funded inventions like prescription drugs and despite Congress's express intention that patents obtained under the Bayh-Dole Act be used in a manner that promotes competition . . . ."[37] But the claim that prices are too high is unsubstantiated. In addition to the extensive costs imposed by massive government controls on healthcare, such as ObamaCare and state and federal regulations on insurance, it costs drug innovators on average $2.6 billion[38] and takes 10–15 years[39] of research and development before any new drug is approved by the Food & Drug Administration ("FDA") for use by patients. The National Institutes of Health grants $30 billion annually in research funding, but this figure pales in comparison to the $139 billion invested annually by private biopharmaceutical companies.[40] Thus, when Lael Brainard talks about "taxpayer funded drugs," she means those funded *in part* by taxpayers. Even with Bayh-Dole's support, drug development is high-risk, with only about 14% of drugs making it through the long R&D process to FDA clinical trials to be approved for use by patients.[41] And even then, there is no guarantee that patients and physicians will use that drug.

Indeed, former President Biden was mistaken when he claimed that twenty-five companies, which control some 70% of the

35. NIST Proposed Regulation on March-In Rights, *supra* note 20.

36. For the complexities of this selective intervention, see EPSTEIN, *supra* note 16.

37. FTC Comment, *supra* note 1, at 2.

38. Joseph A. DiMasi, Henry G. Grabowski & Ronald W. Hansen, *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. HEALTH ECON. 20 (2016).

39. Maxime Derep, *What's the Average Time to Bring a Drug to Market in 2022?*, N-SIDE (Nov. 5, 2022), https://lifesciences.n-side.com/blog/what-is-the-average-time-to-bring-a-drug-to-market-in-2022 [https://perma.cc/WLD2-VJBK].

40. *U.S. Investments in Medical and Health Research and Development: 2013–2018*, RSCH. AM. (2019), https://www.researchamerica.org/wp-content/uploads/2022/09/InvestmentReport2019_Fnl.pdf [https://perma.cc/NYM6-ZLHG].

41. Conor Hale, *New MIT Study Puts Clinical Research Success Rate at 14 Percent*, CENTERWATCH (Feb. 5, 2018), https://www.centerwatch.com/articles/12702-new-mit-study-puts-clinical-research-success-rate-at-14-percent [https://perma.cc/FPT3-5B6A].

biopharmaceutical sector, constitute a monopoly that is driving up prices.[42] Under the standard Herfindahl-Hirschman index ("HHI"), the current concentration level is strong evidence of a competitive market, even without accounting for new entrants that could still drive that index even lower.[43] Branded products often compete with each other and with other drugs in the same space — e.g., statins — that have gone generic.

Notwithstanding these daunting challenges, the U.S. biopharmaceutical industry remains the most innovative in the world. The biotech revolution occurred in the United States, not in Europe or Asia.[44] To this day, more than fifty percent of all new drugs are invented in America.[45] And why? Because of the positive incentive effects of the reliable and effective patent rights secured to inventors, including inventors working in universities receiving some public funding. This economic miracle is driven in part by Bayh-Dole.

B. Unreasonable Regulation under Bayh-Dole

Against this backdrop, just how would this supposed system of rate regulation take place? The Biden administration notes that its objective is to create reasonable prices, which is, of course, in line with the traditional regulatory canon of a system of rate regulation.[46] But note a key difference: The traditional system of regulation deals with industries that were generally regarded as "natural monopolies," that is, those firms whose cost of production reduces over the relevant interval as output expands, which is a common occurrence in such network industries as common carriers (e.g., railroads) and public utilities (e.g., power and light).[47]

Given this constraint and the attendant economies of scale, a higher output can be obtained by a single firm than could be achieved by multiple firms. However, the reliance on a single firm creates the risk of monopoly power, which may call for rate of return regulation in

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42. President Biden (@POTUS), X (FORMERLY KNOWN AS TWITTER) (Dec. 7, 2023, 8:50 AM), https://x.com/POTUS/status/1732759511629173221?t=zRuVQsEVEaiwH_cpf81jRA&s=19 [https://perma.cc/43Y7-FNUJ].

43. Michael Bromberg, *Herfindahl–Hirschman Index (HHI): Definition, Formula, and Example*, INVESTOPEDIA (June 12, 2024), https://www.investopedia.com/terms/h/hhi.asp [https://perma.cc/99H7-CFJ8] ("A market with an HHI of less than 1,500 is considered a competitive marketplace, an HHI of 1,500 to 2,500 is moderately concentrated, and an HHI of 2,500 or greater is highly concentrated.").

44. Kevin Madigan & Adam Mossoff, *Turning Gold to Lead: How Patent Eligibility Doctrine Is Undermining U.S. Leadership in Innovation*, 24 GEO. MASON L. REV. 939 (2019).

45. Yali Friedman, *Where Are Drugs Invented, and Why Does It Matter?*, 8 AM. CHEM. SOC'Y: MED. CHEMISTRY LETTERS 589, 589 (2017) (noting American dominance followed by Europe, with scraps left for everyone else).

46. The variations are summarized in *Duquesne Light Co. v. Barasch*, 488 U.S. 299 (1989).

47. Richard A. Posner, *Natural Monopoly and Its Regulation*, 21 STAN. L. REV. 548 (1968).

some, but not all, markets.[48] Thus, with stable industries like railroads and public utilities, the point of regulation is to split the difference between these two extremes. No rate regulation allows the firm to charge monopoly prices so long as it holds on to that enviable position. But rate regulation is not only costly; it also runs the risk of setting rates so low as to confiscate the capital that the firm invested to create the needed infrastructure. Hence, constitutional rules since the 1890s have long been deployed to guard against these confiscatory rates.[49] No firm already in the market will exit if, going forward, it receives sufficient funds to cover its variable costs plus a bit of its front-end fixed costs. But neither will any new firm enter the industry if it knows that confiscatory rates will not allow it to recover those fixed costs over the lifetime of the product. This necessitates some constitutional control on the rates that any state or federal regulator can impose.

But just how is this done? Here, there are two relevant variables. The first determines what expenditures goes into the rate base — i.e., the investments from the firm that are entitled to a return. The second is the risk-adjusted rate that is needed to secure a risk-adjusted competitive return on those assets. Historically, two major patterns emerged. First, under the rule in *Smyth v. Ames*,[50] the rate base is set under a tough standard that allows the firm to get a return only on the investments that were used and usable within the business, so that mistakes at the outset will be removed from the base as unwise expenditures. The offset to this shrinkage is that the rates to be charged will now have to be higher to make sure that there is a suitable total return. Under the alternative rule of *Federal Power Commission v. Hope Natural Gas*,[51] the difficult cost estimates needed to set the right rate base are avoided by giving the regulated firm a large rate base that includes all its initial investment, whether those dollars panned out or not, coupled with the offset of reducing the allowable rate of return on the larger base. Each system has its advantages and disadvantages so that today either system or some combination of the two systems is generally allowed under *Duquesne Light Co. v. Barasch*,[52] where the precise question was whether it was proper to exclude some canceled investments in nuclear power from the rate base so long as the overall rate satisfied the appropriate rate of return. But with both these

48. *Id.*; *see also* Richard A. Epstein, *The History of Public Utility Rate Regulation in the United States Supreme Court: Of Reasonable and Nondiscriminatory Rates*, 38 J. SUP. CT. HIST. 345 (2013).

49. *See generally Chi., Burlington & Quincy R.R. Corp. v. Chicago*, 166 U.S. 226 (1897) (reading the prohibition against taking property without due process of law to mean without just compensation, in order to attack confiscatory regulations).

50. 169 U.S. 466 (1898) (setting rate base of used and useable assets).

51. 320 U.S. 591 (1944) (setting rate base of total investment, whether or not used and usable, which covers all costs, without any elimination).

52. 488 U.S. 299 (1989).

alternatives the rates can be reviewed through a public hearing subject to judicial review, providing both notice and institutional safeguards on the collection and analysis of the data.

Unlike all of these formalized administrative rate-making determinations, the Biden administration's proposed rule for march-in rights contains no built-in constitutional safeguards. The proposal does not seek to set rates for an entire portfolio of drugs, a practice that would require that the government take into account the sunk costs of drugs that do not make it to market. The targets in these march-in cases will solely be high-profit drugs, to be picked out for separate treatment, whose rate base will not allow for the recovery of costs for drugs that never made their way through the pipeline.[53] If drug manufacturers cannot recover their lost investments in less successful drugs with the profits they obtain from their few market winners, the market will not sufficiently incentivize the creation of a steady stream of new drugs.

This process will thus result in a *systematic* bias to lowball the prices set for targeted drugs. These drugs are often sold in many different dosages through many different markets: for example, the paths are wholly different for sales to retail druggists that carry all lines, and various HMOs and similar health care plans that can play multiple contenders against each other so that the price in the one market will be systematically lower than in the other.[54] Yet, the proposal's discussion of the reasonableness issue skirts all the serious questions about how those "reasonable" rates are going to be set by a single administrator who, for questionable reasons, has already voiced major dissatisfaction with the rates currently charged. And once those rates are set, it is unclear what procedures will be used if the firm that is singled out, as seems likely, wants to challenge them, either administratively or judicially, before the march-in rights are exercised.[55] This *ad hoc* universe could let the government easily strip, without judicial review, the firm of a huge fraction of its sales without any compensation. The

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53. It is just this pattern that is followed in a parallel scheme to reduce drug costs. The Drug Price Negotiation Program ("Program") created by the Inflation Reduction Act of 2022 ("IRA"), 42 U.S.C. § 1320f, designed to impose the lowest maximum fair price for expensive drugs, upheld in *AstraZeneca Pharmaceuticals LP v. Becerra*, No. 23-931, 2024 WL 895036 (D. Del. Mar. 1, 2024).

54. *In re* Brand Name Prescription Drugs Antitrust Litig., 186 F.3d 781, 787 (7th Cir. 1999):

> The least elastic demanders are the pharmacies, because they must stock a full range of drugs in order to be able to fill prescriptions. They can therefore be expected to be charged the highest prices. In contrast, a hospital, nursing home, or HMO or other managed- care enterprise has a more elastic demand because it can influence (for example through a "formulary," a list of approved or recommended drugs) the physician's choice of which brand (or no brand — a generic) to prescribe.

55. This singling out is what happens today under the Program, enacted as part of the IRA.

level of coercion makes this an obvious case of confiscation under the standard rules for regulation.

One purported justification for this aggressive position is the Biden administration's (false) claim that the public pays for all R&D of new drugs and that monopolists with patents are driving up prices.[56] But apart from generalized statements that this skewed system of regulation is "good for competition," the Biden administration offers no evidence to prove this point. Nor could it do so under current antitrust doctrine, given the decision in *Illinois Tool Works, Inc. v. Independent Ink, Inc*.,[57] which rejected the proposition that holding a patented monopoly on a tying product necessarily gave rise to a presumption of market power. The logic here is clear — if the patent law is meant to give a firm monopoly power to encourage disclosure of inventions, then the state cannot then take that monopoly away by refusing to allow the firm to use that power, without collaboration with others, in its key licensing decisions, which cover both pricing issues and tie-in practices.

To make matters worse, the new price control regulations apply to *all* Bayh-Dole patents, not just drug patents. Thus, these price controls could have been applied to Google, forcing Google to permit other tech companies to use, without authorization, its page-rank search algorithm (patented while Sergey Brin and Larry Page were graduate students at Stanford in 1998).[58] All innovations with roots in universities are at risk. Indeed, if a complex product contains just one component of a new invention that has received support under Bayh-Dole, the new regulations allow the finished product to be regulated as if all components were so developed, thus dragging patents created only by private investment into the regulatory maelstrom.[59] The economic implications are massive: Price controls vitiate property rights and destroy markets, as recognized by anyone who lives in cities with rent control laws, experiencing the massive inequities caused when some apartment units are covered by the scheme, thereby driving up the price of unregulated units.[60]

Switching gears, Biden claimed that stopping the supposed cases of price-gouging is "good for the millions of Americans who can't afford their medications — who know all too well that fine line between

56. On the overstatement about the level of government contributions, see *supra* note 23.

57. 547 U.S. 28 (2006).

58. Zlata Verzhbitskaia, *The Past, Present & Future of Google PageRank*, SEO POWERSUITE (June 5, 2024), https://www.link-assistant.com/news/google-pagerank-algorithm.html [https://perma.cc/36WR-KW36].

59. *See* Christine A. Varney, Makan Delrahim, David J. Kappos, Andrei Iancu, Walter G. Copan & Noah Joshua Phillips, *Comments on European Commission's Draft Proposal for Framework for Patent Licensing*, https://ipwatchdog.com/wp-content/uploads/2023/04/Comments-on-European-Commission-Draft-SEP-Regulation-by-Former-US-Officials-1.pdf [https://perma.cc/2EGA-KGZQ] [hereinafter American Letter].

60. EPSTEIN, *supra* note 16, at 82–96.

dignity and dependence that the price of a prescription drug can draw." [61] That argument proves too much, for so long as drug companies sell their drugs at positive prices, there will be some people at some margin who cannot "afford" the stated price. Yet, this concern must be balanced against the business imperative of securing a rate of return that allows the firm to remain in business, so that everyone — including people who can afford to pay market prices — is not left hanging when certain drugs are not available at all.

There is, moreover, a way to reconcile these two goals. The government can buy in quantity the needed drugs from the makers and then sell or grant them to in-need individuals at lower prices or for free. In effect, this purchase system makes the government a market middleman, so that the pharmaceutical companies are not forced to bear the brunt of what should be a public expense. Just that mechanism was suggested by the late Justice Antonin Scalia in *Pennell v. San Jose*.[62] In dealing with a rent control ordinance that sought to impose the entire cost of low rents on a particular set of landlords, he responded:

> The traditional manner in which American government has met the problem of those who cannot pay reasonable prices for privately sold necessities — a problem caused by the society at large — has been the distribution to such persons of funds raised from the public at large through taxes, either in cash (welfare payments) or in goods (public housing, publicly subsidized housing, and food stamps). Unless we are to abandon the guiding principle of the Takings Clause that "public burdens . . . should be borne by the public as a whole," . . . this is the only manner that our Constitution permits.[63]

Taking care of the poor is not a unique function of drug companies, so the purchase and redistribution approach avoids the confiscation issue, putting these expenditures back on the public budget, where as a matter of good democratic theory they ought to be. One abiding

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61. *See* President Biden, *supra* note 42.

62. 485 U.S. 1, 15 (1988) (Scalia, J., concurring in part and dissenting in part).

63. *Id.* at 21–22 (quoting United States v. Armstrong, 364 U.S. 40, 49 (1960)). *Armstrong* is the case law anchor for any system of strong property rights because it makes it clear that the division of property rights (in that case, between the United States as owner of the boat and Armstrong as holder of a materialman's lien) does not dilute the property rights of the owner of a partial interest. It mattered because if the lien could be broken when the vessels were sailed into international waters, then the poor lienor would be forced to foot the bill for an asset from which he derived no greater benefit than anyone else. Rent control involves the same logic. The subsidy, if one is desired, should come from the government, not the particular landlord who derives no special benefit from this system of social control.

advantage of this solution is that it conforms to and reinforces the original understanding that the Bayh-Dole Act does not authorize march-in licenses to lower prices. Senators Birch Bayh and Bob Dole explicitly stated (albeit after the fact) that by proposing Bayh-Dole they "did not intend that government set prices on resulting products. The law makes no reference to a reasonable price that should be dictated by the government. This omission was intentional."[64]

To see how bad the situation could become if their warning is ignored, just take one look at the proposed regulations issued by the National Institute of Standards and Technology, located in the Department of Commerce, on federal "march-in" rights. These potential rules set out a number of conditions relating to the supposed under-exploitation of patents covered by Bayh-Dole. The first is that if government bureaucrats determine that a patentee has not worked to make "practical applications" of its patent, especially in crises, where shortages relating to health and safety beckon.[65] The underlying charge is that some reluctant licensee "fails to license the invention to a willing licensee or insists on unreasonable terms."[66] In that case, even though the government does not have ownership of the invention, the government can grant such a license, even to a competitor of the patent owner, if the government, after exhaustive administrative review, determines that "the price or other terms at which the product is currently offered to the public are not reasonable."[67]

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64. Birch Bayh & Bob Dole, Our Law Helps Patients Get New Drugs Sooner, The Wash. Post (Apr. 10, 2002, 8:00 PM EDT), https://www.washingtonpost.com/archive/opinions/2002/04/11/our-law-helps-patients-get-new-drugs-sooner/d814d22a-6e63-4f06-8da3-d9698552fa24/ [https:// perma.cc/FY8K-6UY4]. Their remarks were made in response to a suggestion, written twenty years after the passage of Bayh-Dole, that price controls were allowable. *See* Peter S. Arno & Michael H. Davis, *Why Don't We Enforce Existing Drug Price Controls? The Unrecognized and Unenforced Reasonable Pricing Requirements Imposed upon Patents Deriving in Whole or in Part from Federally Funded Research*, 75 TULANE L. REV. 631 (2001). That claim is flatly inconsistent with the text of Bayh-Dole: "It is the policy and objective of the Congress to use the patent system to promote the utilization of inventions arising from federally supported research or development." 35 U.S.C. § 200. For a detailed refutation of that position, see Adam Mossoff, *The False Promise of Breaking Patents to Lower Drug Prices*, 98 ST. JOHN'S L. REV. 287, 310–38 (2024). Mossoff's larger point reflected in his title is also correct. In the short term, denying patent protection for all pharmaceuticals will reduce the prices of those drugs. But the adverse effect in the long run will stop innovation in its tracks.

65. 35 U.S.C. § 203(a). These march-in rights are only triggered "if the federal agency determines that such . . . action is necessary" because "the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use" or because there are "safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees." *Id.* No firm has any incentive to slow-walk a profitable invention, especially one related to health and safety.

66. Anne Lanteigne, *What Are the Government's March-In Rights in Subject Inventions?*, JDSUPRA (June 8, 2023), https://www.jdsupra.com/legalnews/what-are-the-government-s-march-in-8175483/ [https://perma.cc/VSL2-URVN].

67. *See* NIST Proposed Regulation on March-In Rights, *supra* note 20, at 85598.

In effect this startling assertion of government power gives A's patent to B, unless A succumbs to the government's demand for A's licensing on more favorable terms to new compulsory licensees or the public at large. The detailed regulations routinely allow the government to review the benefits that Bayh-Dole confers on its contractor-licensees. The proposed regulations offer not one hint of any problem on the ground of its future implementation. Instead, they resort to outlandish hypotheticals, like one that imagines that a firm with a water filtration patent "uniquely able" to remove any trace deadly carcinogens from drinking water has increased its price by 1000 percent, by refusing to expand supply or license any other firm in the industry.[68] But the regulations offer no explanation of why any key technology over time should attract no competitors, or why it is a profit-making strategy for any firm, even a (nonexistent) perfect monopolist, to refuse to expand supply in the face of major demand surges. Yet it seems highly unlikely that any application of Bayh-Dole blocked those needed innovations that easily could have come from the private sector.

Undeterred by the want of any hard evidence, Commerce Secretary Gina Raimondo claims that her job is to "provide greater clarity on march-in rights and maintain a balance" that incentivizes companies to innovate for the benefit of the American people.[69] She should save herself the effort, for there is no reason to fix what is not broken by insisting on first creating and then reviewing nonexistent tradeoffs, by stripping key patent holders, without compensation, of the right to their own inventions.

As written, the proposal attempts to retroactively introduce a set of regulations on existing patented technologies, which is a pure play for redistribution. But suppose the new proposal only applied to new products that rely on government research. That notice might ease the sting of the restriction, but it is far more likely to lead to a massive effort to avoid using government-sponsored research for new product development. Faced with that government threat, any inventor of any new technology in any field must subtract from its projected rate of return the heavy costs that result from losing vital revenues by either form of government intervention, the uncertainty of knowing whether the march-in process will be initiated against them, and the heavy costs in money and delay in fighting this heavy-handed application of state power. There are, as it were, no useless inventions in a rational economy that need liberation from their wayward owners by

68. *Id.* at 85603.

69. *NIST Releases for Public Comment Draft Guidance on March-in Rights*, NAT'L INST. OF STANDARDS & TECH. (Dec. 7, 2023), https://www.nist.gov/news-events/news/2023/12/nist-releases-public-comment-draft-guidance-march-rights [https://perma.cc/3QHQ-D73A].

government intervention.[70] Whatever protections are needed can be supplied against *coordinated* practices of multiple firms to raise prices as needed under the antitrust law — a remedy nowhere mentioned in the regulations. Right now, Commerce should pull its request for information about a misguided proposal that can further unravel today's patent system that actually works. This Biden misadventure should be stopped before it causes permanent damage to the patent system.

III. EUROPEAN REGULATION OF INTELLECTUAL PROPERTY MARKETS

The intellectual atmosphere is much the same in the European unit, which also harbors a deep suspicion about the status of intellectual property rights ("IPRs"). Thierry Breton, Commissioner for the Internal Market — which specializes in trademark law — announced on April 27, 2023, a total revision of the EU's basic rules of engagement in three separate areas: Standard Essential Patents ("SEPs"), Compulsory Licensing, and Supplementary Protection Certificates.[71] Breton offers this defense of his new proposal:

> Intellectual property rights (IPR), and particularly patents that are a critical intangible asset, are called to play a crucial role in scaling up green innovation, while building a business case for clean tech, and fostering also a sustainable digital transformation. In this sense, the European Commission has proposed new rules to help companies, especially small and medium-sized companies (SMEs), make the most of their inventions, leverage new technologies and contribute to the EU's competitiveness and technological sovereignty.[72]

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70. Note that 35 U.S.C. § 101 incorporates "useful" into the basic definition: "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title." The term does not have much bite because no one chooses to invent useless inventions even if many inventions turn out to be useless, at which point they are not the subject of litigation.

71. Alexander Galetovic, Stephen Haber & Ross Levine, *An Empirical Examination of Patent Holdup*, 11 J. COMPETITION L. & ECON. 549 (2015); *see also* Press Conference by Thierry Breton, European Commissioner, on New Rules to Complete the Single Market for Patents (Apr. 27, 2023), https://audiovisual.ec.europa.eu/en/video/I-240304 [https://perma.cc/4S25-DRHU]. I shall not speak further of the Supplemental Protection Certificates, which offer five-year extensions for "human or veterinary pharmaceutical product, or a plant protection product, that has been authorised by regulatory authorities." *Id.*

72. Press Conference by Thierry Breton, *supra* note 71.

Thereafter, the Commission offers its account of how an additional layer of regulation can smooth matters out "by further eliminating Single Market fragmentation, reducing red tape, and enhancing efficiency. This solid patent framework will empower economic operators and competent authorities to better protect innovation while ensuring fair access, including during emergency situations."[73] In its efforts to facilitate efficient licenses on fair, reasonable, and non-discriminatory ("FRAND") terms, the EU Commission will introduce "a SEP register, database, and essentiality checks; expert opinions on SEP aggregate royalty; FRAND determination by means of conciliation in lieu of costly litigation; SME support measures; and the establishment of a 'Competence Centre' at the European Union Intellectual Property Office (EUIPO)" under its standards, all under the watchful eye of the Commission.[74] In effect, it introduces a system of price controls with these two key provisions:

(1) Ensuring that both EU SEP owners and implementers innovate in the EU, make and sell products in the EU, and are competitive on global markets.

(2) Ensuring that end users, including SMEs and consumers, benefit from products based on the latest standardised technologies at fair and reasonable prices.[75]

Two sorts of objections apply to these proposals. The first set rests on general theory of regulation, while the second implicates technical objections to the mechanics of these proposals. The two classes overlap and reinforce each other. Nonetheless, the division helps clarify the distinction.

A. Theoretical Objections

For starters, no one disputes that IPRs are critical for economic growth or that their standardization — the raison d'etre of setting up these standing protocols in the first place — is important. But agreement on these grander ends only supports the obvious conclusion that that the European Union should seek the right solution to optimize innovation. It in no way stands for the very distinct proposition that massive government intervention on Breton's two main axes, SEP standards and compulsory licensing, will make things better rather than worse. Indeed, it is even more dangerous for Breton to play industrial

73. *Intellectual Property: Harmonized EU Patent Rules Boost Innovation, Investment and Competitiveness in the Single Market*, EUR. COMM'N (Apr. 26, 2023), https://ec.europa.eu/commission/presscorner/detail/en/IP_23_2454 [https://perma.cc/5UPS-4SXL].

74. *Id.*

75. *Id.*; *see also* RICHARD A. EPSTEIN, SIMPLE RULES FOR A COMPLEX WORLD 30–35 (1995) (discussing tradeoffs needed to make rules simple).

czar by insisting in his opening salvo that green innovation, clean tech, or digital transformation require special treatment, unlike the rest of the market — or that, alternatively, the entire system has to be transformed to advance innovation in these specialized areas, even at the cost of creating distortions elsewhere.

It is also dangerous to target small- and medium-size companies with the new rules. Indeed, it is hard to think of any sensible generalized rule that could single these companies out for special treatment, when regulators often need to resort to fixed numbers on such matters as market capitalization or total sales. This singling out creates awkward discontinuities that make planning and regulation more difficult — especially as firms could easily grow and contract across categories.[76] Nor is there any theory that explains the proper balance among these categories. Lastly, and perhaps most importantly, the best way to launch new enterprises is *not* to tinker with the patent law. Europe has long had difficulties in generating the next round of Googles, Apples, Metas, and Amazons.[77] Its political leaders have insufficient awareness of the growth cycles for firms that start in garages and slowly expand on personal credit card borrowings, family assistance, and bewildering rounds of venture capital requests.[78] The path, therefore, to making smaller firms bigger requires less by way of central planning and more by way of helter-skelter activity that tolerates lots of failures and surprises. Any targeted regime of IPRs is sure to fail.

In making his case for presumptive intervention, Breton takes his cue from the DOJ and FTC on mergers, namely, that the only way to improve the system is to add another layer of procedural hurdles in the EU system that is already too cumbersome and intrusive. The basic presumption should be set in the opposite direction for two reasons. First, there is no demonstrated area of market failure in this European document that calls for any remedy. Second, any increase in administrative costs has to be justified by some increase in output, which may be possible with the natural monopoly referenced earlier. But these elements are not developed here to explain why, for example, the current methods for determining SEPs are broken, given that there is no obvious competitive solution that emerges, and no evidence of abusive patent stacking leading to excessive rates that were once predicted by the champions of regulation.[79]

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76. EPSTEIN, *supra* note 75, at 30–35.

77. Kate Klonick, *Why Does the EU Have No Tech Industry?*, THE KLONICKLES (May 1, 2024), https://klonick.substack.com/p/why-does-the-eu-have-no-tech-industry [https://perma.cc/UL9C-6CSD].

78. Richard A. Epstein, Keynote Address, *Common Ground: How Intellectual Property Unites Creators and Innovators*, 22 GEO. MASON L. REV. 805 (2015).

79. Galetovic et al., *supra* note 71.

B. Professional Objections

These procedures have also produced stout resistance from within the patent community. European patent court judges are unhappy about how the new proposals, under the guise of promoting "reconciliation," impose a nine-month bar on pursuing claims against infringers, while seeking to negotiate an informal settlement. The parties could do this on their own without this legal intervention that creates delay benefitting only the infringer.[80]

Indeed, these judges are far too circumspect in their denunciations of these proposals, for not only will they strip patentees of their rights, but they will also roil standard-setting practices. One instructive lesson that is learned from the use of the four ad hoc rules of *eBay*[81] is that the difficulty of getting an injunction leads to systematic behaviors, whereby potential licensees make a rational determination that it is better to initiate the use of patented technology without entering in a royalty arrangement, because it forces the patentee to bring complex and time consuming litigation, and often creates a situation where a successful patentee ends up worse after the breach, and far below where he started out in litigation. The situation in the European Union is far worse because it insists that negotiation start before litigation can be initiated, so that only the good offices of the Commission could move the negotiations forward.[82] But there is, in these cases, not the slightest evidence that the breakdowns in FRAND negotiations are so frequent that a new, untested system can be issued by the European Union before it even attempts to identify the failures. In doing so, the European Union follows the dangerous playbook of the Biden administration of introducing ill-defined administrative proposals to address invented crises, as with the new regulation on march-in rights.

On a similar note, senior former government officials in the United States have also strenuously objected to the European Commission

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80. Rory O'Neill, *UPC Chief Urges EU to Rethink SEP Plan*, MANAGINGIP (May 30, 2023), https://www.managingip.com/article/2bqbfr0uyrki1fniy9ou8/breaking-upc-chief-urges-eu-to-rethink-sep-plan [https://perma.cc/7EF4-PGXE] ("Klaus Grabinski, chief judge of the UPC [Unified Patent Court] Court of Appeal, said he feared the draft SEP regulation . . . was not currently compliant with the EU Charter of Fundamental Rights" because of the forced delay in allowing suit). To the same effect, see Letter from Robin Jacob, to Mr. Haak re: Commission Proposal Concerning Standard Essential Patents (Oct. 29, 2023), https://s3.amazonaws.com/media.hudson.org/Intellectual+Property+Judges+Association.pdf [https://perma.cc/WUD2-MV7K]. Draft regulation Art. 5 contains the nine-month prohibition.

81. eBay Inc. v. MercExchange, L.L.C., 547 U.S. 388, 391 (2006) (requiring plaintiffs to demonstrate that they have "suffered an irreparable injury"; that "remedies available at law, such as monetary damages, are inadequate to compensate for that injury"; that "considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted" and that a permanent injunction would serve the public interest).

82. *See* EUR. COMM'N, *supra* note 73.

proposal on several strong but familiar grounds.[83] They noted first that these challenged processes have been in place for many years, having been carefully developed in a bipartisan discussion on both sides of the Atlantic without any ideological overlay.[84] Their letter noted that the draft regulation would "unnecessarily insert the European Union Intellectual Property Office ("EUIPO") — an institution that currently has no meaningful experience with patents — into one of the most complex areas of patent policy, producing delays in enforcing valid patent rights and uncertain royalty guidance that militates against the value of intellectual property rights," unnecessarily allowing "Europe's implementer-dependent international competitors to set binding aggregate royalty rates that severely devalue European innovation."[85] And their letter then noted that the EU proposal "[l]acks [a]ny [e]mpirical [s]upport" to explain why any new proposals are needed.[86]

Given the scope of these untested reforms, it would have behooved the EU Commission to examine the desirable institutional features of FRAND negotiations that have made them so successful in the past. First, the negotiating parties are well aware of the risk of holdout, the common risk that the either side or the other could refuse to bargain with the other side,[87] which is why they impose these FRAND obligations in the first place. It has commonly been asserted that these negotiations are unable to stop the serious problem of "royalty stacking," whereby each of the successive holders of a patent contained in some technological standard will increase the overall burden on the system. I think that the decisive refutation of this claim is found in a paper of Alexander Galetovic, Stephen Haber, and Ross Levine,[88] which references a long list of papers that predicted a holdout problem that failed to materialize.[89] The evidence reveals the exact opposite

83. The impressive list, known to all in the field, includes in alphabetical order: Walter G. Copan, Makan Delrahim, Andrei Iancu, David Kappos, Noah Joshua Phillips, and Christine Varney. *See* American Letter, *supra* note 59.

84. *Id.* (noting the parallels in the law of the two systems).

85. *Id.*; *see also* Tom Duesterberg & Adam Mossoff, *European Commission Undermines Western Innovators, Boosts Chinese Dominance of Telecom Sector*, DAILY SIGNAL (Apr. 28, 2023), https://www.dailysignal.com/2023/04/28/european-commission-undermines-western-innovators-boosts-chinese-dominance-telecoms-sector/ [https://perma.cc/R536-AG6X].

86. American Letter, *supra* note 59.

87. Richard A. Epstein & Kayvan Noroozi, *Why Incentives for "Patent Holdout" Threaten to Dismantle FRAND, and Why It Matters*, 32 BERKELEY J.L. & TECH. 1381 (2017).

88. Galetovic et al., *supra* note 71.

89. *See id.* at 500 (citing Carl Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard Setting*, *in* 1 INNOVATION POLICY AND THE ECONOMY 119 (Adam Jaffe, Josh Lerner & Scott Stern eds., MIT Press 2001); Daniel G. Swanson & William J. Baumol, *Reasonable and Nondiscriminatory (RAND) Royalties, Standards Selection, and Control of Market Power*, 73 ANTITRUST L.J. 1 (2005); Joseph Farrell, John Hayes, Carl Shapiro & Theresa Sullivan, *Standard Setting, Patents, and Hold-Up*, 74 ANTITRUST L.J. 603 (2007); Mark A. Lemley & Carl Shapiro, *Patent Holdup and Royalty Stacking*, 85 TEX. L.

conclusion: "products that are SEP-reliant have experienced faster price declines than any other good in the Consumer Price Index (CPI) over the past 16 years."[90]

These improvements should come as no surprise. From the outset it is commonplace for new technology to experience a rapid rate of depreciation, such that a large fraction of its useful life will be wasted if the parties cannot come to a quick and stable resolution of licensing disputes.[91] The prospect of mutual ruin for multiple parties is thus a strong one. Second, these parties are, of course, repeat players in multiple markets, where overlapping negotiations could be taking place on multiple standards at the same time. Holding out in one negotiation increases the risk of not being asked to join in on a second standard in the future because of the reputational constraints in these closed communities.[92] Thus, holding out has a higher implicit cost than it does when all the activities for a single standard can be done in relative isolation. There are strong incentives for all parties to complete each individual deal, and to make sure that future deals can take place — an issue that the EU Commission states that it cares about, but that it ignores in practice, given its public pronouncements, which have consistently ignored criticisms from the bench and the bar.[93]

The current institutional framework then helps achieve these gains from cooperation by establishing standards. The participants are wise enough to separate the technical discussions on system design from the pricing discussion, so as to pave the way for getting the right mix of technology in the system to facilitate its effective introduction. In addition, they invite implementers to act as observers of the overall discussion, so that their input can be available to the patent holders, who then have a better sense of what needs to be done, without having to make a joint decision with these parties, who have their own distinct interests.[94]

In contrast, as the American regulator letter notes, the EU proposal "appears to permit an unlimited number of stakeholders to participate in each aggregate royalty determination,"[95] which will further delay the resolution and further skew any royalty levels downward. The members of SEP pools also know that they cannot commandeer implementers'

REV. 1991 (2007); Joseph S. Miller, *Standard Setting, Patents, and Access Lock-In: RAND Licensing and the Theory of the Firm*, 40 IND. L. REV. 351 (2007)). For a comprehensive survey, see Edward J. Egan & David J. Teece, *Untangling the Patent Thicket Literature* (Univ. Cal. Berkeley Tusher Ctr. for Mgmt. Intellectual Capital, Working Paper No. 7, 2015).

90. Galetovic et al., *supra* note 71, at 554.

91. *See, e.g.*, Epstein & Noroozi, *supra* note 87, at 1385.

92. Competition Pol'y Int'l, *CPI Talks. Seminar: The Role of Antitrust in Licensing Disputes in ICT Sector, Singapore — April 2016*, ANTITRUST CHRONICLE, Sept. 2016, at 7.

93. *See supra* text accompanying notes 80–86.

94. For a defense of implementer dominance on these issues, *see* Epstein & Noroozi, *supra* note 87.

95. American Letter, *supra* note 59, at 4.

cooperation, and thus must offer quality products on a timely basis at decent prices. The injection of an automatic additional layer of institutional review by an inexperienced regulator will slow down product development and thereby reduce the useful life of the standard and all of its components, as noted by the critics of the EU.[96] The American letter is also right to note that the inexperience of the EU Commission cannot be cured by either a crash course for its many members or by seeking advice (which it might not understand or take) from other groups of experts. It is not as though these complex business transactions aren't regulated, when they are already subject to a full system of courts from the Court of Justice for the European Union.[97] Further, the desirability of additional regulation in this area, like every other, should be evaluated at the margin, and it should, like every other institution, be aware not only of its own objectives but also of its unintended consequences, including the public choice difficulties of organizing a coherent and neutral group of decisionmakers, which does not include the EU Commission.

C. Compulsory Licensing

The EU Commission has also issued an extensive statement in support of the expanded role of compulsory licensing ("CL") in the EU.[98] The chief argument in favor of the EU control fears the possibility that some major crisis will engulf some large social system that lacks reliable and uniform mechanisms for identifying for triggering the need for CL, or the coordinated responses that are needed to execute the particular programs. The details of these programs are not worked out. Instead, the Report states two global aims:

(1) [I]ncentive role: The threat of a compulsory licence can incentivise the IP owner to grant a voluntary agreement, in particular when the IP owner has refused the licensing or the proposed conditions;

(2) [E]nabling role: Should voluntary agreements still not be available or adequate to address the crisis and should another manufacturer be able to produce and deliver the goods to tackle the crisis, the public authority could decide to grant to this manufacturer a compulsory licence allowing/ ramping up production capacity.[99]

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96. *Id.*

97. *See* O'Neill, *supra* note 80.

98 . *Commission Staff Working Document: Impact Assessment Report, Compulsory Licensing*, EUR. COMM'N (Apr. 27, 2023), https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52023SC0121 [https://perma.cc/ANY4-9946].

99. *Id.* § 1.3.

The first of these objections tries to square the circle by using coercion to obtain a voluntary agreement. But any such threat undermines the voluntary nature of the transaction, especially when the IP owner refuses to license on the proposed conditions from the Commission. There is no limit on what conditions could be set, and once those conditions are articulated, the potential licensee should rationally insist that that patent holder accede to all of them. Hence, this process allows the Commission to dictate terms, without ensuring that the resulting "license" does not strip the patent holder of its IP without compensation.

Put otherwise, this formulation presumes that the bargaining breakdown is all on one side of the relationship because it ignores that the proposed conditions could be all too favorable to the licensee, either on price or on other collateral terms. Yet unless some fairness determination can be made, the proposed rule lets private licensees and their government backer use low-ball offers to extract prices that may not even cover the marginal cost of production and sales, let alone any portion of the fixed costs of production. The resulting shortfall will necessarily be thrown back onto other licensees in the voluntary market.

At this point, any analysis of incentives cannot just look at products currently on the market but must also consider the diminished prior incentives to develop drugs and other products for the market. Shrinkage in that innovation market leads to fewer new medications, vaccines and other products needed in good times as well as crisis situations. Yet at no point does the EU analysis seek to estimate the impact of its CL regime on the initial decisions that firms have to make before entering any new product niche. This effect will moreover be systemwide because there is no way that anyone can predict where the next crisis will appear.

The difficulties are every bit as great on the implementation side of the ledger. There must be some sense as to which of the various compounds or products should be subject to these compulsory licenses.[100] That problem has no real answer when the government could choose one from a number of products in the same class, leaving others in the same class unregulated, often challenging the most profitable drugs.[101] That practice results in two key distortions. The regulated product may well be sold at a loss, perhaps at confiscatory rates, against which the proposed power to commandeer offers no protection. At the same time, the unregulated products priced at market levels may well lose market share. It should be evident that even in crisis time, a set of voluntary responses by multiple market players

100. *See* EPSTEIN, *supra* note 16, at 92–96.

101. *See supra* note 53 and accompanying text.

should offer a far better response, given their ability to ratchet up production, by offering their own products in different dosages and delivery forms, either alone or in combination with other products. But once the issue turns to CL, all the incentives are now reversed. These licenses are likely to pay subpar rates, since deciding whether rates are "confiscatory" is not mentioned as one of the constraints on how these CLs are levied. Depending on how these provisions are administered, the upshot could well be that many drug sales or licenses impose both higher compliance costs and generate lower revenues, at which point the innovative firm should *avoid* the dubious honor of being forced to take compulsory licenses.

In addition, the EU Commission does not limit its roster of potential targets to the class of finished products. But then, it notes that "the multi-dimensional links governing the existing value chains" will require that the CL cover not only final products but also "any patented component from some other country," which will then give the agency huge discretion to target whatever combination of finished drugs and components they choose.[102] The system will thus spiral out of control, yet there is not any indication as to the so-called "analytical methods" that European authorities will invoke to determine right from wrong answers. The only guideline is that compulsory licenses should be used "only in exceptional circumstances."[103] But there is no explanation as to why a routine review to uncover exceptional circumstances will improve matters. Indeed, it appears as if the new scheme will verge on public utility pricing, a vast enterprise that is easily moved from major power plants and telephone exchanges to particular drugs, where there is no obvious rate base from which sensible rates (including failed ventures) can be calculated. Why make the possibility of CL processes routine when the Commission offers no explanation of their potential value or any case of their successful invocation?

IV: CONCLUSION: THE BREAKDOWN OF ADMINISTRATIVE PRACTICE

It is now appropriate to take stock of the common features that threaten to reduce both American and EU Commission law to a state of interminable mischief. The explanation starts with the simple observation that the dominant impulse on both sides of the Atlantic is to find ways to expand the power of government regulators, who have not articulated any clear normative framework, to impress their will on the productive forces within the economy. That claim never starts with the grandiose proposition that socialism, or the collective ownership of

102. EPSTEIN, *supra* note 16, at 10. (discussing the powers of the FDA).
103. *Id.* at 52.

the means of production, is desirable. Quite the opposite: rhetorically, the stated major premise for regulators in both systems is to advance competition and to increase the efficiency of these dynamic markets. There is no defender of free markets who could object at this abstract level to the administrative goals.

The huge gap in the argument lies in the articulation of the minor premises that are said to implement this basic program. There are oblique references to some crisis or massive market breakdown. But there is an unjustified refusal to identify what that crisis is. There is no breakdown in services; no massive wave of consumer dissatisfaction; no sign that the level of improvements in these markets has faltered; and where there are evident slowdowns (as with the FDA), there is never any awareness that the present systems of regulation may help trigger the overall declines. Instead of looking for analytical explanations, both reports take the same form. They cite to a vast literature of sympathetic voices, without considering the writings on the other side of these debates. In a political tussle, you must ever try to answer the strongest arguments of your opponents. Hence, it is important not to focus on possible failures, but also on the demonstrable achievements of the pharmaceutical industry that have saved lives and advanced human welfare without government support, or in spite of determined regulatory opposition. The conscientious regulator must guard against moving too fast as well as too slow. Both kinds of error count, so even if a little bit of regulation is a good thing, a lot of regulation may not be a great thing. Living life at the margin matters, and in setting their general rules, conscientious regulators must forget the single most important message of the once regnant system of laissez-faire: set a rebuttable presumption against regulation, unless and until, the gains from regulation are shown to exceed the drawbacks. By that standard these two American and European regimes are convicted of major offenses, for the costs are high and the benefits non-existent.